

The Senate

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Community Affairs  
References Committee

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Number of women in Australia who have had  
transvaginal mesh implants and related matters

March 2018

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## 45<sup>th</sup> Parliament

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Senator Skye Kakoschke-Moore	South Australia, NXT



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# ABBREVIATIONS

ACC	New Zealand Accident Compensation
ACM	Australian College of Midwives
ACSQHC	Australian Commission on Safety and Quality in Health Care
AIHW	Australian Institute of Health and Welfare
APMSG	Australian Pelvic Mesh Support Group
ARTG	Australian Register of Therapeutic Goods
AUA	American Urological Association
CFA	Continence Foundation of Australia
COAG	Council of Australian Governments
Code	Code of Practice
Department	Department of Health
GP	General Practitioner
HCC	Health Consumers Councils across Australia
HIC	Health Issues Centre
ICD	International Classification of Diseases
IRIS	Incident Reporting and Investigation Scheme
ISP	International Society for Pelviperineology
KEMH	King Edward Memorial Hospital
MBS	Medicare Benefit Schedule
MMDR Review	Review of Medicines and Medical Devices Regulation
MTAA	Medical Technology Association of Australia
MUS	mid-urethral sling
NASOG	National Association of Specialist Obstetricians and Gynaecologists

NHS England	National Health Service England
NSW Health	NSW Ministry of Health
Patient implant card	Patient cards for implantable medical devices
PHAA	Public Health Association of Australia
POP	pelvic organ prolapse
PROSPECT	PROlapse Surgery: Pragmatic Evaluation and randomised Controlled Trials
RACGP	Royal Australian College of General Practitioners
RACS	Royal Australasian College of Surgeons
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RCT	randomised controlled trials
Regulations	Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017
SUI	stress urinary incontinence
TGA	Therapeutic Goods Administration
TVT	tension-free vaginal tape
TVT-O	tension-free vaginal tape-obturator
USANZ	Urological Society of Australia and New Zealand
US-FDA	United States Food and Drug Administration
WHRIA	Women's Health and Research Institute of Australia

# **LIST OF RECOMMENDATIONS**

## **Recommendation 1**

**5.55** Noting the vital role of adverse reporting in post-market surveillance, the committee recommends that the Australian Government, in consultation with the states and territories and the Medical Board of Australia, review the current system of reporting adverse events to the Therapeutic Goods Administration to:

- **implement mandatory reporting of adverse events by medical practitioners;**
- **provide guidance on what constitutes an adverse event for use by consumers, medical practitioners and device sponsors;**
- **improve awareness of the reporting system;and**
- **examine options to simplify the reporting process;**

## **Recommendation 2**

**5.56** The committee recommends that the Therapeutic Goods Administration and the Australian Commission on Safety and Quality in Health Care 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 and on reporting the event.

## **Recommendation 3**

**5.66** The committee recommends 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.

## **Recommendation 4**

**5.72** The committee recommends that the Medicare Benefits Schedule Taskforce prioritise release of the report of the Gynaecology Clinical Committee for consultation.

## **Recommendation 5**

**5.77** The committee recommends 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.

## **Recommendation 6**

**5.87** The committee recommends that the Australian Commission on Safety and Quality in Health Care prepare guidance material on effective informed consent processes, with a view to ensuring that a dialogue between a medical practitioner and patient should:

- 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; and
- confirm that the individual patient has understood the information discussed.

## **Recommendation 7**

**5.97** The committee recommends that treatment guidelines developed by the Australian Commission on Safety and Quality in Health Care should clearly indicate that transvaginal mesh implantation should only be undertaken with fully informed consent and as a last resort when other treatment options have been properly considered and determined unsuitable.

## **Recommendation 8**

**5.98** The committee recommends 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 Australian Commission on Safety and Quality in Health Care and implement arrangements which require members to consider the resources in their practice.

## **Recommendation 9**

**5.114** The committee recommends that the Commonwealth, state and territory health Ministers require that guidance developed by the Australian Commission on Safety and Quality in Health Care 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.

## **Recommendation 10**

**5.118** The committee recommends that medical professional colleges and specialist societies implement governance arrangements for transvaginal mesh procedures which require that their members:

- are trained in the use of the specific device;
- are adequately skilled to perform the specific procedure, including procedures for partial or full removal of transvaginal mesh devices;
- work within a multidisciplinary team;
- monitor and report patient outcomes; and
- maintain a record of the outcomes of such procedures, including any complications.

## **Recommendation 11**

**5.123** The committee recommends that Commonwealth, states and territory governments commission the Australian Commission on Safety and Quality in Health Care 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.

## **Recommendation 12**

**5.136** The committee recommends that the Department of Health work with the Medical Technology Association of Australia and the Medical Board of Australia 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.

### **Recommendation 13**

**5.151 The committee recommends that State and Territory governments continue to work with the Australian Commission on Safety and Quality in Health Care 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:**

- **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, comprising:**
  - **comprehensive diagnostic procedures, including relevant diagnostic imaging facilities and expertise;**
  - **specialist pain management expertise; and**
  - **high level expertise in the partial or full removal of transvaginal mesh;**
- **advice and practical assistance for women who are seeking to access their medical records; and**
- **the provision of further guidance for medical professionals on recording the use of implantable devices on medical records and reporting adverse events to the Therapeutic Goods Administration.**

# 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 incontinence<sup>1</sup>

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.<sup>2</sup> Procedures using these devices quickly became the standard in the treatment of SUI.<sup>3</sup>

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

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.<sup>5</sup>

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.<sup>6</sup>

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

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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.<sup>7</sup> A list of adverse events associated with urogynaecological meshes is provided on the Therapeutic Goods Administration's (TGA) website.<sup>8</sup>

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.<sup>9</sup>

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.<sup>10</sup> The Scottish Independent Review of Transvaginal Mesh Implants released its interim report in October 2015 and its final

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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.

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report in March 2017.<sup>11</sup> The NHS Mesh Working Group released an interim report in December 2015 and its final report in July 2017.<sup>12</sup>

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.'<sup>13</sup>

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.<sup>14</sup>

### **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.<sup>15</sup>

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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](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,<sup>16</sup> 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.<sup>17</sup> 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.<sup>18</sup> The committee is grateful to all those who provided evidence to the committee.

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

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## 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.<sup>19</sup> The committee notes that class action against another manufacturer and supplier of urogynaecological mesh products is being investigated.<sup>20</sup>

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.<sup>21</sup>

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.

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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.<sup>22</sup> 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.<sup>23</sup>

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.<sup>24</sup> Up to 50 per cent of women who have given birth will have some prolapse present.<sup>25</sup> 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.<sup>26</sup> 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.<sup>27</sup>

#### ***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

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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.<sup>28</sup>

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.<sup>29</sup> Management of the condition can become progressively burdensome and costly.<sup>30</sup> 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.<sup>31</sup>

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.<sup>32</sup> 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.<sup>33</sup>

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.<sup>34</sup>

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.<sup>35</sup> It is described as minimally invasive surgery, performed under general anaesthesia, and often as day surgery, with a relatively short recovery time.<sup>36</sup>

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.<sup>37</sup> 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.'<sup>38</sup>

### ***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.<sup>39</sup>

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.<sup>40</sup>

### **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.

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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.

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### ***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.<sup>41</sup>

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.<sup>42</sup> 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.<sup>43</sup>

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.<sup>44</sup>

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.<sup>45</sup> 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.

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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.<sup>46</sup>

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.<sup>47</sup>

### ***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.<sup>48</sup>

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.<sup>49</sup>

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.<sup>50</sup> Adjunct Professor Picone told the committee:

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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.<sup>51</sup>

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.<sup>52</sup> The work of the ACSQHC will be discussed further in Chapter 5.

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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.



## Chapter 2

### The impact of transvaginal mesh procedures

For those reading this they are words on paper or on an electronic device, but for those of us living with mesh, and especially those that have suffered complications, they aren't words, but physical pain, emotional trauma, fear, embarrassment, ridicule, shame, disbelief, depression, anxiety, derision, and aloneness.<sup>1</sup>

2.1 Throughout this inquiry, the committee has repeatedly been told that the vast majority of women who have had transvaginal mesh procedures as part of treatment for stress urinary incontinence (SUI) or pelvic organ prolapse (POP) have not experienced complications as a result of their surgery and have experienced improved quality of life.<sup>2</sup> The committee also heard that the incidence and severity of complications was less for transvaginal mesh procedures to address SUI using mid-urethral slings (MUS).<sup>3</sup>

2.2 However, the vast majority of women who have written to the committee have experienced starkly different outcomes. Not only have these outcomes been severely adverse, but most of these women have experienced great difficulty finding medical practitioners who would accept that the symptoms they were experiencing were as severe as they claimed or that they were mesh related. Their struggles to cope with their symptoms and to find support and treatment have had far reaching and devastating impacts on their lives and the lives of their families. As the Health Issues Centre (HIC) noted in its submission to the inquiry, '[m]uch of the debate about the severity of this problem has been framed in terms of the good outcomes for the many outweighing the unfortunate experiences of a few.'<sup>4</sup>

2.3 The committee seeks to redress this by ensuring the voices of the women who bravely recounted their deeply personal and frequently traumatic experiences in submissions and evidence to this inquiry are heard. In this chapter, the committee considers the physical, social, emotional and financial impacts of complications associated with transvaginal mesh procedures. At the same time, the committee notes the accounts provided by women who have had successful outcomes from transvaginal mesh procedures and views of medical practitioners who consider there is a place for transvaginal mesh procedures in the treatment of SUI and POP.

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1 Name withheld, *Submission 110*, p. 1.

2 See, for example: Johnson & Johnson Medical, *Submission 23*, p. 10; Urogynaecological Society of Australasia (UGSA), *Submission 32*, p. 2; Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), *Submission 36*, p. 9.

3 See, for example: UGSA, *Submission 32*, p. 3; Continence Foundation of Australia, *Submission 35*, p. 2; RANZCOG, *Submission 36*, p. 7; Urological Society of Australia and New Zealand (USANZ), *Submission 42*, p. 3.

4 Health Issues Centre (HIC), *Submission 115*, p. 3.

2.4 In Chapter 4, the committee considers the advice and support provided to women prior to transvaginal mesh procedures and to those women who have experienced complications following their surgery.

### **The impact of mesh related health problems on women's lives**

2.5 As noted in Chapter 1, there are a number of different surgical procedures using urogynaecological mesh to address POP and SUI. The committee recognises evidence that indicates complications arising from transvaginal mesh surgery to address POP and SUI can differ in terms of incidence and clinical implications.

2.6 For example, RANZCOG submitted that complications that are specific to the use of MUS for SUI include mesh erosion and pain, particularly groin pain, while complications unique to transvaginal mesh surgery for POP include:

- vaginal exposure;
- mesh erosion into the urinary tract;
- mesh erosion into the bowel or rectum; and
- pain requiring mesh removal.<sup>5</sup>

2.7 In this chapter, while the committee has been mindful of this distinction between devices and procedures and clinical outcomes, the committee's intention is to provide a broad understanding of the range of complications that have been reported to the committee in evidence to the inquiry and, perhaps most importantly, the impact that these complications have had on women's lives.

2.8 The adverse outcomes of mesh procedures reported to the committee cover the gamut of physical, social, emotional and financial impacts. Ms Stella Channing, of the Australian Pelvic Mesh Support Group (APMSG), told the committee:

The women have lost their health, and in many cases they have lost their jobs, their careers, their homes and, in some cases, their husbands. The pain and complications cause them to be isolated from their friends and families, and many suffer from depression, anxiety and PTSD. Many women are shocked and in despair when they realise that they will probably never regain their health or their life back.<sup>6</sup>

### ***Physical impacts***

2.9 As noted in Chapter 1, the TGA has published an extensive list of adverse events that may be associated with mesh procedures.<sup>7</sup> In its submission, The APMSG told the committee that its members suffer with the effects of mesh erosion, nerve and

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5 RANZCOG, *Submission 36*, p. 9.

6 *Committee Hansard*, 25 August 2017, p. 3.

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

tissue damage, urethral damage, perforated organs and debilitating, chronic pain.<sup>8</sup> The Royal Women's Hospital, Melbourne, (RWH) told the committee that the most frequent complications seen at that hospital include pain, mesh exposure through the vagina, infection, urinary problems and recurrence of the prolapse and/or incontinence.<sup>9</sup>

2.10 Many of the women who have provided personal accounts to the inquiry have experienced, or continue to experience, multiple complications following transvaginal mesh surgery. As the husband of one woman explained, since her operation, his wife has experienced extensive and debilitating symptoms that have impacted greatly on her health, wellbeing and quality of life. These symptoms, which have persisted even after the removal of the device, include:

- extreme hyper-sensitivity bilaterally in the groin area to the extent that even light pressure over the lower mid-line pubic area is very painful;
- 'nerve like' pain in both legs, becoming more intense when weight bearing on the leg and when walking for any period of time;
- inflammation and swelling of the lower abdomen;
- periodic greenish vaginal discharge with an offensive odor;
- extreme vaginal and vulva sensitivity and pain which varies in intensity, often manifesting as a sudden, sharp shooting pain when walking;
- periodic bleeding, especially after walking; and
- extreme pain when any attempt is made to examine her vagina, for example by intra-vaginal ultrasound.<sup>10</sup>

2.11 Regrettably, the committee has read and heard many similar catalogues of symptoms in the personal accounts presented to this inquiry.<sup>11</sup>

### ***Vaginal pain***

2.12 Across most of the personal accounts received, a recurring theme is the chronic and debilitating pain that impacts every aspect of women's lives.<sup>12</sup> Associate Professor Christopher Maher told the committee that chronic vaginal pain is the

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8 Ms Stella Channing, Director and Administrator, Australian Pelvic Mesh Support Group (APMSG), *Committee Hansard*, 25 August 2017, p. 3.

9 Royal Women's Hospital (RWH), *Submission 34*, p. 5.

10 *Confidential Submission 465*.

11 See, for example: Name withheld, *Submission 102*; Name withheld, *Submission 106*; Name withheld, *Submission 133*; Name withheld, *Submission 141*, Name withheld, *Submission 289*.

12 See, for example: Name withheld, *Submission 2*; Name withheld, *Submission 4*; Name withheld, *Submission 103*; Name withheld, *Submission 141*; Name withheld, *Submission 258*; Name withheld, *Submission 356*; Name withheld, *Submission 461*.

principal and most debilitating complication following transvaginal mesh for prolapse.<sup>13</sup>

2.13 In its submission to the inquiry, the Women's Health and Research Institute of Australia (WHRIA) told the committee that many women who are suffering as a result of transvaginal mesh pain have consulted the WHRIA and that '[their] suffering is so profound, that often words cannot convey the degree of human suffering we are seeing.'<sup>14</sup>

2.14 Ms Channing described the pain as never ending, debilitating chronic pain.<sup>15</sup> The following description of living with such pain is typical of the personal accounts received by the committee:

My life has been impacted in every way. I am in constant pain, so I cannot do what I used to do, and I must lie down horizontally every hour or so because the pain becomes unbearable. I have experienced bleeding, constant bowel and urination pain, and insomnia every night; I cannot sleep because I am in so much pain. I have always been very active, going to gym, walking, cycling, but everything is very limited now. Every movement hurts. I used to be sexually active prior to this, but now I absolutely cannot. It's just pain, pain, and more pain to merely exist.<sup>16</sup>

2.15 For some women the onset of pain was immediate following their surgery and has not abated:

When I came out of surgery the pain in my left hip was excruciating. Pain in that area over the years affected my pelvis also. I have only been painfree in those areas the past year. I have been to a hip professor who injected needles into my pelvis which has helped me this past year.<sup>17</sup>

2.16 At the committee's Sydney hearing, Gai described how she has lived with constant pain for ten years since surgery to address a prolapsed bladder:

For 10 years—and I don't know how many months, weeks or minutes that is—I have not had a day without pain. I woke up in agonising pain from the surgery. No amount of pain medication could help me. They phoned my implant surgeon who sent his offsider—he didn't even bother to come in....The pain is indescribably, but it doesn't matter because there's not 100 per cent of us—and I don't believe those statistics.<sup>18</sup>

2.17 In other cases, the pain did not commence until sometime after the surgery as the following statements indicate:

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13 *Submission 154*, p. [14].

14 Women's Health and Research Institute of Australia (WHRIA), *Submission 39*, p. 1.

15 *Committee Hansard*, 25 August 2017, p. 3.

16 Name withheld, *Submission 403*, p. 1.

17 Name withheld, *Submission 374*, p. 5.

18 Gai, *Committee Hansard*, 18 September 2017, p. 5.

The surgery was actually successful for quite a few years, but I started experiencing pain on my left side. I thought it was my Mirena coil, so I had it taken out. After several months of this intense pain continuing, I went to two private gynaecologists and through an internal examination they found out that it was actually my mesh implant causing the source of the pain.<sup>19</sup>

My mesh was implanted in the UK in 2007 and I experienced no complications until 2014, seven years later, when I went through menopause. For nearly two years then I experienced debilitating, life changing complications which ultimately resulted in me travelling to the USA for mesh removal in May 2016.<sup>20</sup>

2.18 Many women described the incredible difficulty of going about their daily lives whilst experiencing constant pain:

I kept working as I had to support my family, I have 3 children of my own, including a daughter living with Down Syndrome, and a step son from a blended relationship, but I was in constant pain, and by the end of a working day and often when I was at work, I was so exhausted, to the point of having to just lay down and not move with extreme pain, tiredness and anxiety. Drs kept telling me it had nothing to do with my mesh!<sup>21</sup>

2.19 Dr Thierry Vancaille, the Director of the WHIRIA told the committee that the Chronic Pelvic Pain Clinic at the Royal Hospital for Women in Sydney is seeing patients suffering with chronic pain after mesh surgery with increasing frequency:

Nerve pain is horrible; it burns, it stings, it feels like a ball stuck in the rectum and it does not go away. In 2017 so far, we have seen 54 new patients with nerve pain after mesh surgery and, since the middle of August, we see six new patients every week.<sup>22</sup>

2.20 Joanne, who was implanted with a tension-free vaginal tape-obturator (TVT-O) sling and posterior and anterior mesh, described for the committee the limitations that 'the burning chronic pain' that she has been living with place on her:

I was told by my implanting surgeon that I would be back at the gym within 10 days post implant procedure and that I would be like a 16-year-old virgin after the implants. To this day, I can't sit upright on a chair for longer than 15 minutes at a time due to the searing pain that travels across my lower abdomen and deep into my pelvis. I have pudendal nerve neuralgia that occurred on implant of the two meshes. It took a good 14 weeks, not 10 days, post implant before I was able to get out of bed and walk again. I still, to this very day, experience the same burning pain, even after the removal of both meshes. I describe my pain as being cut open and set alight. It's a deep, burning, searing ache that intensifies with movement.<sup>23</sup>

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19 Melinda, *Committee Hansard*, 3 August 2017, p. 13.

20 Andrea, *Committee Hansard*, 3 August 2017, p. 2.

21 Name withheld, *Submission 102*, p. 4.

22 *Committee Hansard*, 18 September 2017, p. 7.

23 *Committee Hansard*, 18 September 2017, p. 1.

### ***Mesh exposure/erosion***

2.21 Mesh exposure or erosion is also commonly reported in women's personal accounts.<sup>24</sup> Mesh exposure refers to the protrusion of mesh fibres through the vaginal wall.<sup>25</sup> The committee heard that mesh exposure and scarring of the vagina can lead to discomfort and pain, including bleeding and pain during intercourse.<sup>26</sup>

2.22 Respondents to an on-line survey conducted by HIC reported a range of complications related to mesh eroding the vaginal wall, including infections, discharge, adhesions to the bowel and bladder and faecal incontinence.<sup>27</sup>

2.23 The committee heard a range of statistics regarding the incidence of mesh exposure/erosion. Monash Health submitted that 15-20 percent of women present in the first two years following transvaginal mesh procedures and between 70 to 80 percent of these will require minor surgery to address mesh exposure.<sup>28</sup>

2.24 In its submission the Department of Health advised that some studies estimate the risk of mesh exposure following transvaginal mesh procedures to be ten percent for POP related procedures, compared to less than two percent for MUS procedures to address SUI.<sup>29</sup> Associate Professor Paul Duggan, Head of Obstetrics and Gynaecology at the University of Adelaide, advised that in a research trial he conducted, comparing mesh against traditional surgery for vaginal prolapse, nine percent of participants required further surgery to address complications predominantly associated with mesh extrusion.<sup>30</sup> The Urogynaecological Society of Australasia (UGSA) provided similar statistics, noting an incidence of vaginal mesh extrusion of between eight to ten percent for repair of POP and between one to two percent for treatment of SUI using MUS. However, UGSA stated that not all cases of vaginal mesh extrusion required treatment.<sup>31</sup>

2.25 Associate Professor Maher provided the committee with the following breakdown of the incidence of mesh exposure/erosion following transvaginal mesh procedures for POP:

- 18 percent of procedures for apical prolapse, with 9.5 percent of cases requiring surgical intervention; and

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24 See, for example: Name withheld, *Submission 58*, p. 3; Name withheld, *Submission 175*, p. 5; Name withheld, *Submission 176*, p. [1]; Name withheld, *Submission 179*, p. [1]; Name withheld, *Submission 390*, p. [1].

25 Department of Health, *Submission 19*, p. 19; UGSA, *Submission 32*, p. 3.

26 UGSA, *Submission 32*, p. 3; RWH, *Submission 34*, p. 5.

27 HIC, *Submission 115*, p. 9.

28 Monash Health, *Submission 47*, p. [3].

29 Department, *Submission 19*, p. 19.

30 Associate Professor Paul Duggan, *Submission 63*, p. [1].

31 UGSA, *Submission 32*, p. 3.

- 11.3 percent of procedures for anterior prolapse, with 7.3 percent of cases requiring surgical intervention.<sup>32</sup>

2.26 Associate Professor Maher submitted that mesh exposure or erosion was more common with larger mesh devices and that early trials with new low weight mesh suggest significantly lower exposure rates of between one to five percent.<sup>33</sup>

2.27 Medical practitioners advised the committee that erosion of mesh into the vagina can usually be easily addressed. In some cases mesh exposure can be treated with vaginal oestrogen creams, but some patients require surgery to remove the exposed mesh.<sup>34</sup> Dr Jenny King, Chair of UGSA, told the committee:

You can usually trim that really easily. I know that the husbands hate it, and we try to be sympathetic. That would be a complication we could fix quite easily...<sup>35</sup>

2.28 However, the committee understands that for some women the experience of mesh exposure or erosion is far from a minor complication and can be painful and distressing, requiring multiple surgeries,<sup>36</sup> as the following examples indicate:

Add to this my personal experience of trying to teach full time with a piece of plastic hanging out of an open wound in my vagina for the last three months. I can assure you that it was not just an inconvenience or a trivial or superficial incident.<sup>37</sup>

By 3 months post op I was getting pain in my vagina, bleeding and there was mesh eroding out through the side of my Vagina, I noticed a smell that I described as rotting flesh, I went to my GP, who thought I had a fistula and sent me back to my specialist for review. I saw him and he said it was just a small hiccup, he would 'snip' the small bit of mesh out in his surgery, and he did OMG, it hurt so much and I left, with him telling me to take a couple of Panadol and I would feel ok. This went on for a couple of years, with 4 major surgeries for mesh erosion and multiple trims in his rooms. I was assured this was not very common.<sup>38</sup>

2.29 Associate Professor Maher told the committee that erosion of mesh into the bladder or bowel, while reported, is 'incredibly uncommon' and that no case was reported in the 950 women evaluated as part of the Cochrane anterior mesh review.<sup>39</sup>

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32 Associate Professor Christopher Maher, *Submission 154*, pp. [13-14].

33 *Submission 154*, pp. [13-14].

34 UGSA, *Submission 32*, p. 3; RWH, *Submission 34*, p. 5.

35 *Committee Hansard*, 18 September 2017, p. 16.

36 See, for example: Angela, *Committee Hansard*, 3 August 2017, p. 12; Angela, *Committee Hansard*, 25 August 2017, p. 19; Harriett, *Committee Hansard*, 19 September 2017, p. 3.

37 Fiona, *Committee Hansard*, 18 September 2018, p. 23.

38 Name withheld, *Submission 102*, p. [7].

39 *Submission 154*, pp. [12-13].

2.30 However, submissions to the inquiry indicated the debilitating effects experienced by women whose mesh implants had either adhered to or penetrated their bowel or bladder.<sup>40</sup> One woman told of the surprise of medical staff when they discovered that the mesh had perforated her bladder:

After a succession of Urinary Tract Infections, pain when urinating and excruciating pain after urinating I was finally sent to see a Urogynaecologist to see if he could determine the cause of my discomfort. He recommended a Cystoscopy which enables the Doctor to see inside the bladder. I was fully conscious during this procedure watching with great intent the workings of my bladder when everyone – doctors, nursing staff and myself – were surprised to see mesh which had perforated my bladder...it was only after the surgery [to excise the mesh] that my doctor told me that the mesh was dangerously close to my urethra.<sup>41</sup>

2.31 Another woman told the committee of her experience following surgery to correct a prolapse of the bowel in 1989. Having experienced a range of symptoms from 2004 till 2007 she had surgery 'to remove what was assumed to be a partial obstruction in the bowel.' The 'blockage' was found to have been caused by the mesh which had become displaced and had pierced her bowel. While the mesh was removed, this woman now has a permanent colostomy bag.<sup>42</sup>

### *Dyspareunia*

2.32 Many of the women who wrote to the committee reported experiencing dyspareunia, or painful intercourse, following their mesh surgery.<sup>43</sup>

2.33 Monash Health told the committee that between 4.3 to 10 percent of women who received transvaginal mesh procedures at Monash and Mercy Health between January 2002 and December 2012 reported painful intercourse following their surgery.<sup>44</sup>

2.34 However, Associate Professor Maher advised the committee that the incidence of dyspareunia following transvaginal mesh procedures (9.9 percent) was similar to that following native tissue or suture repairs (8.8 percent).<sup>45</sup>

2.35 While many women reported that sexual intercourse was simply too painful to contemplate,<sup>46</sup> others told the committee that their husbands had suffered injuries as a

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40 See, for example: Name withheld, *Submission 109*; Name withheld, *Submission 113*, p. 8; Name withheld, *Submission 472*, p. 1; Name withheld, *Submission 477*, p. [2].

41 Name withheld, *Submission 462*, p. 6.

42 Name withheld, *Submission 109*, p. [2].

43 See for example: Name withheld, *Submission 102*, p. [1]; Name withheld, *Submission 113*, p. [6]; Name withheld, *Submission 148*, p. 1, 5; Name withheld, *Submission 258*, p. [1]; Name withheld, *Submission 289*, p. [2]; Name withheld, *Submission 390*, p. [4-5].

44 *Submission 47*, p. [3].

45 *Submission 154*, p. [13].

46 See, for example: Melinda, *Committee Hansard*, 3 August 2017, p. 14; Melanie, *Committee Hansard*, 25 August 2017, p. 21; Name withheld, *Submission 102*, p. 9.

result of mesh which had eroded through the vaginal wall.<sup>47</sup> One woman described for the committee the impact that her surgery had on her once 'healthy balanced relationship'.<sup>48</sup> She described how intimate sensations felt raw and painful and how she dreaded 'constantly failing with every painful attempt'

To add insult to this situation my husband began complaining that making love to me was like sleeping with a cheese grater. His penis would be cut when we had intercourse. The pain and embarrassment made me anxious, sick and depressed.<sup>49</sup>

2.36 The impact of this on women's personal relationships and emotional wellbeing is discussed further below.

### ***Urinary and voiding problems***

2.37 The most frequent issues reported to the HIC were problems associated with incontinence and persistent UTIs. Some respondents to the HIC survey indicated that while the transvaginal mesh procedure had addressed their incontinence, they were now experiencing difficulty urinating or emptying their bladder. Some respondents reported needing to self-catheterise.<sup>50</sup> These responses are consistent with personal accounts provided to the committee.<sup>51</sup>

2.38 Recurrent urinary tract infections are a common complication noted in the personal accounts provided to the committee, with many women expressing concern regarding their continued reliance on antibiotics.<sup>52</sup>

2.39 Other women have experienced severe incontinence following mesh procedures.<sup>53</sup> In their submissions they described the challenges of going out: the need to wear incontinence pads, to know where the nearest toilet is; to carry spare clothes and the embarrassment and indignity when even these precautions are not enough:

It has completely changed my life. I presented with mild stress incontinence with exercising and 2 years on I have total and uncontrollable urinary incontinence. I have had multiple hospital admissions, surgeries, invasive investigations and a total loss of my pride as a woman.<sup>54</sup>

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47 See, for example: Name withheld, *Submission 4*, p. 1; Name withheld, *Submission 148*, p. 5; Name withheld, *Submission 429*, p. 6; Name withheld, *Submission 529*.

48 Name withheld *Submission 464*, p. 2.

49 Name withheld, *Submission 464*, p. 2.

50 HIC, *Submission 115*, p. 9.

51 See, for example: Kim, *Committee Hansard*, 3 August 2017, p. 1; Robyn, *Committee Hansard*, 25 August 2017, p. 21; Harriett, *Committee Hansard*, 19 September 2017, p. 5; Name withheld, *Submission 147*.

52 See, for example: Name withheld, *Submission 72*; Name withheld, *Submission 79*, *Attachment 1*; Name withheld, *Submission 114*; Name withheld, *Submission 392*.

53 See, for example: Name withheld, *Submission 87*, p. [4]; Name withheld, *Submission 420*, p. [4].

54 Name withheld, *Submission 458*, p. [6].

2.40 A number of women reported experiencing voiding dysfunction following their mesh surgery.<sup>55</sup> Some of these women have been advised that these difficulties are the result of the mesh obstructing the bowel,<sup>56</sup> while others have been advised that the dysfunction stems from the mesh being too tight.<sup>57</sup>

2.41 The Urological Society of Australia and New Zealand (USANZ) noted in its submission that international studies suggest that the incidence of such symptoms after transvaginal mesh surgery to treat SUI is low. USANZ noted 11 percent of patients experience new urgency symptoms (an overactive bladder) after MUS, with 3.9 percent of cases not responding to treatment and 5.3 percent of patients experiencing persistent or recurrent stress urinary incontinence.<sup>58</sup> Dr Atherton submitted that the risk of significant voiding disorder and urge incontinence is much higher following other major surgical procedures for the treatment of SUI than it is for surgery using MUS. However, Dr Atherton also noted 'when a complication is severe, whatever the nature of it, the woman's life is often severely and permanently changed.'<sup>59</sup>

### ***Impact of mesh complications on quality of life***

2.42 It is not surprising that alongside physical complications such as those described above, many women have experienced profound impacts on their quality of life following mesh procedures. Professor Vancaillie described for the committee the disastrous impact these symptoms have had on the lives of the women who have come to the WHRIA:

For some women, things have gotten better, but for quite a few, problems have gotten worse, resulting in true disaster with substantial loss of quality of life. They are unable to sit for any length of time, which means they can't enjoy such basic social interaction as a family dinner. They can't have intercourse. They have difficulty emptying their bladder or bowel. They have difficulty with basic physical activity, such as walking or going up flights of stairs. One patient who just turned 40 summarised it quite succinctly: "I can't afford feeling like an 80-year-old grandmother. I have to look after my young children, and I can't."<sup>60</sup>

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55 See, for example: Name withheld, *Submission 133*; Name withheld, *Submission 147*; Name withheld, *Submission 158*; Name withheld, *Submission 179*; Name withheld, *Submission 384*.

56 Name withheld, *Submission 113*, p. 8.

57 See, for example: Name withheld, *Submission 114*, p. [5]; Name withheld, *Submission 147*, p. 6; Name withheld, *Submission 385*, p. [3]; Name withheld, *Submission 521*, p. [3].

58 *Submission 42*, p. 3.

59 *Submission 98*, p. [7].

60 *Committee Hansard*, 18 September 2017, p. 7.

2.43 Many women described how they have withdrawn from social and family activities, too embarrassed to explain their symptoms to friends and family or simply unable to engage in normal social activity.<sup>61</sup> As one woman stated:

I don't make plans anymore, I don't go out much, I live a very reclusive life because I am embarrassed of my symptoms that I have been left with from these implants.<sup>62</sup>

2.44 Many women described the impact their symptoms had on their once active lives. Many of the personal accounts recounted a dramatic change in the range of activities that women could engage in.<sup>63</sup> One submitter wrote:

It was difficult to return to work, up to the day I had the operation I was very active, for the past 20 years I have worked at a special needs high school for behaviour disorders and emotionally disturbed teenagers. I have always prided myself as being an active team member of our staff. After the operation I felt I couldn't possibly do the things I used to be able to do with the kids. Playing basketball, dodgeball, football, netball, cricket etc. Gradually my weekly workdays diminished from 4 to 3 days to 2 days a week working.<sup>64</sup>

2.45 Another woman told the committee of the difficulty she experienced trying to live a normal life:

I dragged myself to work each day and on weekends I was bedridden. I was unable to do normal things like shopping, cooking and housework without debilitating pain and fatigue. My relationship with my family, friends suffered as I could not handle social activities. Not being able to care for my new grandson broke my heart. Surfing was impossible and walking the dogs or doing other light physical exercise was just too painful.<sup>65</sup>

2.46 Many of the personal accounts received by the committee describe the impact of mesh complications on women's family and personal relationships. As the accounts referred to above reflect, many women wrote of their inability to care for their children or interact with their grandchildren.

It has taken its toll on my family life as I am unable to enjoy many of the activities with my family as I am limited in my movement and still experience debilitating pain.<sup>66</sup>

2.47 Another significant social impact has been the limitations that these symptoms have placed on women's ability to work. While some women have been able to

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61 See, for example: Name withheld, *Submission 340*; Name withheld, *Submission 439*; Name withheld, *Submission 524*.

62 Name withheld, *Submission 101*, p. 3.

63 See, for example: Name withheld, *Submission 133*; Name withheld, *Submission 182*; Name withheld, *Submission 398*.

64 Name withheld, *Submission 289*, p. 4.

65 Name withheld, *Submission 67*, p. 1.

66 Name withheld, *Submission 102*, p. [5].

modify their working arrangements, by taking regular breaks throughout the day, modifying their work environment or the work they do<sup>67</sup>, others have found they are no longer able to work which has created financial stress for them and their families:

I was unable to work for two years ad (sic) then I made a very slow return to work because of the fatigue and relapses. Being unable to work has created financial stress on our family.<sup>68</sup>

2.48 Many of the submissions received from women told of the significant financial burden associated with treatment of complications from mesh surgery. Most of these women have faced significant out-of-pocket expenses, have taken significant time off work and have used up their sick leave and long service leave.<sup>69</sup> Personal accounts received by the committee frequently referred to amounts in the thousands of dollars for treatment of pain and other symptoms, with few of these costs covered by private health insurance.<sup>70</sup> For example:

I have to this point spent over \$12,000.00 to pay for all of this and I have ongoing drugs and acupuncture. Money I didn't have and had to ask friends and family to help.<sup>71</sup>

2.49 One woman told the committee that she had been prescribed a course of six injections of Hyaluronic acid to address nerve pain. She said:

I have currently had six of these injections with no desirable affect or improvement. The 'direct' cost for these injections has amounted to \$6,000, a fraction of the indirect cost on my business and loss of income.<sup>72</sup>

2.50 Another woman told the committee that out of pocket costs associated with her treatment have run into tens of thousands of dollars:

I cannot work because of my medical issues, which has caused financial problems. The costs for treatment for my pain and other symptoms is ongoing. I have spent tens of thousands of dollars out of pocket for treatment, after private health insurance claims. My last surgery cost \$8000+ out of pocket.<sup>73</sup>

2.51 Some women described the difficulties they have experienced accessing financial support through Centrelink.<sup>74</sup> Women have found it difficult to explain their symptoms and the impact this has on their ability to work. One woman described how after her surgery, she found she was only able to manage working 15 hours a week,

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67 See, for example: Name withheld, *Submission 67*.

68 Name withheld, *Submission 459*, p. 1.

69 See, for example: Name withheld, *Submission 220*, p. 4; Name withheld, *Submission 411*, p. 5.

70 See, for example: Joanne, *Committee Hansard*, 18 September 2017, p. 3.

71 Name withheld, *Submission 521*, p. [4].

72 Name withheld, *Submission 92*, p. 2.

73 Name withheld, *Submission 56*, p. 5.

74 See, for example: Joanne, *Committee Hansard*, 18 September 2017, p. 5.

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'and even then it is difficult to maintain these hours.' However, she has been advised by Centrelink that she is capable of working at least 23 to 27 hours a week. Her attempts to explain her condition, even with the help of medical records and letters from her legal advisers have so far been unsuccessful. She said:

It makes me very angry and depress[ed] just because the outside looks fine doesn't mean I am.<sup>75</sup>

2.52 Another woman explained to the committee how low her experience of continually trying to explain her condition had brought her:

In the end, it drove me to the point where I had had enough and I was still in a lot of pain at that stage. About a year ago, I just thought: 'I'm ready to check out. I've had enough.' I had \$200 left in the bank. I had spent all my money that I had saved. I had nothing left.

I got onto a social worker who, ultimately, processed the application for me. But I spoke to, I would say, about 50 different people during that process and wrote so many letters, spent hours on hold. Every time I spoke to a different person in Centrelink, I'd have to tell the story again. It was just a nightmare.<sup>76</sup>

2.53 The committee heard that women have mortgaged or sold their homes, while others have come close to losing theirs as they struggle to meet spiralling medical costs.<sup>77</sup>

2.54 Others have experienced difficulties trying to access their superannuation.<sup>78</sup> As the following examples indicate, for some women, the delays and difficulties associated with this have caused them an additional layer of stress:

I am assisted by my husband who has had to take time off work. I am still on leave from work myself. Forced to serve the 395 day waiting period for my super to pay me 70% of my wage, the addition of \$50,000 to our mortgage means we struggle to make ends meet.

I wrote to my superannuation fund but was denied being able to waive the waiting period regardless of all the evidence my doctors are able to give them going back 5 years. Disgusting really, my family is suffering from this and why should they? My option now is to write to the Superannuation Ombudsman...The government knows the difficulties women are having with this tragic medical outcome yet why am I made to pay the price for something I did not ask to happen – unsure how I will cope financially, mentally, emotionally.<sup>79</sup>

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75 Name withheld, *Submission 68*, p. [2].

76 Joanne, *Committee Hansard*, 18 September 2017, p. 5.

77 Name withheld, *Submission 4*.

78 See, for example: Joanne, *Committee Hansard*, 18 September 2017, p. 3; Gai, *Committee Hansard*, 18 September 2017, p. 3.

79 Ms Harriett Desmond, *Submission 159.1*, p. [2].

2.55 A number of women who are waiting for surgery to remove their mesh told the committee of the lengths they have needed to go to in an attempt to raise the thousands of dollars required. Some have turned to friends and family for financial support:

The surgery cost is \$9,600 which I haven't got yet but have pawned my wedding rings, jewel[le]ry, set up a crowdfunding page and asked my children for money to help as I am determined to have it as I need this product out of me before it causes more damage. My three children live in the United States so going through all this on my own has been very stressful.<sup>80</sup>

2.56 Some women have drawn on every source of funds available to them, leaving them concerned for their future financial security and their ability to enjoy the quality of life many people might take for granted:

Removal costs will be approx. \$50000. I have not worked since this mesh was implanted in me in March 2011. The death of my father and an inheritance sum of money paid [off] the remainder of my mortgage and is funding my surgery...I live [off] income protection from my superannuation and have income streamed my super. Mesh has robbed me of a future, a career and my health. It robbed me of being able to provide family holidays for my children and me. It has taken away my social life and friends. They do not understand what a daily battle I have and it is just getting worse.<sup>81</sup>

2.57 Another woman observed: 'There is one thing I can say that the mesh does hold my pelvic floor up but at what cost now and in the future.'<sup>82</sup>

### ***The emotional toll***

To sum it up mesh has ruined my life.<sup>83</sup>

2.58 So many of the submissions received from individual women related the emotional toll that mesh related complications have had on their lives. The APMSG told the committee:

Many women in the APMSG have pain that is so debilitating, they have given up work, they can no longer have sexual intercourse with their husbands/partners, they are in pain every day, they are on a cocktail of pain medications, many have urinary tract infections and are on antibiotics. They are suffering from depression and anxiety, many have post traumatic stress disorder. Some women have suicidal thoughts because they can find no way out of their crippling pain.<sup>84</sup>

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80 Name withheld, *Submission 521*, p. [3].

81 Name withheld, *Submission 524*, p. 1.

82 Name withheld, *Submission 410*, p. [2].

83 Name withheld, *Submission 459*, p. 6.

84 APMSG, *Submission 130*, p. 6.

2.59 While some women spoke of the incredible support and understanding provided by their families,<sup>85</sup> most women who wrote to the committee about mesh related complications were all too keenly aware of the toll that living with their symptoms has had on their relationships with their families. For some women it is a daily struggle to push through the physical and emotional pain they feel:

On the receiving end are my husband, children and friends. I have attempted to keep my physical and emotional pain from the ones that I love, and I've pushed on through so hard so I always get back on track, back to being the mum that I always was and the hardworking woman I strive to be. Others cannot believe I'd end up broken, but I am. I suffer with post-traumatic stress, huge anxiety and I have recently accepted that, yes, depression is real. I now rely on medication so I can smile at my children, look at my husband and remind him of why he married me. I can't attend work anymore. I am no longer able to pretend that I am okay. The pain slowly kills your soul.<sup>86</sup>

2.60 For others, the deterioration of their relationships with family and friends, has left them isolated and lonely:

My life is broken, my children no longer see me as the person I once was, with the exception of my eldest who is older and more able to understand, therefore is able to tolerate me. The two younger rarely if ever see me. They cannot relate to me and now see me as an old confused lady. I try at times to revive my communication with them but they do not want this, see me as an embarrassment...<sup>87</sup>

2.61 As noted earlier, many women told the committee that following their surgery it was either extremely painful or impossible for them to sustain an intimate relationship and spoke of the emotional pain and grief that this had caused them.<sup>88</sup>

2.62 So many of the women who wrote to the committee spoke of the pain, both physical and emotional, that this had caused them and their partners.<sup>89</sup> One woman told the committee:

The first time we tried to have intercourse it felt like barbed wire inside me. My husband could also feel the mesh. This [came] as a massive shock as my professor had told me I would be like a new woman after childbirth everything would be tighter. I grieved for my sex life for a long time as my husband and I had only been married 6 months.<sup>90</sup>

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85 See, for example: Name withheld, *Submission 118*, p. [5]; Name withheld, *Submission 137*; Name withheld, *Submission 123*, p. 2; Name withheld, *Submission 149*, p. 5.

86 Harriett, *Committee Hansard*, 19 September 2017, p. 3.

87 Name withheld, *Submission 494*, p. 4.

88 See, for example: Name withheld, *Submission 82*; Name withheld, *Submission 105*, p. [5]; Joanne, *Committee Hansard*, 3 August 2017, p. 11.

89 See, for example, Name withheld, *Submission 110*, p. [11].

90 Name withheld, *Submission 374*, p. 6.

2.63 The committee heard that the inability to sustain intimate relationships has had far reaching impacts on women's emotional well-being. As a woman from the Tiwi Islands explained to the committee:

If you look at women in remote Indigenous communities...and at the impact of isolation on Indigenous women, you will find that if they have this mesh, they will be totally ostracised. When our women talk about sex, sex is not just sex; it encompasses a whole community and involves love, intimacy, touch deprivation—everything.<sup>91</sup>

2.64 For many women, the breakdown of their intimate relationships, together with the financial and other stresses associated with their complications, has led to the breakdown of their marriages and their family unit.<sup>92</sup>

I just became non-sexual. I ended up sleeping on the couch for two years and we tried so hard to stay together as a couple and a family but we just couldn't keep going. So 6 weeks ago, I moved in with my parents at the age of 52. I have no money, nothing of value (and neither does he). I left behind everything...we made the decision it would be best for our children to live in our rental home with my husband. I have lost the love of my life, my best friend and we hardly even talk anymore. I hardly see my children and I am absolutely devastated.<sup>93</sup>

2.65 The committee was struck by the number of women who reported the breakdown of their marriage.<sup>94</sup> The responses to the WHRIA's Pelvic Pain Impact Questionnaire suggest that of 124 women surveyed, 72 percent reported that pelvic pain had affected their levels of intimacy or sexual relationships.<sup>95</sup>

2.66 The Health Issues Centre told the committee that of the respondents to its survey of women's experiences following transvaginal mesh surgery, 88 reported a negative impact on their intimate relationships, including avoidance of sexual activity due to their own pain or that of their partner. 110 respondents reported relationship issues both as a result of their physical symptoms and the financial strain caused by the cost of treatment and multiple surgeries and often an inability to work.<sup>96</sup> Ms Elizabeth Howard, from the WHRIA, told the committee that in the WHRIA's

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91 Tracey, *Committee Hansard*, 25 August 2017, p. 23.

92 See, for example: Name withheld, *Submission 62*, p. [3]; Name withheld, *Submission 110*, p. [11]; Name withheld, *Submission 117*, p. 3; Name withheld, *Submission 257*, p. [1, 6]; Name withheld, *Submission 345*, p. [1, 5]; Name withheld, *Submission 395*, p. [1]; Name withheld, *Submission 398*, p. [2]; Name withheld, *Submission 400*, p. [1].

93 Name withheld, *Submission 110*, p. [11].

94 See, for example: Name withheld, *Submission 110*; Name withheld, *Submission 114*.

95 Professor Thierry Vancaillie, *Committee Hansard*, 18 September 2017, p. 11.

96 Health Issues Centre, *Submission 115*, p. 9.

experience perhaps as many as 50 percent of marriages breakdown following complications associated with transvaginal mesh implants.<sup>97</sup>

2.67 Some women have experienced nervous breakdowns that they attribute to the pain and anxiety their symptoms have produced,<sup>98</sup> while others spoke of suicidal ideations:

I feel isolated and alone. I feel angry and violated. I live in fear of not knowing which way to turn. My self-esteem is low. I am consumed with negative thoughts and require ongoing counselling.<sup>99</sup>

...

Its actually destroyed my life to the point that I thought I couldn't go on any further and suicide was an option.<sup>100</sup>

2.68 Many women have suffered these devastating symptoms unaware that other women have had similar experiences.<sup>101</sup> As one woman told the committee:

I have had my own history of mesh problems and it was only this year that I discovered that there are literally thousands of women in Australia and hundreds of thousands around the world who have had complications and side effects. For ten years I have thought that I was just about the only one who continued to suffer, that there was no help for me, nothing that could be done so I gave up...<sup>102</sup>

2.69 One woman told the committee of the relief she experienced once she discovered that she was not alone:

I have honestly thought of ending it all on several occasions as I often feel as if I'm so alone with it all and can't bear it any longer. Until recently I have found a group of ladies with the same issues because of mesh implants, they have helped me feel as though I'm not mad and I'm not alone, there are so many of us out there suffering in silence, like me. Until now we have not had a voice. It has been too embarrassing and personal.<sup>103</sup>

### ***Committee view***

2.70 The evidence provided to the inquiry by individual women demonstrates that complications following transvaginal mesh procedures have far reaching and, in many

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97 Ms Elizabeth Howard, Osteopath and Pain Management, Women's Health and Research Institute of Australia, *Committee Hansard*, 18 September 2017, p. 11.

98 See, for example: Name withheld, *Submission 101*, p. 1; *Submission 345*, p. [5].

99 Kylie, *Committee Hansard*, 18 September 2017, p. 24.

100 Name withheld, *Submission 401*. See also: Name withheld, *Submission 113*; Name withheld, *Submission 118*; Name withheld, *Submission 401*; Name withheld, *Submission 424*; Name withheld, *Submission 521*.

101 See, for example: Name withheld, *Submission 67*, p. 4; Name withheld, *Submission 97*, p. [3]; Name withheld, *Submission 396*, p. [3].

102 Name withheld, *Submission 110*, p. [5].

103 Name withheld, *Submission 551*, p. [1].

cases, devastating impacts on women's lives. In the words of one submitter, '[w]hen it goes wrong, it goes catastrophically wrong.'<sup>104</sup>

2.71 So many of the women who wrote to the committee or appeared at public hearings live with constant pain and a range of other debilitating complications that undermine their quality of life.

2.72 The committee acknowledges the impact of complications from transvaginal mesh procedures which encompass every aspect of women's lives. In many cases, women have become isolated from their families and friends and have had to endure their symptoms with limited practical and emotional support. In so many cases, the committee heard how women have been robbed of so much: their interests; their ability to parent; to work and to sustain close and loving relationships. At the same time they have lost their dignity and self-esteem and many have struggled with depression.

2.73 The committee notes the significant costs associated with managing the complications following transvaginal mesh surgery. In addition to significant out of pocket costs associated with pain management, scans and incontinence and mobility aids, women have used up their leave, drawn upon their superannuation, sold valuables and, in some cases sold or mortgaged houses and drawn on the generosity of friends and family to fund their treatment.

2.74 The committee considers that it is of no consolation to women who have lost so much to be told that they are part of a very small minority. The committee notes the observation of Mrs Elaine Holmes, from the Scottish Mesh Survivors Groups:

We are told that, for the majority of women, mesh is successful. We sincerely wish them continued good health, and hope they never suffer the hell that we do. Every transvaginal mesh survivor knows only too well what it is like to suffer from stress urinary incontinence and/or pelvic organ prolapse. Yes, it is uncomfortable, painful at times, unpleasant and embarrassing. However, neither is a life-threatening condition.<sup>105</sup>

### **Successful outcomes using mesh**

2.75 As mentioned earlier, the committee received evidence emphasising the many women who have experienced positive outcomes following transvaginal mesh procedures. The committee heard that vaginal mesh implants have provided 'excellent anatomical and quality of life results for the silent majority of women who have undergone surgery.'<sup>106</sup> Submitters expressed concern that insufficient attention was being focussed on the positive, life changing impacts of transvaginal mesh

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104 Gai, *Committee Hansard*, 18 September 2017, p. 5.

105 Mrs Elaine Holmes, Scottish Mesh Survivors Group, *Committee Hansard*, 19 September 2017, p. 36.

106 UGSA, *Submission 32*, p. 5.

implants,<sup>107</sup> and that women deserve the right to choose procedures most suitable to their particular circumstances.<sup>108</sup>

2.76 The committee also received submissions from women who were concerned at what they described as 'the Media furore' over the use of vaginal mesh for the treatment of SUI and POP. Many of these women were anxious that the committee should 'not take this knee jerk reaction too seriously.'<sup>109</sup>

2.77 The committee heard that in many cases women have suffered terribly for years before having surgery. A number of women described their experience of living with both bladder and bowel incontinence:

I was completely bladder incontinent, bowel incontinent; I couldn't have sexual intercourse. I continuously had bladder infections. I developed chronic thrush because of it. I was sick for years. My life revolved around having extra clothes, pads, being close to a toilet and hoping to God that when I had a shower my bowels wouldn't release themselves on me. That was my life.<sup>110</sup>

2.78 Another woman recounted similar experienced:

To be clear, my day revolved around timing my bladder and bowels, I had to make sure that I was close to a bathroom at all times, I had to carry spare clothes and underwear in case I soiled myself, I had to wear pads, If I wanted to have sexual intercourse I had to empty my bladder before, during and afterwards and at times my bowels as well. Sometimes I didn't make it to the bathroom on time. I cannot convey enough to you how humiliating this was for me.

This surgery has changed my life, I have not a single urinary infection since, I don't look for the bathrooms wherever I go, I can hold on if I need to, I don't have [to] carry a spare set of cloths with me, I can enjoy an intimate relationship with my husband.<sup>111</sup>

2.79 Another woman, who underwent major repair surgery for POP using mesh, described for the committee the distress caused by severe prolapse:

Whilst waiting to see [the surgeon]. I was extremely uncomfortable & distressed by the severity of my symptoms. Vaginal Prolapse is a very disturbing issue, one that I found very debilitating; it's a hard thing to put up

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107 See, for example: Name withheld, *Submission 176*; Name withheld, *Submission 229*, Name withheld, *Submission 231*, Name withheld, *Submission 235*, Name withheld, *Submission 236*, Name withheld, *Submission 237*, Name withheld, *Submission 296*; Name withheld, *Submission 473*.

108 See, for example: Name withheld, *Submission 300*.

109 See, for example: *Submission 32, Attachment 14*.

110 Timnat, *Committee Hansard*, 18 September 2017, p. 25.

111 Name withheld, *Submission 127*, p. [3].

with and the fact that there is so much discomfort, in my case made me feel unwell.<sup>112</sup>

2.80 This woman went on to say:

Whilst the initial recovery immediately after the surgery, was harrowing to say the least. I went home after 3 days in hospital, & spent a full 6-8 weeks following my specialists advice to take it extremely easy, no lifting, driving, housework, work etc. As this was my second time with this condition I followed her advice to the letter.

It is nearly 3 years since this operation, and for me it appears to be an ongoing success, I am not saying that I don't have issues that could be associated with the operation, but thus far I have no ongoing major complications associated with the actual Mesh.<sup>113</sup>

2.81 Another woman simply stated that '[g]oing from a severe prolapse to normality was a greater relief than I can explain to anyone who has not experienced this difficult problem.'<sup>114</sup>

2.82 This evidence was underscored by photographic evidence provided to the committee that highlighted the realities of living with severe prolapse.<sup>115</sup>

2.83 A number of submitters and witnesses expressed concern that a restriction on the use of transvaginal mesh would deny many women access to treatment appropriate to their particular circumstances.<sup>116</sup>

2.84 Ms Sunny Hutson, expressed concern that the discussion about urogynaecological mesh is 'focusing on only the material itself and not the crucial differences between the procedures that use it, the principles they're based on and their dramatically different outcomes.'<sup>117</sup> Ms Hutson explained to the committee that she had lived with the effects of severe pelvic organ prolapse for 30 years as a result of being disembowelled by a swimming-pool filter at the age of two. In her submission, Ms Hutson described her feelings of desperation prior to her surgery and the dramatic and life changing impact that a procedure using urogynaecological mesh has had in her case.<sup>118</sup>

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112 Name withheld, *Submission 473*, p. 1.

113 *Submission 473*, p. 1.

114 UGSA, *Submission 32, Attachment 15*.

115 See, for example: Dr Jenny King, Urogynaecological Society of Australasia, *Photographs: prolapse*, (tabled 18 September 2017).

116 See, for example: Dr Caroline Dowling, Urologist, USANZ, *Committee Hansard*, 3 August 2017, p. 22; Dr Gary Swift, President, National Association of Specialist Obstetricians and Gynaecologists, 3 August 2017, p. 22.

117 *Committee Hansard*, 18 September 2017, p. 57.

118 Ms Sunny Hutson, *Submission 151*.

### ***The complexity of treating pelvic floor disorders***

2.85 Medical practitioners stressed that pelvic floor disorders can be very complex to treat and that surgeons who manage advanced and/or recurrent prolapse must be able to offer patients a complete range of non-surgical surgical and surgical options.<sup>119</sup>

2.86 UGSA submitted that '[n]o one procedure is appropriate for all patients and for some women a transvaginal mesh procedure may be the most effective and durable treatment.'<sup>120</sup> UGSA went on to explain that clinicians must try to balance the benefits of a treatment against the possibility of uncommon events:

Even without mesh, pelvic floor reconstructive procedures can be complicated by pain, vaginal scarring, bladder symptoms and difficulties with intercourse. For example, a recent large randomised trial demonstrated no significant difference in serious adverse events including dyspareunia between those with native tissue and those with mesh repair (15). And the rate of all intra and post-operative complications is increased if repeat surgery is required due to failure. So for some women, for example those with significant comorbidities or at high risk of recurrence, the smaller risk of a mesh complication may outweigh the risks of redo surgery which is them more likely to need mesh implants.<sup>121</sup>

### ***Mid-urethral slings***

2.87 As noted earlier, while submitters generally acknowledged a higher level of risk associated with transvaginal mesh procedures for the treatment of POP, a number of specialist medical practitioners emphasised the positive outcomes associated with the use of MUS in the treatment of SUI. Dr Alison De Souza, a Urogynaecologist with the Mercy Hospital for Women told the committee

The mid-urethral sling has been life-changing for many thousands of Australian women by correcting their urinary leakage. We feel that the silent majority of women who are happy with the outcome of their mesh procedure also need to be heard and taken into account.<sup>122</sup>

2.88 UGSA submitted that there is extensive data, including data from multiple, high quality randomised controlled trials and long term follow up over 17 years, to support the 'excellent safety and efficacy' of MUS. UGSA stated that procedures using MUS have been performed up to 20 times more frequently than previous abdominal procedures with immense quality of life benefits for women of all ages.<sup>123</sup>

2.89 USANZ, submitted that the results of an Australian study on the frequency of side effects from MUS had demonstrated that health related quality of life improvement at three months after retropubic MUS predicts persistence of

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119 See, for example: RWH, *Submission 34*, p. 6.

120 UGSA, *Submission 32*, p. 1.

121 *Submission 32*, p. 3.

122 Dr De Souza, *Committee Hansard*, 3 August 2017, p. 31.

123 *Submission 32*, p. 2.

improvement at four years. USANZ stated '[a]lthough patient numbers are modest, these data contribute to the scarce longer term HRQL [Health-Related Quality of Life] data on the MUS, which is a safe and durable procedure with a minimal complication profile.'<sup>124</sup> USANZ provided the following breakdown of the incidence of complications associated with MUS requiring surgery:

a 3.2% rate for slings that obstruct (too tight), 2% for mesh erosion or exposure, 0.3% for fistulas (connection between one organ system and another) and 0.1% for bowel injury. Further analysis of complications that were defined as life altering, demonstrated chronic pain in 4.3% of which 0.5% was refractory [resistant] to treatment, 11% of patients had new urgency symptoms (over active bladder) and 3.9% of these were refractory to treatment and 5.3% of patients had persistent or recurrent stress urinary incontinence.<sup>125</sup>

2.90 The committee notes evidence that suggests further research is required to validate claims regarding the high rate of successful outcomes for transvaginal procedures using MUS for SUI.<sup>126</sup> Information provided by the APMG indicates that of 101 incidences of complications reported by its members, involving 176 mesh devices, 70 involved mesh for the treatment of SUI using either TVT or TVT-O compared to 43 involving mesh for the treatment of POP. 27 instances were reported by women who had transvaginal mesh surgery to address both SUI and POP.<sup>127</sup>

### ***The evolution of mesh products***

2.91 As noted earlier, a number of practitioners drew a distinction between the use of devices constructed of large sheets of urogynaecological mesh and devices using tape. Dr Darren Gold told the committee that sheets of mesh positioned to hold up organs have never been shown to improve POP symptoms.<sup>128</sup> The International Society for Pelviperineology (ISP) submitted that the rate of complication associated with mesh sheets as compared to tape is much greater and that mesh sheets tend to shrink creating tension in the tissues which in turn contributes to nerve pain.<sup>129</sup> The ISP stated that complications, including pain, are less with MUS and that most involve 'surfacing of a small segment of mesh which can be dealt with by snipping, usually as an outpatient.'<sup>130</sup>

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124 USANZ, *Submission 42*, p. 3.

125 *Submission 42*, p. 3.

126 See, for example: Mr Danny Vadasz, Chief Executive Officer, Health Issues Centre, *Committee Hansard*, 3 August 2017, p. 19.

127 APMSG, Number of complications involving stress urinary incontinence vs pelvic organ prolapse mesh procedures within the group's membership, received, additional information received 5 February 2018.

128 *Submission 145*, p. 4.

129 International Society for Pelviperineology (ISP), *Submission 48*, pp. 1- 2.

130 *Submission 48*, p. 2.

2.92 The committee heard that overtime mesh devices have evolved. Dr Gary Swift, President of the National Association of Specialist Obstetricians and Gynaecologists, told the committee:

In the very early days of mesh usage we knew that there were design flaws in the very early meshes. They became obvious when the rates of erosions were much higher...There has certainly been an evolution. In the early meshes, no-one will deny that mesh erosions were much higher in the earlier generations. We have certainly seen those. Those products, I understand, were voluntarily recalled once there was clear evidence that there was potentially a design flaw in the product itself.<sup>131</sup>

2.93 Dr Caroline Dowling, from the Urological Society of Australia and New Zealand, told the committee

There is absolutely no contention that the meshes that predated polypropylene were high risk, and they were withdrawn from the market. There has not been a polypropylene mesh product withdrawn from the market that I am aware of apart from a mini-sling called TVT-Secur.<sup>132</sup>

2.94 At the same time, the evidence base for transvaginal mesh has been evolving. Professor John Skerritt, representing the Therapeutic Goods Association, noted that the evidence base for transvaginal mesh has evolved:

We are all older and wiser and as medical experience with surgery and with particular products evolves you know more at a particular point of time than you would have two, five, 10, 12 or 15 years ago. And this is particularly true with mesh devices. The evidence base for meshes has evolved.<sup>133</sup>

2.95 However, the committee notes that, while many of the personal accounts received from individual women during the inquiry relate to transvaginal mesh surgery performed more than five years ago, a number of the accounts relate to surgery performed in the last two years. Information provided by the APMSG indicates that of the 101 women who have reported complications to the APMSG, 16 of these women have had transvaginal mesh surgery in the last two years and 52 have had transvaginal mesh surgery in the last five years.<sup>134</sup>

### ***Committee view***

2.96 The committee does not discount the successful outcomes experienced by many women. Nor does the committee underestimate the complexity of treating SUI and POP. However, the committee is concerned that the plight of those women who

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131 Dr Swift, *Committee Hansard*, 3 August 2017, p. 27.

132 *Committee Hansard*, 3 August 2017, p. 28.

133 Professor John Skerritt, Deputy Secretary, Health Products Regulation Group, Department of Health, *Committee Hansard*, 8 August 2017, p. 46.

134 APMSG, Number of complications involving stress urinary incontinence vs pelvic organ prolapse mesh procedures within the group's membership, received, additional information received 5 February 2018.

have experienced devastating impacts on their health and quality of life not be downplayed, simply because they are in the minority. Rather the committee intends that greater focus be placed on understanding why some women experience positive life changing outcomes and other experience catastrophe.

2.97 In the next two chapters, the committee will consider the extent of usage of transvaginal mesh implants in Australia and the provision of information, clinical care and support to women who present with symptoms of SUI and POP.

## Chapter 3

### The extent of usage of transvaginal mesh implants in Australia

I am not a statistic; I am not a percentage; and I am not collateral damage. I am a wife, a mother, a daughter and a sister.<sup>1</sup>

3.1 There is no clear indication of how many women have had transvaginal mesh implants in Australia or how many women have experienced complications as there is no single source of information.

3.2 This is significant because, as noted in Chapter 2, much of the discussion about the use of transvaginal mesh devices has been framed in terms of the overwhelming success of transvaginal procedures using mesh devices compared to small numbers of adverse events.

3.3 Throughout the inquiry, the committee heard that any understanding of the true extent of the usage of these devices and the rate of complication associated with them must be pieced together from a range of sources.

#### The number of women who have received transvaginal mesh implants

3.4 Submitters highlighted a number of possible sources of data that could potentially be used to estimate the number of Australian women who have received transvaginal mesh implants:

- supply records from sponsors of urogynaecological meshes;
- Medicare Benefit Schedule (MBS) codes relating to pelvic organ prolapse (POP) and stress urinary incontinence (SUI) procedures;
- the number of episodes of prostheses utilisation from the Prostheses List;
- Australian Institute of Health and Welfare (AIHW) ICD-10 codes;
- hospital records for each implanted device; and
- databases maintained by medical professional colleges and individual professionals.<sup>2</sup>

3.5 However, the committee heard that there are important limitations associated with using each of these data sets to accurately track mesh usage:

- Supply records from industry sponsors do not indicate how many devices have been used or circumstances where multiple devices have been used.<sup>3</sup>

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1 Gai, *Committee Hansard*, 18 September 2017, p. 4.

2 Department of Health (Department), *Submission 19*, p. 13; Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), *Submission 36*, p. 3.

3 Department, *Submission 19*, p. 15; RANZCOG, *Submission 36*, p. 5.

- MBS coding is procedure based and does not distinguish between procedures using a mesh device or native tissue.<sup>4</sup>
- MBS codes and Prostheses List data only indicate usage in private hospitals.<sup>5</sup>
- Recording of devices is currently the responsibility of each hospital and the manner in which this data is collected and stored varies between hospitals and states.<sup>6</sup>
- While some colleges' medical practitioners maintain databases, reporting is voluntary.<sup>7</sup>

3.6 The Department of Health (Department) advised that it holds the following sources of information which could contribute to an understanding of the number of women who have received urogynaecological mesh in Australia:

- supply records from Australian sponsors of urogynaecological meshes;
- the MBS codes relating to POP and SUI procedures; and
- Prostheses List data.<sup>8</sup>

3.7 Of these, the Department considers that the most reliable indicator of the extent of use of urogynaecological mesh devices in Australia is the supply numbers provided by the sponsors of the devices.<sup>9</sup>

***Supply information from sponsors who have sold mesh devices in Australia.***

3.8 The current medical device regulations require the sponsors of urogynaecological mesh devices supplied in Australia to hold supply records for ten years.<sup>10</sup> However, the Department advised that many industry sponsors hold records dating back further than ten years.<sup>11</sup> Based on information collected by the Therapeutic Goods Administration (TGA) the Department estimates that since 1998 around 151 000 devices have been supplied in Australia.<sup>12</sup> The Department provided the following breakdown of these figures:

- 31 805 meshes were intended for POP procedures;
- 106 512 were intended for SUI procedures; and

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4 Department, *Submission 19*, pp. 13-14.

5 *Submission 19*, p. 14.

6 RANZCOG, *Submission 36*, p. 5.

7 For example, the Urogynaecological Society of Australasia (UGSA) maintains a voluntary pelvic floor database, *Submission 32*, p. 3; *Committee Hansard*, 3 August 2018, p. 37.

8 *Submission 19*, p. 13.

9 *Submission 19*, p. 14.

10 See Therapeutic Goods (Medical Devices) Regulations 2002, part 8, para 8.1.

11 *Submission 19*, pp. 14-15.

12 *Submission 19*, p. 15.

- 12 144 devices were intended for use for either SUI or POP procedures.<sup>13</sup>

3.9 However, the Department cautioned that this number does not equate to the number of women who have received mesh implants as not all supplied mesh implants are used and surgeons may elect to use more than one mesh device in a single surgical procedure.<sup>14</sup>

3.10 Johnson & Johnson Medical Pty Ltd advised the committee that during the period October 1999 to May 2017 it had supplied 81 356 tape products and 22 086 mesh products in Australia.<sup>15</sup>

### ***MBS codes***

3.11 The Department submitted that it is possible to use MBS items for POP and SUI to gain an approximation of the number of procedures performed in private practice.<sup>16</sup> For the six items listed for POP surgery, 17 599 services were funded in 2015-16. For the six items listed for SUI, 5339 services were funded in the same period.<sup>17</sup>

3.12 However, there are limitations in relying on MBS data. First, the item descriptors for POP and SUI surgeries 'are not defined in a way that allows an accurate determination of the number of procedures where surgical mesh was used, or the type of mesh used (whether biological or synthetic).<sup>18</sup>

3.13 A second limitation is that the services funded under the MBS are principally services provided in the private sector. Dr Megan Keaney from the Department explained:

In this case where we are talking about in-patient surgical procedures, it is the case that most of the patients who are receiving MBS funded services are in fact privately insured patients, whether they are treated through a private hospital or a public hospital. That means that the MBS dataset is itself incomplete in trying to [get] a picture of the number of such surgeries that might be performed in Australia.<sup>19</sup>

3.14 The Urogynaecological Society of Australasia (UGSA) suggested that, based on MBS statistics available online, 80 500 procedures have been performed in the private sector since the introduction of the mid-urethral sling (MUS) in 1998. Noting that two thirds of all elective surgery is performed in the private sector, UGSA

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13 *Submission 19*, p. 15.

14 *Submission 19*, p. 15.

15 *Submission 23*, p. 12.

16 *Submission 19*, p. 13.

17 Dr Megan Keaney, Medical Advisor, Department of Health, *Committee Hansard*, 19 September 2017, p. 42.

18 Department, *Submission 19*, p. 14.

19 Dr Keaney, Department of Health, *Committee Hansard*, 19 September 2017, p. 42.

estimated that 120 000 women Australia wide have undergone a mesh sling procedure.<sup>20</sup>

3.15 Professor Chris Maher also analysed the MBS item data and, after adjusting it to make allowance for public hospital treatments, concluded that the number of transvaginal mesh procedures for the treatment of SUI could be within a range of 125 00 to 155 000. Notwithstanding the difficulty of distinguishing between types of prolapse surgery, Professor Maher estimated that the number of transvaginal mesh procedures performed for POP and SUI could be within the range of 150 000 to 175 000.<sup>21</sup>

### ***Prostheses List***

3.16 The Prostheses List is the list of surgically implanted prostheses, human tissue items and other medical devices for which private health insurers must pay benefits. For a benefit to be paid, the patient must have appropriate health insurance cover, the prosthesis must be provided as part of hospital treatment and there must be a Medicare benefit payable for the service.<sup>22</sup>

3.17 The Department advised that, while there are a number of urogynaecological meshes listed on the Prostheses List, utilisation data from the list only gives an indication of the number of transvaginal meshes used in the private sector. For this reason, both the Prostheses List information and Medicare data provide an incomplete picture of the number of transvaginal mesh procedures performed in Australian hospitals.<sup>23</sup>

### ***AIHW data***

3.18 The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), suggested that data collected by the AIHW using ICD-10 codes could potentially be used to identify the number of women who have had transvaginal mesh implants.<sup>24</sup> The International Classification of Diseases (ICD) is published by the World Health Organisation for worldwide use in translating narrative descriptions of diseases, injuries and procedures in medical records into alphanumeric codes. The AIHW uses the Australian Modification of the ICD-10 and this is largely based on MBS item numbers to facilitate coding of private procedures. RANZCOG notes that the AIHW lists every surgical procedure done in Australia, both in public and private settings.<sup>25</sup>

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20 UGSA, *Submission 32*, p. 2.

21 Associate Professor Christopher Maher, *Submission 154*, p. [10].

22 Department of Health, The Prostheses List, <http://www.health.gov.au/internet/main/publishing.nsf/content/health-privatehealth-prostheseslist.htm> (accessed 18 January 2018).

23 Department, *Submission 19*, p. 14.

24 RANZCOG, *Submission 36*, p. 3.

25 *Submission 36*, p. 3.

3.19 RANZCOG submitted that based on this data 106 150 MUS procedures were recorded for the period 2003-03 to 2013-15. RANZCOG notes that it is possible to identify data for MUS procedures as there is a separate coding for these procedures.<sup>26</sup> However, as item numbers for POP surgery do not distinguish between mesh and non-mesh procedures, it is not possible to gain an indication of comparable numbers for these procedures.<sup>27</sup>

### **The number of women who have experienced adverse events**

3.20 The true incidence of women experiencing complications following transvaginal mesh procedures is also unclear. Furthermore, it is not possible to accurately identify the number of women who have made attempts to have mesh devices removed in Australia or elsewhere.

#### ***Adverse event reporting***

3.21 The primary source of data is adverse event reporting to the TGA. The committee notes that monitoring adverse reporting has played a key role in regulatory decision making since the introduction of mesh products in Australia.

3.22 Adverse events are unintended and sometimes harmful occurrences associated with the use of a medical device (or medicine). The reporting of adverse events assists regulatory agencies to monitor the safety of medical devices once they are made available for general use. While clinical trials provide information about possible adverse events associated with a therapeutic good, they usually do not continue for long enough or include enough patients or a sufficient range of different types of patients to detect all possible adverse events.<sup>28</sup>

3.23 The TGA's medical device Incident Reporting and Investigation Scheme (IRIS) is responsible for the management of all reports of adverse events or problems associated with medical devices. On its website, the TGA states that any medical device adverse incident involving actual harm to a patient/caregiver, or that could have resulted in harm, should be notified to the Quality Risk Manager of the health facility where the device was implanted so that they can coordinate reporting to the supplier of the device and the TGA.<sup>29</sup>

3.24 In its evidence to this inquiry, the TGA noted that adverse events relating to urogynaecological mesh have been underreported.<sup>30</sup> As of 29 May 2017 the TGA had received a total of 226 adverse event reports (covering 249 patients) relating to the

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26 *Submission 36*, p. 3.

27 RANZCOG, *Submission 36*, p. 5.

28 Department of Health, Therapeutic Goods Administration, Reporting adverse events, <https://www.tga.gov.au/reporting-adverse-events> (accessed 29 January 2018).

29 Department of Health, Therapeutic Goods Administration, Reporting adverse events, <https://www.tga.gov.au/reporting-adverse-events> (accessed 29 January 2018).

30 *Submission 19*, p. 15.

implantation of urogynaecological mesh devices.<sup>31</sup> As of 3 January 2018, 327 reports had been lodged, covering 349 patients.<sup>32</sup>

3.25 However, the committee notes that the number of women experiencing complications is significantly higher. Of the hundreds of individual women who made submissions to this inquiry, the majority have provided accounts of adverse complications arising from implantation of mesh devices. The Health Issues Centre (HIC) told the committee that as at 3 August 2017, 2400 women had provided personal accounts to the HIC describing adverse events.<sup>33</sup>

3.26 In evidence to the committee, Professor Skerritt noted that the challenge faced by the TGA with regard to adverse event reports for mesh devices spans the period from the initial introduction of the devices.

I think, at the last hearing, I mentioned that it was some seven years until we had the very first report of an adverse event from mesh. It's most unusual for a medical device on the market to have no report at all for seven years. Indeed, until the end of 2015, we'd only had 12 patients. That is 12 patients in the period to December 2015 in the years from the time of the products being on the market. That's the real challenge for regulators—to look at the number of adverse events to get a good feel for the number of adverse events in terms of the numbers of devices implanted.<sup>34</sup>

3.27 Professor Skerritt observed that the committee's inquiry had played a role in raising the profile of the adverse reporting scheme:

I think what is really important is the ability of an inquiry such as this to raise the profile of being able to report and of doctors, nurses and surgeons to be able to report these adverse events as well as the companies.<sup>35</sup>

3.28 Adverse event reporting to the TGA is only mandatory for sponsors and manufacturers of devices. Reporting is voluntary for surgeons, other healthcare professionals and patients.<sup>36</sup>

3.29 The TGA outlined for the committee the steps it has taken to raise the profile of adverse reporting by medical practitioners and patients. It has implemented the IRIS inSite program to raise the profile of adverse event reporting and encourage spontaneous reporting of all adverse events related to medical devices by health care professionals. This program seeks to enhance relationships with health professionals

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31 Department, *Submission 19*, p. 30.

32 Ms Adriana Plantona, First Assistant Secretary, Medical Devices and Product Quality, Department of Health, *Committee Hansard*, 6 February 2018, p. 4.

33 Mr Danny Vadasz, Chief Executive Officer, Health Issues Centre, *Committee Hansard*, 3 August 2017, p. 17.

34 Adjunct Professor John Skerritt, Deputy Secretary, Health Products Regulation Group, Department of Health *Committee Hansard*, 6 February 2018, p. 1.

35 *Committee Hansard*, 6 February 2018, p. 4.

36 Department, *Submission 19*, p. 16.

and provide training and education about reporting adverse events associated with medical devices. Reports received through IRIS inSite are analysed to identify potential emerging problems for detailed investigation.<sup>37</sup>

3.30 Submissions to this inquiry suggest that more needs to be done to facilitate reporting of adverse events, particularly by patients and medical practitioners. The committee notes that a number of factors will have a bearing on the extent of under reporting of adverse events related to transvaginal mesh devices:

- Many women may be unaware that they have received a mesh implant, either because they were not advised that a device had been implanted or because the device was described to them as a 'sling', 'hammock' or 'tape'.
- Many women have been advised by their medical practitioner that their symptoms are not related to their transvaginal mesh procedure.
- There is a tendency for there to be a significant lag in the onset of symptoms and this may cloud the connection between the symptoms and the mesh procedure.
- Women may be reluctant to report due to the deeply private and personal nature of the symptoms.

#### *Reporting by patients*

3.31 The personal accounts received during this inquiry suggest that women are often unaware that they can report their complications or are unable to access the information necessary to make a report.

3.32 The majority of women had little to no knowledge of the TGA and its role and were unaware that they could report their experiences or how.<sup>38</sup> A member of the Australian Pelvic Mesh Support Group (APMSG) told the committee:

I think there is a matter of reporting to the TGA. We have links up in the group to link the women in there, but a lot of them are elderly and some of them aren't computer savvy and have problems reporting. When they first come into the group, they're just overwhelmed. They're reading all these stories. We have a pin post at the top of the bar saying, 'Please read this. Report your device to the TGA.' You can contact all these various people for help. We also have a list of adverse events. But last year when we went to the TGA I think there were only 12 or something people who had reported.<sup>39</sup>

3.33 For those who were aware of the ability to report to the TGA, many reported that they had found the process of lodging a report daunting or had experienced

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37 Department of Health, Therapeutic Goods Administration, IRIS inSite, <https://www.tga.gov.au/iris-insite>, (accessed 29 January 2018).

38 See, for example: Name withheld, *Submission 105*, p. [7]; Name withheld, *Submission 108*, p. 7; Name withheld, *Submission 110*, p. [11]; Name withheld, *Submission 472*; p. [2].

39 Joanne, *Committee Hansard*, 18 September 2017, p. 6.

difficulty obtaining the information they required to make a successful report. One woman told the committee:

Although I am interested in reporting the adverse events I have experienced to the TGA, the TGA Users Medical Device Incident Report is daunting and I simply do not have the detailed information they request for device identification. As noted in TOR [Terms of Reference] 5 above, I have encountered obstacles in trying to obtain my medical records.<sup>40</sup>

3.34 Submitters commented that the reporting system is confusing and needs to be simplified.<sup>41</sup> One woman noted that this was a deterrent to women reporting their adverse experiences:

I was not aware that I could [do] it until the Australian Pelvic Support Group advised me. It's a difficult page to report on. I can see why other women don't do it. It needs to be simplified.<sup>42</sup>

3.35 Some women expressed disappointment with the TGA's response to their report:

I have reported my issues with the TGA and I received a standard response which meant nothing. I met with the TGA in Canberra and voiced my concerns. They seemed to listen at the time but did not follow through with their promises. They had promised to advertise the adverse effects of mesh implant to GP's, Surgeons and the general public. They spoke about television marketing. Instead they just put it on their website where it was difficult to find and certainly not 'promoted or marketed'.<sup>43</sup>

3.36 Other women advised that when they attempted to access details of the product used, they were either refused access or advised that the records no longer existed:

When I was trying to find out recently the brand of the product that was used on me, my surgeon didn't have it on his records. The hospital didn't have it on their records. The surgeon claims I never signed an authority to use that product. I know I did. He said the only form I signed was to go ahead with the surgery for the hospital; no signature to use the product—that's beside the point. I eventually got the name of the product from my hospital benefit society.<sup>44</sup>

3.37 The committee heard that some hospitals are charging patients to release medical records.<sup>45</sup> Ms Pip Brennan, Executive Director of the Health Consumers'

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40 Name withheld, *Submission 477*, p. 3.

41 See, for example: Name withheld, *Submission 102*, p. [5]; Name withheld, *Submission 110*, p. [12]; Name withheld, *Submission 472*; pp. [2, 5].

42 Name withheld, *Submission 524*, p. [2].

43 Name withheld, *Submission 67*, p. 4.

44 Robyn, *Committee Hansard*, 25 August 2017, p. 21.

45 Ms Carolyn Chisolm, APMSG, *Committee Hansard*, 25 August 2017, pp. 9-10.

Council Western Australia, told the committee that women have been charged amounts of \$40 to \$124 to access their medical records.<sup>46</sup>

3.38 The committee also heard that records may not be available because of the length of time that has elapsed since the surgery. Dr Michelle Yin told the committee that surgeons can face the same challenges accessing records on their patients' behalf:

I would highlight the point that, as part of our group of mesh removal specialists, we face the same hurdles that our patients do in getting the information. As you said, a lot of the information is more than 10 years old and most medical hospitals don't keep records beyond a certain time. We also know that the patients themselves may not understand what operations they've had done. These are the same hurdles that we face and obviously for us, if we're involved in surgery where we have to take out the mesh, it's imperative that we know how that stuff was put in—and also what the stuff has involved.<sup>47</sup>

3.39 The TGA acknowledged that adverse reporting is an area that needs to be addressed. Professor Skerritt told the committee that it was important for the TGA to look at all possible ways within its budget and its legal mandate to stimulate patient reporting and awareness:

So, it's about ways that we can stimulate and step up education about how to report to make it simple and, similarly, to stimulate doctor reporting.<sup>48</sup>

#### *Reporting by medical practitioners*

3.40 A number of submitters to the inquiry expressed concern that reporting of adverse events relies on the voluntary actions of medical practitioners.<sup>49</sup>

3.41 As the following statements indicate, women expressed frustration to the committee that medical practitioners are not required to report adverse events, and a lack of confidence that medical practitioners could be relied upon to report:

...no-one knows about reporting it. I don't understand why it's our responsibility to report it to the TGA when the doctors, who we go back to with our complaints and complications, don't.<sup>50</sup>

I found out via the mesh support group online about the TGA and what its purpose is. I contacted my surgeon to ask if he had reported my erosion and issues along with the partial removal of the [redacted] sling. I also sent him the TGA link with the alert advising Drs they should be reporting any adverse affects. He had not reported anything. So I did it myself.<sup>51</sup>

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46 Ms Pip Brennan, *Committee Hansard*, 25 August 2017, p. 49.

47 *Committee Hansard*, 25 August 2017, pp. 31-32.

48 Professor Skerritt, *Committee Hansard*, 6 February 2018, p. 6.

49 See, for example: Mr Danny Vadasz, HIC, *Committee Hansard*, 3 August 2017, p. 21, Name withheld, *Submission 103*, p. [4]; Kim, *Committee Hansard*, 3 August 2017, p. 2.

50 Gai, *Committee Hansard*, 18 September 2017, p. 6.

51 Name withheld, *Submission 458*, p. [7].

...based on my experience and that of many other women in this town, I would not trust surgeons to report complications or gather accurate research data. We all have similar stories of complications, including crippling pain and terrible bowel and bladder symptoms, which were trivialised or denied, and we were told we were the only one with an adverse outcome, that it was our fault that our body had reacted to the mesh. We were abandoned by our surgeon and left to cope as best we could.<sup>52</sup>

3.42 The APMSG expressed concern that a fundamental difficulty with voluntary reporting is the failure of many medical practitioners to acknowledge women's symptoms. Ms Carolyn Chisholm told the committee:

The problem is acknowledging the symptoms in the first place, though. There are a lot of GPs who won't acknowledge it and there are a lot of gynaecologists who won't acknowledge it. There lies another major problem. How can they report it if they're not acknowledging that your pain and complications are from your mesh?<sup>53</sup>

3.43 Dr Caroline Dowling, from the Urological Society of Australia and New Zealand, told the committee that without clear guidance, there will always be a level of underreporting in a voluntary system:

Reporting to the TGA is an entirely voluntary exercise. As Senator Hinch has highlighted, people's perceptions of what is a serious adverse event versus what is a smaller adverse event vary. Unless there is a defined criteria for what has to be reported and it is obligated on the physician to report, the numbers will always be incomplete.<sup>54</sup>

3.44 Many women experiencing symptoms following surgery had consulted their General Practitioner (GP) in the first instance. While, the Royal Australian College of General Practitioners (RACGP) advised that reporting adverse events is a professional responsibility and part of the RACGP Curriculum for General Practice,<sup>55</sup> Dr Magdalene Simonis explained to the committee that it is often difficult for a GP to determine if a complication is due to a particular incident:

In this particular context, if a woman presents with pelvic pain and she has had a transvaginal mesh implant, the GP very often is not in a position to know that this has been implanted in the woman. One of the issues is that the time line of presentation between surgery and presentation with complaints of pain could be anything from weeks to several years. Some patients might not have continuity of care with the same GP. Sometimes the GP has not been made aware of the details of the actual surgery that the woman had; even if the woman has had surgical interventions by a surgeon whom the GP has referred them to, the GP might still not know that the

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52 Kathryn, *Committee Hansard*, 19 September 2017, p. 4.

53 *Committee Hansard*, 25 August 2017, p. 9.

54 *Committee Hansard*, 3 August 2017, p. 22.

55 Royal Australian College of General Practitioners (RACGP), [answers to questions on notice](#), 19 September 2017 (received 16 October 2017).

patient had mesh inserted. So it becomes difficult to prove what the pain is due to, and I don't necessarily think the GP has the capacity to do that.<sup>56</sup>

3.45 The committee received a significant amount of evidence recommending that reporting of adverse events should be mandatory for medical practitioners.<sup>57</sup> A number of medical practitioners also expressed support for mandatory reporting.<sup>58</sup> Professor Peter Dwyer told the committee:

in the past I think we have been too slack in not picking up problems with devices because there has not been mandatory reporting. I think reporting does need to be mandatory. There is no use having some people who are good surgeons reporting everything and others who are not so good surgeons not reporting anything. Unless you see the whole picture it is very difficult to know whether something is just an isolated, rare complication or something that is happening too frequently and something needs to be done about it.<sup>59</sup>

3.46 The committee notes that mandatory reporting by medical practitioners was considered in the 2011 Community Affairs References Committee inquiry into the regulatory standards for the approval of medical devices in Australia<sup>60</sup>.

#### Recommendation 8

The committee recommends that the Therapeutic Goods Administration put in place mechanisms to educate and encourage doctors to report adverse incidents associated with the use of medical devices. The committee further recommends that the Department of Health and Ageing introduce mandatory reporting for health practitioners to the Therapeutic Goods Administration on relevant issues, in certain circumstances including problems with medical devices.

#### *Reporting by device sponsors*

3.47 The Medical Technology Association of Australia (MTAA) advised the committee that once marketing approval for a device has been provided, there are a

56 Dr Magdalene Simonis, Expert Committee, Quality Care, RACGP, *Committee Hansard*, 19 September 2017, p. 13.

57 See, for example: Associate Professor Angela Dawson, Convenor of the Women's Health Special Interest Group, Public Health Association of Australia, *Committee Hansard*, 3 August 2017, p. 9; Ms Stella Channing, Director and Administrator, Australian Pelvic Mesh Support Group, *Committee Hansard*, 25 August 2017, p. 3.

58 See, for example: Professor Thierry Vancaillie, *Committee Hansard*, 18 September 2017, p. 10; Dr Jenny King, *Committee Hansard*, 18 September 2017, p. 16; Professor Jason Abbott, President, Australasian Gynaecological Endoscopy & Surgery Society, *Committee Hansard*, 18 September 2017, p. 30.

59 *Committee Hansard*, 3 August 2017, p. 36.

60 Community Affairs References Committee, *Inquiry into the regulatory standards for the approval of medical devices in Australia*, 22 November 2011, [https://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate/Community\\_Affairs/Completed\\_inquiries/2010-13/medicaldevices/report/index](https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Completed_inquiries/2010-13/medicaldevices/report/index).

number of circumstances in which the manufacturer is required to notify the TGA, or the sponsor:

- as soon as practicable after becoming aware of any serious adverse event—including events that may cause serious injury or death, may be related to the malfunction or deterioration of a device and also 'near misses' where the event did not result in harm, but may do in future;
- within 48 hours of becoming aware of an event that represents a serious threat to public health; and
- when any technical or medical reason for a malfunction or deterioration has led the manufacturer to recall a device.<sup>61</sup>

3.48 In addition to these reporting requirements, manufacturers are required to systematically review information gained after the device has been supplied to the Australian market. This can include sponsor feedback, expert user groups, customer surveys, customer complaints, device tracking and registration registers, user reactions during training and adverse event reports from users.<sup>62</sup>

3.49 Some submitters expressed concern that the mandatory requirement for device sponsors to report adverse events was flawed as sponsors have no first hand access to data regarding adverse events and rely on reports from other sources.<sup>63</sup>

3.50 The MTAA advised the committee that under the regulations, there are two elements to the requirements for post-market monitoring:

One is proactive and one is reactive. The proactive one is where our manufacturers undertake, on their own initiative, post-market clinical follow-up. That is done for devices where more information is required—novel technologies. A reactive aspect of the post-market monitoring is the vigilance procedures, the complaints system, where the manufacturer collects feedback from the market and analyses it. When there are adverse events that are related to the device then they are obliged to report that to the regulator.<sup>64</sup>

3.51 Representatives from Boston Scientific and Johnson & Johnson Medical Devices assured the committee that they have robust complaint-handling procedures in place and welcome information on any of their products. Each company described for the committee the processes they employ to monitor outcomes from the use of their devices.

3.52 Dr Glen Mason outlined Johnson & Johnson's procedures for post-market surveillance, noting that information is received from a number of sources, including clinicians, patients or the companies own employees in the field. Upon receipt of

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61 Medical Technology Association of Australia (MTAA), *Submission 40*, pp. 2-3.

62 *Submission 40*, p. 3.

63 *Confidential Submission 131*.

64 Ms Val Thiesz, MTAA Director of Regulatory Affairs, *Committee Hansard*, 18 September 2017, p. 44.

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information, the company will investigate and, with the consent of the patient, seek further information to determine if there has been an adverse event. Dr Mason explained:

it may not necessarily be an adverse event. We term them 'product events' because an adverse event is not necessarily always the case when we receive information into the company; sometimes product events can be as simple as purely a packaging issue. So we need to be able to investigate to see what exactly is happening, and, based on the information we receive, we then are able to investigate it locally or globally and determine whether additional action needs to be taken or not.<sup>65</sup>

3.53 Boston Scientific advised that it has a similar system for investigating all complaints. Dr Ronald Morton told the committee:

Yes, the complaints come through and, as Dr Mason Said, we have a similar system that investigates all complaints. But, to the senator's point, we have no ability to know whether or not all physicians are relaying all complaints to us.<sup>66</sup>

3.54 One of the difficulties faced by sponsor companies is the private and confidential nature of the interaction between a patient and their medical practitioner. Dr Mason explained:

One of the things that is obviously clear, from the perspective of the way in which patients have an interaction with clinicians, is that the interaction between the clinician and the patient is a private and confidential situation. As such, the company does not have any involvement or interaction with that. And it is very clear that if there is anything that is on the go, from a healthcare professional's perspective, I would assume it is normal for a healthcare practitioner to try and investigate or at least provide information back to companies or respective authorities such that investigations could take place.<sup>67</sup>

3.55 Dr Mason went on to note:

So, from the perspective of a patient, the interaction between the healthcare professional and the patient is where the decision or the determination of what is on the go should be investigated and then reported to the respective manufacturer so that we can take action as needed.<sup>68</sup>

3.56 The MTAA acknowledged that there is probably insufficient awareness of the importance of report concerns with medical devices to the sponsors or manufacturers:

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65 Dr Glen Mason, Director of Medical Affairs, Johnson & Johnson Medical Devices, *Committee Hansard*, 18 September 2017, p. 41.

66 Dr Ronald Morton, Vice-President Clinical Sciences, Urology and Pelvic Health, Boston Scientific, *Committee Hansard*, 18 September 2017, p. 36.

67 Dr Mason, *Committee Hansard*, 18 September 2017, p. 42.

68 Dr Mason, *Committee Hansard*, 18 September 2017, p. 46.

Both healthcare professionals and patients can raise concern and make notification, either directly to the TGA or to the manufacturer, so that's a choice that's there. It's probably that there isn't enough awareness for patients and health professionals that they should do that.<sup>69</sup>

3.57 The MTAA stated that it recognised the need for improvements in the reporting of adverse events and was fully supportive of 'increased education and raised awareness of the processes, and strengthening and improving those processes, where by clinicians and patients can report adverse events.'<sup>70</sup>

### *Other sources of data*

3.58 The committee is aware that there are a number of other sets of data that have the potential to shed light on the number of women who have experienced complications. These include AIHW data, claim data held by private health insurance providers, and registers maintained by professional colleges or individual medical professionals.

#### *AIHW data*

3.59 As noted earlier, RANZCOG provided data collated by the AIHW from 2002-03 to 2013-15. This data suggests that for MUS, the incidence of sling revision or sling division is 7.3 per cent. However, RANZCOG notes that this figure may be an overestimation, as the codes for mesh revision may include POP cases as there is not ICD code for POP revisions.<sup>71</sup>

#### *Private health insurance claim data*

3.60 Medibank data provided to RANZCOG to assist in preparation of its submission to the inquiry, suggests that claim data held by private health insurance companies may be of assistance in the identification of the number of women who have had transvaginal mesh implants and suffered adverse side effects. Data provided by Medibank indicates that over a five year period from 2012 to 2016, 6508 patients claimed for a surgical procedure relating to the insertion of a polypropylene device.<sup>72</sup>

3.61 By cross matching this data with the ICD-10 codes of a urogenital prostheses for readmission due to complication, Medibank identified that in the years 2012-2013, four per cent of patients insured by Medibank who had transvaginal mesh inserted had

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69 Ms Val Thiesz, Director of Regulatory Affairs, MTAA, *Committee Hansard*, 18 September 2017, p. 46.

70 Mr Ian Burgess, Chief Executive Officer, MTAA, *Committee Hansard*, 18 September 2017, p. 46.

71 RANZCOG, *Submission 36*, p. 4.

72 *Submission 36.1*, p. 5. Medibank notes that private health insurance funds two in every five hospital admissions in Australia, and the majority of elective surgeries are performed in private hospitals. As it has a 28 per cent share of the private health insurance market, through its Medibank and ahm brands, the data it holds constitutes a representative sample.

a readmission within the next three years for a complication associated with that implant.<sup>73</sup>

3.62 Medibank noted a number of limitations pertaining to this dataset:

- The data is confined to prostheses on the Prostheses List and does not include the use of a prostheses not on the list in a private hospital.<sup>74</sup>
- Given the narrow ICD-10 code set (which only relates to hospital admissions for a complication of a urogenital device or implant) the data may underestimate the number of women who have had readmission for a prostheses-related complication. Medicare notes that the most commonly reported adverse event is pain, however pain may not be consistently reported or treated through the private hospital system.
- Medibank patients that were admitted as a public patient to a public hospital would not be included in this data set. Similarly, the data would not include those women may have left Medibank subsequent to the implant insertion or may have had readmission after the three year period applied to the analysis.
- Removal or revision surgery volumes are unlikely to be captured via the Medibank claims data as there are no MBS item numbers specific to removal of mesh implants or to indicate whether the surgery is the implantation or revision.<sup>75</sup>

#### *Urogynaecological Society of Australasia (UGSA) Pelvic Floor Database*

3.63 A number of submitters and witnesses noted the urogynaecological database maintained by UGSA.<sup>76</sup> The database is intended to enable the objective collation of information about surgical complications and outcomes for a wide range of surgical procedures, including mesh. Contributing to the database is voluntary and doctors are able to enter data anonymously.<sup>77</sup> Dr Jenny King, Chair of UGSA, told the committee data in the UGSA database indicated that the incidence of complications as a result of mesh procedures was very low.<sup>78</sup>

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73 RANZCOG, *Submission 36.1*, p. 4. Medibank advises that this analysis sets aside the data sets for the years 2014 to 2016 which are incomplete as the follow up period of three years has not been fully completed.

74 Medibank notes that the reasons for a device not being on the Prostheses List include a device not being TGA registered or not being provisioned by the Prostheses List Advisory Committee for inclusion on the Prostheses List. *Submission 36.1*, p. 4.

75 *Submission 36.1*, pp. 4-5.

76 See, for example: Dr Anna Rosamilia, Urogynaecologist, Monash Health, *Committee Hansard*, 3 August 2017, p. 37; Associate Professor Jason Abbott, *Committee Hansard*, 18 September 2017, p. 30; Dr Marianne Gale, Medical Adviser, Office of the Chief Health Officer, New South Wales Ministry of Health, *Committee Hansard*, 18 September 2017, p. 55.

77 Urogynaecological Society of Australia, *UGSA Pelvic Floor Database*, <http://www.ugsa.org.au/pages/ugsa-pelvic-floor-database.html> (accessed 9 February 2018).

78 *Committee Hansard*, 18 September 2017, p. 16.

3.64 RANZCOG noted that data in the UGSA database is collected predominantly by sub-specialists whose practice is skewed to the more complex patients. However, UGSA had provided data to RANZCOG which appears consistent with the AIHW data, indicating that from 1999, when the first MUS procedures were performed in Australia, approximately 120 000 women have had an MUS procedure.<sup>79</sup>

#### *Comparisons with other countries*

3.65 A number of submitters suggested that data from other countries where more accurate and separately identified data has been collected can be useful in estimating the number of Australian women who have had these procedures.

3.66 UGSA advised that data from Scotland, where mesh procedures have been separately identified since 2006, shows seven per cent of primary vaginal repair procedures involved a mesh implant and data from the United States of America indicates that in 2011, at the peak time of mesh use, 23 per cent of vaginal repairs used mesh.<sup>80</sup>

3.67 RANZCOG told the committee that in 2012, 'other countries reported that the rate of mesh usage was 15.7 per cent and that it would be reasonable to expect that Australian usage was similar.'<sup>81</sup>

3.68 The New Zealand Accident Compensation Corporation Surgical Mesh Review (ACC) considered data relating to the number of mesh devices sold in New Zealand between January 2009 and October 2014. The total number of devices sold was 56 508 and the percentage of claims made to the ACC was 3.3 per cent for POP and 0.7 per cent for SUI.<sup>82</sup> RANZCOG stated that, while it was important to allow for under-reporting of surgical complications, it would be reasonable to expect the Australian experience to be similar to that in New Zealand.<sup>83</sup>

#### **Mesh removal**

3.69 The committee was not able to identify any accurate data on the number of women who had sought either full or partial removal of mesh implants.

3.70 Out of the 243 women for whom the TGA held an adverse report at 29 May 2017, 90 had reported undergoing a procedure for removal of the device. Four of those women had reported that their mesh removal surgery occurred in the United States of America. One report indicated that a partial removal had been performed in Australia, with further removal undertaken in the United States.<sup>84</sup>

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79 RANZCOG, *Submission 36*, p. 4.

80 UGSA, *Submission 32*, p. 2.

81 *Submission 36*, p. 4.

82 *Submission 36*, p. 5.

83 *Submission 36*, p. 5.

84 Department, *Submission 19*, p. 16.

3.71 The APMSG advised that of its members that have sought full removal of mesh devices, 14 have travelled overseas for the procedure.<sup>85</sup>

3.72 As was the case in identifying the number of women who have received mesh implants, MBS data is of limited assistance in identifying the number of women who have attempted to have mesh devices removed, either partially or fully.

3.73 RANZCOG proposed that consideration should be given to the development of a system of coding for both SUI and POP surgery, with and without mesh, and the coding of mesh complications in both public and private sectors with development of separate Medicare item numbers for native tissue repair.

3.74 The Department advised that the Gynaecology Clinical Committee of the MBS Review Taskforce has undertaken a review of MBS items for the use of biological and permanent mesh, and other gynaecology related items and has made the following recommendations in relation to mesh-related items including on the MBS, including:

- revising MBS item numbers so that mesh and non-mesh surgery can be distinguished to enable better data collection;
- restricting the use of mesh to patients who are undergoing revision surgery;
- introducing specific MBS items for mesh removal.<sup>86</sup>

3.75 At its meeting on 20 September 2017, the MBS Taskforce endorsed the release of the Gynaecology Clinical Committee's report for public consultation.<sup>87</sup>

### **A national medical device register**

3.76 Many submitters to the inquiry expressed support for a national medical device register, noting that the ability to collect and analyse data is central to an effective and efficient health care system.<sup>88</sup>

3.77 Many of the women who wrote to the committee questioned why there was not already a national register of medical devices and recommended that this be addressed. One submitter proposed the introduction of a system of unique identifiers for medical devices accompanied by matched numbered reporting forms for patients and surgeons to be returned to the TGA and the manufacturer in the event of an adverse event:

This would track numbers of procedures and allow impartial reporting of short- and long-term outcomes and monitoring of all postoperative symptoms.<sup>89</sup>

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85 APMSG, *Submission 130*, p. 2.

86 Department, *Submission 19*, p. 14.

87 Department of Health, *MBS Review Taskforce meeting outcomes, 20 September 2017*, <http://www.health.gov.au/internet/main/publishing.nsf/Content/MBSR-outcomes-20september2017> (accessed 6 February 2018).

88 See, for example: Dr Wendy Bonython and Mr Bruce Arnold, *Submission 12*, p. [5]; Australian College of Midwives, *Submission 16*, p. 3.

3.78 The committee notes that the basis for such a system may already exist. Each device is identified with a code and both the companies who supply the devices and the hospitals they are supplied to have a record of these. The codes should be attached to the patients records in the form of a sticker at the time of the procedure.<sup>90</sup>

3.79 The committee heard widespread support for the establishment of a national database from medical professionals and professional colleges.<sup>91</sup> RANZCOG told the committee:

As advances in technology and medical science lead to improved outcomes for patients, it is increasingly important that information is captured and that longitudinal data is evaluated to ensure that treatments and interventions are safe and effective.<sup>92</sup>

3.80 RANZCOG recommended the establishment of a national medical device registry, comprising 'both objective success (anatomic) and subjective (patient satisfaction) success, complications and total reoperation rates.'<sup>93</sup> While acknowledging that a simple classification system would be likely to encourage participation, RANZCOG stated that a standardised clinical framework for describing adverse outcomes is critical to ensure consistency and improved reporting. RANZCOG considers that information from a National Register should be shared with surgeons and all stakeholders to enable informed judgements to be made about the use of implantable devices.<sup>94</sup>

3.81 Dr Gary Swift, President of the National Association of Specialist Obstetricians and Gynaecologists told the committee that an important outcome from this inquiry would be to highlight the need for the process around a national register to be advanced.

We do not really have a reporting system or a database to put these complications in. I must say over the last 30 years there have been a number of devices where one receives complications from other surgeons, deals with them and they keep coming back, and the whole process goes on for far too long rather than these problems being detected earlier. I think there needs to be more supervision of devices.

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89 Kathryn, *Committee Hansard*, 19 September 2017, p. 4.

90 Dr Michelle Atherton, *Committee Hansard*, 25 August 2017, p. 32; *Confidential Submission 153.1*.

91 See, for example: Dr Caroline Dowling, Urological Society of Australia and New Zealand, *Committee Hansard*, 3 August 2017, p. 24; Professor Peter Laurence Dwyer, *Committee Hansard*, 3 August 2017, p. 36; Dr King, UGSA, *Committee Hansard*, 18 September 2017, p. 19; Associate Professor Jason Abbott, *Committee Hansard*, 18 September 2017, p. 30.

92 RANZCOG, [answer to questions on notice](#), 19 September 2017, p. 2, (received 18 October 2017).

93 RANZCOG, answer to questions on notice, 19 September 2017, p. 2, (received 18 October 2017).

94 RANZCOG, answer to questions on notice, 19 September 2017, p. 2, (received 18 October 2017).

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...

We support reporting of adverse events and the formation of the mesh registry, which we asked for in 2010. That is why the Urogynaecological Society of Australasia formed, and this was something that was presented at the Australian health commission on safety in 2010.<sup>95</sup>

3.82 Professor Chris Maher noted that key data is already being collected but is not being recorded accurately.<sup>96</sup> He told the committee of the importance of having timely access to data in an appropriately granular form. Professor Maher told the committee that there would be benefits in making the data that is recorded in the MBS schedule more readily available to researchers.<sup>97</sup>

3.83 The committee was interested to explore the extent to which the MBS could be used as the basis for a registry of surgical procedures. Dr Keaney explained that because the MBS is designed principally as a list of services for which government subsidy is payable, it would not provide a useful platform for the development of an outcomes focussed data set.

The MBS, as I said before, is a list of medical professional services and a list of rebates—the government subsidy for those services. So its purpose is fundamentally around financing, and a corollary benefit from it is that it enables some data collection, so it becomes one of the data collections which we can rely upon in health policy planning and the like. It's not an outcomes based data collection. Even the approach to how services are funded is not outcome based. It's a fee for an activity. It's a fee for the surgery that is done by a particular practitioner for a particular patient—in fact, it's a rebate to the patient for that surgery. So I don't think it is the best vehicle for collecting outcomes data, if that's what your interest is.<sup>98</sup>

3.84 However, Dr Keaney outlined for the committee the benefits of maintaining separate data sets that can be used in a complimentary manner. With reference to the National Joint Replacement Registry, Dr Keaney described how the MBS review had been drawing on data in the MBS and cross matching this data with the data held in the National Joint Replacement Registry:

I think the National Joint Replacement Registry—most people would agree—is an example of a well-functioning device registry in Australia. We're undertaking a review, through the MBS review, of the orthopaedic services that are on the schedule. There are 560 of them—I know off the top of my head. The orthopaedic surgeons and others who've been reviewing the MBS items—the service: hip replacement, knee replacement and the like—have been able to marry the MBS data, in terms of utilisation and the like, with the joint registry data to inform them about what should be the services that are funded through the MBS and what should be the clinical

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95 *Committee Hansard*, 3 August 2017, p. 34.

96 Professor Maher, *Committee Hansard*, 19 September 2017, p. 33.

97 Professor Maher, *Committee Hansard*, 19 September 2017, p. 29.

98 Dr Keaney, Department of Health, *Committee Hansard*, 19 September 2017, p. 45.

criteria that attach to that funding. I think, as I said, that's a good example of how you can use different datasets but in a complimentary way, as opposed to trying to use one dataset—the MBS—to try to record everything.<sup>99</sup>

3.85 On behalf of sponsors and manufacturers of devices, the MTAA acknowledged that there was a role for clinical registries in monitoring medical devices. However, the MTAA cautioned that careful thought needs to be given to how such registries are established:

We also believe that there is a contribution that can be made by clinical registries to monitor medical devices once inserted into patients. There does need to be careful consideration given to the types of registries, the specific data to be collected, how the value provided by that data can be shared with transparency across all relevant parts of the health system and, accordingly, how registries are appropriately funded and governed.<sup>100</sup>

3.86 Professor Skerritt advised the committee that committee that work is currently underway, through the Council of Australian Governments (COAG) Health Council to consider what clinical quality registries Australia should adopt.<sup>101</sup> Professor Skerritt noted that, while registers have been established for certain devices such as joints, breast implants and certain cardiac devices, these have been established under interim arrangements and that work was continuing on the broader questions relating to the establishment of device registries:

The problem with registries is there are a whole lot of other registries for particular operations, for particular clinical groups, that have been set up. It depends on who you are. There could 30, 40 or 50 various registries for various things and some of them are surgical procedures; they do not involve a medicine or a device. Now, what the government wants to do is not end up 30, 40, 50 or 60 different ways of data collection, with difference governance and funding arrangements. Every time you set up a register for a device it might cost you \$1 to \$2 million a year plus that sort of set-up fee. There must be economies of scale. There must be ways that these things can talk to each other, given our current IT systems, and so what the government has asked—and this is public information in the budget context—is that the health portfolio and stakeholders consult on appropriate approaches for governance and for which registers.<sup>102</sup>

### **Committee view**

3.87 The committee notes that the number of women who have undergone transvaginal mesh procedures in Australia is likely to be in the order of 150 000 and that the number of women who have experienced adverse events is unknown.

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99 *Committee Hansard*, 19 September 2017, p. 47.

100 Mr Ian Burgess, *Committee Hansard*, 18 September 2017, p. 38.

101 *Committee Hansard*, 6 February 2018, p. 5.

102 *Committee Hansard*, 3 August 2017, p. 54.

3.88 The committee notes that each of the currently available sources of information are limited in the extent to which they can be used to accurately identify the number of women who have received transvaginal mesh implants and the number who have experienced complications. Similarly, the committee notes that the extent to which these data sources could be used to analyse the range and severity of complications is limited. This is of great concern to the committee.

3.89 The committee is particularly concerned by the level of underreporting of adverse events to the TGA. Noting the significance of adverse event reports to post market monitoring by the TGA and individual device sponsors, the committee is concerned that this element of post market regulation is reliant on voluntary reporting by medical professionals.

3.90 The committee is also concerned that the current system appears to allow significant scope for medical practitioners and device sponsors to determine whether an event should be reported. The committee is concerned that this has led to inconsistency in the reporting of events and considers that clear criteria should be available to guide the reporting of adverse events.

3.91 While there is some potential to supplement information available through the adverse reporting system with data from other sources, the committee considers that given the severity of the adverse side effects reported to this inquiry by women who have had these procedures, it is inappropriate to rely on estimates to determine the quality and safety of these medical devices.

3.92 The committee considers that underreporting of adverse events is a matter of concern for the regulation of all medical devices, not just devices used in transvaginal mesh procedures.

3.93 The committee notes that this is not the first occasion on which the Community Affairs References Committee has considered the effectiveness of adverse reporting or the need for a national register of therapeutic devices. In its 2011 inquiry into the regulatory standards for the approval of medical devices in Australia, the committee recommended that the TGA put in place mechanisms to educate and encourage doctors to report adverse incidents associated with medical devices. The committee also recommended that consideration be given to the introduction of mandatory reporting for health practitioners.<sup>103</sup> The government response to that report agreed that adverse reporting plays a vital role in post-market surveillance and committed to a course of action that would encourage greater reporting by medical practitioners. This included a commitment to consult with the Medical Board of Australia on the matter of mandatory reporting and to work with states and territories to identify opportunities to coordinate adverse event reporting currently required in the public hospital sector in each jurisdiction.

3.94 The committee is deeply concerned that the failures of the current reporting system as outlined in this chapter are likely to have resulted in delays in identifying

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103 Senate Community Affairs References Committee Inquiry Report, *The Regulatory Standards for the Approval of Medical Devices in Australia*, November 2011, Recommendation 8, p. 102.

the problems with transvaginal mesh and resulted in more women suffering adverse impacts of these products.

3.95 The committee notes widespread support for the establishment of a national register of medical devices and considers that work currently underway through COAG should be prioritised.

# Chapter 4

## Diagnosis, treatment and support

Other women's good results in no way diminish the hurt that mesh has caused them and you...I recognise that we have not informed you well enough about treatment choices or complications or their management. It's a truth sadly borne out by the recurrent themes being heard of mesh offered as the only choice; potential mesh complications inadequately, or sometimes not at all, discussed; and feeling ignored when complications do arise.<sup>1</sup>

4.1 This chapter considers women's experience of the clinical pathways for treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP) using transvaginal mesh procedures.

4.2 Evidence to the inquiry has raised a range of concerns regarding women's engagement with medical practitioners. Women raised concerns regarding the information they received prior to transvaginal mesh surgery and the treatment and support they received when they presented with complications. The committee was told that many women 'have been left utterly traumatised by their doctor's lack of knowledge, understanding and compassion.'<sup>2</sup>

4.3 The evidence received during the inquiry is consistent with the findings of a series of consumer consultation forums undertaken by the Australian Commission on Safety and Quality in Health Care (ACSQHC).<sup>3</sup>

4.4 Key concerns raised by women attending the ACSQHC forums included the following concerns about their engagement with medical practitioners:

- the need for greater clarity regarding patient selection for POP and SUI procedures;
- concerns regarding women's ability to provide their informed consent prior to surgery and the need for more accessible information concerning the potential complications resulting from transvaginal mesh procedures; and
- recognition by general practitioners (GPs) and specialists of complications relating to transvaginal mesh.

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1 Dr Michelle Atherton, *Committee Hansard*, 25 August 2017, p. 25.

2 Ms Stella Channing, Director and Administrator, Australian Pelvic Mesh Support Group (APMSG), *Committee Hansard*, 25 August 2017, p. 3.

3 Between January and March 2017, the Australian Commission on Safety and Quality in Health Care (ACSQHC) undertook a series of consumer consultation forums with assistance from state health consumer councils in Brisbane, Perth and Sydney to provide women with an opportunity to speak about their experience of transvaginal mesh treatment and inform the development of patient decision support resources. Refer: ACSQHC, Consumer forums to discuss transvaginal mesh, <https://www.safetyandquality.gov.au/our-work/transvaginal-mesh/consumer-forums-to-discuss-transvaginal-mesh/> (accessed 12 February 2018).

4.5 Medical practitioners, including those who spoke in support of the use of urogynaecological mesh in the treatment of SUI and POP, have also emphasised the importance of patient selection, informed consent, and post-operative follow up.

4.6 The committee notes that the ACSQHC forums also identified the need for training and credentialing support for clinicians and the development of guidance for health services organisations and consumers in relation to complications associated with transvaginal mesh implants and its removal. These matters will be considered in Chapter 5.

### **Informed consent**

4.7 A great deal of evidence to the inquiry has centred on the extent to which women have received appropriate information to assist them to give their informed consent prior to transvaginal mesh procedures.

4.8 Common law requires medical practitioners, as part of their duty of care, to provide patients with information necessary to give consent to treatment, including information on all material risks of the proposed treatment.<sup>4</sup>

#### ***What constitutes informed consent?***

4.9 The committee was told that as well as being a legal requirement, the Royal Australasian College of Surgeons' (RACS) Code of Conduct requires surgeons to fully inform patients and obtain consent from the patient (or a substitute decision maker). RACS has stated that patients should be well informed of all risks associated with their surgery and surgeons should assist patients in selecting the form of treatment most appropriate to their particular situation. RACS has also stated that '[s]urgeons need to be able to counsel their patients about the range of options available and tailor treatment to the patient's needs, not their skill base as a surgeon.'<sup>5</sup>

4.10 In its submission to the inquiry, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) stressed that, while standard consent forms are used, 'consent is more the process of consultation between the individual woman and her treating doctor.' RANZCOG stated:

In the case of transvaginal mesh, it would be expected that the treating surgeon explains the treatment options, both non-surgical and surgical, the permanent nature of synthetic mesh and the likely success rates considering the individual woman's clinical factors. It would also be expected that possible risks be explained including general surgical risks and the risks specific to mesh implants ...<sup>6</sup>

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4 Australian Law Reform Commission, *Equality, Capacity and Disability in Commonwealth Laws*, 24 November 2014, p. 282, <https://www.alrc.gov.au/publications/equality-capacity-disability-report-124> (accessed 23 March 2018).

5 Royal Australasian College of Surgeons, *Surgical Mesh Consultation*, Therapeutic Goods Administration, September 2017, p. [3], [https://www.surgeons.org/media/25503864/2017-09-14\\_sbm\\_racs\\_surgical-mesh-2-.pdf](https://www.surgeons.org/media/25503864/2017-09-14_sbm_racs_surgical-mesh-2-.pdf) (accessed 18 January 2018).

6 *Submission 36*, p. 8.

4.11 Submissions from specialist medical colleges and sub-specialist urology and gynaecology units stressed the comprehensive nature of counselling provided to women prior to surgery. The Urological Society of Australia and New Zealand (USANZ) submitted that the standard of care is for routine pre-operative counselling to be undertaken prior to surgery by specialist urologists. USANZ acknowledged that the depth and nature of such counselling will vary between individual specialists and the health services they work within. Specialists may use pre-printed patient information sheets developed by professional bodies or their own personal or health service based, documents. USANZ advised that the framework for pre-operative counselling discussions would comprise:

- the rationale for treatment;
- treatment options, including non-surgical and non-mesh options;
- the likely success and potential complications, with particular emphasis on those that may impact the individual being counselled; and
- the opportunity to ask questions.<sup>7</sup>

4.12 USANZ referred the committee to the American Urological Association (AUA) *Surgical Treatment of Female Stress Urinary Incontinence (SUI): AUA/SUFU Guideline*, and noted

the 'AUA guideline specifies "prior to selecting midurethral synthetic sling procedures for the surgical treatment of stress urinary incontinence in women, physicians must discuss the specific risks and benefits of mesh as well as the alternatives to a mesh sling." It also acknowledges specific risk groups for whom mesh complications may be more common, in particular diabetes and a history of smoking.<sup>8</sup>

4.13 USANZ also noted that the AUA guideline recommends that patients be made aware of prior United States Food and Drug Administration public health notifications regarding the use of transvaginal mesh and be advised of possible mesh-related risks.<sup>9</sup>

4.14 The Urogynaecology Units at the Mercy Hospital for Women and Monash Health, which are subspecialty, multidisciplinary, gynaecology units, advised the committee that women presenting with urinary incontinence receive advice on conservative, non-surgical options as first-line treatment. Where these are unsuccessful, patients receive comprehensive counselling about surgical options, including: the nature of polypropylene mesh; cure and satisfaction rates; information about the transvaginal procedure for the insertion of a mid-urethral sling and information about the incidence of relevant surgical complications.<sup>10</sup>

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7 USANZ, *Submission 42*, p. 4.

8 *Submission 42*, p. 4.

9 *Submission 42*, p. 4.

10 Urogynaecology Departments, Mercy Hospital for Women, Monash Health, *Submission 44*, pp. [1-2]; see also Monash Health, *Submission 47*, pp. [2-3].

4.15 The Urogynaecological Society of Australasia (UGSA) provided the committee with copies of information leaflets developed by UGSA, RANZCOG and the International Urogynaecological Association which it said urogynaecologists and gynaecologists in Australia generally provide patients. These leaflets address a number of aspects of treatment for pelvic floor dysfunction including information on alternative management options and conservative non-surgical treatment, surgical treatment with and without mesh, and complications with mesh and non-mesh procedures.<sup>11</sup>

4.16 Associate Professor Jason Abbott, President of the Australasian Gynaecological Endoscopy and Surgery Society, stressed the importance of doctors ensuring that women understand the information that is provided to them.

Generally speaking, we recommend that we always ask the questions: 'Do you understand? Do you have any other questions? Do you have any concerns? Is there anything specific that you would like to know regarding this procedure?' I think that goes with all medical procedures. It's very important for us to have a depth of understanding as to what our patients think of a particular procedure and what they think is important. We don't always get that right. I think that in this situation we haven't always got that right.<sup>12</sup>

### ***The reality of the consent process***

4.17 Some submitters and witnesses expressed doubt regarding the level of information provided to women prior to surgery. The Australian College of Midwives (ACM) submitted that, in their experience, many women receive very little information prior to their surgery and expressed concern that there are few sources of consistent information available to women in terms of surgery.<sup>13</sup> The ACM told the committee that information provided prior to surgery should include the specialist doctor's experience and training with the procedure as well as the known complications associated with mesh implants published by the TGA. The ACM stated that women rarely have access to full information about the surgery because very few hospitals or specialist doctors make their rates of complications publicly available and very few specialist doctors provide information about their own level of skill and training with specific procedures.<sup>14</sup>

4.18 The Australian Pelvic Mesh Support Group (APMSG) told the committee that a survey of its members, based on the guidance provided in RANZCOG's statement

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11 Urogynaecological Society of Australasia (UGSA), *Submission 32*, p. 4. See also: Attachments 1-15.

12 *Committee Hansard*, 18 September 2017, p. 30.

13 Australian College of Midwives (ACM), *Submission 16*, p. 1.

14 *Submission 16*, p. 2.

*Polypropylene vaginal mesh implants for vaginal prolapse*,<sup>15</sup> concluded that the majority of women have not been asked any of the questions suggested by RANZCOG. Ms Carolyn Chisolm, Founder of the APMSG, told the committee:

The first question was, 'Did your specialist tell you, due to the withdrawal of some of the commonly performed and studied transvaginal mesh products from the market, that very limited robust data is available on the efficacy and safety of the transvaginal mesh products available in Australasia?' Out of 104 responses, 100 per cent said no.

The second question was: 'Did your specialist tell you that patients with asymptomatic prolapse do not necessarily require surgical management and that the decision to operate should be based upon symptomatic bother from the prolapse, defined by the patient? There is little longitudinal data in the literature on untreated asymptomatic prolapse to inform a decision for surgery in this situation.' Ninety-five point two per cent said no.

'Did your specialist tell you there are alternatives to surgical management, including non-surgical options such as pelvic floor muscle training, for mild prolapse, and vaginal support pessaries?' Seventy-nine point eight per cent said no.

'Did your surgeon tell you that complications of transvaginal mesh include mesh exposure, erosion, vaginal scarring, stricture, fistula formation, dyspareunia—which is painful sex—and/or unprovoked pelvic pain at rest and the possibility of mesh surgery resulting in unprovoked pelvic pain at rest that can be difficult to treat?' One hundred per cent said no.

'Did your surgeon tell you, if mesh complications arise, this may require additional surgical intervention and the complications may not completely resolve, even with mesh removal?' Ninety-eight per cent said no.

'Did your surgeon tell you that complete removal of the mesh implant may not always be possible?' Ninety-eight point one per cent said no.<sup>16</sup>

4.19 The Health Consumers Councils across Australia (HCCs) also undertook a survey and reported that 40 percent of women who responded did not consider they were fully informed and 22 percent stated they were given some information, but that the outcome of the surgery was not as suggested.<sup>17</sup>

4.20 The HCCs noted that this is not the first instance in which informed consent processes have been found to be poor, and referred to the findings of the committee's

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15 Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), *Polypropylene vaginal mesh implants for vaginal prolapse*, [https://www.ranzcog.edu.au/getattachment/Statements-Guidelines/Gynaecology/Polypropylene-Vaginal-Mesh-Implants-for-Vaginal-Pr/Polypropylene-vaginal-mesh-implants-for-vaginal-prolapse-\(C-Gyn-20\)-Jan18.pdf?lang=en-AU&ext=.pdf](https://www.ranzcog.edu.au/getattachment/Statements-Guidelines/Gynaecology/Polypropylene-Vaginal-Mesh-Implants-for-Vaginal-Pr/Polypropylene-vaginal-mesh-implants-for-vaginal-prolapse-(C-Gyn-20)-Jan18.pdf?lang=en-AU&ext=.pdf) (accessed 7 March 2018).

16 *Committee Hansard*, 25 August 2017, p. 5.

17 Health Consumers Councils across Australia (HCCs), *Submission 21*, p. 6.

inquiry into the role of the TGA regarding medical devices in July 2012,<sup>18</sup> in which the committee recommended:

Rigorous systems be put in place to ensure that medical practitioners provide consumers with all the information needed to allow them to give fully informed consent.<sup>19</sup>

4.21 The HCCs expressed disappointment with the government response to the report and expressed the view that the practice of relying on doctors to pass on information to patients has not worked to ensure women are able to make informed decisions.<sup>20</sup>

### ***Information provided to women prior to transvaginal mesh procedures***

4.22 The personal accounts of women who wrote to the inquiry generally do not reflect a process of thorough counselling and informed consent.

4.23 The committee is aware that some care may be needed in reviewing patient's recollections of information provided to them prior to surgery. Associate Professor Jason Abbott, President of the Australasian Gynaecological Endoscopy and Surgery Society, told the committee that it can be difficult to communicate the extent and breadth of information that is important to a particular patient. He observed that patients who have not experienced any complications with a device may feel that they have been adequately informed, while the situation may be different for patients who have sustained injury, are in chronic pain and require repeat procedures.

It's one thing to give facts and figures, to say that the number of women who might have a problem from this particular procedure are one per cent, two per cent, 10 per cent or 50 per cent and how that might have an impact. It's another to get that recollection from the woman.<sup>21</sup>

4.24 Dr Jane Manning, a urogynaecologist in private practice, expressed the view that detailed preoperative counselling on all the major surgical risks is routinely provided to patients, but patients do not expect complications will happen to them. She stated that it is difficult for pre-operative counselling to adequately prepare a woman for the eventuality that she could develop lifelong disabling pain, or to convey what chronic pain will be like when it occurs. She also submitted that as evidence available to surgeons suggests the risk of chronic pain is low following transvaginal procedures, they may not emphasise this in preoperative counselling.<sup>22</sup>

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18 Senate Community Affairs References Committee, *The role of the Government and the Therapeutic Goods Administration (TGA) regarding medical devices, particularly Poly Implant Prothese (PIP) breast implants*, 31 May 2012.

19 HCCs, *Submission 21*, p. 6.

20 *Submission 21*, p. 7.

21 Associate Professor Jason Abbott, President of the Australasian Gynaecological Endoscopy and Surgery Society, *Committee Hansard*, 18 September 2017, p. 30.

22 Dr Jane Manning, *Submission 453*, p. [1].

4.25 The committee notes that some women have expressed satisfaction with the level of information they received. One woman, who had successful transvaginal mesh surgery in the treatment of SUI five years ago, told the committee:

All operations carry the risk of failure or complications, and even death, but the individual must make their own decision regarding what risks they are prepared to take for the sake of improved health. These risks are explained by the operating surgeon and, as you are aware, the medical consent form states that there is an element of risk. The patient is asked to read and sign this consent form thereby acknowledging that they are aware of those risks and that they are prepared to accept them.<sup>23</sup>

*Limited and generic information*

4.26 The majority of women who provided personal accounts to the inquiry told the committee they had received little or no information prior to their surgery.<sup>24</sup> One woman who received her implant in 2007 wrote:

Prior to my first surgery I was told briefly of some complications and shown a small piece of mesh. I was told that only a very small percentage of women have complications, for instance some women had pain with sexual intercourse after surgery, and that the [redacted] could cause stress incontinence but this was easily fixed with another surgery where a [redacted] sling could be inserted. It was not made clear that there could be very serious, life-changing and life-threatening complications. I was not told that the mesh was unable to be removed if there were problems.<sup>25</sup>

4.27 Many women recall being told simply that the procedure was safe, minimally invasive and uncomplicated.<sup>26</sup> For example, one woman who underwent a transvaginal mesh procedure for the treatment of SUI in 2010 was told that:

this was the "Gold Standard" in treating SUI, was a day procedure, very safe and came with only minor risks, those being the standard risks associated with all surgeries (reaction to anesthetics, blood loss, small risk of infection or rejection).<sup>27</sup>

4.28 Some women provided the committee with copies of the information they were given, highlighting that this information did not include discussion of the complications they had experienced:<sup>28</sup>

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23 Name withheld, *Submission 295*.

24 See, for example: Name withheld, *Submission 60*; Name withheld, *Submission 66*; Name withheld, *Submission 67*; Name withheld, *Submission 68*; Name withheld, *Submission 86*; Name withheld, *Submission 87*; Name withheld, *Submission 206*; Name withheld, *Submission 472*.

25 Name withheld, *Submission 110*, p. [3].

26 See, for example: Name withheld, *Submission 113*, p. 1; Name withheld, *Submission 133*, p. 1; Name withheld, *Submission 149*, p. 3.

27 Name withheld, *Submission 81*, p. 1.

28 See, for example: Name withheld, *Submission 418*, p. 2 and p. 12.

One of the most infuriating aspects of this experience is not being provided any information about the Mesh before the first operation and only a printout given out regarding the operation. There was no information provided referring me to the complications of the Mesh...I would not wish for any woman to go through this experience or be treated in this manner due to a failure in information and product.<sup>29</sup>

4.29 In many cases, a transvaginal mesh procedure appears to have been the only treatment option offered.<sup>30</sup> One woman, who received a transvaginal mesh implant in 2008 as treatment for a prolapse bladder, told the committee:

Dr [redacted] who performed the surgery, seemed convinced that not only was this the best option, he lead me to believe this was the only option for me. No other options were communicated with me and at no time was I made aware that this device could fail.<sup>31</sup>

4.30 Another woman who received her implant in the treatment of minor incontinence in 2014 wrote:

Being an educator, I chose an Associate Professor Urologist because I felt confident that he would have the 'latest and best' in practice and information. After a round of urodynamic testing, a short trial of tablets, it was recommended that I have tape to lift my bladder so the urine would not tip out. I watched a video on my surgeons website that promoted an attractive energetic woman jumping on a trampoline with her family. I believed that the surgeon could make me just as active and carefree as the portrayed woman. I was not offered any other surgery other than this tape. I was warned that there was 1% risk that I may not be as dry as I would like.<sup>32</sup>

*Lack of awareness that a mesh implant was being proposed*

4.31 Some women were not informed that a medical device was being implanted as part of their surgery.<sup>33</sup> Mr Danny Vadasz, Chief Executive Officer of the Health Issues Centre, told the committee that many women were not told that they had a mesh implant until they began to experience complications. He said:

For many women, they were never told that they had had a mesh implant until they identify symptoms which they recognise to be associated with mesh implants and on further investigation they discover they do. Many women still do not know, because they cannot retrieve their medical

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29 Name withheld, *Submission 85*, p.1.

30 See, for example: Name withheld, *Submission 58*, p. [1]; Name withheld, *Submission, 80*, p. [1]; Name withheld, *Submission 87*, p. [2]; Name withheld, *Submission 103*; p. [1].

31 Name withheld, *Submission 105*, p. [7].

32 Name withheld, *Submission 67*, p. 1.

33 See, for example: Name withheld, *Submission 528*, p. 1; Name withheld, *Submission 29*, p. 1; Name withheld, *Submission 52*; Name withheld, *Submission 122*, p.2; Name withheld, *Submission 147*, p. [1].

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records. Some have had to go freedom of information in order to retrieve their records. That is a very significant problem.<sup>34</sup>

4.32 Other women were not advised that the 'sling' or 'tape' being used in their surgery was in fact polypropylene mesh.<sup>35</sup> As one woman, who had received a tension-free vaginal tape-obturator device in the treatment of SUI in 2014 and had a Sacrocolpopexy later the same year in the treatment of POP, explained:

I had the same specialist for both of these operations and at no time was mesh mentioned, my doctor called it tape. In my mind I imagined it was something similar to the tape that is put over the cotton ball after a blood test. I was not given any information on the damage this tape, mesh could cause. I had no idea that I was having mesh put inside my body! I think that the obvious thing that women should be told before surgery is - the exact nature of the complications that could occur with this mesh, which would allow them to make a carefully thought out decision knowing what the consequences could be of having this mesh implanted. Unfortunately the majority of people believe wholeheartedly what a doctor tells them to do and so don't listen to the doctor as carefully as they should.<sup>36</sup>

4.33 One woman wrote on behalf of her mother who had unknowingly received a transvaginal mesh implant while undergoing surgery for a vaginal hysterectomy in 2009. In this case, the woman had been invited to participate in a trial that the surgeon was undertaking and had declined to take part.<sup>37</sup>

Two weeks ago my mother became aware through hospital records that while in surgery for a vaginal hysterectomy a transvaginal mesh device was inserted. My mother's legal and ethical rights, to provide informed consent for this device were ignored. Prior to surgery my mother was not informed a medical device was being implanted, nor was she informed prior or post surgery about possible complications associated with this medical device.<sup>38</sup>

4.34 Another woman, who had experienced debilitating pain and unexplained episodes of bleeding following vaginal repair surgery in 2015, was prompted to seek clarification of whether she had received a mesh implant after reading an article about complications associated with transvaginal mesh implants. Her doctor was able to confirm this. She told the committee:

At that point I felt completely doomed I put the puzzle together and started crying. How can I have not known a foreign medical device had been implanted in my body without my consent? If I had known I would have

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34 Mr Danny Vadasz, Chief Executive Officer, Health Issues Centre, *Committee Hansard*, 3 August 2017, pp. 19-20.

35 See, for example: Mr Danny Vadasz, Chief Executive Officer, Health Issues Centre, Victoria, *Committee Hansard*, 3 August 2017, p. 19; Name withheld, *Submission 147*, p. 1; Name withheld, *Submission 206*, p. 3; Name withheld, *Submission 523*, p. 1.

36 Name withheld, *Submission 461*, p. 1.

37 Name withheld, *Submission 122*, p. 3.

38 Name withheld, *Submission 122*, p. 2.

done my research and not agreed in the first place. Since at that time there was so many issues regarding this matter.<sup>39</sup>

4.35 A number of women were not informed that the implant is intended to be permanent and that in the event of complications, removal can be difficult.<sup>40</sup> One woman who had transvaginal mesh surgery in 2004 to address her minor incontinence told the committee of her horror when she learnt that the mesh was permanent:

When I returned to my surgeon, I asked about a recent incident when I bent to pick up something and I felt a sharp pain in my left side accompanied by a loose feeling and a "ripping sound". My surgeon told me that this did not indicate any reason for me to be concerned because the implant 'would have grown in by now'. I was horrified as I believed that the mesh implant could be easily removed. I asked what she meant by 'grown in' and I was then given a pamphlet and more detailed information about the procedure, including the fact that the mesh grows in to body organs. I'm confident that had I received this information at the initial consultation, I would not have had the surgery as my incontinence was minor.<sup>41</sup>

*Limited opportunity to ask questions*

4.36 Some women told the committee that they had sought to make an informed decision by asking questions of their implanting surgeon and had given their consent, based on the trust they felt for the medical practitioner. A Registered Nurse told the committee that upon being advised to have a hysterectomy and repair operation, she had researched the mesh involved and found them to be controversial. She raised her concerns with her doctor who dismissed her concerns:

I then brought this to the attention my doctor and strongly voiced that I did not want the mesh. My Doctor then emphasised that with the level of exercise I do and how active my lifestyle was, he would not be doing the right thing by me if he did not use the mesh.

He did not inform me of any side effects of the mesh, or state any history of complications involving the mesh; therefore my initial investigations were dismissed, as the doctor described the operation to not involve any issues, meaning the complications for a hysterectomy were overlooked. Due to the respect and trust I "had" for our medical industry, I signed a consent form, under the impression a "professional" had confidently dismissed the concerns I voiced.<sup>42</sup>

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39 Name withheld, *Submission 528*, p. [1].

40 Name withheld, *Submission 150*, p. 2.

41 Name withheld, *Submission 550*, p. [1].

42 Name withheld, *Submission 92*, p. 1.

4.37 Some women indicated that they felt pressured to agree to the surgery.<sup>43</sup> One woman told the committee that she attended for a routine pap smear and mentioned that she experienced SUI:

Straightaway, like a 'Jack In The Box', he popped his head up from between my legs, "I can fix your USI" and subsequently did his utmost to convince me that I needed what he described as, "a safe and simple straight forward, minimally invasive, uncomplicated and effective surgery". I made it clear that should I agree, I wanted the surgery done privately, but he discovered I had no private health cover and said, "I do the very same surgery in the XXX [sic] so I'll do it there".<sup>44</sup>

4.38 Another woman told the committee that her doctor had shown what she considered to be unusual eagerness to perform transvaginal mesh surgery even though she was not aware that she had any symptoms of POP:

There was pressure on me to agree on that same day to the transvaginal mesh surgery. It was explained to me that if I declined and that surgery was still needed, it would be a lengthy delay before I could reapply to have it done. And it was more efficient to have one operation with two procedures than to have two separate operations. I believe my mesh implant was therefore unnecessary and my years of suffering afterward could have been avoided.<sup>45</sup>

4.39 Many women who wrote to the committee said that they had trusted the judgement of their medical practitioners.<sup>46</sup> As the following statements indicate, women trusted the advice of their GPs who suggested that a particular surgeon was 'very good' and they trusted the advice and opinions of the specialists they saw.

The specialist is an experienced urologist, so I trusted his advice/opinion. I did not investigate his experience in that area, but was reassured by my GP that he was very good.<sup>47</sup>

### *Improving the consent process*

4.40 The Public Health Association of Australia (PHAA) summed up the views of many submitters to the inquiry by saying that it is the doctor's duty, at the point of care, to inform a patient of all potential adverse outcomes associated with transvaginal mesh products and to be aware of any substantial risk factors that could exclude the use of transvaginal mesh to treat a patient. The PHAA stressed

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43 See, for example: Name withheld, *Submission 58*, p. [1], Name withheld, *Submission 390*, p. [1]; Name withheld, *Submission 424*, p. 8.

44 Name withheld, *Submission 113*, p. 1.

45 Name withheld, *Submission 390*, p. 1.

46 See, for example: Name withheld, *Submission 113*, pp. [1-2]; Name withheld, *Submission 133*, p. [2]; Name withheld, *Submission 206*, pp. 4, 10; Name withheld, *Submission 265*, p. 2; Name withheld, *Submission 340*, p. [12]; Name withheld, *Submission 424*, p. 3; Name withheld, *Submission 498*, p. [4]; Name withheld, *Submission 512*, pp. 3-4.

47 Name withheld, *Submission 222*, p. 4.

Patient counselling is very much reliant on effective communication between a woman and her clinician and we know from all other areas of clinical care that it calls for a woman centred approach to shared decision-making. Consideration needs to be given to the development of education and decision-making tools with regard to pelvic mesh to really facilitate a shared understanding of the woman's health issue in order to generate a mutually acceptable evaluation and management plan, that as complications arise they can be identified and acted upon early in the stages after implementation. These tools and education materials not only ensure informed decision-making but they also, really importantly, ensure informed consent.<sup>48</sup>

4.41 Women told the committee that much more information needs to be provided to women prior to surgery regarding potential complications and alternative options. Women emphasised that this information needs to be explicitly and thoroughly communicated before they undergo surgery.<sup>49</sup> One woman echoed the sentiment of many of the women who provided personal accounts to the committee:

Women need to be empowered to make an INFORMED decision prior to receiving a transvaginal mesh implant. In order for this to occur, ALL available treatment options (including non-surgical and other alternative treatment methods) need to be discussed at length, as well as the variety of short- and long-term adverse effects of mesh implants and implications for removal.<sup>50</sup>

4.42 A medical practitioner who was the recipient of a transvaginal mesh implant told the committee that her expectation was that a doctor would not only list the possible risks of the proposed surgery, but discuss how likely they are to occur. She called for the preparation of standardised consent forms, stating that while this is no substitute for good verbal communication between the doctor and patient, it would at least standardise the basic information given to patients and allow them to make a more informed decision.<sup>51</sup>

4.43 Other women recommended that information be made available on a government website:

My hope is that there would [be] a government web site that people could go to get accurate information. This would be about operations that have had adverse out comes and ones that have been found to be successful. That way we could all make informed consent.<sup>52</sup>

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48 Associate Professor Angela Dawson, Convenor of the Women's Health Special Interest Group, Public Health Association of Australia (PHAA), *Committee Hansard*, 3 August 2017, p. 8.

49 See, for example: Name withheld, *Submission 102*, p. [2]; Name withheld, *Submission 105*, p. [3]; Name withheld, *Submission 108*, p. 2; Name withheld, *Submission 293*, p. 4; Name withheld, *Submission 328*, p. 3; Name withheld, *Submission 424*, p. 3.

50 Name withheld, *Submission 467*, p. 3.

51 Name withheld, *Submission 111*, p. [2].

52 Name withheld, *Submission 118*, p. 6.

## Diagnosis - selecting the right procedure for the right patient

4.44 As noted in earlier chapters, the committee has consistently been told that SUI and POP can be complex conditions to treat and that medical practitioners need access to a range of treatment options to provide an appropriate level of care.<sup>53</sup> Associate Professor Abbott told the committee that there is potentially a place for transvaginal mesh procedures undertaken by the right surgeon, in the right patient, for the right clinical scenario.<sup>54</sup>

4.45 However, the committee heard that a significant problem, particularly with the use of transvaginal mesh in the treatment of POP, has been poor diagnosis.<sup>55</sup> Professor Hans Pieter Dietz told the committee that he considered transvaginal mesh had been overused and that in many cases, its use has been based on inadequate diagnosis:

From my point of view, of those 40 cases, there were 20 or so that were urogynaecological; and maybe one or two of those in 20 patients had had the full diagnostic workup that I would consider appropriate. The vast majority had major gaps in their preoperative diagnostic workup. The reason for that is that urogynaecology, from its very start, has been a surgical specialty. Urogynaecologists are surgeons first and foremost and we simply have not been using the technologies that modern imaging provides us with. In some instances, we have not even used the full options that are given to us by our eyes and our hands. We have not been very good at examining those women.<sup>56</sup>

4.46 The committee also heard that there was an overenthusiastic uptake of transvaginal mesh devices. Dr Jenny King told the committee:

Look, you're right. The slings were a hell of a lot better than what we had before and then when the meshes came along we all thought, 'Yes. There will be no more failures. We're going to be able to fix everyone.' And I think it did. It got over used overenthusiastically. A lot of stuff we did not know.<sup>57</sup>

4.47 Associate Professor Christopher Maher, told the committee that it is important to examine the role of clinicians and sponsoring companies in the introduction of new devices. He prefaced his comments by stating:

There's no doubt that all of my colleagues who utilised these products and who were very early adopters of these medical devices for the treatment of

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53 See, for example: Professor Hans Peter Dietz, Associate Professor Clara Shek and Dr Vivien Wong, *Submission 1*, p. 5; The Continence Foundation of Australia (CFA), *Submission 35*, p. 2; USANZ, *Submission 42, Attachment 1*, p. [1]; Dr Anna Rosamilia, Urogynaecologist, Monash Health, *Committee Hansard*, 3 August 2017, p. 33.

54 Professor Jason Abbott, *Committee Hansard*, 18 September 2017, p. 31.

55 Professor Hans Peter Dietz, Associate Professor Clara Shek and Dr Vivien Wong, *Submission 1*, p. 4.

56 Professor Hans Peter Dietz, *Committee Hansard*, 25 August 2017, p. 37.

57 Dr Jenny King, Chair, UGSA, *Committee Hansard*, 18 September 2017, p. 15.

prolapse did so in the hope of obtaining improved clinical outcomes for their patients.<sup>58</sup>

4.48 Professor Maher noted that the interaction between sponsoring companies and leading clinicians in the introduction of new transvaginal mesh products may have contributed to overuse of the devices:

Once these products are utilised and allowed by the TGA, we're able to utilise them pretty freely. The sponsoring companies actively promote medical specialists who utilise their products to referring GPs and company-sponsored educational activities, where one of the aims of that activity is to increase utilisation of those products. Sponsoring companies are also actively involved in the education and provision of training to medical specialists.<sup>59</sup>

4.49 While noting that none of these activities are illegal or inappropriate, Professor Maher noted that the provision of education or training to specialists and GPs should be conducted at arm's length and the nature and extent of any financial conflict should be declared.<sup>60</sup>

#### ***Selecting a treatment option***

4.50 Evidence from specialist colleges and specialist medical units, outlined a careful process of assessment and diagnosis for women presenting with pelvic floor dysfunction. For example, Monash Health, a specialist unit of urogynaecologists and gynaecologists, submitted that when women present with POP, a thorough history and examination is undertaken before first line treatment options are discussed. First line treatment options include pelvic floor muscle rehabilitation and conservative management with pessaries.<sup>61</sup>

4.51 If there is no improvement surgical options are discussed. For women who present with POP for the first time, the usual surgical management is native tissue repair. Monash Health submitted that transvaginal mesh is offered as a surgical option only in very selected cases, such as women presenting with recurrent pelvic organ prolapse who have failed previous surgery and conservative management. In the last 12 months Monash Health has mainly performed transvaginal mesh surgeries when transabdominal mesh surgery was unable to be performed.<sup>62</sup>

4.52 RANZCOG submitted that while conservative treatments may be helpful, in many cases surgical intervention is either requested or required. RANZCOG said:

It has long been recognised that surgical treatments for these conditions (especially POP) are not always successful, particularly in the long term, and surgeons have tried many different surgical approaches in the attempt

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58 Associate Professor Christopher Maher, *Committee Hansard*, 19 September 2017, p. 30.

59 Associate Professor Christopher Maher, *Committee Hansard*, 19 September 2017, p. 30.

60 Associate Professor Christopher Maher, *Committee Hansard*, 19 September 2017, p. 30.

61 Monash Health, *Submission 47*, p. [1].

62 *Submission 47*, p. [1].

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to minimise the disappointment and distress of women having a premature recurrence of their prolapse that might need further surgery.<sup>63</sup>

### *Treating SUI*

4.53 The Continence Foundation of Australia (CFA) submitted that non-surgical measures, such as pelvic floor muscle training and behavioural therapies, should always be the first line treatment options for SUI. However, when these treatment options are unsuccessful, surgical intervention may be indicated and can be highly effective.<sup>64</sup>

4.54 Dr Alison de Souza, a urogynaecologist with the Mercy Hospital for women, explained that, at the Mercy Hospital, the first line management of SUI is conservative and non-surgical. Women are prescribed pelvic floor muscle exercises and/or incontinence aids, such as vaginal pessaries. She stated that approximately 50 per cent of women 'will have a subjective cure of their symptoms with physiotherapy.' Where physiotherapy does not address the symptoms, surgical options are considered.<sup>65</sup>

4.55 The committee was told that mid-urethral slings (MUS) are the most common surgical treatment for SUI and the procedure has been extensively reviewed and found to have a good safety profile.<sup>66</sup> RANZCOG submitted that when compared to alternate procedures, such as the Burch colposuspension, urethral injection and suprapubic sling without mesh, MUS was found to carry a lower overall risk of complications.<sup>67</sup>

4.56 As noted in Chapter 2, a number of the women who have provided personal accounts to the committee have reported experiencing significant complications following MUS.<sup>68</sup> Dr Michelle Atherton, a urogynaecologist working in private practice, told the committee that the reason there are a lot of women with complications following MUS is because 'stress incontinence mesh is used as a first line procedure because there is no other good procedure'. She stated that alternative non-mesh treatments have significant failure rates and higher complication rates.<sup>69</sup>

4.57 Dr De Souza explained that a number of factors made some alternative surgical procedures difficult for women to access. She said the pubovaginal fascial sling and some Burch colposuspension procedures can involve large, open cut abdominal surgery, with longer hospital stays, prolonged recovery time and delayed return to work. She said that bleeding, wound and bladder infections, increased risk of

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63 RANZCOG, *Submission 36*, p. 1.

64 Continence Foundation of Australia (CFA), *Submission 35*, p. 1.

65 Dr Alison De Souza, Urogynaecologist, Mercy Hospital for Women, *Committee Hansard*, 3 August 2017, p. 30.

66 CFA, *Submission 35*, p. 1.

67 *Submission 36*, p. 9.

68 See, for example: Name withheld, *Submission 146*, p. [1]; Name withheld, *Submission 147*, p. [1].

69 Dr Michelle Atherton, *Committee Hansard*, 25 August 2017, p. 26.

blood clots, significant difficulty emptying the bladder, subsequent prolapse and pain are well known complications of these procedures.<sup>70</sup>

### *Treating POP*

4.58 The committee was consistently told that transvaginal mesh should not be used as a first line treatment for POP. Dr Atherton told the committee that transvaginal mesh for the treatment of prolapse is a high-risk product and should only be used in certain circumstances and only by subspecialist urogynaecologists. She said:

The return-to-theatre rate offsets the improved-prolapse-recurrence rate in the woman who has an average risk of prolapse recurrence, which is about a 20 per cent risk of recurrence. Because of this, it should really be reserved only for specific circumstances where there are very, very high risks of recurrence—such as somebody who has had two or three or four prolapse recurrences. We are dealing, in our urogynaecology clinic, with women—and I saw one just yesterday—who have prolapses that come out up to 10 centimetres; they are swollen; they are ulcerated. They have failed multiple previous native tissue—own tissue—repairs. A lot of them are, medically, not really fit for having a big abdominal procedure.<sup>71</sup>

4.59 Dr Atherton noted that mesh inserted abdominally for the treatment of prolapse is a lesser-risk product, but still carries a two to four percent risk. However, she explained that abdominal procedures are mainly used for prolapse of the vaginal vault.<sup>72</sup>

4.60 The ACSQHC told the committee that, consistent with the best international evidence, it had reached the view that transvaginal mesh should only be used in a research context, due to uncertainty about long-term effects and risk of complications.<sup>73</sup> Representatives of the Therapeutic Goods Administration explained that the publication of the results of two very large studies in the last 12 months comparing transvaginal mesh and native tissue procedures<sup>74</sup> had turned the tide for the use of transvaginal mesh as a first line treatment for POP.<sup>75</sup> Ms Adriana Platona, told the committee:

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70 Dr Alison De Souza, *Committee Hansard*, 3 August 2017, p. 30.

71 Dr Michelle Atherton, *Committee Hansard*, 25 August 2017, p. 26.

72 Dr Michelle Atherton, *Committee Hansard*, 25 August 2017, p. 26.

73 Adjunct Professor Debora Picone, Chief Executive Officer, ACSQHC, *Committee Hansard*, 19 September 2017, p. 7.

74 Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT), Published 20 December 2016, and Cochrane Review and International Collaboration on Incontinence, The surgical management of pelvic organ prolapse in women, published in November 2016, evaluated 3332 surgeries.

75 Adjunct Professor John Skerritt, Deputy Secretary, Therapeutic Goods Administration, and Mr Tim Greenaway, First Assistant Secretary, Therapeutic Goods Administration, *Committee Hansard*, 3 August 2017, p. 50.

We have had uncontroverted evidence about the unfavourable benefit and risk profile for this product for pelvic organ prolapse when used transvaginally, when inserted via the vagina, and we are acting on that evidence.<sup>76</sup>

4.61 Dr Gary Swift, President of the National Association of Specialist Obstetricians and Gynaecologists, told the committee that this posed a difficulty for medical professionals:

The difficult thing now that we see is what place mesh should occupy going forward. There is a risk of taking away an option that potentially may be of a very positive benefit to some women, but obviously at the expense that some women are at risk of significant adverse effects...There is also the issue of mesh sacrocolpopexy, as Dr Dowling has mentioned. Apical vaginal prolapse is a particularly difficult issue and without mesh an incredibly difficult condition to treat. We see that if there was a risk of us losing the ability to offer some of these treatments to women, there is a potential for suffering from the lack of ability to treat some of these more significant issues.<sup>77</sup>

### ***Contraindications***

4.62 As noted earlier, accounts from individual women indicate that transvaginal mesh procedures have been advised on some occasions with limited discussion of alternative treatments and with limited consideration of the suitability of the woman for the specific type of surgery. A number of the submissions to the committee were from women who had undergone transvaginal mesh surgery for the treatment of SUI, despite presenting with only mild incontinence or no symptoms of incontinence.<sup>78</sup> Some women told the committee that they had been diagnosed and encouraged to have surgery having attended for a routine pap-smear.<sup>79</sup> The committee was told of one case where a woman experienced debilitating complications as a result of a device implanted just in case she later developed SUI.<sup>80</sup>

4.63 Dr Jennifer King told the committee that transvaginal mesh procedures should generally not be performed as a first line treatment in young women.<sup>81</sup> Dr King told the committee, that in the case of younger patients, medical practitioners were more likely to suggest an alternative to a mesh implant:

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76 Ms Adriana Platona, First Assistant Secretary, Therapeutic Goods Administration, *Committee Hansard*, 3 August 2017, p. 50.

77 *Committee Hansard*, 3 August 2017, pp. 22-23.

78 See, for example: Name withheld, *Submission 103*; Name withheld, *Submission 524*; Name withheld, *Submission 545*.

79 See, for example: Name withheld, *Submission 113*; Name withheld, *Submission 449*; Name withheld, *Submission 482*.

80 *Confidential submission 465*.

81 Dr Jenny King, *Committee Hansard*, 18 September 2017, p. 17.

For the younger ones, we say, 'Nothing's worked conservatively. You've had it and you want an operation,' but I would definitely try something simpler for the younger ones for fascial repair. That's usually what we do.<sup>82</sup>

4.64 However, the committee was concerned by some accounts received from young women who had received mesh implants as first line treatment for their condition.<sup>83</sup> For example, the committee was particularly concerned to learn of the experiences of one woman who had received a tension-free vaginal tape (TVT) implant to address mild SUI in 2008, when she was just 22 years old. Apart from sessions in a Neotonus chair<sup>84</sup>, she was not offered alternative treatments. The surgeon advised her that TVT surgery would be quick and that she was a prime candidate. She was not advised of possible complications, or that the device was permanent. She recalls being told 'that this was a new wonderful tension free tape that cures incontinence' and she formed the impression that it was a small flexible tape that would dissolve over time. The surgery was performed just six weeks after the birth of her second child and she was not made aware that this could pose additional risk. During her third pregnancy, doctors appeared unfamiliar with mesh implants or how they might impact on her pregnancy.

I had to explain what a TVT was and they couldn't help me and they told me there is no studies/research done for TVTs and pregnancy. All they could say was that a C-section is recommended.<sup>85</sup>

4.65 This woman has experienced recurrent urinary tract infections, pain and bleeding after sex, but has been advised that these symptoms are not associated with the implant. She has now been advised to have the mesh removed, once she has finished having her family. She told the committee that she feels 'broken' knowing that she is going to require a lot of medical assistance and support for the rest of her life.<sup>86</sup>

### ***Information available to medical practitioners***

4.66 A number of women questioned the information available to medical practitioners to guide them in diagnosis of treatment options for SUI and POP. A midwife who received a transvaginal mesh implant in 2005 to correct a rectocele, questioned the use of synthetic mesh in the vagina, noting the inherent elasticity of the organ. She expressed concern that there appears to be a lack of communication between the specialist disciplines regarding the use of transvaginal mesh procedures and evidence regarding complications.<sup>87</sup>

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82 Dr Jenny King, *Committee Hansard*, 18 September 2017, p. 20.

83 See, for example: Name withheld, *Submission 111*; Name withheld, *Submission 393*.

84 Neotonus chair therapy employs pulsing magnetic fields to stimulate nerve activity in the pelvic floor, which in turn exercises the muscles that control bladder function.

85 Name withheld, *Submission 523*, p. [2].

86 Name withheld, *Submission 523*, p. [3].

87 Name withheld, *Submission 324*, p. 4.

4.67 RANZCOG advised that it provides statements on transvaginal mesh for SUI and POP, but that these are intended as guidelines only and clinicians are expected to understand the current literature regarding these procedures if they are performing them.<sup>88</sup> The provision of information and training to medical practitioners is considered further in Chapter 5.

### **Recognition of complications**

4.68 Evidence to the inquiry suggests that in many cases women reporting complications following transvaginal mesh surgery have experienced poor responses from medical practitioners. The committee received many accounts describing the challenges and frustration that patients have faced in having their symptoms addressed, or indeed taken seriously. Dr Thierry Vancaillie told the committee:

My first observation is that almost all patients have seen multiple physicians from various specialties, who either did not understand them or simply did not believe them. Of the three patients I saw on Wednesday last week, only one had received some treatment despite being in pain for at least 14 months. One of the other patients was in pain for more than 10 years.<sup>89</sup>

4.69 Sadly many women recounted being spoken to angrily or disrespectfully when they have asked questions about their symptoms and spoke of feeling humiliated, embarrassed and upset.<sup>90</sup> One woman told the committee that six months after her surgery, she began to experience a range of symptoms for which tests failed to identify a cause. She said that no one would believe her when she explained 'I have something sticking out into my vagina.' Finally, after seeing a television program, she consulted her doctor again and told him about the program

So he sent me back to my implanting gynaecologist, well he just said nothing wrong with you I told him about the protruding mesh and he said. It's working what more do you want. I told him about all the pain and did he know about nerve damage. Don't know So for \$200.00 I got nothing, no support about how I was, he knew I was very upset. He gave me an internal, said nothing, your fine it's working. I left in tears. As if I wasn't important.<sup>91</sup>

4.70 Another woman told the committee that her surgeon dismissed her symptoms and told her there was nothing further he could do for her:

This pain continued and I returned for my 6 week check up where I was patted on the head and told that it would settle down. I returned again to this dr who was more concerned with if I had commenced having sex. As I didn't have a partner I was unable to answer that question. I spoke to him

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88 RANZCOG, *Submission 36*, p. 8.

89 Professor Thierry Vancaillie, Director, Women's Health and Research Institute of Australia, *Committee Hansard*, 18 September 2017, p. 7.

90 See, for example: Name withheld, *Submission 110*, p. [3]; Name withheld, *Submission 182*, p. [1]; Name withheld, *Submission 527*; Name withheld, *Submission 549*, p. [3].

91 Name withheld, *Submission 552*.

about my constant pain in my coccyx, inability to sit or stand as I had a terrible dragging feeling inside my abdomen down to my vagina. I had trouble being able to lift my leg where I was told that he had no idea why I would have that problem. Maybe I had fallen on my coccyx as a child and that was resurfacing. I was again patted on the head and told maybe I was the 1% that suffered pain from the procedure. I was told not to return there was nothing else he could do for me.<sup>92</sup>

4.71 One husband told the committee that his wife contacted her surgeon regarding her symptoms, only to be told she was healing normally and to go home and have sex.<sup>93</sup>

4.72 Women reported being told that they were the only woman the surgeon had treated who had experienced complications, that theirs was an unusual case or that they were simply unlucky.<sup>94</sup>

4.73 Other women have been told that their symptoms are imagined. For example, one woman told of her frustration trying to find a doctor who 'knows or understands what I am trying to say about what I am going through. They keep telling me it's in my head.'<sup>95</sup> Others have had their symptoms dismissed as their body rejecting the device. One woman reported being told: 'it was just me, it's my body rejecting the device, I am the problem.'<sup>96</sup>

4.74 Accounts received by the APMSG following recent publicity surrounding mesh implants, suggest that women still meet with this type of dismissive and disrespectful response. Ms Stella Channing, the Director and Administrator of the APMSG, told the committee:

To add insult to injury, many women who have gone for consultations have been scoffed at, mocked, humiliated and disregarded by some of their doctors. These are some of the quotes: 'So you're one of those following the hype.' Another: 'I went to a GP who told me not to believe all the hype about mesh, and he wouldn't give me a referral to a specialist. He sent me home with a sheet of back exercises to do. He then scoffed and said that the doctor in Sydney will be driving around in luxury cars paid for by ladies like myself. I felt humiliated.'

Another: 'My doctor told me that my mesh wasn't the issue and only a few women are having problems. He told me not to believe all the drama that is going on in the media and online.'<sup>97</sup>

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92 Name withheld, *Submission 524*.

93 *Confidential Submission 465*.

94 See, for example: Name withheld, *Submission 67*, p. [4]; Name withheld, *Submission 102*, p. [1]; Name withheld, *Submission 396*; Name withheld, *Submission 397*.

95 Name withheld, *Submission 430*, p. 4.

96 Name withheld, *Submission 487*, p. 2.

97 *Committee Hansard*, 25 August 2017, p. 3.

4.75 Ms Channing told the committee that such comments are an invalidation of women's lived experience. She said that such responses demonstrate 'how the health system silences, shames and blames the victims.'<sup>98</sup>

4.76 The APMSG told the committee that some women have driven significant distances or have flown interstate in search of doctors who willing and able to help them.<sup>99</sup> Women told the committee of their relief when they finally found a practitioner who was willing to provide understanding and support:

Finally just to meet a specialist who gave belief, understanding and hope was a pure god send in knowing I was not alone and my story was real.<sup>100</sup>

### ***Practitioner's knowledge of transvaginal mesh***

4.77 Some submitters expressed concern that the medical practitioners they approached seemed unaware of the symptoms associated with mesh implants. Ms Stella Channing, from the APMSG told the committee that one of the difficulties is that women often approach their GP in the first instance, who may have no understanding of complications associated with transvaginal mesh:

What happens is that women who are suffering with their pain and complications such as mesh erosion or they are bleeding go to their doctor—and, to be honest it starts at the GP level. The GPs don't understand mesh or mesh complications and the women are usually fobbed off. They might be sent for a scan or an x-ray and they are sent away. The X-ray comes back with nothing and then the doctor says, 'There's nothing wrong with you' because they don't show anything. Women go back again and again to doctors and they are being sent away, and doctors are saying, 'We don't know what it is.' Some women go on for years in that same cycle...<sup>101</sup>

4.78 Women told the committee of the frustration and stress caused by delays in identifying and treating symptoms. In other cases, the length of time taken to identify and treat symptoms women were experiencing was a cause of frustration and stress. Andrea told the committee:

I began to dread attending the GP for fear of being made to feel a hypochondriac, again dismissed and told it was very unlikely my symptoms were due to the mesh, and all the hype on the internet was not to be believed anyway.

4.79 Another woman provided the committee with a timeline spanning two years during which she presented with a range of symptoms, including: pelvic pain; difficulty voiding; urinary tract infections and ineffectual emptying of her bladder. She raised suspicions that her symptoms were related to her transvaginal mesh device, but it took another 12 months before her surgeon suggested that this might be the case.

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98 Ms Stella Channing, *Committee Hansard*, 25 August 2017, p. 3.

99 Ms Stella Channing, *Committee Hansard*, 25 August 2017, p. 3.

100 Name withheld, *Submission 451*, p. 5.

101 *Committee Hansard*, 25 August 2017, p. 4.

She was advised that she was the only patient her surgeon had with complications and states that at various points she felt her surgeon was stalling and not taking her symptoms seriously. She was concerned that it took more months before the surgeon proposed a cystoscopy.<sup>102</sup>

4.80 Evidence to the committee stressed the importance of medical practitioners having some awareness of the transvaginal mesh procedures and the possible complications that may arise. As one woman wrote:

All doctors need to [be] aware of the complications and adverse effects of transvaginal mesh and be open to what their patients are telling them. The specialists need to keep up with the current research so that at an early stage the problems could be dealt with rather than them being left leading to chronic life altering conditions. It should not be a closed shop for gynaecologists and urogynaecologists as the complications are far reaching across all specialities.<sup>103</sup>

4.81 Mrs Charlotte Korte, representing the New Zealand support group, Mesh Down Under, told the committee it is remarkable that the way women with mesh complications are being treated by doctors has not changed. She said that many doctors are still not trained to recognise mesh injuries and that this needed to be urgently addressed to cut the time it takes to diagnose mesh related complications.<sup>104</sup>

4.82 Noting that GPs are often a primary point of contact with the medical profession for many patients, the committee sought to understand the steps being taken to ensure that GPs were aware of mesh related symptoms. Dr Magdalena Simonis, of the Royal Australian College of General Practitioners (RACGP), explained the challenges faced by GPs in treating women who present with pelvic pain or other symptoms following mesh procedures. Dr Simonis noted that the GP is often not in a position to know that the woman has had a mesh procedure due to the lag between the procedure and the onset of complications:

One of the issues is that the time line of presentation between surgery and presentation with complaints of pain could be anything from weeks to several years. Some patients might not have continuity of care with the same GP. Sometimes the GP has not been made aware of the details of the actual surgery that the woman had; even if the woman has had surgical interventions by a surgeon whom the GP has referred them to.<sup>105</sup>

4.83 One of the complicating factors in identifying mesh related complications is the delay in the onset of symptoms. As noted elsewhere, it can be some years before

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102 Name withheld, *Submission 147*, pp. [2-5].

103 Name withheld, *Submission 139*, pp. [2-3].

104 Mrs Charlotte Korte, Lead Representative, Mesh Down Under, *Committee Hansard*, 25 August 2017, p. 13.

105 Dr Magdalena Simonis, Member, Expert Committee, Quality Care, Royal Australian College of General Practitioners, *Committee Hansard*, 19 September 2017, p. 13.

women begin to experience problems associated with their implant.<sup>106</sup> In addition, the range of symptoms that women experience may not be easily identified as related to a transvaginal mesh implant. As one woman explained:

Despite having my GP, gynecologist and neurosurgeon all trying to help sort out the source of my pain, nobody, seemed to know anything about mesh complications. The problem with women talking to doctors about mesh implants is that when you begin to experience these side effects you have no idea that it could even be related to the mesh. The debilitating pain etc presents itself in a way that makes you think it could be your hip, back or legs? I had countless spinal and nerve blocks, Xrays, MRI's and Cat Scans. I spent years on the medical merry-go-round. When these results are always coming back negative and nothing is being diagnosed the medical professionals start to treat you like you are crazy or deluded. I don't think there is enough education of these doctors to the reality of transvaginal mesh implant side effects.<sup>107</sup>

4.84 Dr Simonis told the committee that this poses particular challenges for GPs who are often less familiar with the complexities of mesh related complications:

There has been a lag between the surgery and the complications, which is the case in many of these situations where the lag has been so long. And it is very unfortunate that the woman (sic) who have been interviewed have actually had the experiences that they've had. As a college, we take that on board and we'll need to really inform our GP community of the reality and the complexity of pelvic pain and how prior surgery may well be one of the reasons for this.<sup>108</sup>

4.85 Dr Simonis told the committee that GPs are now aware of the need to specifically ask if the patient has had a vaginal mesh procedure:

I think that's what we've not been aware of to date, and this has certainly brought this to our attention.<sup>109</sup>

4.86 The committee notes recommendations for greater education of GPs, nurses and medical clinics about complications associated with transvaginal mesh so that they are better able to provide or refer patients for appropriate treatment and support. Some women advocated the establishment of specialist clinics to provide support in pain management and other complications associated with mesh implants.

For the future: I'd like to see my local doctors, nurses and medical clinics become more educated and become more aware of TVT issues. It would be great if a local mesh clinic is established focusing on pain management, life management, free removal and aides, and help with all the other problems associated that I'm trying to live with. But at the moment my options are

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106 See, for example: Name withheld, *Submission 72*, p. [1]; Andrea, *Committee Hansard*, 3 August 2017, p. 2; Professor Thierry Vancaillie, *Committee Hansard*, 6 February 2018, p. 2.

107 Name withheld, *Submission 464*, pp. 1-2.

108 Dr Magdalena Simonis, *Committee Hansard*, 19 September 2017, p. 14.

109 Dr Magdalena Simonis, *Committee Hansard*, 19 September 2017, p. 13.

limited. In my opinion TVT should be banned or at the very least be limited to a last resort option, with all warnings given to patients prior.<sup>110</sup>

### ***Follow up and on-going monitoring***

4.87 A number of women expressed concern that there was limited or no follow up after their surgery.<sup>111</sup> Women told the committee that there should be comprehensive follow up after surgery, to document the progress of each patient and treat complications as they arise.<sup>112</sup> One woman who had transvaginal mesh surgery for POP in 2006 told the committee:

I believe there needs to be monitoring of women who have had these devices implanted, and comprehensive follow up at regular intervals 6 weeks 3 months 12 months and annually from there after, so that a comprehensive data base can be created to monitor the actual numbers of women who experience these complications, and so that we can have a clearer picture to the outcome of these issues at present nothing like this exists.<sup>113</sup>

4.88 The committee received evidence regarding surgical audits and research studies that have tracked the progress of women after surgery. For example, Professor Peter Dwyer, speaking on behalf of the tertiary referral Urogynaecology Units at both the Mercy Hospital for Women and Monash Health told the committee that those units follow up all of their mesh patients 'to look at their outcomes and to look at complications associated with them'. Professor Dwyer clarified that this follow up is partly a surgical audit and partly for research purposes.<sup>114</sup> The results of this work have been published, including:

- a five year follow up study of 1225 consecutive women who underwent a MUS between 1999 and 2007, published in 2010, indicated an 86 percent subjective cure rate for SUI;
- a study of sexual function following MUS, published in 2011, indicated a reduction in urinary leakage and fear of leakage during sex; and
- a five year follow up of a randomised controlled trial comparing a single incision MUS with a transobturator MUS in 235 women, published in 2017, revealed a greater than 95 percent cure rate and less than 1 percent exposure rate.<sup>115</sup>

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110 Name withheld, *Submission 523*, p. [3].

111 See, for example: Name withheld, *Submission 29*, p. [1]; Name withheld, *Submission 108*, p. 10; Name withheld, *Submission 113*, pp. [1, 4]; Name withheld, *Submission 114.1*, p. 2.

112 See, for example: Name withheld, *Submission 108*; Name withheld, *Submission 111*, p. 4; Name withheld, *Submission 119*, p. 8; Name withheld, *Submission 155*, p. 4.

113 Name withheld, *Submission 102*, p. 1.

114 Professor Peter Dwyer, *Committee Hansard*, 3 August 2017, p. 37.

115 Urogynaecology Departments, Mercy Hospital for Women, Monash Health, *Submission 44*, p. [3].

4.89 Dr Anna Rosamilia, a urogynaecologist at Monash Health's tertiary referral centre, told the committee that surgical audit and follow up conducted at Monash Health and is used to inform patient counselling and discussion prior to surgery. By way of example, Dr Rosamilia told the committee that by doing audit and follow-up, Monash Health had identified that the risk of mesh exposure had decreased, possibly due to a changes in materials but also experience and changes in surgical technique.<sup>116</sup>

### **Mesh removal**

4.90 As noted in Chapter 2 and Chapter 3, a number of women have undergone procedures for the removal of transvaginal mesh devices. Some of these have travelled overseas for this surgery, at significant cost and continue to face debts associated with this.<sup>117</sup> A number of other women advised the committee that they were intending to have surgery to remove their implants.<sup>118</sup>

4.91 Some women wrote that they had been advised their mesh could not be removed safely without risking further complications.<sup>119</sup> Others told the committee that they have heard that there are no surgeons in Australia who could remove mesh safely or that are appropriately skilled to undertake such surgery,<sup>120</sup> and that if they wished to have their mesh implant removed, their only option would be to travel overseas to have this surgery.<sup>121</sup>

4.92 RANZCOG advised the committee that the risks associated with mesh removal are 'not insignificant' and that the risks associated with full mesh removal may exceed the possible benefit. RANZCOG submitted:

If the mesh has eroded into bladder and/or bowel, a combined surgical team with urogynaecologist/gynaecologist and urologist and/or colorectal surgeon may be required. Whilst the mesh can be removed, it cannot always be safely removed completely, and the long-term pain associated with mesh may not be completely resolved despite mesh removal.<sup>122</sup>

4.93 Some women have told the committee of positive outcomes following full or partial removal of their mesh. However, the experiences of some of the women who have had their mesh removed indicate that they continue to live with significant complications. For example, one woman who had a full mesh removal in Australia in 2017 wrote:

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116 Dr Anna Rosamilia, *Committee Hansard*, 3 August 2017, p. 34.

117 See, for example: Name withheld, *Submission 103*, p. [2]; APMSG, *Submission 130*, p. 2; Kim, *Committee Hansard*, 3 August 2017; p. 2; Andrea, *Committee Hansard*, 3 August 2017; p. 2; Joanne, *Committee Hansard*, 18 September 2017, p. 2.

118 See, for example: Name withheld, *Submission 112*, [2]; Name withheld, *Submission 521*, p. [3].

119 See, for example: *Submission 102*, p. 5; Name withheld, *Submission 498*, p. [9].

120 See, for example: Name withheld, *Submission 134*, p. [3]; Name withheld, *Submission 137*; Name withheld, *Submission 538*, p. [1]; Melinda, *Committee Hansard*, 3 August 2017, p. 14.

121 See, for example: Name withheld, *Submission, 137*; Name withheld, *Submission 554*.

122 *Submission 36*, p. 10.

While feeling better that the mesh has been removed I am left with pudendal nerve damage, fibromyalgia, inability to sit or stand for any length of time, inability to be intimate or have sexual relations with my husband, inability to pursue an active lifestyle, and the inability to attend regular family functions (sport practices/events, movies, dinners, parent/teacher conferences, etc.) due to the pain in my vaginal and gluteal areas.<sup>123</sup>

4.94 RANZCOG stated that it is appropriate in such circumstances to inform women that the mesh cannot be removed safely. RANZCOG noted that 'some women may misconstrue this advice as meaning that the mesh cannot be removed because Australian Urogynaecologists are not trained in mesh removal, and believe they must seek a surgical solution overseas or wait for an overseas trained Urogynaecologist to come to Australia to perform and teach mesh removal.'<sup>124</sup>

4.95 The committee heard that there are a number of surgical units in Australia that have expertise to undertake mesh excision and that further units are in the process of gaining expertise from overseas surgical facilities.<sup>125</sup>

4.96 Professor Vancaillie told the committee that medical practitioners needed to improve their knowledge of chronic pain and the way they respond to it. He said that where severe pain occurs immediately after insertion of a transvaginal mesh device, the device should be removed immediately. However, if the pain occurs with delay, then the pain should be managed first and if that is unsuccessful, the mesh should be removed. Professor Vancaillie said that in his experience, there is a fifty percent chance that pain will be immediately significantly better after removal of the device and a 50 percent chance that it will still take some time to control the pain.<sup>126</sup>

### **Committee view**

4.97 The committee is deeply concerned by the accounts it has received of women's experiences at the hands of medical practitioners. Even allowing for the positive accounts provided to the committee and the fact that some accounts are recalling events of over ten or fifteen years ago, they present the medical profession in a very poor light.

4.98 The committee considers that informed consent is fundamental in the provision of healthcare. The committee notes the guidance provided by RANZCOG to support informed consent and the evidence provided by specialist urology and gynaecology units regarding the comprehensive nature of pre-operative counselling provided in those units. However, the committee is concerned that the vast majority of personal accounts received from women indicate a lack of consistency and care in eliciting women's consent prior to transvaginal mesh procedures.

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123 Name withheld, *Submission 81*, p. [1].

124 *Submission 36*, p. 10.

125 National Association of Specialist Obstetricians and Gynaecologists, *Submission 49*, p. [3].

126 *Committee Hansard*, 18 September 2017, pp. 8-9.

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4.99 The committee is concerned that in many cases women's consent has been obtained following a perfunctory or generic discussion of the risks involved. In many cases, no alternate measures have been discussed. The committee is particularly concerned by accounts of women receiving transvaginal mesh implants without their knowledge. The committee considers that informed consent must involve discussion and understanding of the risks and benefits specific to the individual patient and the procedure they are being offered. Simply providing a patient with a form to sign is not sufficient.

4.100 The committee is concerned about the apparent inconsistency in the care with which the initial diagnosis of women's conditions has been undertaken. The committee notes the evidence regarding rigorous systems in place in specialist units. However, the committee is deeply troubled by personal accounts which reflect diagnosis made following limited examination and the recommendation of transvaginal mesh procedures as a first line response to reportedly minor SUI or POP.

4.101 From reading the personal accounts received from individual women, the committee considers there is a need for clear and accessible information about complications associated with transvaginal mesh procedures, and options for addressing these, for both patients and medical practitioners. In particular, there is a need for clear guidance in relation to options for partial or full removal of transvaginal mesh. The committee will consider this further in the next chapter.

4.102 Finally, the committee is concerned at the response of some medical practitioners to women presenting with complications. The committee appreciates a range of factors can complicate a medical practitioner's ability to quickly and accurately identify the underlying cause of symptoms. However, the committee can find no reasonable justification for the dismissive and disrespectful treatment many women have experienced from trusted medical professionals.

4.103 The committee encourages women not to accept unprofessionalism by medical practitioners and to consider reporting any concerns they might have, either to the medical practice or hospital, or in the case of more serious complaints, to the health care ombudsman in the relevant state.



# Chapter 5

## Responding to the evidence

[W]e believe this is a catastrophic failure of the health system to protect women and ensure they have access to safe health care. We feel that women have been let down by their doctors, by the manufacturers of mesh and by the TGA as the regulator.<sup>1</sup>

5.1 The committee concurs with the Public Health Association of Australia's (PHAA) description of the complications resulting from transvaginal mesh implants as constituting a serious public health issue requiring a response at both an individual and at a population level, including counselling, public education, clinical interventions and long-lasting protective mechanisms.<sup>2</sup> The committee also considers that this inquiry has highlighted significant shortcomings in Australia's reporting systems for medical devices, with flow-on consequences for the health system's ability to respond to in a timely and effective way to concerns arising from the use of medical devices.

5.2 The committee is acutely aware that at the heart of this serious public health issue is a group of women who have borne a great cost: the cost of living with, and trying to seek treatment for, debilitating complications that have undermined their quality of life and that of their families. As the committee has heard, this in turn has exacted an enormous toll on their emotional wellbeing.

5.3 These women have also shouldered the burden of drawing attention to their plight and mobilising action to address it. In the process, they have borne the opprobrium of those who fear transvaginal mesh devices will be banned. It has taken a great deal of courage for women to come forward and discuss these most intimate and traumatic details in public. The committee makes no apology for placing these women and their lived experience at the forefront of this inquiry.

5.4 The committee is aware that, concurrent with this inquiry, a number of initiatives have been being progressed to respond to the concerns raised. In some cases, this work spans the period from the introduction of urogynaecological mesh for use in Australia. In other cases, the initiatives under consideration are a direct response to more recent accounts of pain and suffering from women living with complications from transvaginal mesh implants.

5.5 At the same time, the committee is acutely aware that for many of the women suffering as a result of transvaginal mesh implants, the responses to date have been slow in addressing the concerns they have raised and, for some, will make little difference to their circumstances.

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1 Ms Josephine Root, Policy Manager, Consumers Health Forum of Australia, *Committee Hansard*, 3 August 2017, p. 16.

2 Associate Professor Angela Dawson, Convenor of the Women's Health Special Interest Group, Public Health Association of Australia, *Committee Hansard*, 3 August 2017, p. 8.

5.6 This final chapter considers the responses of regulators, the medical profession and device manufacturers and presents the committee's conclusions and recommendations.

### **Regulation of the introduction and use of transvaginal mesh implants**

5.7 As noted in Chapter 1, responsibility for investigating the suitability of medical devices for use in Australia rests with the Therapeutic Goods Administration (TGA).

5.8 Throughout this inquiry, the committee has heard criticism of the TGA's management of the introduction and regulation of transvaginal mesh products.<sup>3</sup>

5.9 The key concerns raised in submissions to the committee have focused on:

- the stringency of the TGA's premarket assessment of transvaginal mesh devices for use in Australia;
- the pace of the TGA's response to evidence regarding serious complications associated with transvaginal mesh products; and
- the effectiveness of the TGA's adverse event reporting system, as discussed in Chapter 3.

5.10 However, Professor John Skerritt told the committee that, while no one should be proud or happy about the sequence of events that have happened, Australia's response has been ahead of that of the United States Food and Drug Administration (US-FDA) and ahead of Europe in many cases.<sup>4</sup>

5.11 In evidence to the inquiry, the TGA explained that assessment of the safety and efficacy of medical devices is undertaken on the basis of a combination of pre-market assessment and ongoing post market review. Professor Skerritt explained that:

the evidence that you use to look at whether it is appropriate for a product to be on the register [Australian Register of Therapeutic Goods (ARTG)] is a combination of the evidence that was provided and reviewed at the time of the application to be put on the market as well as the continuously evolving nature of evidence from clinical studies and day-to-day experience with these products worldwide.<sup>5</sup>

5.12 In its submission to the inquiry, the Department of Health (Department) advised that the TGA has continued to monitor evidence regarding the safety of urogynaecological mesh devices as it has evolved. As new evidence has emerged, the TGA has taken steps to apply greater stringency to pre-market assessment processes.

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3 See, for example: Health Consumers Councils across Australia, *Submission 23*; Consumers Health Forum of Australia, *Submission 26*; Health Issues Centre, *Submission 115*, Australian Pelvic Mesh Support Group, *Submission 140*.

4 Adjunct Professor John Skerritt, Deputy Secretary, Therapeutic Goods Administration, *Committee Hansard*, 6 February 2018, p. 2.

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

In some cases, this has resulted in devices being removed from the register, either by the TGA or the device manufacturer or sponsor.<sup>6</sup>

### *Pre-market assessment*

5.13 Submitters and witnesses to the inquiry have questioned the TGA's pre-market assessment of transvaginal mesh devices, suggesting that the TGA has approved mesh devices for use in the Australian market without a strong evidence base and on the basis of substantive equivalence.<sup>7</sup>

5.14 In responding to these criticisms, the TGA told the committee that there is a tension for regulators between acceding to the desire to gain timely access to new treatments and the need to assess the evidence regarding the efficacy and safety of each device.<sup>8</sup>

### *Clinical trials*

5.15 A commonly expressed concern throughout the inquiry has been that transvaginal mesh devices were introduced without rigorous clinical trials.<sup>9</sup>

5.16 Professor Skerritt explained that one of the challenges in the assessment of medical devices is the time it takes to establish the safety and performance of a new technology. He explained that it is not possible to conduct 'double blind, randomised clinical controlled trails on a device, especially an implanted device' in the same way as can be done with medicines.<sup>10</sup>

...one of the challenges with medical devices, especially those used in fairly specialised surgical techniques, is that you'll never be able to go out and say, 'We'll do a trial of a thousand people,' and then come back when you've done a trial of a thousand people and it's all one big trial. The evidence base is always evolving. I know that sounds easy to say but that's just the nature of it. It is the same with medicines for rare diseases—because the disease is rare you're never going to get enough people to do a trial with 1,000 people before you put it on the market.<sup>11</sup>

5.17 The committee notes evidence received from medical practitioners proposing that new medical devices should, in the first instance, be approved for use in carefully

6 Department of Health (Department), *Submission 19*, p. 5.

7 See, for example: APMSG, *Submission 130*, p. 23; Associate Professor Christopher Maher, *Submission 154*, p. [10]; Kathryn, *Committee Hansard*, 19 September 2017, p. 4.

8 Dr Tim Greenaway, First Assistant Secretary, Therapeutic Goods Administration (TGA), *Committee Hansard*, 19 September 2017, p. 45.

9 See, for example: RANZCOG, *Submission 36*, p. 11; Health Issues Centre, *Submission 115*, p. 25; Name withheld, *Submission 28*, p. 2; Name withheld, *Submission 101*, p. [2]; Chantal, *Committee Hansard*, 3 August 2017, p. 24; Kathryn, *Committee Hansard*, 19 September 2017, p. 4.

10 Adjunct Professor John Skerritt, *Committee Hansard*, 3 August 2017, p. 46.

11 Adjunct Professor John Skerritt, *Committee Hansard*, 6 February 2018, p. 10.

monitored clinical trials with ethics approval and by surgeons who have adequate training.<sup>12</sup>

### *Substantive equivalence*

5.18 Submitters have also raised concerns that some transvaginal mesh devices appear to have been introduced to the Australian market without a thorough pre-market assessment purely because they were considered similar to a device already listed on the Australian Register of Therapeutic Goods (ARTG), known as substantive equivalence.<sup>13</sup>

5.19 Ms Adriana Platona explained that, in order for the TGA to approve an application on the basis of substantive equivalence, the sponsor of the device would need to provide comparative analysis to demonstrate that any differences between the products—in materials, design, clinical evidence—would not impact on the safety and efficacy of the device. Ms Platona explained that the two devices would need to have the same intended purpose, in the same anatomy and have the same manufacturer.<sup>14</sup>

5.20 Professor Skerritt explained that the TGA's approach is not the same as the process applying in the United States:

All medical device products—and these were class IIb or class III, depending on whether they contained a biological origin component—all class IIb products, are required to have undergone conformity assessment either within Australia or by a European organisation. The Americans have a process that's a 'me too'. They call it their 52K process. We don't have such a process. When our regulatory system was reviewed by government, or by a panel of three experts who reported to government, over the last three years, it was recommended that we did not adopt such a process. We've never had one. So any product that has been put onto our register in the last decade or more has been through a review, either in Europe or by ourselves.<sup>15</sup>

5.21 The TGA advised that whether or not the assessment of a device is conducted overseas, the decision to include it on the ARTG is always a decision of the TGA.<sup>16</sup>

### *Re-classification of surgical mesh devices and introduction of patient implant cards*

5.22 As part of the government's agreement that the TGA should align its processes with the European Union regulatory framework,<sup>17</sup> the TGA recently

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12 See, for example: Dr Anna Rosamilia, Urogynaecologist, Monash Health *Committee Hansard*, 3 August 2017, p. 34; Professor Robson, President, Royal Australian and New Zealand College of Obstetricians and Gynaecologists, *Committee Hansard*, 19 September, pp. 22-23.

13 See, for example: APMSG, *Submission 130*, p. 23; Associate Professor Christopher Maher, *Submission 154*, p. [10].

14 Ms Adriana Platona, First Assistant Secretary, TGA, *Committee Hansard*, 19 September 2017, p. 45.

15 *Committee Hansard*, 6 February 2018, p. 3.

16 Ms Adriana Platona, *Committee Hansard*, 19 September 2017, p. 49.

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announced that surgical mesh devices would be reclassified as Class III (high risk) from 1 December 2018. As noted in Chapter 1, in Australia, synthetic surgical meshes are currently classified as Class IIB. The change in classification means that all new applications for marketing approval for surgical mesh in Australia will require additional conformity assessment certification. Manufacturers of existing urogynaecological devices will need to lodge a reclassification application no later than December 2020.<sup>18</sup>

5.23 In announcing the measures, the TGA advised that:

In light of concerns expressed by many women who have undergone surgery with an urogynaecological mesh device, a two years transition period applies for this up-classification measure from the commencement of the regulations.<sup>19</sup>

5.24 At the same time, measures were introduced to address concerns about the level of information provided to consumers about surgical devices. These measures comprise:

- patient cards for implantable medical devices (patient implant cards): to be implemented from 1 December 2018 for all new urogynaecological mesh devices and from December 2021 for all existing implantable devices; and
- a patient information leaflet for all implantable medical devices: to be implemented from 1 December 2018 for all new permanently implantable devices, from 1 December 2019 for all existing urogynaecological mesh devices and from 1 December 2021 for all other existing surgical mesh devices.

5.25 The TGA told the committee that, while, the regulatory framework finalised by the European Union in May 2017 includes extensive revisions, these two measures were progressed first due to their ability to positively impact on patient safety around mesh devices.<sup>20</sup>

5.26 Patient implant cards are intended to ensure that patients are aware of the details of the device they have been implanted with. The committee notes that this should assist the traceability of devices and patients in the event of the need to alert

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17 The government accepted the recommendation of the 2015 Review of Medicines and Medical Devices Regulation (MMDR Review) that the TGA should align itself more closely with the European Union regulatory framework in September 2016.

18 Department of Health, Therapeutic Goods Administration, *Strengthening the assessment of medical devices and information for consumers*, 26 October 2017, <https://www.tga.gov.au/media-release/strengthening-assessment-medical-devices-and-information-consumers> (accessed 19 March 2018).

19 Department of Health, Therapeutic Goods Administration, *Strengthening the assessment of medical devices and information for consumers*, 26 October 2017, <https://www.tga.gov.au/media-release/strengthening-assessment-medical-devices-and-information-consumers> (accessed 19 March 2018).

20 Adjunct Professor John Skerritt, *Committee Hansard*, 6 February 2018, p. 5.

patients and health practitioners to safety issues such as precautions or recalls. Under the Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017 (regulations), the patient implant card must include the name and model of the device, either the batch code, lot number or serial number of the device, the device's unique device identifier and the manufacturer's name, address and website.<sup>21</sup>

5.27 The patient information card will be complemented by a patient information leaflet which must also be provided with each device. The leaflet will provide more detailed information and must identify the device, its intended purpose and include information such as the kinds of patients for whom the device is intended to be used and warnings about potential adverse effects and relevant precautions. The regulations also provide that the leaflet must be able to be readily understood by patients.<sup>22</sup>

#### *Committee view*

5.28 The committee welcomes the recently announced measures to increase the level of pre-market scrutiny applied to all surgical mesh devices. While noting the breadth of devices captured by the measures, the committee considers that the reclassification of these devices as high risk is an appropriate regulatory response to the evidence available regarding the risks associated with transvaginal mesh devices.

5.29 The committee is concerned at the length of time afforded to manufacturers of devices that are currently listed on the ARTG to provide a reclassification application. The committee considers that compliance with the new requirements ought to be achievable in a shorter timeframe. At the same time, the committee notes that the significance of the up-classification of surgical mesh devices, for the regulation of transvaginal mesh devices currently listed on the ARTG must be seen in the context of other measures announced in December 2017 and January 2018.

5.30 The committee welcomes the requirements to increase the level of information available to consumers regarding medical devices. The committee considers that these requirements will go some way to addressing some of the key concerns identified in this inquiry. In particular, a patient implant card should ensure that all patients know exactly which device has been implanted and this should in turn assist them, and their medical practitioners, should they need to seek advice or treatment in relation to possible complications. The card should also make it easier for patients to monitor any developments in relation to the safety of the particular device they have received.

#### ***Postmarket review and monitoring***

5.31 The TGA advised the committee that it continually monitors international developments in the use and regulation of devices. Since the introduction of mesh devices in Australia in 1998, the TGA has undertaken three post-market reviews: in

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21 Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017, Explanatory Statement, p. 4.

22 Explanatory Statement, pp. 4-5.

2008; 2010 and a major review in 2013. The Department's submission provides a chronology that places the actions of the TGA in the context of regulatory responses internationally up to the release of the Scottish Independent Review of Transvaginal Mesh Implants on 27 March 2017.<sup>23</sup> This chronology is included at Appendix 1 to this report.

5.32 In late 2017 the TGA took steps to remove certain urogynaecological mesh devices used in the treatment of pelvic organ prolapse (POP) and single incision mini-slings used in the treatment of stress urinary incontinence (SUI) from the ARTG.

5.33 On 17 January 2018, the TGA announced that it had amended the information that must be provided to consumers in relation to adverse events associated with urogynaecological mesh implants.

#### *Removal of transvaginal mesh products*

5.34 On 30 November 2017, the TGA announced that it had decided to remove transvaginal mesh devices solely used for the treatment of POP from the ARTG.<sup>24</sup> In making this announcement, the TGA advised that, following a review of the latest international studies and the clinical evidence for each product, it was of the belief that the benefits of using transvaginal mesh products in the treatment of pelvic organ prolapse do not outweigh the risks the devices pose to patients.<sup>25</sup>

5.35 The committee notes that the Australian Commission on Safety and Quality in Health Care (ACSQHC) had reached a similar conclusion in September 2017. Professor Debora Picone advised the committee that the ACSQHC had reached the view that transvaginal mesh implants for the treatment of POP should be used only in a research context due to the uncertainty surrounding long term effects and risks of complications.<sup>26</sup>

5.36 The decision includes single incision mini-slings which are used in the treatment of SUI, as distinct from mid-urethral slings. The TGA noted that there was a lack of adequate scientific evidence for it to be satisfied that the benefits of these devices outweigh the risks to patients.<sup>27</sup>

5.37 The committee notes that special arrangements will enable medical practitioners to access unapproved devices either through the Special Access Scheme,

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23 Department, *Submission 19, Attachment 1*, pp. 32-34.

24 Department of Health, Therapeutic Goods Administration, 'TGA undertakes regulatory actions after review into urogynaecological surgical mesh implants', *Media release*, 30 November 2017; Adjunct Professor Skerritt, *Committee Hansard*, 6 February 2018, p. 2.

25 Department of Health, Therapeutic Goods Administration, *TGA actions after review into urogynaecological surgical mesh implants*, 22 December 2017, <https://www.tga.gov.au/node/768243> (accessed 23 March 2018).

26 Adjunct Professor Debora Picone, Chief Executive Officer, Australian Commission on Safety and Quality in Health Care, *Committee Hansard*, 19 September 2017, p. 7.

27 Department of Health, Therapeutic Goods Administration, *TGA actions after review into urogynaecological surgical mesh implants*, 22 December 2017.

by becoming an Authorised Prescriber or for the purposes of clinical trials. Professor Skerritt explained:

So it's not an outright ban. Access to cancelled devices is still possible through a special access scheme—through authorised prescriber clinical trials schemes. But all of these schemes require additional oversight by an ethics committee and/or a medical expert, who will look at the individual case for using that product. It won't be, 'Just grab something off the shelf that happens to be available in the hospital.'<sup>28</sup>

5.38 Professor Skerritt emphasised to the committee that this latest regulatory action is the outcome of a process that has been evolving over several years as evidence has emerged:

As the evidence evolved, we then assessed the clinical evidence. We then went out to the companies. We gave them time to answer, 'Show us your evidence as to why you believe the benefit risk is still appropriate.' A number of companies said, 'We don't have it,' and they withdrew the products, and we withdrew some of their other products.<sup>29</sup>

5.39 The TGA noted that there have been suggestions that the TGA should restrict access to mesh devices to certain individual medical practitioners with particular high-level skills. The TGA explained that it has no legal authority to apply such a restriction, but that consideration of credentialing is being undertaken by the ASQHC.

Some people have suggested that we should, as TGA, only allow particular individual expert surgeons to use those particular products. We have no powers under our legislation to restrict particular devices to particular individual medical practitioners with particular high-level skills.<sup>30</sup>

*Increased information requirements for urogynaecological mesh implants.*

5.40 On 17 January 2018, the TGA announced that as a result of further post-market review of urogynaecological mesh implants, it had required sponsors of mid-urethral sling implants used in the treatment of SUI, to include information about certain adverse events, such as severe chronic pain, groin pain and bladder perforation, in the device instructions for use of the product. Ms Platona advised the committee that two sponsors had chosen to update the information and a third sponsor—Johnson & Johnson—elected to withdraw its devices from the market.<sup>31</sup>

5.41 Ms Platona confirmed that there are now seven entries on the ARTG for urogynaecological mesh and 14 devices remaining.<sup>32</sup>

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28 *Committee Hansard*, 6 February 2018, p. 3.

29 *Committee Hansard*, 6 February 2018, p. 2.

30 Adjunct Professor John Skerritt, *Committee Hansard*, 6 February 2018, pp. 2-3.

31 *Committee Hansard*, 6 February 2018, p. 3.

32 *Committee Hansard*, 6 February 2018, p. 3.

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*Committee view*

5.42 The committee welcomes the TGA's decision to remove transvaginal mesh products solely used for transvaginal POP procedures from the ARTG. The committee also welcomes the removal of single incision mini-slings. The committee remains concerned about the continued listing of MUS. Notwithstanding evidence provided to the committee regarding the apparent safety of MUS devices, the committee is concerned by the personal accounts it received from women who have experienced severe complications following transvaginal mesh procedures employing MUS.

5.43 The committee notes the changed requirements regarding the type of information to be provided in the Instructions for Use for each device. However, the committee is concerned that such information may not be readily accessible to consumers, in particular, to enable them to make an informed decision about such devices. These concerns are considered under the committee's findings on informed consent.

5.44 The committee accepts that the assessment and approval of medical devices is a continuous process of review and that regulatory responses to emerging issues need to be carefully considered and evidence based. However, the committee considers that criticisms of the lag in the regulatory response to emerging evidence of complications in relation to transvaginal mesh products are justified.

**Capturing and recording data**

5.45 A key concern to the committee is that there is no clear indication of how many women have received transvaginal mesh implants in Australia or how many women have experienced complications. Not only is there no single source of data on the use of transvaginal mesh implants, but each of the potential sources of data available is subject to significant limitations.

5.46 The ability to collect and analyse data is central to an effective and efficient health care system. The committee considers that the ability of regulators and the medical profession to arrive at evidence based responses to concerns relating to medical procedures involving implantable devices is greatly impeded without access to accurate and timely data about the use of such devices in Australia. The committee considers that there is an urgent need to improve existing reporting systems and examine options for greater complementarity between data sets.

***Reporting adverse events***

5.47 The committee is particularly concerned about the lack of reliable data available to inform the TGA's post-market monitoring activities. In Chapter 3, the committee noted its concern at the level of underreporting of adverse events involving transvaginal mesh implants and noted the significance of this for post-market monitoring by the TGA and individual device sponsors. The committee is particularly concerned that underreporting of adverse events associated with transvaginal mesh products has provided a false indication of the safety of such devices and contributed to delays in responding to the issues identified. The committee is deeply concerned that this has resulted in more women suffering complications.

5.48 The committee considers that accurate and timely reporting of adverse events is fundamental to a robust post-market monitoring scheme. This in turn has flow on benefits for effective and timely regulation of the use of medical devices. The committee is concerned that failures in the current adverse reporting system have contributed to delays in the identification of complications associated with the use of transvaginal mesh products.

5.49 As previously discussed, while adverse event reporting is mandatory for device sponsors, it is voluntary for medical practitioners. In Chapter 3, the committee noted that, to a significant degree, device sponsors are reliant on reporting from medical practitioners and patients to identify adverse events. The committee also expressed concern that there was some potential for inconsistency in the reporting of adverse events and concluded that clear criteria should be available to guide the reporting of adverse events.

5.50 Evidence to the committee indicates that many women who have been implanted with transvaginal mesh devices were not aware that they could report the complications they were experiencing to the TGA or to the device manufacturer. The committee notes that discussion in the media of complications associated with mesh devices, together with the activities of the Australian Pelvic Mesh Support Group, and to some extent this inquiry, may have contributed to an increased awareness of adverse reporting among women who have received mesh implants. However, many women who have attempted to report adverse events have told the committee that they have found the process difficult.

5.51 Many women have experienced difficulty gaining access to their medical records. The committee considers that the introduction of patient implant cards will assist in this regard in the future. However, the committee is concerned that there is a large cohort of women who have experienced complications following transvaginal mesh implants who should be encouraged to report these complications to the TGA. Many of these women will require assistance to access their health records. The committee considers that these women should not be required to pay to access their medical records.

5.52 In its 2011 inquiry into the regulatory standards for the approval of medical devices in Australia, this committee recommended that the TGA put in place mechanisms to educate and encourage doctors to report adverse incidents associated with medical devices. The committee also recommended that consideration be given to the introduction of mandatory reporting of adverse events by medical practitioners.

5.53 The committee notes that the TGA has periodically published media releases on its website encouraging both patients and medical practitioners to report adverse events. The TGA has also met with patient groups and provides alerts through RSS and Twitter to patient groups, individual doctors and medical colleges. However, the TGA is not funded to undertake large-scale consumer/community information

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programs. In this regard, it relies upon partnerships with clinical and consumer groups.<sup>33</sup>

5.54 The committee notes that the TGA is committed to examining the scope within its budget and within its legal mandate to stimulate reporting by patients and doctors.<sup>34</sup> The committee notes that the TGA does not have a legal basis to mandate doctors to report adverse events.<sup>35</sup>

### **Recommendation 1**

**5.55 Noting the vital role of adverse reporting in post-market surveillance, the committee recommends that the Australian Government, in consultation with the states and territories and the Medical Board of Australia, review the current system of reporting adverse events to the Therapeutic Goods Administration to:**

- **implement mandatory reporting of adverse events by medical practitioners;**
- **provide guidance on what constitutes an adverse event for use by consumers, medical practitioners and device sponsors;**
- **improve awareness of the reporting system;and**
- **examine options to simplify the reporting process;**

### **Recommendation 2**

**5.56 The committee recommends that the Therapeutic Goods Administration and the Australian Commission on Safety and Quality in Health Care 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 and on reporting the event.**

#### *Establishment of a national register of medical devices*

5.57 As noted previously, the committee is concerned that it is not possible to accurately identify the number of women who have received transvaginal mesh implants. The committee considers that an understanding of the true scale of the risk posed by transvaginal mesh devices, or any implantable medical device, is fundamental to tailoring an effective regulatory response.

5.58 The committee notes that there is widespread support for the establishment of a national register of medical devices. Medical practitioners and professional colleges emphasised the importance of capturing and evaluating longitudinal data to facilitate the evaluation of the safety and efficacy of medical devices. As noted in Chapter 3, many of the women who wrote to the committee could not understand why there was not already a register of medical devices.

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33 Adjunct Professor John Skerritt, *Committee Hansard*, 3 August 2017, p. 47.

34 Adjunct Professor John Skerritt, *Committee Hansard*, 6 February 2018, p. 6.

35 Dr Tim Greenaway, *Committee Hansard*, 6 February 2018, p. 7.

5.59 The committee notes that some medical specialists and colleges have been maintaining their own registers or databases. While there is no doubt that there is merit and value in this, the committee considers that the issues identified in this inquiry demonstrate a clear need for a national database.

5.60 Professor Stephen Robson, President of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists summarised the arguments for a national register by stating:

One of the key issues identified has been the need for a register of women who have had mesh surgery. It's likely that other implantables in the future will be subject to question and concern, and I call on the government to establish a national implantables register. Many Australians have or will have different implants—joints, mesh, other implants—and, rather than having multiple different registries, there should be a single, appropriately funded and independently run national register of implantables. It could be funded by the manufacturers of implants and it should be integral to the e-health records system in Australia. The next phase of implants in Australia will be genetic implants, and it's imperative that a national register is embedded in health care in this country before that phase arrives.<sup>36</sup>

5.61 The significance of a national device register was identified by the Review of Medicines and Medical Devices Regulation (MMDR Review). The MMDR Review noted that the timely and effective post-market monitoring of medical devices is an essential element of an effective regulatory system.<sup>37</sup> It stated that device registries play an important role in post-market monitoring as they can provide detailed information about patients, procedures and devices not routinely collected through other means.<sup>38</sup>

5.62 Recommendation 22 of the MMDR Review recommended the establishment of a registry for all high-risk implantable devices, noting that the Australian regulatory body should continue to collaborate with overseas medical device regulators to actively share registry data, with a view to facilitating timely identification of emerging safety concerns.<sup>39</sup>

5.63 The Government deferred consideration of this recommendation on the ground that establishing and maintaining registries requires careful consideration of

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36 *Committee Hansard*, 19 September 2017, p. 20.

37 MMDR Review, *Report on the regulatory framework for medicines and medical devices*, March 2015, p. 126.

38 MMDR Review, *Report on the regulatory framework for medicines and medical devices*, March 2015, p. 127.

39 MMDR Review, *Report on the regulatory framework for medicines and medical devices*, March 2015, p. 129.

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the range of registries managed by a variety of organisations and how they could be sustainably managed and funded in the future.<sup>40</sup>

5.64 The Department and the Medical Technology Association of Australia (MTAA) noted that any consideration of how an implantable devices registry would be funded, should recognise that such a registry would have benefits across the health system including to hospitals, patients and device manufacturers.<sup>41</sup>

5.65 The committee recognises that there are important considerations in the establishment of a database, not least of all the cost of establishing and maintaining it. The committee notes that registers have been established under interim arrangements for certain devices. The committee also notes advice received during the inquiry that work is currently underway to consider the appropriate approach to the establishment of a register or registers.

### **Recommendation 3**

**5.66 The committee recommends 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.**

#### *Improving the accuracy of other data sources*

5.67 In Chapter 3 the committee noted a range of potential sources of data that could be used to gain an informed understanding of complications arising from the use of transvaginal mesh devices and procedures. These include the claim data held by private health insurance companies, Prostheses list data, hospital records and databases maintained by medical professional colleges. In each case the committee noted some important limitations on these data sets.

5.68 In particular, the committee noted evidence that suggested the Medicare Benefits Schedule (MBS) codes relating to surgical procedures for POP and SUI are a potential source of valuable data about the use of medical devices. However, these codes are procedure based and do not distinguish between procedures using a mesh device or native tissue and is of limited assistance in identifying the number of women who have attempted to have mesh devices removed, either partially or fully.

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40 Department of Health, *Australian Government Response to the Review of Medicines and Medical Devices Regulation*, 15 September 2016, p. 21, <http://www.health.gov.au/internet/main/publishing.nsf/Content/MMD-govresp> (accessed 20 March 2018).

41 Adjunct Professor John Skerritt, *Committee Hansard*, 3 August 2017, p. 54; Mr Ian Burgess, Chief Executive Office, Medical Technology Association of Australia, *Committee Hansard*, 18 September 2017, pp. 38, 47; Adjunct Professor John Skerritt, *Committee Hansard*, 6 February 2018, p. 5.

5.69 While the committee understands that the MBS is primarily a mechanism for providing a subsidy for listed services, the committee considers that there is benefit in revising the codes allocated to surgical procedures for the treatment of POP and SUI to improve the accuracy of the data collected.

5.70 The committee notes that the Gynaecology Clinical Committee of the MBS Review Taskforce has reviewed MBS items for the use of biological and permanent mesh, together with other gynaecology related items, and has recommended:

- revising MBS item numbers so that mesh and non-mesh surgery can be distinguished to enable better data collection;
- restricting the use of mesh to patients who are undergoing revision surgery (i.e. primary operative repairs have failed to relieve symptoms); and
- introducing specific MBS items for mesh removal.

5.71 The committee was advised that these recommendations would undergo public consultation during 2017, before the MBS Taskforce makes its final recommendations to government. The committee notes that it has been six months since the MBS Taskforce endorsed the release of a report by the Gynaecology Clinical Committee for public consultation on 20 September 2017.<sup>42</sup> The Gynaecology Clinical Committee's report has not been released to date.

#### **Recommendation 4**

**5.72 The committee recommends that the Medicare Benefits Schedule Taskforce prioritise release of the report of the Gynaecology Clinical Committee for consultation.**

5.73 The committee considers that improved coding and reporting of procedures for implantable devices has the potential to contribute valuable information to the post-market monitoring of all medical devices. Further, the integration of existing data sets has the ability to contribute to a more complete understanding of the level and seriousness of complications with medicines and medical devices as they arise.

5.74 The committee notes that the MMDR Review recommended the establishment of a more comprehensive post-market monitoring scheme for medicines and medical devices. It recommended better integration of available datasets to support the analysis of data from the Pharmaceutical Benefits Scheme, the Medicare Benefits Scheme, eHealth records, hospital records and device and other relevant registries and datasets.<sup>43</sup>

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42 Release of the report for public consultation was endorsed by the MBS Taskforce at its meeting on 20 September 2017. See: Department of Health, *MBS Review Taskforce meeting outcomes, 20 September 2017*, <http://www.health.gov.au/internet/main/publishing.nsf/Content/MBSR-outcomes-20september2017> (accessed 22 March 2018).

43 MMDR Review, *Report on the regulatory framework for medicines and medical devices*, March 2015, p. 160.

5.75 The government accepted this recommendation, noting the development of a more comprehensive post-market monitoring scheme will enhance consumer protection and complement existing post-market monitoring processes.<sup>44</sup>

5.76 The committee received evidence during the inquiry that as part of its work on the development of clinical guidance, the ACSQHC is also considering appropriate recording of the details of products that are implanted, either through administrative data collections, such as the MBS and clinical coding of hospital separations, clinical registries or electronic records such as My Health Record.<sup>45</sup>

## **Recommendation 5**

**5.77 The committee recommends 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.**

### **Improved clinical practice**

5.78 The committee notes the evidence from medical practitioners throughout the inquiry acknowledging the need to improve the standard of care provided to women with POP and SUI. In particular, the committee notes the acknowledgement that there have been circumstances where the doctor-patient relationship has not supported women through their treatment for POP and SUI as it should and cases where the medical profession has not dealt with women correctly.<sup>46</sup>

### ***Informed consent***

5.79 The committee is deeply concerned by the evidence received regarding the information provided to women to enable them to provide their informed consent to a transvaginal mesh procedure. The committee is particularly concerned that, despite the availability of detailed guidance and patient information leaflets produced by specialist colleges and societies, many women appear to have received little or no information to assist them to make a decision or provide their informed consent. The committee is dismayed by reports that some women were not advised that a transvaginal mesh implant was being used as part of their treatment.

5.80 The committee notes the comprehensive and systematic consent processes outlined by sub-specialist urology and gynaecology units and considers that these provide a useful model for other practitioners.

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44 Department of Health, *Australian Government Response to the Review of Medicines and Medical Devices Regulation*, 15 September 2016, p. 24, <http://www.health.gov.au/internet/main/publishing.nsf/Content/MMD-govresp> (accessed 20 March 2018).

45 ACSQHC, *Submission 46*, p. 4.

46 See, for example: Dr Gary Swift, President, National Association of Specialist Obstetricians and Gynaecologists (NASOG), *Committee Hansard*, 3 August 2017, p. 29; Dr Caroline Dowling, Urologist, Urological Society of Australia and New Zealand, *Committee Hansard*, 3 August 2017, p. 27; Dr Michelle Atherton, *Committee Hansard*, 25 August 2018, p. 30.

5.81 The committee notes the evidence received that an effective consent process must involve a dialogue between the medical practitioner and the patient and must be tailored to the need of the individual patient. As a minimum this dialogue should:

- outline the full details of the proposed treatment;
- 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; and
- confirm that the individual patient has understood the information discussed.

5.82 The committee notes that the ACSQHC is currently finalising resources that should assist women to inform themselves about procedures recommended to them. The resources will provide explanations of the symptoms of POP and SUI together with the range of treatment options available. The committee notes that these resources have been developed following extensive consultation with women affected by complications of transvaginal mesh.<sup>47</sup>

5.83 The committee is interested to see how women will be directed to these resources. The committee is mindful that many people experience difficulty locating information on websites. The committee believes that helplines established by state and territory governments (discussed further below) should ensure that they direct women affected by transvaginal mesh to these resources.

5.84 The committee supports the development and publication of information resources by the ACSQHC for women experiencing POP or SUI and notes that these resources will support the process of informed consent between a patient and their medical practitioner.

5.85 However, the committee notes evidence to the inquiry about the inconsistent and at times cursory manner in which consent has been obtained from patients undergoing transvaginal mesh procedures. The committee is deeply concerned by reports that some medical professionals have not provided patients with detailed guidance and patient information leaflets. The committee is particularly concerned by the evidence of the APMSG that guidance prepared by RANZCOG has not been used to guide the process of informed consent in many cases.

5.86 Therefore, the committee considers that, in addition to patient information resources, the ACSQHC should develop guidance material on effective informed consent.

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47 ACSQHC Update, additional information received 6 February 2018, p. [1].

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## Recommendation 6

**5.87** The committee recommends that the Australian Commission on Safety and Quality in Health Care prepare guidance material on effective informed consent processes, with a view to ensuring that a dialogue between a medical practitioner and patient should:

- 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; and
- confirm that the individual patient has understood the information discussed.

### *Care pathways for POP and SUI*

5.88 In addition to patient information resources, the committee notes that the ACSQHC is also developing care pathways for POP and SUI to describe the clinical consideration to be made when assessing women with POP and SUI. The ACSQHC told the committee:

The pathways provide clinicians with an evidence-based approach to first line management, specialised surgical and non-surgical care and the types of medical specialists who may be involved in providing care.<sup>48</sup>

5.89 The ACSQHC told the committee that the surgical pathways being developed will use a traffic light approach to help identify options for surgical treatments based on the strength of evidence and patient outcomes for each type of procedure.

5.90 The ACSQHC's guidance on care pathways is intended to improve the provision of appropriate, safe care through the standardisation of care processes, to enable patients to receive 'the sequence of evidence-based assessment and treatment actions that will deliver the best outcomes.'<sup>49</sup>

5.91 In its submission the ACSQHC states that in developing this guidance, it has drawn on the most recent evidence and clinical advice, including statements issued by RANZCOG, the Urogynaecological Society of Australasia and the United Kingdom National Institute for Health and Care Excellence. The ACSQHC has also considered an international consensus pathway on treatment of POP developed by the International Consultation on Incontinence Surgical Management Prolapse Committee.<sup>50</sup>

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48 ACSQHC, Update, additional information received 6 February 2018, p. [2].

49 ACSQHC, *Submission 46*, p. 4.

50 *Submission 46*, p. 4.

5.92 Consideration has also been given to the role played by General Practitioners (GPs) in the assessment of women with POP and SUI, as well as their role in caring for women following transvaginal mesh procedures. In its submission, the ACSQHC recognises the important role accessible information on care pathways for POP and SUI can play in raising the awareness of GPs of the complications that may be associated with transvaginal mesh procedures, available referral pathways and management of symptoms. This work is being undertaken in partnership with Primary Health Networks and the Royal Australian College of General Practitioners.<sup>51</sup>

5.93 The committee notes that interactive web versions of the pathways are being developed and that this should allow easier access for clinicians reviewing treatment options and also in explaining various care pathways to women seeking treatment.<sup>52</sup>

5.94 The committee notes that professional colleges and specialist societies have an important role to play in the continuing professional development of specialist doctors and in providing guidance on effective practice in their specialty. RANZCOG explained their role to the committee:

Once doctors have specialist qualifications, it is our role to monitor their continuing professional development activities, but it's also our role to guide practice and provide guidance to the profession: guidance as the appropriate ways to manage clinical conditions in women's health and standards for professional behaviour.<sup>53</sup>

5.95 The committee considers that resources of the type described by the ACSQHC have the potential to greatly improve the standard of information available to both patients and medical practitioners and looks forward to reviewing these resources once they have been released.

5.96 The committee notes that final approval processes for the care pathways resource are underway and that the ACSQHC is also developing a care pathway for the removal of transvaginal mesh following complications.<sup>54</sup>

### **Recommendation 7**

**5.97 The committee recommends that treatment guidelines developed by the Australian Commission on Safety and Quality in Health Care should clearly indicate that transvaginal mesh implantation should only be undertaken with fully informed consent and as a last resort when other treatment options have been properly considered and determined unsuitable.**

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51 ACSQHC, *Submission 46*, pp. 4-5.

52 ACSQHC Update, additional information received 6 February 2018, p. [2].

53 Professor Stephen Robson, *Committee Hansard*, 19 September 2018, p. 19.

54 ACSQHC Update, additional information received 6 February 2018, p. [2].

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## Recommendation 8

**5.98** The committee recommends 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 Australian Commission on Safety and Quality in Health Care and implement arrangements which require members to consider the resources in their practice.

### **Appropriate governance for the introduction of new devices and procedures**

5.99 The committee received a range of evidence regarding the governance that should be applied to the use of new devices. Some witnesses to the inquiry have suggested that new devices should be used in restricted circumstances initially.

5.100 The committee understands that there are already well-accepted governance procedures available through ethics approval committees that medical practitioners could use to ensure the timely and safe introduction of new devices and procedures. The committee was told that ethics approval committees ensure that the use of the device or procedure is subject to an appropriate model of oversight, supports informed consent and provides for appropriate follow up with patients post- surgery.<sup>55</sup>

5.101 Evidence has also been received proposing that transvaginal mesh procedures should be restricted to medical practitioners who are highly skilled in such procedures.

### ***Training and credentialing of senior medical practitioners***

5.102 In Chapter 4, the committee noted concerns regarding the knowledge and skill of surgeons practicing transvaginal mesh procedures. Based on the evidence of personal accounts received from individual women, the committee considers that there is a need to improve the awareness of medical practitioners, especially General Practitioners, of symptoms associated with surgical mesh devices. There is also a clear need to improve the communication skills of some medical practitioners to ensure that they are communicating effectively with, and listening to patients.

5.103 The committee understands that registered medical practitioners must ensure they comply with Continuing Professional Development requirements set by the Medical Board and medical practitioners with specialist registration must continue to meet the requirements set out by their relevant college.

5.104 RANZCOG advised the committee that it had been providing guidance and advising caution regarding transvaginal mesh surgery to its member for a decade.<sup>56</sup> The committee heard similar evidence from a number of professional colleges and

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55 Associate Professor Maher, *Committee Hansard*, 19 September 2017, pp. 29-30.

56 Professor Stephen Robson, *Committee Hansard*, 19 September 2017, p. 19.

societies regarding their role in the provision of training and information to their members.<sup>57</sup>

5.105 The committee is therefore concerned by reports that transvaginal mesh has been used as a first response treatment, without considering alternative treatment options, indicating to the committee that transvaginal mesh has been overused by some medical professionals.

5.106 Evidence to the committee indicates that there is a need to review the current training models to ensure that the skill levels of medical practitioners to diagnose and treat POP and SUI meet minimum quality standards.

5.107 In particular, the committee notes evidence that procedures involving transvaginal mesh devices should only be performed by surgeons who can demonstrate that they have the requisite skills, in settings where their performance can be audited and complication rates can be recorded. For example, RANZCOG stated that there is evidence which indicates more highly skilled surgeons with big caseloads tend to have fewer complications. RANZCOG told the committee that this is true for any surgical procedure, not just transvaginal mesh devices.<sup>58</sup>

5.108 The committee received evidence that some surgeons have been keeping their own personal data bases to enable them to review their own complications rates.<sup>59</sup> The committee received evidence that, based on such analysis, some surgeons no longer use transvaginal mesh devices in the treatment of their patients.<sup>60</sup> The committee notes that some specialist surgical units have a practice of holding regular multidisciplinary meetings to discuss all planned surgery, complimented by regular surgical audits and use this to inform their practice.<sup>61</sup>

5.109 Specialist colleges and associations told the committee that there was merit in reviewing how surgeons are trained and accredited.<sup>62</sup> RANZCOG told the committee that it considers that a formal mechanism is required to ensure that training in new surgical techniques occurred. Professor Robson told the committee:

it's become clear to us that there is the need for a formal mechanism to ensure that training in new surgical techniques should be undertaken by experienced surgeons with an ongoing audit of the cases that they do—

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57 See, for example: Urogynaecological Society of Australasia, *Submission 32*; Urological Society of Australia and New Zealand, *Submission 42*; NASOG, *Submission 49*; Australasian Gynaecological Endoscopy and Surgery Society Limited, *Submission 18*.

58 Associate Professor Jason Abbott, President, Australasian Gynaecological Endoscopy and Surgery Society, *Committee Hansard*, 18 September 2017, p. 30.

59 *Committee Hansard*, 18 September 2017, p. 30.

60 *Confidential Submission 153*.

61 Monash Health, *Submission 47*, p. [2].

62 See, for example: Professor Picone, *Committee Hansard*, 3 August 2017, pp. 40-41; Dr Jenny King, Chair, UroGynaecological Society of Australasia, *Committee Hansard*, 18 September 2017, pp. 16, 23; Professor Stephen Robson, *Committee Hansard*, 19 September 2017, pp. 19-20.

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certainly during their training period. We have been recommending this, again, but we don't have any actual power to enforce our own recommendations. I believe there's an opportunity to include these sorts of mechanisms and pathways as part of revalidation, and this could be an ongoing project we'd be happy to work with the Medical Board of Australia in realising.<sup>63</sup>

5.110 ACSQHC advised the committee that it considers there is potential to apply credentialing to other health professions and indicated that this would form a key part of the resources being developed to support improved care to women requiring treatment for mesh complications and mesh removal surgery.<sup>64</sup>

5.111 The committee notes that the ACSQHC has developed guidance for the credentialing and training of senior medical practitioners who implant transvaginal mesh for the treatment of POP and SUI and also for the removal of transvaginal mesh.<sup>65</sup> The credentialing guidance has been developed in consultation with the Royal Australasian College of Surgeons, RANZCOG, the Urological Society of Australia and New Zealand, the Transvaginal Mesh Reference Group and state and territory health departments.<sup>66</sup>

5.112 The guidance will set out the experience and qualifications that senior medical practitioners need to be credentialed to implant and remove mesh for treatment of POP and SUI. It includes recommendations on:

- device specific training;
- requirements for maintaining skills;
- monitoring and reporting patient outcomes;
- the type of specialty support services hospitals should have if they offer implantation and removal of transvaginal mesh; and
- the requirement for post-operative follow-up.<sup>67</sup>

5.113 The ACSQHC advised that states and territories will use the guidance in their local credentialing processes and that it would be working to promote the use of the guidance for credentialing across private hospitals.<sup>68</sup>

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63 *Committee Hansard*, 19 September 2017, pp. 19-20.

64 *Submission 46*, p. 6.

65 ACSQHC Update, additional information received 6 February 2018, p. [2].

66 ACSQHC, *Submission 46*, p. 6.

67 ACSQHC Update, additional information received 6 February 2018, p. [2].

68 ACSQHC Update, additional information received 6 February 2018, p. [2].

## **Recommendation 9**

**5.114 The committee recommends that the Commonwealth, state and territory health Ministers require that guidance developed by the Australian Commission on Safety and Quality in Health Care 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.**

5.115 The committee acknowledges that the changes by the TGA to restrict the use of transvaginal mesh for POP means that transvaginal mesh will in effect only be available under a special access scheme and will limit the ability of medical professionals to utilise transvaginal mesh for the treatment of POP except in certain circumstances.

5.116 At the same time, the committee is deeply concerned by the personal accounts of women expressing their lack of faith in medical professionals following their experience with transvaginal mesh. The committee heard that women trusted their doctor to fully inform them of the risks and benefits of transvaginal mesh, alternative treatment options, and to be adequately skilled to perform the transvaginal mesh procedure and identify complications arising from the procedure. For many women this trust has now been lost.

5.117 The committee believes that professional medical colleges and specialist societies should demonstrate leadership in this area by implementing governance arrangements which limit the use of all transvaginal mesh to skilled specialists. The committee believes this would go some way to restoring the faith in medical professionals of women who have suffered from transvaginal mesh related complications.

## **Recommendation 10**

**5.118 The committee recommends that medical professional colleges and specialist societies implement governance arrangements for transvaginal mesh procedures which require that their members:**

- **are trained in the use of the specific device;**
- **are adequately skilled to perform the specific procedure, including procedures for partial or full removal of transvaginal mesh devices;**
- **work within a multidisciplinary team;**
- **monitor and report patient outcomes; and**
- **maintain a record of the outcomes of such procedures, including any complications.**

### *Auditing transvaginal mesh procedures*

5.119 The committee has received a great deal of evidence emphasising the important distinctions between treatment of POP and SUI and the important differences between transvaginal mesh devices. Medical practitioners have

encouraged the committee to note the differences in complication rates between different procedures and different devices.

5.120 The committee notes that the personal accounts it has received cover a very wide range of procedures and devices. These personal accounts underscore the importance of gaining a much closer understanding of the factors that may contribute to either success or severe failure in individual cases. The committee has heard variously that complications can be attributed to the device, the procedure or the patient or a combination of these.

5.121 While noting the number of studies and trials drawn to its attention throughout this inquiry, the committee considers that there is a pressing need to undertake an audit of all available sources of data in Australia to gain a more complete understanding of the use of transvaginal mesh procedures and the incidence and nature of complications associated with different types of devices and procedures. The committee considers it is important that such an audit should endeavour to capture information on the impact of transvaginal mesh procedures on the quality of life of the women who have received them.

5.122 The committee is all too aware that the currently available sources of data make this a challenging task, however, the committee considers that without an appropriately expert review of this nature, Australia risks repeating mistakes made in the introduction of transvaginal mesh products in the introduction of future devices.

### **Recommendation 11**

**5.123 The committee recommends that Commonwealth, states and territory governments commission the Australian Commission on Safety and Quality in Health Care 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.**

#### *The role of device manufacturers in promoting the use of transvaginal mesh implants*

5.124 The committee heard a range of evidence regarding the interactions between device manufacturers or sponsors and medical practitioners. Such concerns ranged from questions over the presence of sponsor representatives in the surgical theatre to the possibility of financial inducements to medical practitioners to use specific products.<sup>69</sup>

5.125 The Health Consumers Councils across Australia (HCC) expressed concern that such incentives could lead to unsafe treatment practices. The HCC submission stated that Health Consumers Councils have been informed that there are clinical variations with a higher number of mesh procedures performed in certain states. The

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69 See, for example: Public Health Association Australia, *Submission 20*, p. 5; TFS Surgical, *Submission 22*; Johnson & Johnson Medical Pty Ltd, *Submission 23*; pp. 14-15; Associate Professor Christopher Maher, *Submission 154*, p. [13].

HCC was not able to substantiate this claim, but submitted that such concerns warrant further investigation.<sup>70</sup>

5.126 The Australian Pelvic Mesh Support Group (APMSG) drew the committee's attention to urogynaecological conventions sponsored by device manufacturers where the programs have included 'mesh' updates. The APMSG questioned the reason for this involvement, noting that many surgeons seemed to be unaware of the severe complications posed by urogynaecological mesh devices.<sup>71</sup>

5.127 The committee has been assured that the majority of medical practitioners have been motivated only by a desire to provide relief to women suffering with POP and SUI. Medical practitioners explained the importance of receiving training and guidance in the use of new devices and of the role played by surgeons the provision of such training.

5.128 Specialist medical colleges assured the committee that there are appropriate governance systems in place to guard against unprofessional relationships between device manufacturers and medical practitioners. RANZCOG advised the committee that the vast majority of surgeons do not have any financial incentive to use particular transvaginal mesh products. The committee notes that any doctors who do have a financial relationship with a company are expected to declare any interest as recommended by the Code of Conduct for Doctors in Australia<sup>72</sup>.

5.129 Representatives of device manufacturers assured the committee they have acted ethically and responsibly in the research, development and supply of medical devices. Each emphasised the care and compassion they feel for patients who have experienced adverse side effects as a result of devices they manufacture and affirmed their commitment to support and help patients.<sup>73</sup>

5.130 The MTAA advised the committee that its members are bound by a Code of Practice (code) to promote ethical interactions with healthcare providers. The aim of the code is to ensure that healthcare providers are not influenced in their decision making around the use of medical devices through financial or other inducements.<sup>74</sup>

5.131 The code requires that:

- any supplier expenditure on education events be reasonable and set in an appropriate context;

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70 *Submission 21*, p. 8.

71 *Submission 130*, pp. 5-6.

72 Medical Board of Australia, *Good Medical Practice: A code of conduct for doctors in Australia*, March 2014, <http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx> (accessed 23 March 2018).

73 Mr Gavin Fox-Smith, Managing Director, Johnson & Johnson Medical Devices, *Committee Hansard*, 18 September 2017, p. 36; Mr Pat Callanan, Business Unit Director Australia and New Zealand, Urology and Pelvic Health, Boston Scientific, *Committee Hansard*, 18 September 2017, p. 37.

74 MTAA, *Submission 40*, p. 4.

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- supplier financial contribution to conferences should be reasonable and proportionate to the educational content of the of the event; and
  - gifts to be restricted to those that are of educational value and very small value.<sup>75</sup>

5.132 Compliance with the code is monitored and Mr Ian Burgess told the committee that there is a self-regulatory and disciplinary process for non-compliance that can result in the imposition of fines.<sup>76</sup>

5.133 The committee understands the symbiotic nature of the relationship between device manufacturers and medical practitioners but, while it notes the codes of conduct that each sector has in place to guard against unprofessionalism, it is concerned by some of the evidence it has received. In particular, evidence that medical practitioners have proposed transvaginal mesh products as a 'quick fix' or preventative option for minor symptoms of POP and SUI or been overenthusiastic in their embrace of this new technology is troubling.

5.134 In its inquiry into the regulatory standards for the approval of medical devices in Australia, the committee recommended that then Department of Health and Ageing undertake work to address the issue of inducements paid by pharmaceutical companies and medical device manufacturers to doctors and teaching hospitals.<sup>77</sup>

5.135 In its response to the report, the Government agreed with the recommendation in principle, but noted 'that a legislative framework for ethical conduct of industry in the promotion of therapeutic goods to healthcare professions is not warranted in the Australian context at this time. The Government committed to working with industry to support stronger self-regulation, better communication and shared systems for complaints reporting.

## **Recommendation 12**

**5.136 The committee recommends that the Department of Health work with the Medical Technology Association of Australia and the Medical Board of Australia 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.**

### **Addressing the needs of women living with mesh related complications**

5.137 The committee is very mindful of the need to ensure adequate and readily accessible support is available for all women who have received transvaginal mesh implants and those who may be considering such surgery in the future. In particular,

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75 MTA, *Submission 40*, p. 4.

76 *Committee Hansard*, 18 September 2017, p. 45.

77 Senate Community Affairs References Committee, *The regulatory standards for the approval of medical devices in Australia*, 22 November 2011, p. 106.

the committee understands the importance of ensuring treatment and support is available for all women currently living with mesh related complications.

5.138 The committee notes evidence that emphasises the need for standardised, multidisciplinary, holistic care to support women in their rehabilitation.<sup>78</sup> In particular, the committee notes the importance of specialist pain management in the treatment of complications following transvaginal mesh surgery. The committee recognises concerns that the current resources and supports available to women may be inadequate to address their needs.

5.139 The ASQHC advised the committee that each state and territory is reviewing the provision of services for the use and removal of transvaginal mesh, and some have developed specific information resources and support services, including dedicated telephone information and referral services and improved coordination and designation of services to promote more coordinated access services.<sup>79</sup>

5.140 The ASQHC advised that the service model framework it is developing regarding the optimal service for removal of mesh will also draw together information on the services available in each jurisdiction.<sup>80</sup>

5.141 In the meantime, the committee notes that a number of states and territories are implementing support services to respond to the needs of women living with mesh related complications. The services differ between states and are in various stages of implementation, but give an indication of the types of services under consideration.

### ***Western Australia***

5.142 In September 2017, the Western Australian Minister for Health announced the:

- Establishment of a confidential free contact line to provide a link to expertise and clinical services and help determine how many women in WA have mesh-related symptoms; and
- Establishment of a mesh register to prospectively record the use of pelvic and abdominal mesh.<sup>81</sup>

5.143 The Western Australian Government's Healthy WA website provides information on pelvic mesh, possible complications and symptoms; and treatment for these. The website advises that the King Edward Memorial Hospital (KEMH) is planning to commence a mesh complication service (Mesh Clinic) run by Urogynaecologists with a dedicated multidisciplinary team. The website advises that

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78 Kim, *Committee Hansard*, 3 August 2017, pp. 3-4.

79 ACSQHC Update, additional information received 6 February 2018, p. [3].

80 ACSQHC Update, additional information received 6 February 2018, p. [3].

81 Government of Western Australia, The Hon Roger Cook, Deputy Premier, Minister for Health, Mental Health, 'New Phone line to help WA women affected by mesh implants', *Media release*, 8 September 2017, <https://www.mediastatements.wa.gov.au/Pages/McGowan/2017/09/New-phone-line-to-help-WA-women-affected-by-mesh-implants.aspx> (accessed 1 February 2018).

KEMH will be seeking consumer input, including from the APMSG, in establishing this clinic.<sup>82</sup>

### **Victoria**

5.144 The Victorian Minister for Health made an announcement on 19 December advising:

- the establishment of the Victorian mesh information and help line; and
- the availability of specialist programs to assist women with complications following mesh procedures.<sup>83</sup>

5.145 The Victorian Government has provided further information regarding the use of transvaginal mesh, possible complications, alternative treatment options and the availability of support services on its Better Health Channel website.<sup>84</sup>

### **New South Wales**

5.146 At the committee's Sydney hearing, Dr Kerry Chant, Chief Health Officer, NSW Ministry of Health (NSW Health), described work that it was undertaking in consultation with specialist urogynaecologists and the State's five public sector specialist clinics to address the needs of women who have sustained injuries following transvaginal mesh procedures. This work comprised steps to ensure that mesh-injured women are supported by a multidisciplinary team, led by a urogynaecologist and incorporating effective pain management. This work is being complemented by the development of information resources to support informed consent and guidance for general practitioners to enable them to provide appropriate care. NSW Health is liaising with the ACSQHC in developing these resources.<sup>85</sup>

5.147 Dr Marianne Gale told the committee that NSW Health is considering the need to ensure device information is appropriately captured and the development of stronger guidance about the need to record implanted devices on the discharge summary for each patient.<sup>86</sup> NSW Health also advised that it supported strengthening adverse reporting requirements.<sup>87</sup>

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82 Western Australian Department of Health, Healthy WA health information for Western Australians, *Pelvic Mesh*, [http://healthywa.wa.gov.au/Articles/N\\_R/Pelvic-mesh](http://healthywa.wa.gov.au/Articles/N_R/Pelvic-mesh) (accessed 1 February 2018).

83 Victorian Minister for Health, The Hon Jill Hennessy, 'Transvaginal Mesh Support for Victorian Women', *Media release*, 19 December 2017, <https://www.premier.vic.gov.au/transvaginal-mesh-support-for-victorian-women/> (accessed 1 February 2018).

84 Victorian State Government, Better Health Channel, *Transvaginal mesh*, <https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/Transvaginal-mesh> (accessed 1 February 2018).

85 Dr Kerry Chant, *Committee Hansard*, 18 September 2017, p. 53.

86 Dr Marianne Gale, Medical Adviser, Office of the Chief Health Officer, New South Wales Ministry of Health, *Committee Hansard*, 18 September 2017, p. 54.

87 Dr Kerry Chant, *Committee Hansard*, 18 September 2017, p. 53.

5.148 In December 2017, the NSW Government released a safety notice advising:

- Patients seeking access to medical records should be assisted and where health information sought relates to continued treatment and/or future management, no charge should be raised.
- Patients presenting with symptoms following transvaginal mesh procedures should be provided with information sheets and supported to access multidisciplinary specialist services for the assessment and management of complications.
- Mesh removal should only be considered at specialist centres with the appropriate multidisciplinary model in place, including a qualified urogynaecologist as the lead, and comprehensive diagnostic procedures in place, including someone experienced in performing and interpreting pelvic floor ultrasound.
- Supporting disciplines to include: pain services; pelvic floor physiotherapists and psychology. Urology and colorectal units should be available for consultation.
- The location of specialist multidisciplinary services with an experienced urogynaecologist.
- Guidance on reporting adverse events to the TGA and incidents, near-misses or complaints to the Incident Information Management System.<sup>88</sup>

### *Australian Capital Territory*

5.149 On 9 January 2018, the ACT Health announced that it is directly contacting all women who have been identified as having undergone transvaginal mesh procedures at Canberra Hospital and Health Services within the past 10 years to notify them of the issues and the options available to them if they are concerned. A dedicated phone service and email address has also been established.<sup>89</sup>

### *Committee view*

5.150 The committee considers that the support and referral services being established by the states and territories go some way to providing an appropriate level of care for women suffering from mesh related complications. The committee encourages states and territories to continue to work with the ACSQHC and women affected by transvaginal mesh in the implementation of services.

### **Recommendation 13**

**5.151 The committee recommends that State and Territory governments continue to work with the Australian Commission on Safety and Quality in**

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88 NSW Government, Safety Notice 015/17, *Transvaginal mesh implants for Pelvic Organ (Vaginal Prolapse)*, 20 December 2017, <http://www.health.nsw.gov.au/sabs/Pages/default.aspx> (accessed 17 January 2018).

89 ACT Government, ACT Health, *Transvaginal Mesh*, 9 January 2018, <http://www.health.act.gov.au/node/8925> (accessed 9 February 2018).

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**Health Care 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:**

- **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, comprising:**
  - **comprehensive diagnostic procedures, including relevant diagnostic imaging facilities and expertise;**
  - **specialist pain management expertise; and**
  - **high level expertise in the partial or full removal of transvaginal mesh;**
- **advice and practical assistance for women who are seeking to access their medical records; and**
- **the provision of further guidance for medical professionals on recording the use of implantable devices on medical records and reporting adverse events to the Therapeutic Goods Administration.**

### **Concluding comments**

5.152 The committee wishes to say to the women who have given us evidence that it has heard them. It understands the different perspectives that have been brought to this inquiry. The committee hopes that the findings and recommendations that it has made as a result of this inquiry serve women well by improving regulatory processes and care pathways such that they are robust, evidence based, clinically sound and focused on good patient outcomes.

5.153 The committee thanks all women for their courage in coming forward to provide their very personal accounts to the inquiry.

**Senator Rachel Siewert**

**Chair**



# **APPENDIX 1**

## **Terms of Reference**

### **INQUIRY INTO THE NUMBER OF WOMEN IN AUSTRALIA WHO HAVE HAD TRANSVAGINAL MESH IMPLANTS AND RELATED MATTERS**

- (1) The number of women in Australia:
  - (a) who have had transvaginal mesh implants;
  - (b) who have had transvaginal mesh implants who have experienced adverse side effects; and
  - (c) who have made attempts to have the mesh removed in Australia or elsewhere.
- (2) Information provided to women prior to surgery about possible complications and side effects.
- (3) Information provided to doctors regarding transvaginal mesh implants and possible complications and side effects.
- (4) Any financial or other incentives provided to medical practitioners to use or promote transvaginal mesh implants.
- (5) The types and incidence of health problems experienced by women with transvaginal mesh implants and the impact these health problems have had on women's lives.
- (6) The Therapeutic Goods Administration's:
  - (a) role in investigating the suitability of the implants for use in Australia;
  - (b) role in ongoing monitoring of the suitability of the implants; and
  - (c) knowledge of women suffering with health problems after having transvaginal mesh implants.
- (7) Options available to women to have transvaginal mesh removed.



# **APPENDIX 2**

## **Public hearings**

*Thursday, 3 August 2017*

*Victorian Parliament, Melbourne*

### **Witnesses**

**Kim**, private capacity

**Andrea**, private capacity

### **Public Health Association of Australia (including Women's Health Special Interest Group)**

DAWSON, Associate Professor Angela, Convenor of the Women's Health Special Interest Group

**Joanne**, private capacity

**Angela**, private capacity

**Janice**, private capacity

**Christeena**, private capacity

**Melinda**, private capacity

**Andree**, private capacity

**Chantal**, private capacity

### **Consumer Health Forum of Australia**

ROOT, Ms Josephine, Policy Manager

### **Health Issues Centre**

VADASZ, Mr Danny, Chief Executive Officer

### **National Association of Specialist Obstetricians and Gynaecologists**

SWIFT, Dr Gary, President

**Urological Society of Australia and New Zealand**

DOWLING, Dr Caroline, Urologist

**Urogynaecology Departments at Mercy Hospital for Women and Monash Health**

DE SOUZA, Dr Alison, Urogynaecologist, Mercy Hospital for Women

DWYER, Professor Peter Laurence, private capacity

**Monash Health**

ROSAMILIA, Dr Anna, Urogynaecologist

CHAO, Dr Fay, Urogynaecologist

**Australian Commission on Safety and Quality in Health Care**

PICONE, Adjunct Professor Debora, Chief Executive Officer

HERKES, Dr Robert, Clinical Director

MELEADY, Adjunct Professor Kathy, Director

**Department of Health (including Therapeutic Goods Administration)**

SKERRITT, Adjunct Professor John, Deputy Secretary, Therapeutic Goods Administration

GREENAWAY, Mr Tim, First Assistant Secretary, Therapeutic Goods Administration

PLATONA, Ms Adriana, First Assistant Secretary, Therapeutic Goods Administration

McRAE, Ms Cheryl, Assistant Secretary, Therapeutic Goods Administration

*Friday, 25 August 2017*

*Four Points by Sheraton Hotel, Perth*

**Witnesses**

**Australian Pelvic Mesh Support Group**

CHISHOLM, Ms Carolyn, Founder

CHANNING, Ms Stella, Director and Administrator

**Mesh Down Under**

KORTE, Mrs Charlotte, Lead Representative

SULLIVAN, Ms Patricia, Health Advocate

**Angela**, Private capacity

**Deisy**, Private capacity

**Helen**, Private capacity

**Hope**, Private capacity

**Katrina**, Private capacity

**Linda**, Private capacity

**Melanie**, Private capacity

**Robyn**, Private capacity

**Tracey**, Private capacity

**KOAY, Dr Audrey**, Executive Director, Patient Safety and Clinical Quality,  
Department of Health, Western Australia

**ATHERTON, Dr Michelle**, Private capacity

**YIN, Dr Michelle Ann (Jessica)**, Private capacity

**TSOKOS, Dr Nikolas**, Private capacity

**DIETZ, Professor Hans Peter**, Private capacity

**BONYTHON, Dr Wendy Elizabeth**, Private capacity

**ARNOLD, Associate Professor Bruce Baer**, Private capacity

**Health Consumers' Council (WA) Inc**

**BRENNAN, Ms Pip**, Executive Director, Health Consumers' Council (WA) Inc

*Monday, 18 September 2017*

*NSW Parliament, Sydney*

**Witnesses**

**Gai**, Private capacity

**Joanne**, Private capacity

**Women's Health and Research Institute of Australia**

VANCAILLIE, Prof. Thierry, Director

HOWARD, Ms Elizabeth, Osteopath and Pain Management

**UroGynaecological Society of Australasia**

KING, Dr Jenny, Chair

**Fiona**, Private capacity

**Kylie**, Private capacity

**Madeleine**, Private capacity

**Timnat**, Private capacity

**Australasian Gynaecological Endoscopy & Surgery Society**

ABBOTT, Associate Professor Jason, President

**Medical Technology Association of Australia**

BURGESS, Mr Ian, Chief Executive Officer

THEISZ, Ms Val, Director of Regulatory Affairs

**Boston Scientific**

CALLANAN, Mr Pat, Business Unit Director Australia and New Zealand, Urology and Pelvic Health

MORTON, Dr Ronald, Vice-President Clinical Sciences, Urology and Pelvic Health

**Johnson & Johnson Medical Devices**

FOX-SMITH, Mr Gavin, Managing Director

MASON, Dr Glen, Director of Medical Affairs

**TFS Manufacturing Pty Ltd**

ZADOW, Mr Paul, Managing Director

**New South Wales Ministry of Health**

CHANT, Dr Kerry, Chief Health Officer

GALE, Dr Marianne, Medical Adviser, Office of the Chief Health Officer

**International Society for Pelviperineology**

GOLD, Dr Darren, Secretary

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**Sunny**, Private capacity

*Tuesday, 19 September 2017*

*Parliament House, Canberra*

**Witnesses**

**Harriett**, Private capacity

**Kathryn**, Private capacity

**Margaret**, Private capacity

**Stephanie**, Private capacity

**Toni**, Private capacity

**Australian Commission on Safety and Quality in Health Care**

PICONE, Adjunct Professor Debora, Chief Executive Officer

HERKES, Dr Robert, Clinical Director

MELEADY, Adjunct Professor Kathy, Director, Commonwealth Programs

**Royal Australian College of General Practitioners**

SIMONIS, Dr Magdalena, Member, Expert Committee, Quality Care

**Royal Australian and New Zealand College of Obstetricians and Gynaecologists**

ROBSON, Professor Stephen, President

KILLEN, Ms Alana, Chief Executive Officer

BENNESS, Associate Professor Christopher, Deputy Chairman of Urogynaecology  
Subcommittee

**MAHER, Associate Professor Christopher**, Private capacity

**Scottish Mesh Survivors Group**

HOLMES, Mrs Elaine, Patient Representative

McILROY, Mrs Olive, Patient Representative

**Sling The Mesh**

SANSOM, Ms Kath, Founder Member

**Department of Health**

PLATONA, Ms Adriana, First Assistant Secretary, Therapeutic Goods Administration

GREENAWAY, Dr Tim, First Assistant Secretary, Therapeutic Goods Administration

KEANEY, Dr Megan, Medical Advisor

*Tuesday, 6 February 2018*

*Parliament House, Canberra*

**Witnesses**

**Department of Health**

SKERRITT, Dr John, Deputy Secretary, Health Products Regulation Group

GREENAWAY, Dr Tim, Chief Medical Adviser, Health Products Regulation Group

PLATONA, Ms Adriana, First Assistant Secretary, Medical Devices and Product  
Quality

KEANEY, Dr Megan, Medical Adviser, Technology Assessment and Access Division

**VANCAILLIE, Professor Thierry**, Private capacity

# APPENDIX 3

## Submissions and additional information received by the Committee

### Submissions

- 1 Professor Hans Peter Dietz, Associate Professor Clara Shek and Dr Vivien Wong (plus three attachments)
- 2 Name Withheld
- 3 Confidential
- 4 Name Withheld
- 5 Name Withheld
- 6 Name Withheld (plus an attachment)
- 7 Name Withheld (plus an attachment)
- 8 Name Withheld
- 9 Confidential
- 10 Name Withheld
- 11 Confidential
- 12 Dr Wendy Bonython and Mr Bruce Arnold
- 13 Confidential
- 14 Confidential
- 15 Confidential
- 16 Australian College of Midwives
- 17 Office of the Health Ombudsman

- 18 Australasian Gynaecological Endoscopy and Surgery Society Ltd
- 19 Department of Health
- 20 Public Health Association of Australia
- 21 Joint submission by Health Consumers Councils across Australia
- 22 TFS Manufacturing (plus an attachment)
- 23 Johnson & Johnson Medical Pty Ltd (plus a supplementary submission)
- 24 NSW Agency for Clinical Innovation
- 25 The Hon Roger Cook MLA, Deputy Premier, Western Australia (plus a supplementary submission)
- 26 Consumers Health Forum of Australia
- 27 Confidential
- 28 Name Withheld
- 29 Name Withheld
- 30 Name Withheld
- 31 Prostheses List Advisory Committee
- 32 Urogynaecological Society of Australasia (plus fifteen attachments)
- 33 Boston Scientific Pty Ltd
- 34 The Royal Women's Hospital
- 35 Continenence Foundation of Australia
- 36 Royal Australian and New Zealand College of Obstetricians and Gynaecologists (plus two supplementary submissions)
- 37 Scottish Mesh Survivors Group
- 38 Royal Australian College of General Practitioners

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- 39** Women's Health and Research Institute of Australia
- 40** Medical Technology Association of Australia
- 41** nib health funds limited
- 42** Urological Society of Australia and New Zealand (plus four attachments)
- 43** Independent Private Hospitals of Australia
- 44** Urogynaecology Departments, Mercy Hospital for Women, Monash Health (plus two attachments)
- 45** Maurice Blackburn Lawyers
- 46** Australian Commission on Safety and Quality in Health Care
- 47** Monash Health (plus an attachment)
- 48** International Society for Pelviperineology Australian Branch (plus five attachments and a supplementary submission)
- 49** National Association of Specialist Obstetricians and Gynaecologists
- 50** Name Withheld
- 51** Name Withheld
- 52** Name Withheld
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- 55** Name Withheld
- 56** Name Withheld
- 57** Confidential
- 58** Name Withheld
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- 60 Name Withheld (plus an attachment)
- 61 Name Withheld
- 62 Name Withheld
- 63 Associate Professor Paul Duggan
- 64 Confidential
- 65 Dr David Hodgson
- 66 Name Withheld
- 67 Name Withheld
- 68 Name Withheld
- 69 Confidential
- 70 Confidential
- 71 Name Withheld
- 72 Name Withheld
- 73 Ms Kath Sansom
- 74 Confidential
- 75 Confidential
- 76 Name Withheld (plus an attachment)
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- 94** Confidential
- 95** Name Withheld
- 96** Name Withheld
- 97** Name Withheld
- 98** Dr Michelle Atherton (plus three attachments)
- 99** Confidential
- 100** Dr Max Haverfield
- 101** Name Withheld
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- 114** Name Withheld (plus a supplementary submission)
- 115** Health Issues Centre (plus five attachments)
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- 124** Confidential
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- 127** Name Withheld
- 128** Name Withheld
- 129** Mrs Charlotte Korte (plus an attachment and two supplementary submissions)
- 130** Australian Pelvic Mesh Support Group
- 131** Confidential
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- 144** Confidential
- 145** Dr Darren Gold (plus nine attachments and a supplementary submission)
- 146** Name Withheld

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- 149** Name Withheld
- 150** Name Withheld
- 151** Ms Sunny Hutson
- 152** Ms Joanne Mannion
- 153** Confidential
- 154** Associate Professor Christopher Maher
- 155** Name Withheld
- 156** Confidential
- 157** Confidential
- 158** Name Withheld
- 159** Ms Harriett Desmond (plus a supplementary submission)
- 160** Name Withheld
- 161** Confidential
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- 167** Ms Gale Pocock
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- 223 Ms Gwendoline Baxter
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- 226 Confidential
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- 242** Ms Fiona Milner
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- 246** Ms Nola Pearse
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- 259** Ms Val Hutchinson
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- 366** Mrs Simone Dalton

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- 375** Ms Eileen Hayes
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- 386** Dr Zufar Tameev
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- 481 Analytica Ltd
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- 511** Name Withheld
- 512** Name Withheld
- 513** Name Withheld
- 514** Dr Sally Wortley
- 515** Name Withheld
- 516** Faculty of Allied Health Profession, AIMST University (plus five attachments)
- 517** Name Withheld
- 518** Professor Peter Petros (plus an attachment)
- 519** Name Withheld

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- 533 Ms Justine Watson
- 534 Name Withheld
- 535 Name Withheld (plus an attachment)
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### **Additional Information**

- 1 PHAA submission to the TGA consultation on mesh implants, from Public Health Association of Australia, received 7 September 2017
- 2 Article: MRI visible Fe<sub>3</sub>O<sub>4</sub> polypropylene mesh: 3D reconstruction of spatial relation to bony pelvis and neurovascular structures, *Int Urogynecol J* (2017), from Dr Michelle Atherton, received 8 September 2017
- 3 Correspondence between Dr Tim Jeffery and the Therapeutic Goods Administration, from Dr Michelle Atherton, received 8 September 2017
- 4 Letter and invitation, from Associate Professor Christopher Maher, received 21 September 2017

- 5 Number of complications involving stress urinary incontinence vs pelvic organ prolapse mesh procedures within the group's membership, from Australian Pelvic Mesh Support Group, received 5 February 2018
- 6 Update on the work of the Committee in regard to the use of transvaginal mesh, from Australian Commission on Safety and Quality in Health Care, received 6 February 2018

### **Answers to Questions on Notice**

- 1 Answers to Questions taken on Notice during 3 August public hearing, received from Department of Health, 1 September 2017
- 2 Answers to Questions taken on Notice during 18 September public hearing, received from Urogynaecological Society of Australasia, 12 October 2017
- 3 Answers to Questions taken on Notice during 18 September public hearing, received from Johnson & Johnson Medical, 18 October 2017
- 4 Answers to Questions taken on Notice during 18 September public hearing, received from NSW Ministry of Health, 18 October 2017
- 5 Answers to Questions taken on Notice during 18 September public hearing, received from Medical Technology Association of Australia, 24 October 2017
- 6 Answers to Questions taken on Notice during 19 September public hearing, received from Toni, 19 September 2017
- 7 Answers to Questions taken on Notice during 19 September public hearing, received from Royal Australian College of General Practitioners, 16 October 2017
- 8 Answers to Questions taken on Notice during 19 September public hearing, received from Royal Australian and New Zealand College of Obstetricians and Gynaecologists, 18 October 2017
- 9 Answers to Questions taken on Notice during 19 September public hearing, received from Department of Health, 24 October 2017
- 10 Answers to Questions taken on Notice during 19 September public hearing, received from Royal Australian and New Zealand College of Obstetricians and Gynaecologists, 12 February 2018

### **Tabled Documents**

- 1 Image of tissue anchor, tabled by Dr Michelle Atherton, at Perth public hearing, 25 August 2017

- 2 Example of document produced in response to FOI request, tabled by Dr Nicolas Tsokos, at Perth public hearing, 25 August 2017
- 3 Photographs: prolapse, tabled by Urogynaecological Society of Australasia, at Sydney public hearing, 18 September 2017
- 4 Statement, tabled by Australasian Gynaecological Endoscopy and Surgery Society, at Sydney public hearing, 18 September 2017
- 5 TGA Device Incident Report, tabled by TFS Manufacturing, at Sydney public hearing, 18 September 2017
- 6 TGA Section 41JA Notice requiring information/documents, tabled by TFS Manufacturing, at Sydney public hearing, 18 September 2017
- 7 Published article: Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT), *The Lancet*, 20 December 2016, tabled by Dr Darren Gold, at Sydney public hearing, 18 September 2017
- 8 Repair of damaged ligaments with tissue fixation system minisling is sufficient to cure prolapse in all three compartments: 5-year data, *Journal of Obstetrics and Gynaecology Research*, tabled by Dr Darren Gold, at Sydney public hearing, 18 September 2017
- 9 Paper: Is overactive bladder in the female surgically curable by ligament repair? *Central European Journal of Urology*, tabled by Dr Darren Gold, at Sydney public hearing, 18 September 2017
- 10 Images, tabled by Royal Australian and New Zealand College of Obstetricians and Gynaecologists, at Canberra public hearing, 19 September 2017

## **Correspondence**

- 1 Correspondence clarifying evidence given at Melbourne public hearing on 3 August 2017, received from Department of Health, 25 August 2017
- 2 Correspondence clarifying evidence given at Melbourne public hearing on 3 August 2017, received from Mercy Urogynaecology Unit and Monash Pelvic Floor Unit, 29 August 2017
- 3 Correspondence clarifying evidence given at Melbourne public hearing on 3 August 2017, received from Urological Society of Australia and New Zealand, 8 September 2017
- 4 Correspondence responding to evidence given at Canberra public hearing on 19 September 2017, received from International Society for Pelviperineology, 20 September 2017

## **APPENDIX 4**

### **Therapeutic Goods Administration – Urogynaecological mesh chronology**

## ATTACHMENT 1 – UROGYNAECOLOGICAL MESH CHRONOLOGY

Year	Details	Domestic/Foreign
1996	First urogynaecological meshes approved for supply in the USA	USA
1998	First urogynaecological meshes approved for supply in Australia	Australia
2006	The first adverse event relating to a urogynaecological mesh was received by the TGA.	Australia
2008	The US-FDA issues a Safety Communication recommending that surgeons should undertake specialized further training and should notify patients that mesh is permanent, complications can occur, and cannot always be resolved with further surgery.	USA
2008	TGA investigates Australian adverse event reports for urogynaecological meshes and consults an expert panel. It is agreed that the TGA will continue to monitor mesh reports and emerging clinical evidence.	Australia
2008	The TGA and NZ Medsafe seek advice from the Medical Device Incident Review Committee. The committee emphasises the need for informed patient consent and surgeon training when using such devices.	Australia New Zealand
2009	US-FDA releases statement: a literature review demonstrates conflicting information on the success rates for transvaginal mesh placement and further investigation is required.	USA
2010	Health Canada releases a notice to hospitals informing healthcare professionals of the complications associated with urogynaecological mesh.	Canada
2010	The TGA undertakes a targeted postmarket review of specific urogynaecological meshes in response to a report that meshes difficult to visualise once implanted. Broader review and consultation finds that most meshes are coloured or have radiopaque markers included within the mesh.	Australia
2011	FDA releases an updated communication advising that adverse events are no longer considered rare, there is no compelling evidence of greater success with mesh in posterior compartment, and some evidence of greater	USA

	efficacy in anterior compartment. All patients should be advised that long term data on safety of mesh is limited and alternatives to mesh should be discussed.	
<b>2012</b>	US-FDA issues orders for manufacturers to conduct postmarket surveillance for meshes - "522 studies"	USA
<b>2012</b>	The TGA publishes a web article <i>Concerns with urogynaecological surgical mesh implants</i>	Australia
<b>2012</b>	The TGA commences a comprehensive postmarket review of published literature for urogynaecological meshes	Australia
<b>2013</b>	The Australian Department of Health establishes a Urogynaecological Devices Working Group to consider the available clinical evidence and to contribute to the postmarket review activities being undertaken by the TGA	Australia
<b>2013</b>	The TGA commences a broad review of all urogynaecological meshes available for supply in Australia.	Australia
<b>2014</b>	Health Canada issues an updated notice to hospitals and patients advising that Health Canada continues to receive reports of complications, including some serious and life-altering events.	Canada
<b>2014</b>	Scottish Cabinet Secretary for Health and Wellbeing appeals to NHS Scotland to suspend transvaginal mesh procedures pending the outcome of an independent review.	Scotland
<b>2014</b>	The MHRA releases a statement that there is no regulatory justification for removing surgical mesh from use in UK hospitals.	UK
<b>2014</b>	The TGA reports on the postmarket review into all urogynaecological meshes available for supply in Australia and there is a significant reduction in the number of urogynaecological meshes available on the Australian market.	Australia
<b>2015</b>	New Zealand report into the safety of surgical mesh is published	New Zealand
<b>2015</b>	Scottish independent review into urogynaecological mesh – interim report is published	Scotland
<b>2015</b>	NHS England Releases the Mesh Working Group Interim Report.	UK
<b>2015</b>	European Commission (SCENIHR 2015) report into the safety of urogynaecological meshes suggests limiting mesh surgical procedures wherever possible, certification systems for surgeons, and appropriate patient selection and	EU

	counselling.	
<b>2016</b>	The FDA reclassifies urogynaecological POP mesh as Class III – a high risk device. Manufacturers are given 30 months to provide updated evidence. The reclassification does not apply to all implantable meshes.	USA
<b>2016</b>	The NZ House of Representatives Health Committee releases a report which includes a recommendation for the establishment of a centralized surgical registry. RANZCOG releases a response welcoming the report and the recommendation that meshes remain available as a surgical option.	NZ Australia
<b>2016</b>	The Australian Pelvic Mesh Support Group meets with Ministerial Advisors and senior Department of Health officers. This meeting includes discussion on how to encourage patient adverse event reporting in Australia.	Australia
<b>2016</b>	The TGA publishes a web article urging the reporting of adverse events relating to urogynaecological surgical mesh	Australia
<b>2016</b>	Health Canada considers powers to require mandatory reporting of adverse events by healthcare institutions – Vanessa’s Law.	Canada
<b>2016</b>	RANZCOG publishes a statement advising that transvaginal mesh is not recommended as the first line of treatment for any vaginal prolapse. Surgeons should consider clinical trial recruitment for use of any new mesh types.	Australia NZ
<b>2016</b>	A Cochrane Review is released comparing mesh to native tissue repair for POP and reports that while permanent mesh has some advantages over native tissue, there are also disadvantages in its routine use.	International
<b>2016</b>	The Lancet publishes a Scottish multi-centre trial into urogynaecological mesh (PROSPECT study). This study finds no benefit in using mesh for surgical treatment of POP in comparison to traditional surgical methods. TGA is considering taking appropriate regulatory action.	Scotland
<b>2017</b>	The EU confirms regulatory reclassification of all surgical mesh to Class III and Australia proposes to commence the regulatory process to reclassify all surgical meshes as Class III (the USA the reclassification of meshes which occurred in 2016 is limited to urogynaecological mesh used in POP).	Australia EU
<b>2017</b>	Scottish independent review into urogynaecological mesh – final report published	Scotland