

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.¹

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.'²

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).³

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.

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.⁴

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.'⁵

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 ...⁶

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 (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.⁷

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.⁸

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.⁹

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.¹⁰

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.¹¹

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.¹²

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.¹³ 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.¹⁴

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

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,¹⁵ 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.¹⁶

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.¹⁷

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

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 2012,¹⁸ 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.¹⁹

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.²⁰

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.²¹

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.²²

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.²³

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.²⁴ 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.²⁵

4.27 Many women recall being told simply that the procedure was safe, minimally invasive and uncomplicated.²⁶ 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).²⁷

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:²⁸

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.²⁹

4.29 In many cases, a transvaginal mesh procedure appears to have been the only treatment option offered.³⁰ 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.³¹

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.³²

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.³³ 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

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].

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

4.32 Other women were not advised that the 'sling' or 'tape' being used in their surgery was in fact polypropylene mesh.³⁵ 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.³⁶

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.³⁷

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.³⁸

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

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.³⁹

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.⁴⁰ 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.⁴¹

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.⁴²

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.⁴³ 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".⁴⁴

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.⁴⁵

4.39 Many women who wrote to the committee said that they had trusted the judgement of their medical practitioners.⁴⁶ 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.⁴⁷

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

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.⁴⁸

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.⁴⁹ 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.⁵⁰

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.⁵¹

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.⁵²

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.⁵³ 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.⁵⁴

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.⁵⁵ 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.⁵⁶

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.⁵⁷

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

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.⁵⁸

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.⁵⁹

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.⁶⁰

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.⁶¹

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.⁶²

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

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].

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

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.⁶⁴

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.⁶⁵

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.⁶⁶ 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.⁶⁷

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.⁶⁸ 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.⁶⁹

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

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.⁷⁰

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.⁷¹

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.⁷²

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.⁷³ 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 procedures⁷⁴ had turned the tide for the use of transvaginal mesh as a first line treatment for POP.⁷⁵ Ms Adriana Platona, told the committee:

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.⁷⁶

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.⁷⁷

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.⁷⁸ Some women told the committee that they had been diagnosed and encouraged to have surgery having attended for a routine pap-smear.⁷⁹ 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.⁸⁰

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.⁸¹ 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:

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.⁸²

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.⁸³ 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 chair⁸⁴, 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.⁸⁵

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.⁸⁶

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.⁸⁷

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.⁸⁸ 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.⁸⁹

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.⁹⁰ 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.⁹¹

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

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.⁹²

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.⁹³

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.⁹⁴

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.'⁹⁵ 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.'⁹⁶

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.'⁹⁷

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.'⁹⁸

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.⁹⁹ 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.¹⁰⁰

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...¹⁰¹

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.

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.¹⁰²

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.¹⁰³

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.¹⁰⁴

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.¹⁰⁵

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

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.¹⁰⁶ 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.¹⁰⁷

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.¹⁰⁸

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.¹⁰⁹

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

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.¹¹⁰

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.¹¹¹ 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.¹¹² 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.¹¹³

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.¹¹⁴ 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.¹¹⁵

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.¹¹⁶

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.¹¹⁷ A number of other women advised the committee that they were intending to have surgery to remove their implants.¹¹⁸

4.91 Some women wrote that they had been advised their mesh could not be removed safely without risking further complications.¹¹⁹ 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,¹²⁰ and that if they wished to have their mesh implant removed, their only option would be to travel overseas to have this surgery.¹²¹

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.¹²²

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:

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.¹²³

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.'¹²⁴

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.¹²⁵

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.¹²⁶

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.

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.

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.

