

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.¹

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.²

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.³

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.⁴
- MBS codes and Prostheses List data only indicate usage in private hospitals.⁵
- 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.⁶
- While some colleges' medical practitioners maintain databases, reporting is voluntary.⁷

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.⁸

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.⁹

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.¹⁰ However, the Department advised that many industry sponsors hold records dating back further than ten years.¹¹ 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.¹² 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

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.¹³

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.¹⁴

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.¹⁵

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.¹⁶ 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.¹⁷

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).¹⁸

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.¹⁹

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

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.²⁰

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 175 000.²¹

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.²²

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.²³

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.²⁴ 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.²⁵

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.²⁶ 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.²⁷

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.²⁸

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.²⁹

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

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.³¹ As of 3 January 2018, 327 reports had been lodged, covering 349 patients.³²

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.³³

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.³⁴

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.³⁵

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.³⁶

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

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.³⁷

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.³⁸ 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.³⁹

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

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.⁴⁰

3.34 Submitters commented that the reporting system is confusing and needs to be simplified.⁴¹ 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.⁴²

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'.⁴³

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.⁴⁴

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

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.⁴⁶

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.⁴⁷

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.⁴⁸

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.⁴⁹

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.⁵⁰

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.⁵¹

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.⁵²

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?⁵³

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.⁵⁴

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,⁵⁵ 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

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.⁵⁶

3.45 The committee received a significant amount of evidence recommending that reporting of adverse events should be mandatory for medical practitioners.⁵⁷ A number of medical practitioners also expressed support for mandatory reporting.⁵⁸ 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.⁵⁹

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 Australia⁶⁰.

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.

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.⁶¹

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.⁶²

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.⁶³

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.⁶⁴

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

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.

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.⁶⁵

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.⁶⁶

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.⁶⁷

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.⁶⁸

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:

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.⁶⁹

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.'⁷⁰

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.⁷¹

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.⁷²

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

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 is a representative sample.

a readmission within the next three years for a complication associated with that implant.⁷³

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.⁷⁴
- 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.⁷⁵

Urogynaecological Society of Australasia (UGSA) Pelvic Floor Database

3.63 A number of submitters and witnesses noted the urogynaecological database maintained by UGSA.⁷⁶ 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.⁷⁷ 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.⁷⁸

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.⁷⁹

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.⁸⁰

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.'⁸¹

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.⁸² 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.⁸³

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.⁸⁴

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.⁸⁵

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.⁸⁶

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.⁸⁷

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.⁸⁸

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.⁸⁹

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.⁹⁰

3.79 The committee heard widespread support for the establishment of a national database from medical professionals and professional colleges.⁹¹ 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.⁹²

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.'⁹³ 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.⁹⁴

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.

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).

...

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 2010.⁹⁵

3.82 Professor Chris Maher noted that key data is already being collected but is not being recorded accurately.⁹⁶ 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.⁹⁷

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.⁹⁸

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

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.⁹⁹

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.¹⁰⁰

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.¹⁰¹ 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.¹⁰²

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.

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.¹⁰³ 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

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.