Parliament of South Australia

INQUIRY INTO THE SURGICAL IMPLANTATION OF MEDICAL MESH IN SOUTH AUSTRALIA

FORTY-FOURTH REPORT

OF THE

SOCIAL DEVELOPMENT COMMITTEE

Laid on the Table of the Legislative Council, and ordered to be printed 25th May 2021

Second Session of the Fifty-Fourth Parliament

Social Development Committee
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Abbreviations

Abbreviation	Meaning
ABDR	Australian Breast Device Register
ACSQHC	Australian Commission on Safety and Quality in Health Care
AIHW	Australian Institute of Health and Welfare
AOANJRR	Australia Orthopaedic Association National Joint Replacement Registry
APMSG	Australian Pelvic Mesh Support Group
ARTG	Australian Register of Therapeutic Goods
CQR	Clinical Quality Registries
DOH	Department of Health
GP	General Practitioner
HCC	Health Consumers Council
IRIS	Incident Reporting and Investigation Scheme
IUGA	International Urogynaecological Association
MBS	Medicare Benefit Schedule
MIA	Mesh Injured Australia
MTAA	Medical Technology Association of Australia
MUS	Mid-urethral sling
NZ Review	Hearing and responding to the stories of survivors of surgical mesh: Ngā kōrero a ngā mōrehu – he urupare - A report for the Ministry of Health, New Zealand, 2019
NSQHS	National Safety and Quality in Health Services
PICMORS	Process; Improvement; Consumer participation; Monitoring; Reporting and Systems
POP	Pelvic organ prolapse
PROSPECT	PROlapse Surgery: Pragmatic Evaluation and randomised Controlled Trials
RACGP	Royal Australian College of General Practitioners
RACS	Royal Australasian College of Surgeons
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Scottish Inquiry	Scottish Independent Review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women, 2018
Senate Inquiry	Senate Inquiry into the number of women in Australia who have had transvaginal mesh implants and related matters, 2018
SUI	Stress urinary incontinence
TGA	Therapeutic Goods Administration
TVT	Tension-free vaginal tape
TVT-O	Tension-free vaginal tape-obturator
UDI	Unique Device Identification
UGSA	Urogynaecological Society of Australasia
UK Inquiry	First Do No Harm - United Kingdom Inquiry and Report of the Independent Medicines and Medical Devices Safety Review, 2020
USANZ	Urological Society of Australia and New Zealand

Establishment and Functions of the Committee

The Social Development Committee is established under section 13 of the *Parliamentary Committees Act 1991.*

Functions of the Social Development Committee as set out in section 15 of the Act—

(a) to inquire into, consider and report on such of the following matters as are referred to it under this Act:

(i) any matter concerned with the health, welfare or education of the people of the State;
(ii) any matter concerned with occupational safety or industrial relations;
(iii) any matter concerned with the arts, recreation or sport or the cultural or physical development of the people of the State;
(iv) any matter concerned with the quality of life of communities, families or individuals in the State or how that quality of life might be improved;

(b) to perform such other functions as are imposed on the Committee under this or any other Act or by resolution of both Houses.

As set out in section 14 of the Act, the Social Development Committee is comprised of an equal number of members from the Legislative Council and the House of Assembly.

Members of the fifty-fourth Parliament:

Presiding Member	Honourable Dennis Hood MLC (Absent for part-duration of Inquiry)
Acting Presiding Member for part of Inquiry	Dr Richard Harvey MP
Members	Honourable Connie Bonaros MLC
	Honourable Emily Bourke MLC
	Ms Paula Luethen MP
	Ms Dana Wortley MP

The Committee is assisted by:

Secretary	Ms Robyn Schutte
Research Officer	Ms Mary Ann Bloomfield

Terms of Reference

Terms of reference referred by the House of Assembly on a motion of Ms Dana Wortley MP on 14 February 2019

Inquire into and report on the surgical implantation of medical mesh in South Australia and in doing so consider –

(a) the number of people in South Australia adversely affected following the implantation of medical mesh;

(b) the benefits of establishing a South Australian register of mesh implant recipients, including a prospective and retrospective audit, which includes the public and private hospital sectors;

(c) identifying the current role of South Australian medical practitioners in reporting medical mesh associated adverse outcomes and the consequences of nonmandatory reporting;

(d) assessing the usefulness of current patient information provided prior to surgery, including options for non-surgical treatment, possible adverse outcomes and fully informed consent;

(e) the credentialing of medical practitioners conducting implantation and the removal of medical mesh;

(f) identifying the extent to which there exists a need for physical and psychological support, including family members, following adverse outcomes;

and

(g) any other related matter.

Conduct of Inquiry

The Social Development Committee (the Committee) advertised the inquiry in the Advertiser Newspaper on 27 July 2019; the Adelaide Primary Health (PHN) Network Newsletter 'Connect' and PHN online news on 19 July 2019; the Country South Australia Public Health Network news on 26 July 2019 inviting submissions to be provided by Friday 13 September 2019.

On a motion of the Committee on 22 July 2019, a call for submissions were also sent to the following country news publications inviting submissions by Friday 13 September 2019:

- Border Watch
- Port Lincoln Times
- Yorke Peninsula Country Times
- Barossa News and Light Herald
- Northern Argus (Clare)
- Flinders News (Port Pirie)
- Transcontinental (Port Augusta)
- Border Chronicle
- Whyalla News
- Murray Valley Standard (Murray Bridge)
- Eyre Peninsula Tribune
- West Coast Sentinel
- Coober Pedy Times
- The Islander
- Murray Pioneer (Renmark)

The Committee contacted a large number of advocacy and support groups, peak organisations, medical associations and colleges, and government agencies to invite submissions.

Details of the inquiry were also published on the Parliament of South Australia's Facebook page and the Committee's parliamentary webpage.

The Committee received 69 written submissions and held 15 hearings at Parliament House, Adelaide. Due to COVID-19, a number of these hearings were conducted via videoconferencing. A list of written submissions and oral evidence hearings is provided at the end of this report however, many individual submitters and witnesses who provided their personal evidence requested that their names be withheld from publication or that a pseudonym be used to protect their identity. The Committee has honoured these requests.

Acknowledgements

To all of the individual witnesses who have experienced the trauma of mesh injuries, and their families, the Committee members thank each and every one of you for appearing before the Committee or writing to the Committee and providing your individual accounts to this inquiry.

The Committee acknowledges this was brave and courageous to undertake and commends you for the persistence you have in surviving and in continuing your efforts to obtain appropriate treatment and care from a health system that has let you down in the past. Out of respect, and as requested, the Committee has chosen not to list your individual names.

However, to those whose first name or alternative name appears in the Hansard as evidence, the Committee extends its thanks:

Kim
Jared
Alicia
Franciszka
Penny
Robert
Tracey
Anne
Chelsea
Ebony
Elsie
Eunice
Gordon
Jacob
John
Sarah
Sharon

The Committee would also like to thank Ms Kim Blieschke, SA Pelvic Mesh Support Group and Vice President of Mesh Injured Australia Inc; Ms Justine Watson, President, Ms Andrea Walter, Public Officer /Secretary from Mesh Injured Australia Inc; and Ms Julia Overton, Chief Executive, Health Consumer Alliance of South Australia, and the advocacy groups that have campaigned about this important issue for many months, and years, and for providing thoughtful and insightful evidence, both oral and written.

The Committee would like to thank representatives of Commonwealth departments for providing oral evidence during COVID-19, in difficult circumstances:

Dr Robert Herkes, Chief Medical Officer and Assoc Professor Kathy Meleady, Stream Director from the Australian Commission on Safety and Quality in Health Care.

Ms Tracey Duffy, First Assistant Secretary, Medical Devices and Product Quality Division in the Commonwealth, Department of Health, Therapeutic Goods Administration, for providing lengthy and detailed oral submissions and follow up evidence in response to questions on notice.

The Committee also thanks the Australasian Pelvic Floor Procedure Registry Steering Committee representatives Professor Helen O'Connell, Chair and Professor Susannah Ahearn, Primary Chief Investigator.

The Committee would extend a thank you to the Department for Health and Wellbeing, SA Health representatives for providing evidence and many detailed responses to questions taken on notice, particularly when dealing with the COVID-19 pandemic:

Professor Guy Maddern, Director of Research, Basil Hetzel Institute for Translational Health Research
Dr Roy Watson, Head of Gynaecology, Central Adelaide Local Health Network
Ms Michele McKinnon, Executive Director, Provider Commissioning and Performance
Ms Bronwyn Masters, Executive Director, Operations, Central Adelaide Local Health Network
Dr Meredith Craigie, Specialist Pain Medicine Physician, Central Adelaide Local Health Network
Ms Bonnie Fisher, Principal Project Manager, SA Maternal Neonatal and Gynaecology Community of Practice
Ms Alexandra Emerson, Nurse Consultant, SA Pelvic Mesh Clinic

The Committee was very pleased to have evidence from the Queensland Pelvic Mesh Service Queensland Pelvic Mesh Service Prof. Malcolm Frazer, Head of Unit and Ms Nicolle Germano, Consumer Rep. QPMS Committee, and extends a warm thank you for the enlightening and useful information you provided.

Thank you to the professional associations and medical specialty colleges for providing both oral and written evidence, sometimes at short notice:

Dr Christopher Benness, Chair and Dr Steve Robson, Immediate Past President, Royal Australian and New Zealand College of Obstetricians and Gynaecologists

Dr Samantha Pillay, Royal Australasian College of Surgeons

Dr Magdalena Simonis, Royal Australian College of General Practitioners

Dr Ian Tucker, Gynaecologist and Urogynaecologist, who provided the Committee with some very useful insights in the difficulties in the field of urogynaecology in South Australia.

The Committee also wishes to extend its thanks to the Shine Lawyers representatives Ms Jan Saddler, Head of Litigation and Loss Recovery and Ms Bridget Cook, Senior Associate, Class Action Team. The Committee was very pleased to hear your evidence and congratulates you on the outcome of the Class action in the High Court of Australia on 5th March 2021.

Executive Summary

The *Inquiry into Issues Related to the Surgical Implantation of Medical Mesh in South Australia* (the Inquiry), by the Social Development Committee (the Committee) was championed by mesh injured advocates through Ms Dana Wortley MP, who moved a motion in the House of Assembly in February 2019 for this inquiry to be undertaken.

The report of the Committee looks at a number of issues in the evidence, which suggest the physical, material and psychological damage that can be caused by failed mesh devices, is at least as severe as it has been claimed to be by mesh injured people and, is likely to be more widespread than it was thought to be by the health system and medical profession. Alongside these matters, the Committee has also inquired into the services that have been made available to those who have been injured by mesh, and the legislative, regulatory and professional systems that are in place to protect patients, consumers and the public from faulty mesh devices.

A defining feature in the accounts of mesh injured people, has been the reluctance of the medical profession in adequately recognising and responding to the injuries and symptoms of patients.

Most written and oral submissions provided to this inquiry by mesh injured people, describe catastrophic and debilitating injuries that could not have been easily ignored, least of all by a family physician, but in many cases, ultimately were.

In two cases, family members were said to have passed away because of conditions alleged to be attributable to mesh injuries. The accounts given by the families show that in both cases their loved ones had gone through years of pain and suffering, along with many visits to GPs and medical specialists, following mesh implantation. However, the role of mesh in their injuries was not identified or, was ignored.[1, 2] Many adjectives could describe the two families' accounts and the accounts provided by mesh survivors: Calamitous. Shocking. Disastrous. Preventable. Their accounts are referenced in this report.

At the same time, the Committee heard that the majority of people who have a mesh implant, do not experience complications, or the kinds of adverse effects described during this inquiry.[3] The Committee notes this. The Committee also understands that some types of mesh products have been implicated in complications in pelvic organ prolapse (POP) at a higher rate than some types of meshes have been in stress urinary incontinence (SUI), or in hernia repair.

However, as the evidence also shows, when mesh injuries do occur, they can occur over many years, cause a multitude of symptoms and can have devastating consequences for the injured person and the people around them.

The SA Health Pelvic Mesh Clinic

The Committee heard women who have suffered from injuries caused by implantable urogynaecological mesh devices in South Australia, and to some extent, people with other types of implantable mesh devices, such as those used in hernia repairs, are still being let down by systems that should provide treatment, care and assistance to them. While the subject of the SA Health Pelvic Mesh Clinic (SA Pelvic Mesh Clinic or the Clinic) is not a specific term of reference in this inquiry, the inquiry could not have been conducted without reviewing aspects of the SA Pelvic Mesh Clinic relative to the terms of reference.

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1 Franciszka and Robert. Oral evidence, *Hansard*, 17 February 2020: 14.

2 Name confidential, *Written submission No. 57*, 23 September 2019: 1 - 3.

3 Dr Samantha Pillay, Royal Australasian College of Surgeons, Oral evidence, *Hansard*, 15 June 2020: 99.

Given the SA Pelvic Mesh Clinic is the principal service for the treatment of mesh injured women in South Australia, the Committee found the Clinic to be falling short of what it should and must do for mesh injured women.

This report shows that the Clinic, which was set up in response to Recommendation 13 of the Australian 2018 Senate Community Affairs References Committee's Inquiry on the *Number of women in Australia who have had transvaginal mesh implants and related matters* (the Senate Inquiry), is yet to provide a full suite of services in a timely fashion to eligible mesh injured women, despite being operational for more than two years.[4]

Evidence provided by SA Health also shows while much work has gone into implementing the Senate Inquiry's recommendations by the Department for Health and Wellbeing, despite best efforts, the waiting time for a patient to be accepted into the Clinic and have a first appointment with a gynaecologist, is more than 110 days.[5]

The Committee notes with some disappointment, that the SA Pelvic Mesh Clinic Transvaginal Mesh Audit conducted by SA Health in 2018, ascertained approximately 150 women would require the services of the Clinic in the first year of operation; yet the Clinic has not seen half that many patients in the two years it has been operational.[6, 7]

The Committee also notes with interest the high threshold for eligibility to be accepted as a patient of the SA Pelvic Mesh Clinic and understands from December 2018 to September 2020, more than forty women have been determined to be ineligible to receive treatment by the Clinic.[8] SA Health advised, the Clinic only accepts women who have 'complex complications' from pelvic mesh implants.[9]

Of a number of other concerns raised about the Clinic, the Committee observes that:

1. the Clinic still does not have a credentialed, properly trained and experienced Urogynaecologist employed at the Clinic. This means the Clinic is unable to meet one of the key parts of Recommendation 13 of the Senate Inquiry, which is to be able to give many of its patients what they most want and need – full surgical removal of their mesh devices. Further, the Clinic is "dealing with a backlog, of five to 10 years of patients"[10]

2. the women with the most serious complications will still be required to be assessed by a highly experienced surgeon inter-state as the proposed Urogynaecologist being recruited to SA will not be able to operate in the most complicated cases[11]

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4 Ms Michele McKinnon, Executive Director, Provider Commissioning and Performance, Department for Health and Wellbeing, Oral evidence, *Hansard*, 7 September 2020: 150.

5 Dr Roy Watson, Head, Gynaecology Unit, Central Adelaide Local Health Network, SA Health. Oral evidence, *Hansard*, 1 February 2021: 242.

6 SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 10.

7 Ms Bonnie Fisher, Principal Project Manager, SA Maternal Neonatal and Gynaecology Community of Practice, SA Health, Oral evidence, *Hansard*, 7 September 2020: 151.

8 SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 13.

9 SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 11.

10 Ms Bonnie Fisher, *Hansard*, 7 September 2020: 160

11 Dr Roy Watson, *Hansard*, 1 February 2021: 237.

3. it is not clear why the threshold for acceptance is so high and women are being turned away when they are in terrible pain. Because of the dedicated services offered by the SA Pelvic Mesh Clinic, the Committee considers this may be the best place for these women to receive their treatment, in South Australia where they also have family support[12]

4. allied health service clinics for patients to receive treatment from physiotherapy, psychology, urology and pain management specialists are not full-time and a patient may not receive back-to-back appointments in a single month. This means patients may have to wait weeks, or months for their next appointment as they move through the Clinic's schedule of appointments[13]

5. while efforts are now being made, appointment times for regional and rural patients are spaced out with difficult timeframes to be met, meaning patients have to travel long distances while nursing injuries, pain and discomfort, on numerous occasions. For most regional women, the time between appointments with allied professionals is too long.[14]

Disappointing, or perhaps alarming, are the accounts from mesh injured women who have accessed services at the Clinic and have allegedly been treated with impatience, irritation, or disrespect by some of the staff at the Clinic.[15, 16, 17]

The Committee has made a number recommendations to the Minister for Health and Wellbeing to give consideration to addressing some of the problems identified about the Clinic's services in this report, urgently and into the near future.

Mesh Injured South Australians

No evidence provided to this inquiry could reliably show how many people in South Australia have had an implanted mesh device, or how many people have experienced adverse effects from an implanted mesh device.

In seeking to understand the prevalence of mesh related adverse events in the South Australian context, the Committee noted the difficulties in determining the number of women adversely affected by transvaginal mesh implants across Australia, evidenced in the Senate Inquiry.[18] The Committee found similar problems identifying how many South Australians are adversely affected by mesh.

Evidence shows during the period urogynaecological meshes appear to have been used most prolifically in South Australia, paper records and hospital database systems did not maintain reliable data due to various issues in record-keeping.

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12 Kim, SA Pelvic Mesh Support Group, Consumer Advocate, Oral evidence, *Hansard*, 30 November 2020: 194.

13 Ms Bonnie Fisher, *Hansard*, 7 September 2020: 160

14 Associate Professor Meredith Craigie, Specialist Pain Medicine Physician, Central Adelaide Local Health Network, SA Health, Oral evidence, *Hansard*, 7 September 2020: 163 – 164.

15 Kim, *Hansard*, 30 November 2020: 194.

16 Eunice, Oral evidence, *Hansard*, 20 July 2020: 146.

17 Sarah, Oral evidence, *Hansard*, 20 July 2020: 146 - 147.

18 Parliament of Australia, Senate Community Affairs References Committee, Inquiry Report, *Number of women in Australia who have had transvaginal mesh implants and related matters*, Canberra, March 2018: 56 - 57.

Additionally, Medicare Benefits Schedule (MBS) item numbers failed to accurately describe mesh procedures. Until recently, MBS item numbers have only been available for certain procedures, often did not differentiate between a procedure with mesh or of native tissue repair and there were no item numbers for some mesh removals, such as with POP meshes.[19] These issues have been compounded by the MBS data only relating to a private patient setting.

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) were able to give 'an idea' of the number of mesh implantation procedures 'likely' to have been carried out in South Australian hospitals, within a private patient setting, for vaginal prolapse from MBS data from 2004 to 2018, being, 19 262 total procedures. However, the data did not specify if mesh was or was not used.[20]

Evidence on MBS data provided in relation to mesh devices for SUI was more reliable, as MBS item numbers did exist for the mid-urethral mesh procedure. This evidence suggested from 1999 to 2020 there were 7 327 mesh 'sling' procedures performed in South Australia in a private patient setting.[21]

The 2018 Senate Inquiry heard that approximately 150 000 people may have received a urogynaecological mesh implant across Australia.[22] If South Australia's procedures are assessed as a percentage of the population, around 8 per cent, approximately 12 000 people, may have had a mesh implant for urogynaecological purposes in South Australia, from 1999.[23]

The Department for Health and Wellbeing (the Department) provided data obtained from various sources such as hospital admissions from selected SA Health facilities. The Committee was provided with a copy of an audit report summary which was undertaken by the Department in 2018, which looked at selected hospital records of patients admitted for pelvic organ treatments with transvaginal mesh devices from 2003 to 2018 (the TVM Audit).[24]

The TVM Audit reviewed 230 SA Health hospital records and found 34 per cent of patients were determined to have had a pelvic mesh implant and 37 per cent of those would experience reoccurrence of their pre-mesh condition symptoms.[25] This, according to the TVM Audit report would see around 100 women requiring the services of the SA Health Pelvic Mesh Clinic annually, with 150 women in the first year.[26]

The Committee noted with interest that the SA Health Patient Incident Recording system, which is mandatory for clinicians to record adverse events into if they have occurred at an SA Health facility (public health system), was not referenced in the TVM Audit. The Committee questions the projected number of women in South Australia who may require treatment at the newly established SA Health Pelvic Mesh Clinic.

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19 Ms Tracey Duffy, First Assistant Secretary, Medical Devices and Product Quality Division, of the Department of Health (DoH), Email *RE: SA Parliament inquiry - surgical implantation of medical mesh in SA*, 26 November 2020: 1.

20 RANZCOG, *Written submission No. 45*, 13 September 2019: 8 – 9.

21 Dr Samantha Pillay, *Hansard*, 15 June 2020: 98.

22 Senate Community Affairs References Committee, Inquiry Report, *Number of women in Australia who have had transvaginal mesh implants and related matters*, March 2018: 39.

23 Australasian Pelvic Floor Procedure Registry Steering Committee (APFPR Committee), Monash University, *Written submission No. 41*, 13 September 2019: 3.

24 SA Health, *Transvaginal Mesh Audit 2018 Report Summary*, received 8 September 2020: 3.

25 SA Health, *Transvaginal Mesh Audit 2018 Report Summary*, received 8 September 2020: 5.

26 SA Health, *Transvaginal Mesh Audit 2018 Report Summary*, received 8 September 2020: 5.

The lack of an implantable mesh device register and too few adverse event reports made to the Therapeutic Goods Administration (TGA), has contributed to inaccurate views on the numbers of people adversely affected by mesh, along with issues in the online reporting system of the TGA. Although it is mandatory for medical device sponsors to report adverse events associated with their products under the *Therapeutic Goods Act 1989,* crucially, reporting by medical professionals and health care facilities was, and still remains voluntary.

Further, the Committee heard it was identified that reporting adverse events in the TGA's Incident Reporting and Investigation Scheme database (IRIS) is difficult.[27] Evidence also suggested that there has been a significant lag in the time between an adverse event occurring, and a patient or medical professional making a report to the TGA.[28]

At the same time, the TGA Database of Adverse Event Notifications (DAEN) listing medical devices that have adverse events against them, does not identify if the event is the result of the clinical capabilities of the medical practitioner or of the health service. The DAEN therefore, does not contain a complete picture or dataset, of an individual event or adverse events that may be attributed to surgical technique or practice.[29, 30]

A further issue identified for the purpose of this inquiry, is TGA adverse event records refer to the total number of reports across Australia, rather than broken down state-by-state.[31]

The TGA has been working with the states and territories to improve the manner in which adverse events are reported and advised that consultation for mandatory reporting has commenced with selected stakeholders and will continue into 2021.[32]

In relation to mesh for hernia repair, the Committee was advised that there were 2 751 separations (discharges) from the public hospital system in 2018/19, which may have involved a mesh product however, data was as equally obscure to that of information concerning pelvic mesh.[33] No evidence was received in relation to numbers of hernia mesh repairs performed in a private patient setting.

The Committee learned that in many cases of hernia repair, mesh is often not identified as a device, but simply part of the surgical procedure and may therefore be unidentifiable in MBS data or medical records.[34]

Support for Mesh Devices Registers

All witnesses who gave oral evidence and many who provided written submissions to this inquiry, were supportive of a register for mesh device implantations. Some submissions stated such a register should include details of patients, surgical procedures, device identification, referring GPs, surgeons, hospitals/ day-surgery centres and any adverse events associated with a device.

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27 Dr Ian Tucker, Gynaecologist, Certified Urogynaecologist, Oral Evidence, *Hansard*, 7 December 2020: 233; Dr Ian Tucker, *Written submission No. 69*, 7 December 2020: 5.

28 Dr Magdalena Simonis, Royal Australian College of General Practitioners (RACGP), Oral evidence, *Hansard*, 21 September 2020: 168.

29 TGA, *Database of Adverse Event Notifications – medical devices*. Accessed 22 September 2020 https://apps.tga.gov.au/prod/DEVICES/daen-entry.aspx

30 Ms Tracey Duffy, *Hansard*, 11 May 2020: 68; 70.

31 Ms Tracey Duffy, *Hansard*, 11 May 2020: 73.

32 Ms Tracey Duffy, *Hansard*, 7 December 2020: 215.

33 Hon. Stephen Wade MLC, Minister for Health and Wellbeing, *Written submission No. 65*, 15 October 2019: 1 - 2.

34 Ms Julia Overton, Chief Executive Officer, Health Consumers Alliance of South Australia, Oral evidence, *Hansard*, 23 March 2010: 48.

One concern identified was that the lack of a register for implantable mesh devices and associated adverse events, allowed for cynicism, disbelief and criticism of the accounts of people with mesh related injuries, by many in the medical profession. The Committee learned that in many cases some injuries caused by pelvic mesh may have been lessened in severity, or even prevented from occurring, if a register of urogynaecological meshes had existed before patients had received a mesh implant, and had been accessed by their doctors.

The Committee found there is great support amongst mesh injured people, advocates and the medical profession for the register that has been developed and is now operational, by Monash University and the Australasian Pelvic Floor Registry (APFPR) Steering Committee.[35] The APFPR is funded by the Federal Government, has the backing of the states and territories and has been developed by Monash University's Clinical Quality Registries' (CQR) division, in consultation with consumers and key stakeholders.[36] Based on other CQRs such as the Australia Orthopaedic Association National Joint Replacement Registry (AOANJRR), the APFPR has the potential to achieve a 98 per cent cohort participation, without being made mandatory.[37]

Although retrospective data is highly desirable, difficulties in recording retrospective data were identified by a number of witnesses, including the APFPR Steering Committee representatives.[38] It is acknowledged by the Committee the prospect of facilitating this would be onerous, time-consuming, expensive and data would still be incomplete, and potentially unusable as a consequence.

The APFPR as a prospective register has the potential on the other hand of being highly robust in its data capture and resources that could have been used for retrospective data collection, would be better utilised in ensuring the medical profession is up to date and capable of recognising and promptly responding to the needs of mesh injured patients.

Opinions were divided as to whether the APFPR should solely record urogynaecological mesh or if this register should be expanded to include all implantable mesh devices. There is support amongst stakeholders for a national register of hernia mesh devices to be developed alongside the APFPR, as evidence of recent recalls and hazard notifications by the TGA suggests problems related to hernia mesh implants may increase over time. Investigations into establishing a hernia mesh register could be undertaken at the Federal Government level.

There were differing views presented as to whether a separate register should be developed for South Australia only, or if it is better to operate at a national level. Most medical practitioners and organisations consider a national register to be the best approach to provide the most consistent data across jurisdictions.

The Committee is in agreement with the need for a national registry of implantable devices so that the information recorded about a device is not reliant on the patient or medical practitioner being in a particular location. Other benefits to a national register include there being a nationally consistent approach to data collection and greater scope for comparisons across states and territories.

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35 See Australasian Pelvic Floor Procedure Registry Communique #2 – February 2021 https://apfpr.org.au/wp-content/uploads/2021/02/20210218_APFPR_Communique_2.pdf

36 Professor Helen O'Connell, Director of Surgery and Head of Urology, Western Health Melbourne, and Urology Representative of the Australasian Pelvic Floor Procedure Steering Committee (APFPR Committee). Oral evidence, *Hansard*, 27 April 2020: 54.

37 Professor Helen O'Connell, *Hansard*, 27 April 2020: 60.

38 Professor Susannah Ahern, Head, Registry Science, Monash University, and Chair and Primary Chief Investigator, Australasian Pelvic Floor Procedure Steering Committee (APFPR Steering Committee). Oral evidence, *Hansard*, 27 April 2020: 56.

Also, importantly, there could be greater useability in linking the register with other state, territory and national databases and regulatory systems such as hospital databases, the TGA DAEN and the proposed Unique Device Identification (UDI) system.

The APFPR became operational in February 2021, and the Committee notes the Royal Adelaide Hospital, Queen Elizabeth Hospital and the private Calvary North Adelaide Hospital are participating in the initial operational phase.[39]

The Committee has recommended to the Minister for Health and Wellbeing that the State Government continue to provide support through the National Cabinet Reform Committee (Health), for the progression of this important work. The Committee noted that the federal funding for the APFPR when given, was for three years to 2022, and is supportive that this should be continued thereafter.

The Committee found there is also great support for the continued investigations by the TGA for the development and implementation of a UDI system for all implantable medical devices, noting the consultative work already commenced.[40] The Committee has recommended this be continued to be advocated for through the National Cabinet Reform Committee (Health).

Mandatory Reporting of Adverse Events

Many of the accounts provided to this inquiry detailed the way mesh injured patients were repeatedly disbelieved by their GP, gynaecologist or treating surgeon when seeking help for mesh related adverse events. It is unsurprising then, particularly given reporting is voluntary for patients and medical professionals, that so few adverse event reports on mesh devices have been made to the TGA.

The TGA provides on its website a comprehensive list of symptoms that can be attributed to a urogynaecological mesh related adverse event. Some of the symptoms listed appear to be minor, while others are very serious, or life-threatening.[41] Detailed information on adverse event symptoms has been available since the United States' Food and Drug Administration (FDA) reported in a 2011 review of urogynaecological mesh repair procedures.[42]

According to the TGA, mesh was first monitored by the TGA in 2008 and in 2012, the TGA commenced its own review, publishing its findings in 2014.[43] The TGA only received 32 adverse event reports involving urogynaecological meshes during this period, despite having consulted with the RANZCOG and the Urogynaecological Society of Australia (UGASA) as part of the review.[44]

In May 2020, the TGA submitted to this inquiry that there had been 635 adverse event reports made from 2006 to April 2020.[45] However, this still does not compare to the many cases that have been

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39 Ms Tracey Duffy, *Responses to questions on notice*, 18 December 2020. *Hansard*, 7 December 2020: 214. Received 1 February 2021: 1 - 2.

40 Ms Tracey Duffy, *Responses to questions on notice*, 18 December 2020. *Hansard*, 7 December 2020: 214. Received 1 February 2021: 1.

41 TGA, *Urogynaecological surgical complications*, "TGA urges reporting of adverse events", August 2016. Accessed https://www.tga.gov.au/alert/urogynaecological-surgical-mesh-complications

42 FDA, *Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse*, July 2011: 7.

43 TGA, *Results of review into urogynaecological surgical mesh implants*, August 2014. Accessed 7 January 2021 https://www.tga.gov.au/behind-news/results-review-urogynaecological-surgical-mesh-implants

44 TGA, *Review into urogynaecological surgical mesh implants*, May 2014. Accessed 7 January 2021 https://www.tga.gov.au/behind-news/review-urogynaecological-surgical-mesh-implants

45 Ms Tracey Duffy, *Hansard*, 11 May 2020: 68.

identified through the Senate Inquiry, the Health Issues Centre (Victoria) and the Class action against Johnson & Johnson undertaken by Shine Lawyers, which has identified at least 10 000 potential mesh injured women across Australia.[46] The reporting of adverse events for hernia mesh patients is even lower, with the TGA advising that only 170 reports were made during the same period.[47]

Support from mesh injured people for mandatory reporting of mesh related adverse events to the TGA by medical practitioners and health care facilities, was overwhelming; medical practitioners and professional medical associations were less supportive.

One issue identified with the reporting provisions as they exist is, in some cases device sponsors may not be made aware there is an issue with their device if medical practitioners do not advise them. The device sponsor cannot then report the adverse event to the TGA, and as there is no legal incentive for the medical professional to do so, the burden of reporting rests with the patient.

Reticence on the part of medical practitioners to make adverse event reports appears to centre on concerns around having the time to make reports, using the TGA's online forms; as well as concerns a clinician may have for their professional reputation if they report a 'negative' outcome. The evidence suggested that because of this perceived impost, some practitioners are lax about their duty to report adverse events.

Evidence of poor reporting amongst medical practitioners caused the APFPR to reduce the data entry time required for medical practitioners to participate.[48] The APFPR will require one minute of a surgeon or GP's time to do the data entry, but there are still concerns about participation rates. However, given the APFPR is a 'community service' rather than a 'compliance system', it is considered more appropriate for participation in the register to remain voluntary.

In contrast, the TGA's regulatory regime has different functions and seeks to protect consumers and patients from dangerous or faulty medical devices. The evidence suggests it is reasonable for the reporting of adverse events for mesh devices to be mandatory for medical practitioners, surgeons and health care facilities, because of the protective powers in the *Therapeutic Goods Act 1989*, however, attitude and behaviour change towards reporting amongst medical practitioners must also occur.

The TGA is aware of the problems medical practitioners have had in the past with its online reporting forms and advised the Committee that a number of these have been addressed to make the forms faster, simpler and easier for clinicians to use. Also, of note is the recent implementation of mandatory reporting in Canada, which the Committee understands the TGA will be monitoring closely for outcomes.[49]

Provision of Information and Informed Consent

The Committee was concerned to learn during this inquiry, that there were many witnesses from whom medical practitioners had not obtained 'fully informed consent' prior to implantation of medical mesh.[50]

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46 Shine Lawyers, *Johnson and Johnson/ Ethicon Class Action*. Accessed 1 March 2021 https://www.shine.com.au/service/class-actions/johnson-johnson-ethicon-class-action

47 Ms Tracey Duffy, *Hansard*, 11 May 2020: 68.

48 Professor Helen O'Connell, *Hansard*, 27 April 2020: 60.

49 Ms Tracey Duffy, *Hansard*, 11 May 2020: 77.

50 Names confidential, *Written submission No. 1*, 8 August 2019: 1; *Written submission No. 5*, 9 September 2019: 1; *Written submission No. 7*, 10 September 2019: 1; *Written submission No. 10*, 10 September 2019: 2; *Written submission No. 12*, 10 September 2019: 1; *Written submission No. 14*, *Written submission No. 15*, 11 September 2019: 1; *Written submission No. 19*, 12 September 2019: 1; *Written*

A large number of witnesses with a mesh implant, stated they were not informed appropriately or adequately prior to their surgery. Some examples showed there was some information given, but this was often not comprehensive, and excluded details about available alternative treatments. In other accounts witnesses relayed that mesh was given as the first and only option for treatment of their condition, or they were simply not informed at all.

Failing to transparently disclose the risks involved in a medical procedure and failing to obtain fully informed consent from a patient prior to a procedure, places medical professionals at odds with both certain state laws, as well as numerous codes of conduct, ethical practices and safety and quality in health services standards.

The inquiry report thus considers some of the legal and ethical obligations that medical practitioners have to comprehensively inform and consult with their patients prior to a proposed treatment or medical procedure.

The Committee found although almost every individual account demonstrated there had been a lack of informed consent given, there are ample instruments in place, which provide medical professionals with the necessary guidance and obligation, to ensure that they engage in an open and transparent dialogue with their patients, with the full facts of a treatment plan given.

Indeed, in the field of gynaecology, and sub-specialty of urogynaecology, the Committee learned graduate training with the RANZCOG requires trainees to undertake specific learning modules on professional conduct, ethical attributes, legal obligations and obtaining informed consent from a patient.[51] The Committee also found that the Royal Australasian College of Surgeons and the UGASA require their members to adhere to specific codes of conduct.[52]

The Committee understands the *Consent to Medical Treatment and Palliative Care Act* 1995, applicable in South Australia and precedents under common law are unambiguous regarding the duty of a medical professional's duties to their patients. Medical professionals have a duty of care, a duty to warn a patient of the risks involved in a proposed treatment and a duty to obtain consent to a proposed treatment. Common law establishes that all 'competent' adults can consent to or refuse a medical treatment.

This inquiry highlights the *Australian Charter of Health Care Rights* and the South Australian *Charter of Health and Community Services Rights* under the *Health and Community Services Complaints Act 2004,* provide patients with rights in relation to services received in the South Australian health system. These include a person's right to health care access, safety, quality, respect, information, participation and comment, in health services received. [53]

The Committee understands an effective consent process must involve dialogue between the medical practitioner and the patient and must be tailored to the need of the individual patient.
Evidence from SA Health showed that all SA Health staff, working in an SA Health facility are required to adhere to the *Consent to Medical Treatment and Health Care Policy Guideline*, which

submission No. 20, 12 September 2019: 1; *Written submission No. 21*, 12 September 2019: 1; *Written submission No. 25*, 12 September 2019: 1; *Written submission No. 26*, 12 September 2019: 1; *Written submission No. 28*, 13 September 2019: 1; *Written submission No. 33*, 13 September 2019: 1; *Written submission No. 40*, 13 September 2019: 1; *Written submission No. 46*, 13 September 2019: 1; *Written submission No. 47*, 13 September 2019: 1; *Written submission No. 54*, 20 September 2019: 1; *Written submission No. 56*, 20 September 2019: 1; *Written submission No. 63*, 11 October 2019: 1.

51 RANZCOG, *RANZCOG Curriculum*, 3rd edition, Melbourne, 2016: 58.

52 RACS, *Informed Consent 2019*. Accessed 29 October 2020 https://www.surgeons.org/en/about-racs/position-papers/informed_consent_2019

53 Health and Community Services Complaints Commissioner*, Know your rights when receiving a health or community service*. Accessed h_know_you_rights_charter_brochure.pdf (hcscc.sa.gov.au)

contributes to the requirements of the National Safety and Quality in Health Services Standards (NSQHS Standards).[54]

Private hospitals are also required to meet the NSQHS Standards, and the Committee understands, the Medical Board of Australia requires all medical practitioners to conduct themselves in accordance with the *Good Medical Practice: A Code of Conduct for Doctors in Australia*, in order to be registered with the Australian Health Practitioner Regulation Agency.[55]

The Committee found the materials to be thorough and unambiguous about what is expected of medical professionals in the performance of their duties to their patients. The same was found in relation to requirements for health care facilities in meeting both state and federal legal requirements and standards.

The Committee also reviewed the improvements made by the ACSQHC and the TGA on the information they have available for patients, medical professionals and health services as a result of the Senate Inquiry.[56, 57] The Committee's report shows there is a need for medical practitioners and health services to be reminded of the obligations that exist under these policies.

Further, there is some room for improvement, particularly in relation to the respect that should be afforded to an individual's right to choose a medical treatment and the communication processes that exist in the medical professional / patient relationship.

The guidelines for medical practitioners on informed consent along with the guidelines for patients and medical practitioners on the treatment of POP and SUI, recommended by the Senate Inquiry and published by the ACSQHC give detailed information to patients about what options are available to them and what to expect from their medical practitioner.[58, 59] At the same time, the informed consent information serves to remind medical practitioners of their ethical obligations.

The TGA advised, its online 'urogynaecological mesh hub' has been received well. The TGA advised as part of the *Action Plan for Medical Devices*, lengthy consultation with consumers has resulted in an online brochure called *Five questions to ask your health professional before you get a medical implant*, which covers all implantable medical devices, including all types of mesh.[60, 61]

Changes to the regulation of all implantable mesh devices now requires a patient information leaflet to be supplied to all patients, while a patient implant card provides details on the product, its surgical implantation process and any adverse events associated with it, which must be recorded in a patient's

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54 Department for Health and Wellbeing, SA Health, *Consent to Medical Treatment and Health Care Policy Guideline*, V.2, December 2014: 3.

55 Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia,* March 2014: 4. Accessed on 3 February 2021 Medical-Board---Code-of-conduct.PDF

56 See ACSQHC https://www.safetyandquality.gov.au/our-work/health-conditions-and-treatments/transvaginal-mesh

57 ACSQHC, *Fact sheet for clinicians: Informed consent in healthcare*, 2020: 1. Accessed 19 January 2021 Fact Sheet for clinicians- Informed consent in health care (safetyandquality.gov.au)

58 ACSQHC, *Treatment options for pelvic organ prolapse*, 2018. Accessed 5 November 2019 Treatment Options for Pelvic Organ Prolapse (POP) | Australian Commission on Safety and Quality in Health Care

59 ACSQHC, *Treatment options for stress urinary incontinence*, 2018. Accessed 5 November 2019 Treatment Options for Stress Urinary Incontinence (SUI) | Australian Commission on Safety and Quality in Health Care

60 Ms Tracey Duffy, *Hansard*, 7 December 2020: 214.

61 TGA, *Five questions to ask your health professional before you get a medical implant*, 25 June 2020. Accessed https://www.tga.gov.au/community-qa/five-questions-ask-your-health-professional-you-get-medical-implant

medical notes.[62] The Committee understands all SA Health facilities have implemented the TGA requirements.[63]

The Committee acknowledges actions that have been taken during the course of this inquiry, have resulted in more information being available to the public via the internet, than there was prior to the 2018 Senate Inquiry, and recommendations. At the same time, this report shows medical professional organisations, regulators and patients alike, acknowledged that in the past, too few patients received adequate information regarding pelvic mesh prior to their surgery occurring.

The new regulatory requirements are welcomed, but they are too recent to have been reviewed as part of this inquiry to determine whether they are assisting prospective patients. While the guidelines and detailed information produced by the ACSQHC and the TGA are very useful, there are some concerns around issues of access and equity for people without access to the internet and for those without internet skills.

The Committee considers the issues faced by patients with pelvic mesh may to some extent have also occurred with hernia repair procedures, and more needs to be done to raise awareness of the risks associated with hernia and other types of surgical mesh. The Committee considers that continued education campaigns and awareness training for medical professionals regarding the risks and complications associated with all surgical mesh is still required, given there will likely be many more people who experience complications from mesh devices into the future. The medical profession must be prepared for this and know when and how to respond in the interests of future patients.

Medical Practitioner Credentialing

The Committee heard there are concerns about the credentialing of medical practitioners who will be continuing to provide services to women for pelvic mesh excisions, partial removals and full mesh removals. Concerns were also raised regarding the continued implant of transvaginal mesh for SUI, by medical practitioners who may not be appropriately credentialed. Evidence suggested there needs to be checks and balances in place to ensure surgeons are appropriately trained, experienced and credentialed to perform gynaecological surgical procedures on mesh injured women, because of the complexities of mesh injuries, as well as in the implantation of TGA approved meshes.

The ACSQHC guidance documents go some way to provide detailed guidelines for hospitals on the credentialing of senior medical practitioners for the implantation and explantation of mesh devices.[64] The Committee did not receive any evidence to show that private hospitals have adopted these guidelines but understands SA Health has implemented them.

The Committee understands credentialing and scope of clinical practice for medical practitioners is a responsibility of the employing hospital or day procedure centre. The states and territories have obligations to ensure their public hospitals meet requirements under state and federal laws, policies and charters as well as the requirements of the National Safety and Quality in Health Service Standards (NSQHS Standards).[65]

Individual organisations in the private hospital sector are also required to meet the NSQHS Standards and their credentialing processes are determined by individual organisation by-laws. The process of

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62 Ms Tracey Duffy, *Hansard*, 11 May 2020: 67.

63 Ms Michele McKinnon, *Hansard*, 7 September 2020: 150.

64 ACSQHC, *Guidance for Hospital Credentialing of Senior Medical Practitioners to Undertake Transvaginal Mesh Implant Removal Surgery*, 2018

65 ACSQHC, *NSQHS Standards*. Accessed 9 February 2021 https://www.safetyandquality.gov.au/standards/national-safety-and-quality-primary-healthcare-nsqph-standards

credentialing and defining the scope of clinical practice in health care organisations is listed under the NSQHS Standard 1, Clinical Governance.[66]

The RACS submitted that while the policy frameworks and administration of credentialing is undertaken at the organisation level, individual surgical practitioners must ensure they are familiar with all aspects of continuing education, throughout the life of their surgical practice, meaning individuals must be responsible for making sure their credentials match their clinical skills and practice.[67]

There is no doubt that individual practitioners must be responsible for their own professional practice, at the same time, the Committee understands the *Health Care Act 2008* provides a legislative framework, for public hospital facilities to ensure they have proper policies and processes in place for the credentialing and defining the scope of clinical practice of medical practitioners employed in public hospitals.[68]

The Committee considers that greater emphasis needs to be placed on individual responsibilities of surgeons and adherence to the relevant legal and ethical instruments that govern medical practice. Yet, at the same time hospitals need to be responsible for ensuring staff are appropriately credentialed and are working within the agreed scope of clinical practice.

The Committee acknowledged there are several matters that require consideration in credentialing of surgeons who perform mesh surgery. Further, although the Committee was advised that gynaecologists can perform the routine and 'simple' surgeries – even in their consulting rooms – there is more than ever, a need to review these practices to ensure the new regulatory requirements are being followed.

The relevant colleges and professional associations could help to achieve this and ensure compliance obligations are being met by medical practitioners. The Committee was also cognisant of the issues put to it by the relevant colleges concerning the need to adopt a policy of 'credentialing by quality not quantity'.[69, 70]

The Committee accepts the view that, surgery should always be a last resort and surgery with an implantable mesh device should be treated with caution, by a surgeon credentialed to address all of the associated factors. In that respect, the guidelines published by the ACSQHC for the credentialing of senior medical practitioners are unambiguous.

In relation to the SA Health Pelvic Mesh Clinic, the Committee acknowledges the problems that COVID-19 has presented, along with other setbacks, in SA Health recruiting a credentialed and experienced Urogynaecologist to practice at the SA Pelvic Mesh Clinic.

COVID-19 has also presented issues for progressing a memorandum of understanding with the Royal Women's Hospital in Melbourne for South Australian women to travel to for full mesh removal appraisal and surgery.

Notwithstanding, it is a matter of urgency, that mesh injured women in South Australia receive immediate access to a surgeon who can not only perform full mesh removal surgery, but in fact

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66 ACSQHC, *NSQHS Clinical Governance Standard*. Accessed 9 February 2021 Clinical Governance Standard | Australian Commission on Safety and Quality in Health Care

67 RACS, *Written submission No. 62*, 8 October 2019: 5.

68 See SA Health, *Credentialling and Defining the Scope of Clinical Practice for Medical and Dental Practitioners Policy Directive*, V. 2, 6 August 2018.

69 RACS, *Written submission No. 62*, 8 October 2019: 5.

70 Dr Samantha Pillay, *Hansard*, 15 June 2020: 100.

properly assess the complications of the 27 or 28 patients on the SA Pelvic Mesh Clinic waiting list.[71] That these patients have been waiting to be appropriately assessed by a credentialed Urogynaecologist since the Clinic started in late 2018, is unacceptable in the Committee's view.

Psychological and Physical Service Needs

The evidence provided by mesh injured people was at times confronting. While the acute and sometimes devastating physical damage caused by mesh cannot be understated, the toll on the psychological wellbeing of victims of mesh is also acute.

The Committee heard from witnesses who have as a consequence of mesh related complications developed mental health difficulties including depression, anxiety and suicidal thoughts. The Committee found that all of the symptoms of mesh injuries, whether physical or psychological, affect the families and people around the mesh injured person.

Accounts from witnesses told of years spent managing injuries and pain, without hope, while opportunities to participate in family life, relationships, social life, and recreational activities diminished. At the same time, these witnesses, and their families suffered from the degradation forced on them by the medical profession through the failure of GPs, surgeons and gynaecologists who refused to believe mesh was the cause of their patients' suffering. These families also need recognition, support and assistance in managing the many impacts of mesh.[72]

Evidence suggests there is a need to treat people who have had adverse events from mesh devices with a person-centred approach. As part of this, care for the 'whole' of a person is crucial and involves including in the person's treatment plan, their family, friends and loved ones.[73] As part of the person-centred approach which was highlighted by the Queensland Pelvic Mesh Service (QPMS) as a best practice model for mesh injured women; service providers must respect the knowledge of the patient, and understand that the patient brings with her, lived experience of physical and mental traumas. The QPMS advises, health services must partner with patients and patients need to be able to lead in designing their treatment plans. [74]

The Committee was impressed with the QPMS, and the emphasis the service placed on the lived experience of mesh survivors, incorporating their contributions into the service delivery framework. The Committee would like to see a similar model developed at the SA Pelvic Mesh Clinic and believes this model has potential to provide more respectful and holistic care to mesh injured people.[75]

As at September 2020, 23 per cent of the SA Pelvic Mesh Clinic's active patients have utilised the Psychology service,[76] and the Committee understands there will be a long journey to rebuild trust in the medical profession for many of the patients attending the Clinic.

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71 Evidence provided by Dr Roy Watson was not clear exactly how many women are still waiting, for example if the number is 27 or 28. See Dr Roy Watson, *Hansard*, 1 February 2021: 236.

72 Queensland Pelvic Mesh Service, Ms Nicolle Germano and Ms Michelle Kennedy, *A Person-Centred Care Approach in the Treatment of Mesh Injured Women,* 2018: 9. Received 25 November 2020.

73 Queensland Pelvic Mesh Service, Ms Nicolle Germano and Ms Michelle Kennedy, *A Person-Centred Care Approach in the Treatment of Mesh Injured Women,* 2018: 9. Received 25 November 2020.

74 Queensland Pelvic Mesh Service, Ms Nicolle Germano and Ms Michelle Kennedy, *A Person-Centred Care Approach in the Treatment of Mesh Injured Women,* 2018: 2; 7. Received 25 November 2020.

75 Queensland Pelvic Mesh Service, Ms Nicolle Germano and Ms Michelle Kennedy, *A Person-Centred Care Approach in the Treatment of Mesh Injured Women,* 2018: 9. Received 25 November 2020.

76 SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 7.

In South Australia, as in other states, territories and indeed other advanced economies, we can as a general rule, expect a very high standard of care from our health system, including in the regulation of medical devices. Disappointingly, where these systems have concerned women with urogynaecological medical needs and for some people with hernia, the standard has fallen short of expectation.

While the Committee acknowledges the apology given by the Hon Greg Hunt, Federal Minister for Health, in 2018, the Committee believes as a step towards healing for South Australians who have been injured by mesh, the Government could issue an apology of its own, on behalf of the health system. The Committee has made a recommendation to that effect.

Current Regulatory Requirements for Mesh

Evidence given to this inquiry shows, the perception that mesh was a "cure-all" for women's urogynaecological conditions has been pervasive. While the Committee did not receive any evidence to suggest that mesh implants were being performed riskily, there is substantial evidence that suggests GPs and gynaecologists were quick to recommend mesh as the first treatment option for many of the mesh injured witnesses.

Some witnesses expressed concerns that this preference is still prevalent in the gynaecological profession. Although there is evidence to suggest mesh can still provide benefits for women with SUI, by way of a mid-urethral implant, the specialty colleges and associations may still have some way to go to change the culture of acceptance of mesh as the 'first line' treatment in any urogynaecological procedure.

Efforts to change such a persistent culture may be helped by the TGA's cancellation from the ARTG, of all transvaginal implanted urogynaecological meshes for the treatment of POP. The TGA also cancelled all transvaginal implanted single incision 'mini-sling' meshes approved in the ARTG for the treatment of SUI, due to a lack of scientific evidence that the benefits outweigh the risks to patients.

However, the TGA did not cancel the transvaginal retropubic and transobturator mid-urethral 'slings' approved for the treatment of SUI, as the TGA found there was enough evidence to support their continued supply in Australia.[77] Approval by the TGA for continued entry in the ARTG for these devices, took into consideration the results of 34 long-term, randomised controlled trials.[78]

All implantable meshes have been reclassified by the TGA as Class III devices requiring greater evidence of efficacy and safety. As a consequence, there are now only four transvaginal implanted urogynaecological meshes, which are approved by the TGA for supply in Australia. These include two retropubic and two trans-obturator devices, all manufactured by Johnson & Johnson.[79]
Additionally, the following MBS items have been amended to clarify that MBS rebates will only be payable for procedures that do not employ the use of mesh, for example, only native tissue repairs will receive rebate:

35570 - Anterior vaginal compartment repair by vaginal approach for pelvic organ prolapse
35571 - Posterior vaginal compartment repair by vaginal approach for pelvic organ prolapse

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77 Government of Australia, Department of Health, Therapeutic Goods Administration (TGA), *TGA actions after review into urogynaecological surgical mesh implants. Stress urinary incontinence mid-urethral slings.* Accessed https://www.tga.gov.au/alert/tga-actions-after-review-urogynaecological-surgical-mesh-implants

78 Ms Tracey Duffy, Oral evidence, *Hansard*, 7 December 2020: 216.

79 TGA, *Up-classification of surgical mesh devices as of 1/12/20*. Accessed 1 December 2020 https://www.tga.gov.au/information-medical-practitioners-pending-classification-surgical-mesh-devices

35573 - Anterior and posterior vaginal compartment repair by vaginal approach for pelvic organ prolapse
35577 - Manchester (Donald Fothergill) operation for pelvic organ prolapse.[80, 81]

At the same time, references to 'with or without mesh' were removed from the following MBS items and MBS rebates will only be payable for procedures using 'autologous fascial sling', including the harvesting of sling material:

37042 - Bladder stress incontinence, sling procedure for, using autologous fascial sling
37043 - Bladder stress incontinence, Stamey or similar type needle colposuspension
37044 - Bladder stress incontinence, suprapubic procedure, Burch colposuspension.[82, 83, 84]

The Committee was deeply concerned to learn that as mesh was ubiquitously the 'go-to' treatment option, there are very few surgeons left in South Australia who can perform a native tissue repair for SUI, and virtually none who can perform a vaginal prolapse reconstruction from biological material.[85] This raises issues for women who will need to seek surgical treatment for POP or SUI in the future.

In looking ahead, it is hoped the upward reclassification of mesh, refinement of MBS item numbers, the APFPR and the proposed UDI will improve the safety of future mesh procedures, where they are used as a last option, and ensure prospective data of the number of women having mesh procedures and, potentially, all mesh procedures, will ensure the level of damage and heartbreak the Committee has heard of will not continue.

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80 Medicare Benefits Schedule Review Taskforce, *Gynaecology Clinical Committee Report 2018*, 2018:[105].

81 Ms Tracey Duffy, Email *RE: SA Parliament inquiry - surgical implantation of medical mesh in SA*, 26 November 2020: 1.

82 Ms Tracey Duffy, Email *RE: SA Parliament inquiry - surgical implantation of medical mesh in SA*, 26 November 2020: 1.

83 Medicare Benefits Schedule Review Taskforce, *Gynaecology Clinical Committee Report 2018*, 2018: [108-109 for item numbers 37043 & 37044].

84 See also Medicare Benefits Schedule Online: Standard Search | Medicare Benefits Schedule (health.gov.au)

85 Dr Ian Tucker, *Hansard*, 7 December 2020: 225 – 226.

Recommendations

The following recommendations of the Social Development Committee are made to the Minister for Health and Wellbeing, that the Minister:

1. Ensure compliance with requirements for reporting of adverse incidences in SA Health. Undertake an education program to increase the understanding by SA Health facilities staff, about what is a mesh related incident, in order to facilitate reporting in the Patient Incident Reporting system.

2. Undertake a broad consultation with the public and private hospital systems to ensure that all providers claiming services on the Medicare Benefits Schedule meet the requirements of the item descriptor in order for benefits to be payable for any medical mesh-related services.

3. Provide support through the National Cabinet Reform Committee (Health), for the progression of the National Clinical Quality Register (CQR) Strategy, including specifically a CQR for hernia mesh, and other mesh devices or a full mesh register, using the Australasian Pelvic Floor Procedure Registry as a model.

4. Continue to provide support through the National Cabinet Reform Committee (Health) for the progression of the Unique Device Identification system and associated research necessary to implement such a reporting system through the Therapeutic Goods Administration.

5. Through the National Cabinet Reform Committee (Health), advocate for the introduction of mandatory reporting by health care organisations and health professionals of adverse events associated with medical mesh implantable devices to the Therapeutic Goods Administration.

6. Undertake an audit to determine how South Australia is tracking with the newly implemented patient information leaflets and patient implant cards for pelvic mesh.

7. Provide funding for an education campaign to be targeted at SA Health facilities, to ensure that all patients considering a medical mesh device implant, receive adequate information prior to making a decision, and giving consent.

8. In relation to increasing the awareness of mesh-related injury and improving visibility of treatment options for mesh injured patients, as soon as practicable, undertake to:

    (a) Continue to urgently progress the SA Health Pelvic Mesh Clinic Communications plan for General Practitioners and ensure that the communications plan is published in the relevant medical associations and colleges' newsletters to their members, through the assistance of the Royal Australian College of General Practitioners; and that the plan include direct mail to doctors.

    (b) That SA Health, as a matter of urgency, pursue avenues to ensure South Australian women be included in the Australasian Pelvic Floor Procedure Registry pilot.

    (c) Give consideration to undertaking a further audit of women in South Australia, who having had urogynaecological surgery in the course of the last three years followed by a sequence of three year blocks going back to 2006, within both the private and public hospital systems (including day surgery centres), and notify

them of the issues that have been identified concerning pelvic mesh implants, and where they may seek advice and assistance.

9. Provide funding for an education campaign across SA Health regarding issues that may occur with medical meshes for hernia, which could extend to the private sector, through partnering with the Royal Australian College of General Practitioners and the Royal Australasian College of Surgeons.

10. Review the 'comprehensive education strategy' proposed by CALHN and the SA Pelvic Mesh Clinic for staff at the Royal Adelaide Hospital (RAH) to ensure that once an experienced credentialed Urogynaecologist surgeon is recruited to the SA Pelvic Mesh Clinic, the RAH is appropriately staffed to support South Australian women undergoing full and partial mesh removals, including post-operative staff. Further, that the existence of the SA Pelvic Mesh Clinic be widely communicated throughout the RAH and other SA Health facilities.

11. Investigate the potential for developing a 'hub and spoke' model of services, similar to the one being developed by the Queensland Pelvic Mesh Service, with the primary Centre of Excellence located in the SA Pelvic Mesh Clinic in Adelaide. This would benefit SA regional and rural mesh injured patients who have no choice but to travel long distances on numerous occasions for treatment in Adelaide.

12. Urgently raise for discussion at the earliest convenience, through the National Cabinet Reform Committee (Health), a proposal to urgently develop a 'hub and spoke' model for the full surgical removal of pelvic mesh for women across the States and Territories, whose mesh removals are considered to be the most complicated, and will require the most experienced urogynaecological surgeons in Australia.

13. On behalf of the Government of South Australia, consider issuing a public apology to the women and their families affected by medical mesh in South Australia, for the systemic failures of the Healthcare system in detecting and acting promptly on issues around medical mesh, and for continuing to implant mesh in the public hospitals, despite a lack of robust clinical and longitudinal research data on the efficacy and safety of medical mesh.

14. In relation to funding identified by SA Health for mesh injured women in South Australia undertake to:

    (a) Urgently develop a policy to release existing funding (that has been previously identified for approved Mesh Clinic patients to travel to Victoria for assessment for full removal of their mesh implants under a Memorandum of Understanding (MOU) with the Royal Women's Hospital), so that these patients may seek care and surgery in Victoria without additional suffering.

    (b) Following the successful establishment of an MOU, those women who were, or are, on the SA Pelvic Mesh Clinic waiting list for full mesh removal surgery and have proceeded with surgery, be assessed for compensation so they are not financially disadvantaged.

(c) As soon as practicable commit additional funding to the SA Pelvic Mesh Clinic so that the Clinic can increase the services the clinic can provide to mesh affected women. This funding could provide for additional staff including: urogynaecologist surgeon(s); nurse consultant; physiotherapist(s); counsellor(s); lived experience advocates; social worker(s); pain management professionals to provide services to mesh injured women and assist with lodgement of adverse events reports to the Therapeutic Goods Administration. Further, in determining a suitable funding increase, consideration should be given to lowering the threshold or level of complexity for acceptance to the clinic and the access to the specialist services it offers.

15. Provide funding for the SA Pelvic Mesh Clinic to re-establish the Consumer Advisory Group of the Clinic to be led by appropriately remunerated lived experience staff.

16. Whilst a 'hub and spoke' model is being examined, urgently consider implementing a program of 'mobile services' to regional and rural mesh injured patients on a twice-yearly basis. Patients should have access to all services they would ordinarily have access to when they attend clinics in Adelaide, with SA Health providing for specialist consultants to visit regional and rural patients in situ.

17. To inform services provided by the SA Pelvic Mesh Clinic, initiate a review to be led by people with lived experience of mesh injuries and contributed to, by a Consumer Advisory Group, of the available services and continuity of care for mesh affected patients who have had a full mesh removal but still experience ongoing pain associated with mesh and mesh related injuries.

(a) the number of people in South Australia adversely affected following the implantation of medical mesh

The Social Development Committee (the Committee) received evidence suggesting data sources for determining the number of people affected by the implantation of medical mesh are incomplete and therefore unreliable. The data that was able to be sourced provides a limited understanding of the extent of the possible adverse effects of *Pelvic Mesh* (urogynaecological) used in the treatment of pelvic organ prolapse (POP), including posterior and anterior vaginal prolapse and stress urinary incontinence (SUI) in women; and *Hernia Mesh* for meshes that are used to treat various kinds of hernias in both women and men.

The majority of written and oral submissions received were in relation to POP, SUI and Hernia. Three written submissions were received concerning mesh used in the treatment bowel prolapse.[86]

The Committee did not receive any evidence concerning meshes used in other procedures, for example in cosmetic treatments and as such, has not inquired into the number of people with adverse effects from these other meshes.

For each of these different types of mesh there are also different types of surgical procedures. The 2018 Senate Inquiry on the *Number of women in Australia who have had transvaginal mesh implants and related matters* (the Senate Inquiry) found it was difficult to gain accurate information relating to the number of pelvic mesh devices that have been used in Australia, as well as the number of procedures involving pelvic mesh. As a consequence, determining how many people have been adversely affected was also very difficult.[87]

This has also been true in relation to mesh devices implanted and procedures carried out in South Australia. However, as a result of recommendations made by the Senate Inquiry, it is expected that prospective records will hold much more valuable information than those concerning the years 1999 to 2019.

Context

The majority of individual witnesses who gave personal evidence to this inquiry, suffer from complications associated with the implantation of transvaginal pelvic mesh. Much of the medical professional evidence and studies contained in the literature reviewed, also related primarily to the transvaginal implantation of pelvic mesh. This includes mesh devices for POP and SUI, and involves mesh products from a number of different manufacturers.

The Committee's inquiry into the surgical implantation of medical mesh in South Australia has the benefit of findings and recommendations made by the Senate Inquiry, but it aims to address issues specific to South Australians where the use of both pelvic and hernia meshes are concerned. Although procedures involving transvaginal mesh (TVM) are now not standard procedure, some witnesses claim TVM is still considered "Gold Standard" by surgeons continuing to implant these products.

According to mesh victim advocates, there are still many women in South Australia who had a transvaginal mesh procedure undertaken and continue to live with severe and debilitating complications. Procedures for SUI can still be performed using TVM, and are continuing to be carried out in South Australia.

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[86] Names confidential, *Written submission No. 11*, 10 September 2019: 1; *Written submission No. 53*, 16 September 2019: 1; *Written submission No. 63*, 11 October 2019: 1.

[87] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 26 – 27.

There are also concerns that there may be many more people who have had a mesh device implanted and who may not have experienced problems associated with it, but may do so in the future.[88] Professor Guy Maddern, Director of Research at the Basil Hetzel Institute for Translational Health Research, suggested it may be more widespread and underappreciated than previously thought.[89] This was also indicated in relation to the mesh devices used in hernia, and Professor Maddern suggested more presentations of complications may come to the fore.[90]

It is noted that the majority of women who have had a surgical procedure involving pelvic mesh, and the vast majority of those people who have received a mesh implant for hernia, do not experience severe complications.[91, 92, 93] However, it has also been noted throughout the course of this inquiry, from the evidence received, that, for those people who do experience complications following implantation of mesh, the symptoms and resulting impacts are likely to be, more often than not catastrophic and long lasting. These impacts have the capacity to have negative, detrimental effects on many different aspects of a person's life.

Some of the women's individual submissions discuss the brand and type of mesh products used in their surgeries. The Committee has not reviewed individual mesh products as part of this inquiry, but it is known that given some medical meshes are still considered the best option for surgical treatment in some conditions, they are still being used in for the treatment of SUI and hernia repair.

Concern was raised by witnesses and submitters who have suffered adverse impact from mesh implant, that without mesh being banned entirely, surgeons will continue to use it as a 'first line' treatment, without providing patients with other treatment options. There was also concern raised, that there were still stockpiles of mesh products in circulation that had been cancelled by the Australian Register of Therapeutic Goods (ARTG), and that surgeons are still implanting mesh without fully informed consent.[94, 95, 96, 97, 98]

The Senate Inquiry, 2018 – Number of Women with Transvaginal Pelvic Mesh

The Report of the Senate Community Affairs References Committee's Inquiry on the *Number of women in Australia who have had transvaginal mesh implants and related matters* (the Senate Inquiry), in March 2018, found that the problems associated with pelvic mesh for the treatment of POP and SUI were largely located with pelvic mesh implanted through the transvaginal method. This included the surgical processes and techniques involved, as well as the products used.[99]

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88 Kim, *Hansard*, 30 November 2020: 194 - 195.

89 Professor Guy Maddern, Director of Research, Basil Hetzel Institute for Translational Health Research, Oral evidence, *Hansard*, 30 November 2020: 206.

90 Professor Guy Maddern, *Hansard*, 30 November 2020: 209.

91 Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 13; 30.

92 Professor Guy Maddern, *Hansard*, 30 November 2020: 206.

93 Dr Samantha Pillay, *Hansard*, 15 June 2020: 101.

94 Alicia, Oral evidence, *Hansard*, 17 February 2020: 3.

95 Tracey, Oral evidence, *Hansard*, 17 February 2020: 7.

96 John, Oral evidence, *Hansard*, 20 July 2020: 130.

97 Ebony, Oral evidence, *Hansard*, 20 July 2020: 129.

98 Eunice, Oral evidence, *Hansard*, 20 July 2020: 146.

99 Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 1 - 2.

The Senate Inquiry stated that there is no clear indication of how many Australian women have had transvaginal pelvic mesh implants, nor of the number of women experiencing complications following transvaginal pelvic mesh procedures.[100]

Although the Senate Inquiry only examined matters related to the use of transvaginal implanted pelvic mesh, evidence provided to the Social Development Committee (the Committee) in relation to the number of South Australian women who have had pelvic mesh surgically implanted, through a transvaginal procedure or via the abdomen (including laparoscopically) is consistent with the Senate Inquiry's findings that the data is incomplete, and therefore largely inaccurate.

There is no single source of data that is easily and readily available to determine an accurate number of people who have had a pelvic mesh implant, nor of the number of occurrences of adverse events amongst this cohort. Likewise, there is no way to know the number of mesh recipient's support people, family, friends, carers, who have been affected more broadly, when adverse events occur.

The Senate Inquiry found that while there was sound data available from the following sources, these sources were incomplete and, the evidence showed "…there are important limitations associated with using each of these data sets to accurately track mesh usage."[101] These included:

- 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.[102]

The Senate Inquiry found, data sourced from the MBS item numbers did not differentiate mesh from non-mesh procedures and did not include inpatient medical and surgical procedures for public hospital funded patients.[103]

Evidence was provided to the Senate inquiry by Medibank for health insurance claims on "a surgical procedure relating to the insertion of a 'polypropylene device' from 2012 to 2016" however, as with the MBS data, were only for private patients and thus are incomplete.[104]

Data obtained through searches of the Australian Institute for Health and Wellbeing (the AIHW) was considered relatively limited due to narrow coding in the ICD-10 (10th edition of the International Statistical Classification of Diseases and Related Health Problems (ICD)) used by the AIHW in recording hospital admissions.[105, 106]

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[100] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 37.

[101] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 37.

[102] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 37.

[103] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 39.

[104] Medibank/ RANZCOG cited Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 50.

[105] RANZCOG cited Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 41.

[106] Medibank/ RANZCOG cited Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 51.

Data provided to the Senate Inquiry from the pelvic floor procedures database, kept by the Urogynaecological Society of Australasia , was considered consistent with the AIHW and MBS data, which indicated that from 1999, approximately 120 000 women had a mid-urethral sling mesh procedure in Australia.[107]

However, as with reporting by medical professionals to the Therapeutic Goods Administration (the TGA), reporting of adverse events in this database is voluntary, and as a consequence figures for complications were lower than expected.[108] Associate Professor Christopher Maher of the University of Queensland, advised the Senate Inquiry:

> […] after adjusting it [the MBS item data] 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 [since introduction in Australia] could be within the range of 150 000 to 175 000 [Australia-wide].[109]

In response to the Senate Inquiry, the Australian Government recognised the limitations in the existing data collection methods and the link longitudinal data has to the post-market surveillance activities by the TGA, by funding the Australasian Pelvic Floor Procedure Registry.[110, 111]

Department for Health and Wellbeing

As part of the South Australian Government's commitment to implementing the recommendations of the Senate Inquiry, the Department for Health and Wellbeing through SA Health, undertook an audit of public hospital records to estimate the percentage of women who had had urogynaecological surgery during the period 2003 to 2018, to estimate how many women may be likely to require the assistance and support of the SA Health Pelvic Mesh Clinic (the Mesh Clinic).[112]

According to SA Health, the Transvaginal Mesh Audit, 2018 (the TVM Audit) examined the records of 230 patients from seven SA Health sites, from 2003 until 2018. SA Health advised, of its 33 hospital facilities, only seven were audited.

The audit did not include the Royal Adelaide Hospital, the Flinders Medical Centre, or the Repatriation General Hospital because they did not use ORACLE iProcurement Solution for procurement data.

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[107] UGSA/RANZCOG cited Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 52.

[108] UGSA/RANZCOG cited Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 51.

[109] Associate Professor Christopher Maher, University of Queensland, Faculty of Medicine. Cited Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 40.

[110] Australian Government, Department of Health, *Written submission No. 66*, 31 October 2019: 4.

[111] Australian Government, *Australian Government Response to the Senate Community Affairs References Committee Report: Number of women in Australia who have had transvaginal mesh implants and related matters*, October 2019: 12.

[112] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 2.

The TVM Audit indicated:

Results: All sites

- 10,989 possible procedures – SA Health Hospital Activity data (i.e. from 2003 – 2018).
- 230 medical records were audited across seven SA Health sites, 15 of which were excluded from the audit due to incorrect coding, a medical record or all volumes of a medical record not being available.
- 37% patients re-presented following the TVM procedure – with either SUI and/or POP symptoms.
- The audit data from the above diagnosis codes indicated the average age of the patient (on the day of the procedure) to be 56 years old.
- The average number of days between procedure and re-presentation with:
    - SUI symptom was 3.3 years.
    - POP symptom was 3.8 years.
- Applying the audit findings, it is expected that approximately 34% had a mesh implant; and it is estimated that:
    - approximately 37% of patients who had a mesh implant have or will re-present with either SUI or POP symptoms
    - annually approximately 100 women will re-present with SUI or POP symptoms post their mesh procedure
    - patients re-presenting with SUI symptoms following a mesh procedure will be 59 years old
    - patients re-presenting with POP symptoms following a mesh procedure will be 60 years old.[113]

SA Health advised that the above findings were based on the following listed diagnoses of patients at the seven SA Health sites during the relevant period:

Diagnosis (C)	Diagnosis (D)
N813	Complete uterovaginal prolapse
N393	Stress incontinence
N812	Incomplete uterovaginal prolapse
N814	Uterovaginal prolapse unspecified
N816	Rectocele
N811	Cystocele
T830	Mech comp urinary (indwelling) catheter
N394	Other specified urinary incontinence
T8389	Oth comp foll GU prosth dev impl gft
N993	Prolapse vag vault after hysterectomy
T831	Mechanical comp oth urinary dev impl
N815	Vaginal enterocele
N819	Female genital prolapse unspecified
N818	Other female genital prolapse
N810	Female urethrocele
T8385	Erosion of GU prosth materials
T8383	Pain foll GU prosth dev impl gft
T839	Unsp comp GU prosth dev impl gft

Fig. 1: SA Health provided Hospital Activity data based on a list of prescribed diagnoses from 2003 – 2018.[114]

[113] SA Health, *Transvaginal Mesh Audit 2018 Report Summary*, received 8 September 2020: 5.

[114] SA Health, *Transvaginal Mesh Audit 2018 Report Summary*, received 8 September 2020: 3.

SA Health provided that the following procedures may involve the use of pelvic mesh, and were still being performed in SA Health hospitals:

Code	Procedure	Code	Procedure
35684.00	Laparoscopic Burch Colposuspension	37044.02	Revision of retropubic proc for female stress incont
35599.00	Sling proc for stress incont female	07T00ZZ	Vaginal hysterectomy - Resection of Head Lymphatic, Open Approach
35570.00	Anterior repair	37340.00	Div Ureth s/g foll stress incont proc
35599.01	Revision Sling proc for stress incont female	36660.00	Vaginal reconstruction
35571.00	Posterior repair	35577.00	Repair pelvic floor prolapse
37043.00	Transvaginal needle suspension stress incont	N39.4	Other specified urinary incontinence
35573.00	Anterior & Posterior Repair	N813	Complete uterovaginal prolapse
37044.01	Retropubic proc for female stress incont	37339.00	Inj/o paraurethral bulk, female incontinence
35597.01	Sacrospinous Colpolexy	N993	Prolapse vag vault after hysterectomy
35597.00	Laparoscopic sacral colpoexy	35597.01	Sacral colpoexy

Fig. 2: SA Health List of procedures with a Diagnosis-related group (DRG) Code that address implantation of pelvic mesh (provided by SA Health as at Oct 2020).[115]

However, the Committee notes recent actions in up-classifying mesh as a Class III risk medical device by the TGA, may affect those procedures.

Associate Professor Christopher Benness, Chair, Urogynaecology Subcommittee, Royal Australian and New Zealand College of Obstetricians and Gynaecologists, stated the rate of complications from the transvaginal implantation of mesh for vaginal prolapse was around 12 per cent, with the complication rates for transvaginal implanted mesh slings for SUI at around 5 per cent.[116] Assoc. Professor Benness advised:

> It is estimated that approximately 33,000 women in Australia have had a vaginal mesh repair for prolapse since 2005, when the mesh kits became generally available. Up to about 3,000 of these were performed in South Australia. There is no reliable data source regarding the number of women adversely affected. However, it is estimated from the data that is available that approximately 100 women in South Australia have been adversely affected.[117]

It is not clear if the figures given by Assoc. Professor Benness relate to one type of prolapse procedure involving mesh. However, SA Health confirmed, based on the data reviewed in the Mesh Audit, approximately 3374 women had received a pelvic mesh implant during the period 2003 to 2018 in South Australian public hospitals, however, this was not specific as to the type of device.[118]

The SA Health data also provides that approximately 100 women per year with a mesh implant will experience adverse effects, or as SA Health advised, "…will re-present with SUI or POP symptoms post their mesh procedure."[119]

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[115] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 8.

[116] Associate Professor Christopher Benness, Chair, Urogynaecology Subcommittee, Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Oral evidence, *Hansard*, 1 June 2020: 81.

[117] Associate Professor Christopher Benness, *Hansard*, 1 June 2020: 81.

[118] SA Health, *Responses to Questions on Notice, Hansard,* 7 September 2020, received 3 November 2020: 8.

[119] SA Health, *Transvaginal Mesh Audit 2018 Report Summary*, received 8 September 2020: 5.

SA Health suggested, issues with obtaining accurate data for both the use of, and complications resultant from pelvic mesh in SA public hospitals, was due to the use of differing procurement systems across hospital sites.[120]

SA Health procurement of mesh devices

As an indication of the mesh products still in circulation within the State's public health system, SA Health provided procurement details for all surgical mesh purchased by SA Health in 2019/20. Fifty-five different types of mesh devices, comprising 1441 devices from seven suppliers, for the use in surgical procedures, including for POP, SUI and hernia were procured by SA Health in the 2019/20 financial year.[121] The suppliers included the following companies:

- Getinge Australia Pty Ltd
- Atrium Medical
- Stryker Australia Pty Ltd
- Bard Australia Pty Ltd
- Medtronic Australasia Pty Ltd
- Johnson & Johnson Medical Pty Ltd
- Cook Medical Australia Pty Ltd[122]

In 2018/19, there were 1460 mesh devices ordered, with the Minister for Health and Wellbeing noting:

> It is noted that this is considerably lower than separations shown in Table 1 [2751 separations], reflecting the difficulty in isolating which procedures used mesh devices. In some instances the product description can be matched to the procedure type (eg. 'mesh hernia partially absorbable'), but in other cases the description of the device is generic (eg. 'mesh knitted vicryl').[123]

Medicare Benefits Schedule Data and Private Hospitals

All medical services that are subsidised through the Medicare Benefits Schedule (MBS) and contain an item number are publicly reported. Medical services performed in a public hospital, for private patients, are also captured by the MBS. It is estimated that services performed in the public system, that do not attract an MBS rebate, account for one third of all gynaecological procedures.[124]

According to Dr Samantha Pillay of the Royal Australasian College of Surgeons (RACS), there are reliable statistics through the MBS data, for the number of women who have had a mesh implant and/or removal for SUI via the *retropubic mid-urethral* surgical process.[125]

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[120] SA Health, *Transvaginal Mesh Audit 2018 Report Summary*, received 8 September 2020: 4.

[121] SA Health, *Responses to Questions on Notice*, *Attachment 26, Hansard*, 7 September 2020, received 3 November 2020: 1 – 6.

[122] SA Health, *Responses to Questions on Notice*, *Attachment 26, Hansard*, 7 September 2020, received 3 November 2020: 1 – 6.

[123] Hon. Stephen Wade MLC, Minister for Health and Wellbeing, *Written submission No. 65*, 15 October 2019: 1 - 2.

[124] Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), *Written submission No. 45*, 13 September 2019: 5.

[125] Dr Samantha Pillay, *Hansard*, 15 June 2020: 98.

Until the review of urogynaecological surgery procedures by the Gynaecology Clinical Committee of the Medicare Benefits Schedule Review Taskforce (MBS Review Taskforce) (2018), other than for mid-urethral 'sling' revisions and division, there have been no item numbers specific to removal of other pelvic mesh implants. This means repeat surgeries for other pelvic mesh complications have not been recorded through the MBS.[126]

Evidence provided by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) shows estimated numbers for pelvic mesh used in POP is unknown.[127]

However, RANZCOG stated, based on the MBS procedure codes from 2004 to July 2018, an estimated 19 262 procedures were undertaken for the most common causes of prolapse in South Australia.

These included both transvaginal and abdominal procedures, but do not specify whether mesh was or was not used, or how many were repeat surgeries:

35570 – Anterior vaginal repair
35571 – Posterior vaginal repair
35573 – Combined anterior and posterior vaginal repair
35568 – Vaginal vault suspension procedure
35597 – Abdominal vault support procedure with mesh sacral colpopexy.[128]

Also based on the MBS data, according to RANZCOG, from 2002 to 2019 there were 6 697 sling procedures (MBS item 35599) undertaken in South Australia. There were also 470 mesh sling divisions (MBS item 37340).

RANZCOG also advised that the Australian Institute for Health and Welfare (AIHW) data could generally be relied upon to provide an estimate of the number of mesh sling related procedures for SUI as it "lists every surgical procedure done in Australia, both in a public and private setting."[129]

RANZCOG provides that the AIHW data shows there were 106 150 sling procedures (AIHW item 35599-00) undertaken in Australia from 2002 – 2019, with 7 777 listings for mesh sling revisions and divisions (AIHW items 35599-01 and 37340-00). However, it is not possible to extract complete data from the AIHW for South Australia only.[130]

Dr Pillay's evidence showed that the Medicare data for slings in South Australia from January 1999 to April 2020 was 7 327 mesh slings implanted in South Australia, with approximately 7.4 per cent of these or 542 procedures resulting in a division or a removal.[131]

However, Dr Pillay warned that complications for non-mesh related issues and repeat surgeries for a single patient need to be taken into consideration, which may reduce the overall percentage of complications:

> […] there are limitations with this data because it includes what would be considered non-mesh related complications, such as obstruction, where any sling, mesh or fascial can result in enough difficulty voiding that the sling is subsequently divided. [132]

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[126] RANZCOG, *Written submission No. 45*, 13 September 2019: 5.

[127] RANZCOG, *Written submission No. 45*, 13 September 2019: 8.

[128] RANZCOG, *Written submission No. 45*, 13 September 2019: 8 – 9.

[129] RANZCOG, *Written submission No. 45*, 13 September 2019: 5.

[130] RANZCOG, *Written submission No. 45*, 13 September 2019: 5 – 7.

[131] Dr Samantha Pillay, *Hansard*, 15 June 2020: 98.

[132] Dr Smanatha Pillay, *Hansard*, 15 June 2020: 98.

Dr Pillay commented that the data for mesh explantation, as with the data for implantation, does not indicate patients who could be counted more than once due, for example where more than one procedure for mesh removal and multiple procedures for one patient were reported.[133]

Unlike mesh sling removal or division procedures for SUI, until recently, Medicare did not provide numbers for POP mesh removal procedures nor did the MBS item numbers separate a mesh from a non-mesh repair.[134] Dr Pillay advised:

> The anterior repair is the most common type of prolapse repair performed and the number of anterior repairs in South Australia from 1999 to April 2020, either performed alone or in combination with other repairs, is 17,235, but the data does not provide details over who had mesh implants and who did not.[135]

The Australasian Pelvic Floor Procedure Registry Steering Committee (APFPR Committee), Monash University commented:

> Submissions to the Australian Senate inquiry estimated that up to 150,000 women may have received mesh implants in Australia. Assuming South Australian hospitals perform approximately 8% of SUI and POP procedures (based on MBS item numbers), as many as 12,000 may have had an SUI or POP mesh procedure, depending on the number of South Australian surgeons using mesh. There is currently no accurate source for estimating the number of women adversely affected by SUI or POP mesh, differentiating what is a mesh complication separate from complications associated with pelvic floor surgery in general.[136]

MBS items updated

The Urogynaecology Working Group of the MBS Review Taskforce (MBS review taskforce), which reported in the Gynaecology Clinical Committee Report, 2018, recommended MBS item numbers be introduced for POP and SUI mesh removals (Recommendation 50).[137] The following item numbers have subsequently been introduced to the Medicare Benefits Schedule:

35581 – *Vaginal procedure for excision of graft material in symptomatic patients with graft related complications, including graft related pain or discharge and bleeding related to graft exposure, less than 2cm^2 in its maximum area, either singly or in multiple pieces, other than a service associated with a service to which item 35582 or 35585 applies.*

35582 – *Vaginal procedure for excision of graft material in symptomatic patients with graft related complications, including graft related pain or discharge and bleeding related to graft exposure, more than 2cm^2 in its maximum area, either singly or in multiple pieces, other than a service associated with a service to which item 35581 or 35585 applies.*

35585 – *Abdominal procedure either open, laparoscopic or robotic, for removal of graft material in patients symptomatic with graft related complications, including graft related pain or discharge and bleeding related to graft exposure or where the graft has penetrated adjacent organs such as the bladder (including urethra) or bowel, including retroperitoneal dissection and mobilisation of*

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133 Dr Samantha Pillay, *Hansard*, 15 June 2020: 99.

134 Dr Samantha Pillay, *Hansard*, 15 June 2020: 99.

135 Dr Samantha Pillay, *Hansard*, 15 June 2020: 99.

136 APFPR Committee, Monash University, *Written submission No. 41*, 13 September 2019: 3.

137 Medicare Benefits Schedule Review Taskforce, *Gynaecology Clinical Committee Report 2018*, 2018:[107]. Accessed 21 September 2020 https://www1.health.gov.au/internet/main/publishing.nsf/Content/mbs-review-2018-taskforce-reports-cp/$File/Gynaecology-Clinical-Committee.pdf

bladder and/or bowel, other than a service associated with a service to which item 35581 or 35582 applies.[138]

Changes were also recommended by the MBS review taskforce to increase the list of reasons for removal of mid-urethral slings, to include issues such as urethral or sling related pain or infection.[139] This will allow for a larger cohort of patients to access the Medicare rebate for removals.

Dr Pillay advised since introduction there have been four, nine and 10 cases under item numbers 35581, 35582 and 35585 respectively, performed in South Australia, since the MBS Review Taskforce report, to the end of April 2020.[140]

The MBS review taskforce recommended amending MBS items to clarify that MBS rebates will only be payable for procedures that do not employ the use of mesh, for example, only native tissue repairs will receive rebate (Recommendation 49): [141, 142]

35570 - Anterior vaginal compartment repair by vaginal approach for pelvic organ prolapse
35571 - Posterior vaginal compartment repair by vaginal approach for pelvic organ prolapse
35573 - Anterior and posterior vaginal compartment repair by vaginal approach for pelvic organ prolapse
35577 -Manchester (Donald Fothergill) operation for pelvic organ prolapse, for the surgical repair of POP

At the same time, references to 'with or without mesh' were removed from MBS items clarifying that that MBS rebates will only be payable for procedures using autologous fascial sling, including harvesting of sling (Recommendation 51):[143, 144, 145]

37042 - Bladder stress incontinence, sling procedure for, using autologous fascial sling
37043 - Bladder stress incontinence, Stamey or similar type needle colposuspension
37044 - Bladder stress incontinence, suprapubic procedure for, eg. Burch colposuspension.

The changes have been welcomed by mesh injured advocates, however the reliance on MBS item numbers as a source for recording how many people access mesh-related services will still be problematic.

According to Ms Duffy, while the MBS item numbers have clearer descriptions regarding the services performed, there will still be a lack of 'granularity' in the data retrieved. This is because the

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[138] Australian Government, Medicare Benefits Schedule Online. Accessed 11 December 2020 Item 35581 | Medicare Benefits Schedule (health.gov.au).

[139] Ms Tracey Duffy, Email *RE: SA Parliament inquiry - surgical implantation of medical mesh in SA*, 26 November 2020: 1.

[140] Dr Samantha Pillay, *Hansard*, 15 June 2020: 98.

[141] Medicare Benefits Schedule Review Taskforce, *Gynaecology Clinical Committee Report 2018*, 2018:[105].

[142] Ms Tracey Duffy, Email *RE: SA Parliament inquiry - surgical implantation of medical mesh in SA*, 26 November 2020: 1.

[143] Ms Tracey Duffy, Email *RE: SA Parliament inquiry - surgical implantation of medical mesh in SA*, 26 November 2020: 1.

[144] Medicare Benefits Schedule Review Taskforce, *Gynaecology Clinical Committee Report 2018*, 2018: [108-109 for item numbers 37043 & 37044].

[145] See also Medicare Benefits Schedule Online: Standard Search | Medicare Benefits Schedule (health.gov.au)

MBS was not intended to perform as a registry in the same way a unique device identification system might.[146]

Therapeutic Goods Administration - Adverse Event Reporting

The first recorded adverse events in Australia, for both transvaginal mesh and hernia mesh implants were only reported to the Therapeutic Goods Administration (TGA) in 2006.[147] Since then, there has been a steady increase in the number of reports made to the TGA concerning complications in the use of medical mesh, as the issues with mesh have received more wide-spread attention.[148]

The medical device Incident Reporting and Investigation Scheme (IRIS) of the TGA, is responsible for the administration of all reports of adverse events or problems associated with medical devices.

On its website, the TGA advises 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.[149]

Under the *Therapeutic Goods Act 1989* it is mandatory for sponsors and manufacturers to report serious or potentially serious adverse events associated with their medical device to the TGA. The TGA also advises that "In cases where it is difficult to judge whether to report or not, then reporting is recommended."[150]

An "adverse event" is described by the TGA as constituting the following:

- death
- a serious injury or serious deterioration to a patient, user or other person, including
    - a life-threatening illness or injury
    - permanent impairment of a body function
    - permanent damage to a body structure
    - a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.[151]

A "near adverse event" is described by the TGA as:

- A 'near adverse event' is an event that might have led to a death or serious injury. It may be that due to the timely intervention of a healthcare practitioner a death or serious injury did not occur. For an event to be defined as a near adverse event, it is sufficient that:

    - an event associated with the device happened
    - if the event occurred again, it might lead to death or serious injury

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146 Ms Tracey Duffy, *Hansard*, 7 December 2020: 220.

147 Ms Tracey Duffy, *Hansard*, 11 May 2020: 66.

148 Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 2.

149 TGA, *Medical Device Incident Reporting and Investigation Scheme (IRIS),* "What should be reported?" Accessed 22 September 2020 https://www.tga.gov.au/medical-device-incident-reporting-investigation-scheme-iris

150 TGA, *Medical Device Incident Reporting and Investigation Scheme (IRIS)*. Accessed 22 September 2020 https://www.tga.gov.au/medical-device-incident-reporting-investigation-scheme-iris

151 TGA, *Medical Device Incident Reporting and Investigation Scheme (IRIS)*. Accessed https://www.tga.gov.au/medical-device-incident-reporting-investigation-scheme-iris

- testing or examination of the device or the information supplied with the device, or scientific literature indicated some factor that could lead to a death or serious injury.[152]

The Medical Technology Association of Australia (MTAA) noted in their written submission, adverse event reporting functions as an early warning system; something the DoH recognised did not happen for transvaginal mesh devices:[153]

> Adverse event reporting is an essential part of post-market safety monitoring of therapeutic goods, because it provides important information on the nature and magnitude of the problem, and reassess, if necessary, the risk profile of the therapeutic good. Early signal detection enables minimising harm to patients.[154]

The MTAA further advised that not all incidents are medical device adverse events, and they do not need to be reported if:

- The issue was found by the user prior to using the device.
- The adverse event was caused solely by patient conditions.
- The adverse event occurred after the medical device reached its end-of service life.
- The device protection against a fault functioned correctly.
- There is a remote likelihood of occurrence of death or serious injury.
- The adverse event represents an expected and foreseeable side effect that is documented in manufacturer's Instructions for Use or labelling.
- The adverse event is described in an advisory notice
- TGA has granted a reporting exemption.

None of the above exemption from reporting obligations apply if:

- TGA identified the adverse event as an issue that requires close monitoring; or
- A change in trend (usually an increase in frequency) or pattern is identified; or
- The adverse event is associated with user error, which indicated that the manufacturer's Instructions for Use may require improving.[155]

The Database of Adverse Event Notifications (the DAEN) is the collation of medical devices used in Australia, that have had adverse events recorded against them. One of the concerns raised about the role of the DAEN as a registry of adverse events for implanted devices, is that it does not contain a complete picture, or dataset of an individual event. Indeed, the TGA advises that the report of an adverse event in relation to a medical device should not be taken to mean that the medical device is the cause of the adverse event.[156]

Another issue in the DAEN's reporting capacity, is the DAEN's primary function is for the regulation of medicines and medical devices, not the clinical capabilities and practices of the medical profession, and surgeons. The TGA has no jurisdiction over the training, qualifications or abilities of medical practitioners and does not require information relating to any incidents that may have been caused through the clinical process.[157]

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[152] TGA, *Medical Device Incident Reporting and Investigation Scheme (IRIS)*. Accessed https://www.tga.gov.au/medical-device-incident-reporting-investigation-scheme-iris

[153] Department of Health, *Written submission No. 66*, 31 October 2019: 5.

[154] Medical Technology Association of Australia (MTAA). *Written submission No. 39*, 13 September 2019: 7.

[155] MTAA, *Written submission No. 39*, 13 September 2019: 5.

[156] TGA, *Database of Adverse Event Notifications – medical devices*. Accessed 22 September 2020 https://apps.tga.gov.au/prod/DEVICES/daen-entry.aspx

[157] Ms Tracey Duffy, *Hansard*, 11 May 2020: 70.

In light of this, the IRIS is unable to provide any accurate line of sight on which events are thought to be directly caused by a device, and which events may be attributed to surgical technique or practice.

The Committee heard adverse event reporting for mesh devices had been sparse prior to the Senate Inquiry.[158] A number of factors have been cited as potential encumbrances to patients and medical professionals using the online adverse event reporting forms, along with evidence that there was a significant lag in the time between an event occurring, and a patient or medical professional making the report to the TGA.[159]

Information recorded into the IRIS by a consumer or medical professional is voluntary and as such not all data sets are 'required' information for the report to be uploaded. Further, the TGA adverse event recording system looks at the total across Australia, rather than looking at specific state-by-state comparisons.[160]

Ms Tracey Duffy explained the TGA had been working with the states and territories to improve the manner in which adverse events were reported:

> […] we've focused on working more proactively with state and territory health departments and also private hospitals to try to improve the rate of adverse event reporting that's coming through from healthcare facilities. On the other hand, in terms of consumers and GPs, being able to make the general public aware that the TGA actually exists is a really big part of the knowledge base and the understanding that needs to improve in the community and how to report adverse events and what is an adverse event.[161]

Despite pelvic mesh being approved for use in Australia since the late 1990s, the first adverse events for mesh weren't recorded with the TGA until 2006. The TGA did not undertake investigations into any adverse events until 2008, the TGA then began actively monitoring pelvic mesh devices. This included monitoring clinical evidence, and publishing information for the public and health professionals.[162]

In 2012, the TGA undertook a post-market literature review of mesh devices however, it wasn't until 2013 that the TGA undertook a comprehensive post-market review of all urogynaecological mesh devices, reporting in 2014.[163, 164]

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158 Ms Tracey Duffy, *Hansard*, 11 May 2020: 68.

159 Dr Magdalena Simonis, Royal Australian College of General Practitioners (RACGP), Oral evidence, *Hansard*, 21 September 2020: 168.

160 Ms Tracey Duffy, *Hansard*, 11 May 2020: 73.

161 Ms Tracey Duffy, *Hansard*, 11 May 2020: 69.

162 Ms Tracey Duffy, *Hansard*, 11 May 2020: 66.

163 Senate Community Affairs and References Committee, *Inquiry Report*, *Attachment 1- Urogynaecological Mesh Chronology*, March 2018: 32 – 33.

164 TGA, *Urogynaecological surgical mesh implants review*. Accessed 22 September 2020 https://www.tga.gov.au/publication-issue/medical-devices-safety-update-volume-2-number-6-november-2014

Year	Health Care Professional	Patient/Carer	Sponsor	Annual Total
2006			1	**1**
2007			7	**7**
2008			17	**17**
2009			3	**3**
2010			8	**8**
2011		3	10	**13**
2012	1	5	17	**23**
2013	1	2	32	**35**
2014	25	5	10	**40**
2015	1	4	2	**7**
2016	6	26	4	**36**
2017	4	118	12	**134**
2018	10	102	13	**125**
2019	50	51	5	**106**
2020	64	14	2	**80**
TOTAL	**162**	**330**	**143**	**635**

Fig. 3: Device incident reports received by the Therapeutic Goods Administration in relation to Urogynaecological Mesh for All of Australia, as of 30 April 2020, by year and source of report.[165]

The Senate Inquiry reported it had received hundreds of submissions from women impacted by mesh, which was significant given the low reporting rates to the TGA, but the Senate Inquiry also noted the Health Issues Centre in Victoria had received more than two thousand:

> 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.[166]

While the number of adverse events recorded with the TGA shows there have been 635 reports in relation to urogynaecological pelvic mesh implants from 2006 to 30 April 2020 Australia-wide,[167] the number of women in South Australia who have been adversely affected by the implantation of pelvic mesh, remains unknown.

Without mandatory reporting by the medical profession the DAEN will continue to provide incomplete or inaccurate data on the extent of the numbers affected by mesh.[168]

Recent Actions taken by the TGA

As a result of the 2018 Senate Inquiry, the TGA proceeded to cancel all mesh devices approved in the Australian Register of Therapeutic Goods (ARTG) for the treatment of POP via transvaginal implant, and single-incision 'mini-slings' used in the treatment of SUI via transvaginal implant.[169]

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[165] Ms Tracey Duffy, Information taken on notice, *Hansard*, Monday 11 May 2020: 72, received 25 May 2020: 2.

[166] Health Issues Centre cited Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 42.

[167] Ms Tracey Duffy, *Hansard*, 11 May 2020: 68.

[168] Department of Health, *Written submission No. 66*, 31 October 2019: 5.

[169] Ms Tracey Duffy, *Hansard*, 11 May 2020: 66.

Since 2013, until 1 December 2020, forty-nine urogynaecological mesh devices were cancelled from inclusion in the ARTG.[170] Thirteen other pelvic mesh devices such as the mid-urethral 'sling' used to treat SUI, were found by the TGA to continue to have a positive risk-benefit profile and were still included in the ARTG until new 'up-classification' of the devices, from a medium risk profile (Class IIb) to a high-risk profile (Class III), came into effect on 1 December 2020. Eleven of those were for the treatment of SUI and two for the treatment of POP.[171]

Ms Tracey Duffy, advised the Committee on 7 December 2020 in her oral evidence that, as a result of the stronger regulatory requirements for mesh devices to receive approval for entry into the ARTG, there are now only four devices approved.[172]

All new implantable pelvic mesh devices (and hernia mesh devices), which are offered for sale on the Australian market are now required to meet the Class III requirements to be entered in the ARTG. Following is a list of urogynaecological mesh devices included in the ARTG that have met the regulatory requirements.

Sponsor	ARTG	Product range
Johnson & Johnson	351635	GYNECARE TVT Device Tension Free Vaginal Tape - Product code 810041B
Johnson & Johnson	351637	GYNECARE TVT Obturator System - Product code 810081
Johnson & Johnson	351636	GYNECARE TVT EXACT Continence System - Product code TVTRL
Johnson & Johnson	351638	GYNECARE TVT ABBREVO Continence System - Product code TVTOML

Fig.4 TGA Classification of urogynaecological surgical mesh devices[173]

The TGA approved supply of four urogynaecological mesh devices as Class III devices, which was published in ARTG on 11 December 2020 (Fig. 4). All other surgically implantable mesh devices must be upgraded to Class III by 1 December 2021 or they will be cancelled in the ARTG.[174]

According to the DoH, the TGA had commenced a program of improvements to adverse event reporting and feedback from consumers, consumer advocacy groups and healthcare professionals that has informed changes to online reporting forms to simplify and make them more user friendly. Further enhancements were being looked at for implementation later in 2020.[175, 176]

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[170] Australian Government, Department of Health, *Written submission No. 66*, 31 October 2019: 6.

[171] Ms Tracey Duffy, *Hansard*, 11 May 2020: 67.

[172] Ms Tracey Duffy, *Hansard*, 7 December 2020: 216.

[173] TGA, *Information for medical practitioners on pending up-classification of surgical mesh devices,* 21 December 2020. Accessed 12 February 2021 https://www.tga.gov.au/information-medical-practitioners-pending-classification-surgical-mesh-devices

[174] TGA, *Up-classification of surgical mesh devices as of 1/12/20*. Accessed 1 December 2020 https://www.tga.gov.au/information-medical-practitioners-pending-classification-surgical-mesh-devices

[175] Australian Government, *Progress Report on the Australian Government Response to the Senate Community Affairs References Committee Report: Number of women in Australia who have had transvaginal mesh implants and related matters*, October 2019: 5.

[176] Ms Tracey Duffy, *Hansard*, 7 December 2020: 214.

SA Health Policies and Procedures for Reporting Adverse Events in Public Hospitals

SA Health advised that the SA Health policy 'Safety Learning System Reporting Framework' guides SA Health staff in the reporting of all adverse events, that occur in SA Health facilities, including those associated with mesh implants.[177] The *Patient Incident Management and Open Disclosure Policy Directive*, which has been in place since 2011, requires compliance from all SA Health employees or persons who provide a health service on behalf of SA Health.[178]

No data was provided in evidence to the Committee by SA Health, pursuant to the *Patient Incident Management and Open Disclosure Policy Directive*, which would show how many public hospital incidents had been recorded.

Further, the data provided by the TGA cannot provide a breakdown as to how many reports were made by South Australian women or, how many procedures had been undertaken in a public or private hospital setting.[179] Ms Duffy commented that the Therapeutic Goods Act does not allow for the TGA to "prescribe" what hospitals should and should not do.[180]

Recording adverse events in private hospitals

All hospitals in Australia, including private hospitals and day procedure services, are required to comply with the National Safety and Quality Health Service Standards (NSQHS Standards) and there are a number of legislative mechanisms associated with the Commonwealth *Private Health Insurance Act 2007* requiring compliance from private hospitals.[181]

The NSQHS Standards provide:

> [Hospital governing bodies and managers] should ensure that an effective system is in place for recording, communicating, using and securely storing patient clinical information.
> This is to provide safe, high-quality care to individual patients, and to enable relevant information to be extracted for quality assurance, teaching and research purposes.[182]

Evidence suggests that approximately one third of women's gynaecological surgical procedures are performed in the public hospital system, meaning the remaining two thirds are performed in a private patient setting.[183] Despite this majority in patient numbers, there is no single source available to determine how many adverse events have occurred in this context.

Ms Duffy advised that as part of the consultation process for increasing awareness of mesh related issues, and the reporting of adverse events to the TGA, meetings were held with Day Hospitals Australia and the Australian Private Hospitals Association.[184]

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[177] SA Health, *Responses to Questions on Notice, Hansard,* 7 September 2020, received 3 November 2020: 2.

[178] SA Health, *Patient Incident Management and Open Disclosure Policy Directive*, V2.2, 2017: 6.

[179] Ms Tracey Duffy, *Hansard*, 11 May 2020: 73.

[180] Ms Tracey Duffy, *Hansard*, 7 December 2020: 221.

[181] Australian Government, Australian Commission on Safety and Quality in Health Care (ACQSHC). Accessed 5 November 2019 https://www.safetyandquality.gov.au/standards/nsqhs-standards

[182] ACSQHC, *Healthcare Clinical Governance Standard, Patient safety and quality systems, Action 1.16 Healthcare records.* Accessed 22 December 2020 Action 1.16 | Australian Commission on Safety and Quality in Health Care

[183] RANZCOG, *Written submission No. 45*, 13 September 2019: 5.

[184] Ms Tracey Duffy, *Hansard*, 11 May 2020: 70.

No submissions were received by the Committee from the private hospital system, and seeking a manual audit from each private hospital in South Australia was considered to be unfeasible.

Shine Lawyers – Numbers of Women from the J&J Class action

A number of witnesses disclosed they are pursuing legal action against manufacturers of pelvic mesh, and a number of witnesses have been or are involved with a class action. The most notable case in Australia to date, is *Gill v Ethicon Sàrl & Ors,* 2019, which was found in favour of the applicants.[185]

Ms Bridget Cook, Senior Associate with Shine Lawyers and who worked for the applicants in this class action, commented on the difficulties in seeking information regarding women who were implanted with mesh without a reliable registry of such information:

> In the absence of a registry to assist us in understanding the number of women implanted with mesh and the number of failed devices as part of a Johnson & Johnson action, we were required to seek the assistance of the court in identifying women who had likely been implanted with a Johnson & Johnson product. This process, in the absence of a registry, was a protracted and an expensive one but absolutely necessary in the circumstances. The result of that was that approximately 60,000 notices were distributed to Australian women identified as potentially having been implanted with a Johnson & Johnson device. Of those 60,000, on the information currently available to us, an estimated 2,500 notices were distributed to women who reside in South Australia.[186]

Adverse Outcomes from Hernia Mesh Implantation

The use of polypropylene mesh in the surgical repair of hernia in Australia has been considered fairly standard practice since the 1980s. The numbers of South Australians who have been adversely affected by mesh implantation for hernia, are even less clear than those affected by pelvic mesh.

The Committee heard oral evidence from two witnesses whose family member had experienced an adverse event following the implantation of mesh for hernia.[187]

The Committee also received nine written submissions, which detailed incidences of hernia mesh damage to the submitters or a family member.[188] However, information concerning the impacts of hernia mesh on South Australians is still relatively obscure.

In February 2019, the Health Issues Centre (HIC) in Victoria, reported on adverse outcomes from hernia mesh Australia-wide, through an online, self-reporting survey of hernia mesh recipients (the HIC report).[189]

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[185] *Gill v Ethicon Sàrl & Ors* (No 5) [2019] FCA 1905. See Gill v Ethicon Sàrl (No 5) [2019] FCA 1905 - BarNet Jade - BarNet Jade

[186] Ms Bridget Cook, Senior Associate, Class Actions Team, Shine Lawyers, Oral evidence, *Hansard*, 29 June 2020: 117.

[187] Franciszka and Robert. Oral evidence, *Hansard*, 17 February 2020: 14.

[188] Names and/or submissions confidential, *Written submission No. 3*, 4 September 2019: 1; *Written submission No. 8*, 10 September 2019: 1; *Written submission No. 11*, 10 September 2019: 3; *Written submission No. 14*, 11 September 2019: 1; *Written submission No. 32*, 13 September 2019: 1; *Written submission 44*, 13 September 2019: 1; *Written submission No. 64*, 8 October 2019: 1; *Written submission No. 67*, 1 May 2020: 1; *Written submission No. 68*, 8 June 2020: 1

[189] Health Issues Centre, *Adverse outcomes from hernia mesh: A report on the consumer experience of mesh implants for treatment of hernia*. Melbourne, February 2019: 3.

According the HIC report, of the 183 respondents to the survey, 91 percent stated they suffered ongoing post-operative chronic pain and other debilitating adverse outcomes from their mesh implant. Further, 87 per cent advised they had reported these adverse events to their GPs or specialists which, received "gross minimalisation" with some refusing to recognise the problems.[190]

The Minister for Health and Wellbeing provided that SA Health's Medical Advisory Unit identified fifty procedure codes for which there were 2,751 separations in SA public hospitals for 2018-19 that were likely to involve mesh for hernia. The majority of these were associated with hernia repair; particularly inguinal (64%), umbilical (32%) and epigastric (4%) of the hernia repair procedures identified.[191]

It is understood that some mesh is supplied in "a roll of mesh", where a piece is simply cut off when needed. In this way the mesh is considered a product of the surgery rather than a device.[192] In the Department for Health and Wellbeing's written submission it was advised that of the identified fifty procedure types, it is difficult to identify which procedures involve the use of medical mesh "because the individual procedure codes do not necessarily make reference to the surgical material used during the procedure."[193]

With that in mind, it is likely that there may be many people who have had mesh implanted without knowledge of it, and in that event, there is no way to trace or know what kind of mesh product has been used. It is also understood that six hernia mesh devices which were approved for entry in the ARTG and by the TGA available in Australia, have since 2012, received hazard notifications or have been cancelled. These are:

- Parietex Composite Parastomal Mesh, 15cm & 20cm
  ARTG Number: 176136
  26/10/2018 Hazard Alert
  Hospital level recall, market removal follows receipt of reports of mesh failure of two item codes leading to hernia recurrence.

- Versate Monofilament Mesh, 50x50 cm
  ARTG Number: 237409
  8/03/2018 Revised instructions for use due to reports of abdominal hernia recurrence following hernia repair, with the majority of patients having undergone a Transversus Abdominis Muscle Release procedure.

- LiquiBand FIX8 Hernia Mesh Adhesive Fixation Device
  ARTG Number: 233374
  6/04/2017 Revised instructions for use
  Hospital level recall due to claims were extended in the instructions for use in May 2015. More data was required to support these extended claims.

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[190] Health Issues Centre, *Adverse outcomes from hernia mesh: A report on the consumer experience of mesh implants for treatment of hernia*, 2019: 1.

[191] Hon. Stephen Wade MLC, Minister for Health and Wellbeing, *Written submission No. 65*, 15 October 2019: 1.

[192] Ms Julia Overton, *Hansard*, 23 March 2010: 48.

[193] Hon. Stephen Wade MLC, Minister for Health and Wellbeing, *Written submission No. 65*, 15 October 2019: 1.

- Ethicon Physiomesh Flexible Composite Mesh (All product codes)
  ARTG Number: 182785
  30/05/2016 Product Recall, Hospital level recall due to worldwide removal of the laparoscopic version of the device. The product is being removed following an analysis of overseas registry data.

- C-Qur, C-Qur TacShield and CQur V-Patch
  ARTG Number: 163310
  ARTG Number: 182852
  ARTG Number: 174772
  26/07/2013 Updated Instructions for Use, updated storage requirements on labelling. Hospital level recall due to potential to cause coating on the mesh to strongly adhere to the inner handling sleeve of packaging if exposed to excessive humidity for an extended period of time, due to increased humidity occurring inside the pouch.

- Proceed Surgical Mesh Product
  ARTG Number: 117402
  24/02/2014 Hospital level recall due to possible incomplete seal on the packaging, compromised sterility, introducing potential for delamination.[194, 195]

Year	Health Care Professional	Patient/ Carer	Sponsor	Other	Annual Total
2006			1		**1**
2007			5		**5**
2008	1		6	1	**8**
2009			5		**5**
2010			6		**6**
2011			1		**1**
2012			9		**9**
2013			14		**14**
2014	3		25		**28**
2015			14		**14**
2016		2	10		**12**
2017		3	7		**10**
2018	1	10	9		**20**
2019	2	21	8		**31**
2020		3	3		**6**
TOTAL	**7**	**39**	**123**	**1**	**170**

Fig. 4: Device incident reports received by the Therapeutic Goods Administration in relation to Hernia Mesh, as of 30 April 2020, by year and source of report. [196]

Information provided by the TGA to the Committee shows from 2006 to 30 April 2020 there were 170 device incident reports received by the TGA in relation to hernia mesh in Australia. Adverse events for hernia mesh are also expected to be underreported to the TGA.

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[194] TGA, *Recall Action Result Summary report, between 01/01/2013 –28/11/2020*. Accessed 30 November 2020 System for Australian Recall Actions (tga.gov.au)

[195] Ms Tracey Duffy, *Responses to questions on notice*, 18 December 2020. *Hansard*, 7 December 2020: 214. Received 1 February 2021: 3.

[196] Ms Tracey Duffy, *Information taken on notice*, *Hansard* , 11 May 2020: 74, received 25 May 2020: 2.

Committee's View

The Committee notes that public hospital records for both pelvic and hernia mesh implantation in South Australia, are incomplete and cannot provide reliable data in terms of the true number of people who have had mesh surgically implanted. Likewise, data that can be extrapolated from the various records and databases regarding private hospitals and privately insured patients is at best, a guess.

The Committee also notes that the SA Health PIR system is mandatory for SA Health staff working in an SA Health facility. The SA Health 2018 Transvaginal Mesh Audit did not mention that the PIR system was either a useful repository of adverse event records, or that it had been searched for reports of pelvic mesh related incidents as part of the Transvaginal Mesh Audit. Future need for data on mesh adverse events in SA's public hospital system could be met by greater compliance with the PIR Policy.

Further, it is the Committee's view that given the voluntary nature of reporting to the TGA and in the absence of a cohesive register of mesh implant devices, data on incidences of complications, reports of adverse events and secondary surgeries including explantations, are even more unreliable.

Recommendations

The Minister for Health and Wellbeing:

1. Ensure compliance with requirements for reporting of adverse incidences in SA Health. Undertake an education program to increase the understanding by SA Health facilities staff, about what is a mesh related incident, in order to facilitate reporting in the Patient Incident Reporting system.

2. Undertake a broad consultation with the public and private hospital systems to ensure that all providers claiming services on the Medicare Benefits Schedule meet the requirements of the item descriptor in order for benefits to be payable for any medical mesh-related services.

(b) the benefits of establishing a South Australian register of mesh implant recipients, including a prospective and retrospective audit, which includes the public and private hospital sectors

> One of the things that struck me when we were interviewing the affected women and they were telling us their stories, was that the whole of the medical profession hadn't recognised the pain and suffering and the damage that these women were experiencing. I am an intensive care doctor and I was shocked that people were presenting with such catastrophic symptomatology, and very little seemed to be being done for them. So I think this whole mesh saga has highlighted that the whole sequence of symptoms and signs of mesh going wrong have been completely missed both by general practitioners and by specialists.[197]

The Social Development Committee (the Committee) received evidence that there is an urgent need for a Clinical Quality Registry (CQR) to be established, for surgically implantable mesh devices.[198] The Committee heard from witnesses that such a registry should have the capacity and capability to record retrospective, current and prospective information on patients, clinicians and devices.[199]

What was less clear in the evidence, is whether the registry should be established exclusively for use in South Australia or whether it should be a national registry, such as the registry recommended by the *Senate Inquiry into the Number of women in Australia who have had transvaginal mesh implants and related matters* (the Senate Inquiry).[200]

The Committee received many submissions from individuals who, after having had a pelvic or hernia mesh implant and upon experiencing debilitating complications from the procedure, were then ridiculed, referred on, or dismissed as being hypochondriacal by some health professionals; for others, they have been consistently told they do not even have a mesh implant, and their symptoms must be the result of a separate condition, or 'it is all in their head'.[201, 202, 203, 204, 205]

Some witnesses who provided evidence, and who have been living with catastrophic symptoms of failed mesh for years, now also suffer from mental illness; others, have told the Committee, they have considered suicide, or assisted dying as the only viable options left available to relieve their pain.[206, 207]

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197 Dr Robert Herkes, Chief Medical Officer, Australian Commission on Safety and Quality in Health Care (the ACSQHC). Oral evidence, *Hansard*, 1 June 2020: 94 – 95.

198 South Australian Pelvic Mesh Support Group, *Written submission No.29*, 13 September 2019: 1 – 2.

199 Kim, *Hansard*, 2 March 2020: 20.

200 See: Recommendation 3, Community Affairs References Committee, *Inquiry Report*, March 2018: xi.

201 "Anne", SA Pelvic Mesh Support Group. Oral evidence, *Hansard*, 2 March 2020: 31 – 32.

202 Tracey, *Written submission No. 2*, 2 September 2019: 1.

203 "Sarah", *Written submission No. 5*, 9 September 2019: 3.

204 Names confidential, *Written submission No. 11*, 10 September 2019: 2; 4; *Written submission No. 12*, 10 September 2019: 1; *Written submission No. 19*, 12 September 2019: 2; *Written submission No. 20*, 12 September 2019: 1; *Written submission No. 25*, 12 September 2019: 2; *Written submission No. 42*, 13 September 2019: 1; *Written submission No. 46*, 13 September 2019: 1.

205 Franciszka and Robert. Robert, Oral evidence, *Hansard*, 17 February 2020: 14.

206 Names confidential, *Written submission No. 43*, 13 September 2019: 1; *Written submission No. 44*, 13 September 2019: 2; *Written submission No 50*, 13 September 2019: 1; *Written submission No. 52*, 15 September 2019: 2; Written submission No. 53, 16 September 2019: 1; *Written submission No. 55*, 20 September 2019: 1; *Written submission No. 61*, 8 October 2019: 1; *Written submission No. 64*, 8 October 2019: 1; *Written submission No. 67*, 1 May 2020: 1.

207 Name confidential, *Written submission No. 38*, 13 September 2019: 1.

From Witnesses Affected by Mesh

Robert and Franciszka - Oral evidence

Franciszka and Robert, mother and brother to Edward, told the Committee in their oral evidence, that Edward had suffered immensely while trying to find the cause of his chronic pain following an operation to repair a surgical accident involving his bladder. Robert advised that Edward spent 3 years attending appointment after appointment in the hope one of his specialists or GPs would make the connection to the mesh that was used to repair his injured bladder. Robert stated:

> The surgeon made many referrals to physicians engaged in seeking to relieve Edward's chronic pain. None of them mentioned anything regarding medical mesh adverse outcome or mesh implant as cause of chronic pain; indeed, the surgeon threw all manner of red herring hypotheses to physicians he wrote referrals to. Therefore, Edward was not believed, stayed in debilitating pain whilst being labelled with the term 'all in your head'. Concurrent to this, in full knowledge that the inadvertent cystotomy actually occurred, gen prac did continue to supply Edward with high doses of opioid narcotics. This caused respiratory depression that culminated in a lethal cardiac event on 6 August 2010.[208]

Robert advised he believed Edward would have been better served, had a mesh registry existed before Edward had been treated and eventually, died:

> Medical mesh registry would have enabled Edward to categorically establish that the mesh problem actually existed to any attending doctor and thus, perhaps, receive appropriate treatment.[209]

"Anne" - Oral evidence

Likewise, "Anne", who provided oral evidence to the Committee explained how a mesh registry could have helped her following years of devastating complications resulting from a laparoscopic sacrocolpopexy for anterior and posterior prolapse with mesh, and a transvaginal obturator "tape":

> Since implantation, I have seen numerous GPs, gynaecologists, physios, chiropractors, Eastern medicine practitioners and naturopaths. While I could tell them I had a TVT and some mesh inside of me, not one of these medical personnel, including my hometown medical clinic, was aware of what was inside of me. I did not know the full extent of my mesh implant until I obtained my hospital operation notes when my symptoms became unbearable. If my implantation had been registered it would have provided insight to those treating me and perhaps they would have been better equipped to help me and to then report my associated adverse outcomes.[210]

"Anne", who is a representative of the South Australian Pelvic Mesh Support Group, advised that the existence of a mesh register would assist in the follow-up of the implanted patients during the life of the device; it would assist in contacting patients when a device was found to be a failed or faulty product; it would assist in the association of implantation cards; and it could allow for the recording of alterations to the device including partial or full removal.[211]

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[208] Robert, *Hansard*, 17 February 2020: 14.

[209] Robert, *Hansard*, 17 February 2020: 15.

[210] "Anne", *Hansard*, 2 March 2020: 32.

[211] "Anne", *Hansard*, 2 March 2020: 32.

"Anne" further advised:

> […] we believe the benefits of establishing a register of mesh implant recipients include being able to ascertain the number of implants in South Australia; a register would give the ability to contact those with a particular implant for reasons such as if there is a change, concern or recall of a product or adverse effects; the ability to cross-reference and have comprehensive access throughout both the public and private system; long-term monitoring of adverse health outcomes; the recognition of delayed symptoms and adverse effects of consumers with positive initial responses following implantation being related to the medical mesh; and we recommend the establishment of a mandatory prospective and retrospective audit to establish a mesh implant register with a view to link this up to national and international registers.[212]

With the absence of an accurate and immediate CQR for implantable mesh devices in Australia, the medical profession remains out of step with the patients who seek their help. As another example of this, Written submission 25 relayed to the Committee that the medical professionals she attended did not believe her symptomology, did not believe there was a problem with the mesh device she had implanted and were supposedly unaware of any previous complications with the product or procedure.

Name confidential - Written submission 25

Written submission 25 (WS 25) told the Committee that after casually mentioning her mild stress-incontinence to her family GP, her GP advised her there was "a very simple surgery" that could rectify this.[213] WS 25 explains, following surgery by a gynaecologist in 2018, whereby a sub-urethral transobturator sling was implanted, WS 25 experienced debilitating and painful complications, which went on for months.[214]

After following this up with her GP and gynaecologist who dismissed her claims on a number of occasions, she resorted to searching the internet for help. WS 25 describes her realisation that everything was not alright with her mesh:

> In April 2019 I read an article about a women who was having extreme complications from her sling. This is when I realised that I was truly in trouble and the pain I was feeling was not going to go away or get better. I was in-fact likely to get worse & more damage would be done to my organs […] At this point I was experiencing significant tingling, shock type pain throughout my pelvic regions (like someone was stabbing me with needles), along with a grating feeling. It was extremely uncomfortable to sit for long periods of time but I dreaded standing up as the pain would increase. I was also now getting pain in my upper right leg which radiated down which at times made me loose (Sic) strength.[215]

It is common for people experiencing health problems to utilise the internet to find answers. It is also just as likely that the medical profession view "Dr Google" as problematic and discourage self-diagnoses. However, where there are no other sources of comprehensive, vetted, and reliable information available to patients, they will continue to use whatever resources they can find.

The Committee understands misinformation may occur with some sources on the internet, however, as with WS 25, there were many examples from witnesses who have mesh complications who deferred to the internet in the absence of another source, in order to identify issues and symptoms. Dr Samantha Pillay commented in her oral evidence that it will be important for standardised information to be given to prospective surgery patients as well as available for those with complications to be able to access readily. Dr Pillay advised:

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[212] "Anne", *Hansard*, 2 March 2020: 37 - 38.

[213] Name confidential, *Written submission No. 25*, 11 September 2019: 1.

[214] Name confidential, *Written submission No. 25*, 11 September 2019: 2.

[215] Name confidential, *Written submission No. 25*, 11 September 2019: 2 - 3.

> […] The registry, say, unlike other registries, will actually be involved. It will be receiving information prior to surgery, because some of the outcome data that's collected relates to pre-surgery versus post-surgery. Is there a way that this standardised information could be ensured to get to all patients? That may be a possibility through the registry. Or is there another way that can ensure that clinicians providing this surgery [and patients] can access that information even before deciding on surgery?
>
> It probably even goes further back than that along the treatment pathway in knowing that the GPs also have access to that patient information, because there's GP education that might influence whether a patient is encouraged or discouraged to even seek treatment, especially with everything that's happened. Then there are also patients who, going back even further than that along their journey, prior to them even speaking to their GP to discuss treatment or referral, may access information nowadays themselves through their own internet searches and also speak to friends or other people they know. The information they gain through their personal contacts, and especially through their own personal internet searches, could actually influence their decision to even mention it to their GP, the accuracy of that information could be that first barrier.[216]

A mesh registry may have assisted WS 25 to understand the symptoms she was experiencing, nevertheless, after reading the stories of other women who had experienced mesh complications, WS 25 sought a referral to a specialist in Melbourne who could perform a 'full removal' of the "sling". Following successful removal of the mesh by the urogynaecologist in Melbourne, WS 25 reflected on the damage she had experienced in the physical, emotional, material and relationship capacities of her life, claiming the preceding 18 months had been "the darkest period of her life", with the damage caused by the mesh possibly being irreversible. [217]

WS 25 made a personal appeal for the medical profession to heed the pleas of women suffering from mesh trauma, and for implantations, revisions and removals of mesh to be recorded for patients and medical professionals to access:

> I would […] like to see the medical profession be educated in the damage mesh can do. The medical profession needs to recognise and act on the symptoms being experienced by women who have had this procedure and not simply brush it under the carpet as some sort of hypochondria or "female hysteria". I was told for months by two doctors that nothing was wrong, that I was imagining the pain and that there was no way a "sling" could cause damage. If my doctors were aware and accepting that this could happen there perhaps would have been no need for me to go through what I did.[218]

The examples cited are just a few of the many cases provided to the Committee where the existence of a CQR for implantable mesh devices may have been beneficial in assisting these patients to retain and maintain their quality of life, had it existed when medical mesh was introduced in South Australia.

Instead of confusion, frustration and desperation for answers, systematic monitoring, analysing and reporting on the safety, quality and variations in implantable mesh devices could potentially provide patients, clinicians, health services, and regulators with the tools to identify and address a device or

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[216] Dr Samantha Pillay, *Hansard*, 15 June 2020: 104 - 105.

[217] Name confidential, *Written submission No. 25*, 11 September 2019: 4.

[218] Name confidential, *Written submission No. 25*, 11 September 2019: 4.

a particular procedure's issues.[219] In turn this may prevent intense suffering, such as that, experienced by these patients and their families.[220, 221, 222]

Australian Clinical Quality Registries

The Australian Commission on Safety and Quality in Health Care (the ACSQHC), provides that Clinical Quality Registries (CQRs) have the potential to report on retrospective, current and prospectively collected data which includes:

- processes of care
- health outcomes
- patient reported outcome measures
- patient reported experience measures and
- health system costs.[223]

Clinical Quality Registries (CQRs) can provide detailed, routinely collected information that can be utilised in a variety of ways by patients, governments, clinicians, health service providers and health insurers. At the same time, there is also benefit in the data being able to provide a 'device performance system' for procedures involving the implantation of medical devices, which, can inform delivery of care to patients, provide real time updates to clinicians, and provide valuable information to policymakers and regulatory authorities. [224]

Professor Susannah Ahern, Head, Registry Science, Monash University, and Chair and Primary Chief Investigator, Australasian Pelvic Floor Procedure Steering Committee (APFPR Steering Committee), advised as an example, the Australian Breast Device Surgery Registry (the ABDR) which was established in 2015, contains detailed data on more than fifty thousand patients who have had breast implants, and has over five hundred participating surgeons from various disciplines in more than three hundred hospitals and day procedure centres. Professor Ahern advised the ABDR operates with around an 80 per cent capture range of eligible participants.[225] Information retrieved from the Australian CQR website regarding the ABDR states:

> The [Australian Breast Device Surgery Registry] ABDR collects information about breast devices using a simple data collection form (DCF) completed by surgeons at the time of surgery across the eligible sites Australia-wide […] This include insertions, revisions of in situ devices, and explants without replacement. Information from the DCFs generates a powerful set of accurate and validated data that can be analysed and reported to individual surgeons, hospitals, the department of health and other key stakeholders. The ABDR produces information on device failure rates, complications and revision rates of procedures involving breast devices nationally. […][226]

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219 Professor Susannah Ahern, *Hansard*, 27 April 2020: 57.

220 Robert, *Hansard*, 17 February 2020: 14.

221 Health Issues Centre, *Adverse outcomes from hernia mesh: A report on the consumer experience of mesh implants used for treatment of hernia*, Melbourne, February 2019: 13 – 14.

222 Name confidential, *Written submission No. 57*, 23 September 2019: 3.

223 ACSQHC, *National arrangements for clinical quality registries.* Accessed 20 November 2020 https://www.safetyandquality.gov.au/our-work/indicators-measurement-and-reporting/national-arrangements-clinical-quality-registries#australian-register-of-clinical-registries

224 See: Australian Government, *Australian Government Response to the Senate Community Affairs References Committee Report: Number of women in Australia who have had transvaginal mesh implants and related matters*, October 2018: 7.

225 Professor Susannah Ahern, *Hansard*, 27 April 2020: 55.

226 ACSQHC, *Australian Register of Clinical Registries*. Accessed 20 November 2020 Australian Register of Clinical Registries | Australian Commission on Safety and Quality in Health Care

As such the ABDR is an invaluable tool which can provide up-to-date information to health professionals in instances of device warnings and recalls. The ability to collect and analyse detailed data on patients and their devices, clinical outcomes and the procedures they have had, provides potential for clinicians and health services to review and choose the best performing devices available, thereby enhancing patient outcomes into the future.[227]

A foreseeable beneficial outcome of such CQRs would be that they assist in providing rigour to the manufacturing, regulation and clinical processes of surgically implanted medical devices.

The Australasian Pelvic Floor Procedure Registry

> In Australia, there were hundreds of thousands of products put into the market. We know that Johnson & Johnson products amounted to approximately 110,000 products into the Australian market, and the AMS products amounted to approximately 60,000 into the Australian market. Regardless of whether or not a product is found to be defective, the development of the product from concept to market is significant and involves interconnected scientific, medical and legal considerations across all aspects of the process. In addition, as I am sure you know, manufacturers, distributors and users of medical devices have ongoing obligations once the products do come onto the market.[228]

In its 2018 Senate Inquiry report, the Community Affairs References Committee recommended the Australian Government establish a register for all high-risk implantable devices. The Senate Inquiry recommendation 3, provides that:

> […] the Australian Government prioritise consideration of the implementation of Recommendation 22 of the report of the Review of Medicines and Medical Devices Regulation recommending the establishment of a registry for all high-risk implantable devices, together with consideration of the feasibility of establishing such a registry on a cost recovery basis, and provide to the Senate by 29 November 2018 a progress report on work to date.[229]

Recommendation 22 of the Review of Medicines and Medical Devices Regulation reads:

> The Panel recommends that:
> 1. All high-risk implantable devices are included in a registry that is compliant with the requirements for registries established by the Australian Commission on Safety and Quality in Health Care (ACSQHC).
> 2. Responsibility for ensuring that registries are operated consistent with the ACSQHC requirements should rest with the NRA [Australian National Regulatory Authority].
> 3. Data collected by device registries should be made available to the NRA in a timely manner to inform post-market monitoring.
> 4. The NRA should implement an active programme of analysis and reporting on adverse events, and associated data, collected through registries or by other means.
> 5. The NRA should continue collaborative activities with overseas medical device regulators to actively share registry and other monitoring data, with a view to facilitating timely identification of emerging safety concerns and to inform better clinical practice.[230]

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[227] Professor Susannah Ahern, *Hansard*, 27 April 2020: 55.

[228] Ms Jan Saddler, Head of Litigation & Loss Recovery, Shine Lawyers. Oral evidence, *Hansard*, 29 June 2020: 114.

[229] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: xi.

[230] Emeritus Professor Lloyd Sansom AO, Mr Will Delaat AM, Professor John Horvath AO. Expert Panel Review of Medicines and Medical Devices Regulation, *Recommendations to the Minister for Health on the Regulatory Frameworks for Medicines, Medical Devices, Complementary Medicines and Advertising of Therapeutic Goods*, July 2015: 11. Accessed 20 November 2020

While the Senate Inquiry recommended a registry for all high risk implantable devices, including meshes, in response, the Federal Government made provision for 3 years funding announced in April 2019, for the establishment and management of the Australasian Pelvic Floor Procedure Registry (the APFPR), and the APFPR Steering Committee.[231] The APFPR was jointly developed between Monash Clinical Registries, the ACSHQC, TGA, state and federal health jurisdictions, and professional societies and associations. [232]

The consultation also had consumer representation, which was emphasised as having importance for establishing the "modules" for the registry's data collection.[233] The TGA established a dedicated consumer representation working group to provide advice for progressing the action plan for medical device strategies [234]

The development of the APFPR was in response to the complications with outcomes associated with transvaginal mesh. However, evidence suggests it will be critical for there to be capability to record data for POP and SUI surgeries that involve the use of mesh as well as non-mesh procedures to "calculate denominators and compare outcomes for procedures, existing and new."[235]

According to Professor Helen O'Connell, Director of Surgery and Head of Urology, Western Health Melbourne and the Urology Representative of the APFPR Steering Committee, the Registry resembles the Australian Orthopaedic Association National Joint Replacement Registry (the AOA Joint Registry), which provides a highly detailed dataset for a patient's first procedure.[236] Professor O'Connell advised that over time, the degree of data has proved to be extremely helpful in looking at the risks and consequences of revision surgery, through early detection of problematic devices and identification of outliers. Professor O'Connell advised:

> There is potentially greater risks associated with mesh removal surgery and the further surgery to rectify the secondary complications. Again, these complications are poorly documented and their number and severity unknown. It is a very important function of the registry to provide detailed patient-recorded outcome measures and the scope to analyse mesh explantation cases in detail.[237]

Ms Tracey Duffy advised that Monash University has been responsible for the management of several CQRs for many years, for example the ABDR and the AOA Joint registries, and will be in a position to "leverage" off the existing relationships within the public and private hospital systems. It is expected this will assist to generate a high level of participation in the APFPR.[238]

Consideration of whether reporting information in the APFPR should be voluntary or mandatory was raised as an ongoing question throughout this inquiry.

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https://www1.health.gov.au/internet/main/publishing.nsf/Content/8ADFA9CC3204463DCA257D74000EF5A0/$File/Review%20of%20Medicines%20and%20Medical%20Devices%20-%20Recommendations_Accessible.pdf

231 Australian Government, *Australian Government Response to the Senate Community Affairs References Committee Report: Number of women in Australia who have had transvaginal mesh implants and related matters*, October 2018: 7.

232 RANZCOG, *Written submission No. 45*, 13 September 2019: 11.

233 Ms Tracey Duffy, *Hansard*, 7 December 2020: 214.

234 Ms Tracey Duffy, *Hansard*, 7 December 2020: 214.

235 Daly, J. Oliver; Susannah Ahern, Robert Herkes, Helen E. O'Connell. "The Australasian Pelvic Floor Procedure Registry: Not before time", *Australian and New Zealand Journal of Obstetrics and Gynaecology*, 2019; 59: 475.

236 Professor Helen O'Connell, *Hansard*, 27 April 2020: 54.

237 Professor Helen O'Connell, *Hansard*, 27 April 2020: 54.

238 Ms Tracey Duffy, *Responses to questions on notice*, 18 December 2020. *Hansard*, 7 December 2020: 214. Received 1 February 2021: 1 - 2.

The Committee was advised that it was important to consider participation in the registry as a voluntary process and as such, cooperation in it would be based on similar registries already in operation.[239, 240] Professor Susannah Ahern explained:

> [It] goes to the model of the registry, the amount of information and what we call the 'data burden' that you are expecting clinicians to put into the registry. It is also making sure the registry has a leadership from all the clinical craft groups. Our model has a number of senior clinicians that have been represented by all the relevant clinical craft groups—I think I mentioned six. Also, participation in these activities provides them with CME points and audit points, which they require for their medical registration. So, there are a number of levers that we can use, but we have been very impressed with the general support among the craft groups for a device-based registry.[241]

Professor O'Connell provided:

> […] with the credentialling guidelines by the commission, it is very clear that it is expected that you will have a robust audit program. The registry is putting a lot of effort into getting that minimum dataset, so you get that very parsimonious, critical piece of information. At the same time the data burden per patient entered is likely to be of the order of a minute.
>
> We have put a lot of effort into getting the craft group buy-in, which meant surveying, getting the results and acting on that. All these things take time, and my inclination would be to just get the patients onto the registry because I can see it's so important. All these steps ensure, or make it much more likely, that we will get up to that sweet spot of, ideally, 98 per cent participation. If you have a really small dataset and it has been really honed, you've got a much better chance of getting a near-complete cohort.[242]

Retrospective and Prospective Data Collection

In a written submission to this inquiry, Mesh Injured Australia (MIA) referred to recommendation 11 of the Senate Inquiry, claiming the extent of the problems and complications with pelvic mesh will not be known until a systematic audit has been performed.[243] Such an audit would then inform the mesh registry providing a databank of as many people in South Australia as possible who have had a mesh implant.

Other appeals were made during this inquiry for an audit to include both retrospective and prospective data. Individuals and pelvic mesh support groups called for the full audit to be undertaken.[244, 245] Mesh Injured Australia Inc. advised:

> The benefits to a register are:
> - To ascertain real numbers of those adversely affected and true failure rates;
> - It will allow those affected to get treatment and support;
> - It will validate the horrific journeys of those who have been injured;
> - This will send a message to health professionals, governing bodies etc around the flaws in our system, highlighting the lack of support and services these mesh injured people whom will require life-long care;

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239 Professor Susannah Ahern, *Hansard*, 27 April 2020: 60.

240 Ms Tracey Duffy, *Responses to questions on notice*, 18 December 2020. *Hansard*, 7 December 2020: 214. Received 1 February 2021: 2.

241 Professor Susannah Ahern, *Hansard*, 27 April 2020: 60.

242 Professor Helen O'Connell, *Hansard*, 27 April 2020: 60.

243 Mesh Injured Australia Inc., *Written submission No. 49*, 13 September 2019: 2.

244 Mesh Injured Australia Inc., *Written submission No. 49*, 13 September 2019: 2.

245 SA Pelvic Mesh Support Group, *Written submission No. 29*, 13 September 2019: 1.

- It will highlight the need for reform of our current health system; and
- Facilitate proper research into why these devices have failed a large percentage of people.[246]

However, as already cited in the Senate Inquiry, such an undertaking would be extremely difficult to achieve due to the limitations of availability of complete data.[247] While recognising the value of an audit to collect full data, some professional associations and medical professionals acknowledged the limitations cited by the Senate Inquiry. Dr Samantha Pillay, RACS, advised:

> Unfortunately, there are difficulties in a retrospective audit as doctors are unlikely to be able to provide this data due to the requirement to only keep medical records for seven years. Many surgeons may not have searchable electronic records to identify patients and may not have records of adverse outcomes, especially if the patients were treated elsewhere. The correctness of conclusion from retrospective data, the quality will depend on the accuracy and completeness of that data set. Prospective independent data collection is optimal such as a national registry to capture patients with an independent person to follow up patients.[248]

Dr Magdalena Simonis, GP and Fellow of the Royal Australian College of General Practitioners (the RACGP) commented that a retrospective register would be very costly to undertake, and because of the removal of some types of mesh products from hospitals, would not provide confidence in the accuracy of the data.[249]

The Medical Technology Association of Australia (the MTAA) advised in their written submission:

> Any prospective and retrospective auditing should be nationally harmonised to ensure that best practice is implemented across Australia, and appropriate resources should be budgeted for this activity.[250]

Dr Robert Herkes, Chief Medical Officer, ACSQHC commented that the main difficulty in obtaining consistent data across states and territories, was that each jurisdiction has different record-keeping policies and practices in place:

> Some of the jurisdictions have looked at doing a retrospective audit. The problem with a retrospective audit is that because there is no coding way of discovering the patients who have had mesh, to have to actually go into every individual patient's notes and go and manually search them. Each of the jurisdictions has a different policy for the maintenance of medical record, but in most places the medical records only has to be maintained for seven or eight years.[251]

Another issue identified by Dr Herkes is the issue of the age of records and the record-destruction policies of organisations:

> One of the other issues we struck when we were doing our consumer consultation was that many of the women had approached the hospitals where they had a urogynaecological procedure 10 or 15 years ago and the records had been culled, so they were completely unable to find out whether they had an historic operation, whether they had had mesh implanted or not. So a confounder for a potential retrospective audit is that many places won't have records past eight years ago, which is obviously, for something like mesh, too short.[252]

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246 Mesh Injured Australia Inc., *Written submission No. 49*, 13 September 2019: 2.

247 Senate Community Affairs References Committee, *Inquiry Report*, March 2018, 57.

248 Dr Samantha Pillay, *Hansard*, 15 June 2020: 100.

249 Dr Magdalena Simonis, *Hansard*, 21 September 2020: 173.

250 MTAA, *Written submission No. 39*, 13 September 2019: 6.

251 Dr Robert Herkes, *Hansard*, 1 June 2020: 94.

252 Dr Robert Herkes, *Hansard*, 1 June 2020: 94.

Another issue concerning complications in retrospective auditing of the mesh is the recording of mesh as a 'product' rather than as a 'device' in historical surgeries. This was raised by Ms Julia Overton, Chief Executive of the Health Consumers Alliance of South Australia in her evidence to the Committee.

Ms Overton stated that some mesh that is used in procedures is taken from a "roll of mesh", where identification is different to mesh that is identifiable as a distinct item.[253] In that way, the mesh that is taken from a roll of mesh is being treated as a product of surgery, not as 'a device' that is being implanted, and it is therefore less easily traceable.[254]

Clinical Quality Registries for all Implantable Medical Mesh Devices

Despite the recommendation by the Senate Inquiry for the development of a national register for all high risk implantable devices, based on the recommendation of the Review of Medicines and Medical Devices Regulation, 2015, the Royal Australasian College of Surgeons (RACS) advised the Committee it is unaware of plans to develop a registry beyond pelvic floor surgery. [255]

However, according to the Australian Government's response to the Senate Inquiry, the Federal Government has committed to working with the ACSQHC, state and territory governments and key stakeholders to develop a National CQR Strategy.[256]

RACS advised that the Australian Hernia CQR Working Group has approached RACS to "investigate the feasibility of establishing a pilot hernia registry."[257] And in their submission to the TGA's consultation on the Alignment with European medical device regulatory framework: Up-classification of surgical mesh & patient implant cards, RACS advised:

> General Surgeons Australia is investigating the feasibility of establishing a mesh audit, particularly for ventral hernias where the implanted mesh is >15cm^2. This would be a useful tool to ensure rigorous safeguards are in place for the use of mesh and would help identify ways of improving and maintaining quality of care for patients. It's estimated around nearly 100,000 Australians are hospitalised for hernia each year, so a registry represents good value for money. [258]

Professor Guy Maddern:

> […] I would say—and you ought to talk to the TGA about this—you should be pushing very strongly to have a register of hernia placement. I think that would be incredibly useful. How it is funded, there are a number of ways it could be done, but I would think the AOA way is quite a good way of doing it with what they did for their hip joints.
>
> I think that it should be part of—within the public hospital system, […] within the private system it should be part of maintaining hospital accreditation because you are a bit limited in

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253 Ms Julia Overton, *Hansard*, 23 March 2010: 48.

254 Ms Julia Overton, *Hansard*, 23 March 2010: 48.

255 RACS, *Written submission No. 62*, 8 October 2019: 3.

256 Australian Government, *Australian Government Response to the Senate Community Affairs References Committee Report: Number of women in Australia who have had transvaginal mesh implants and related matters*, October 2018: 7.

257 RACS, *Submission to the Therapeutic Goods Administration consultation on Alignment with European medical device regulatory framework: Up-classification of surgical mesh & patient implant cards*, 14 September 2017: 6.

258 RACS, *Submission to the Therapeutic Goods Administration consultation on Alignment with European medical device regulatory framework: Up-classification of surgical mesh & patient implant cards*, 14 September 2017: 6.

> what you can do in terms of the federal level, but you can at least say, 'You won't keep your accreditation unless all you hernias are entered into the data set,' then if people don't want to work there they can stop doing hernia repairs. I think that would be very useful. It would be more useful, of course, if it was done nationally—and I know you have made the example of the women with vaginal meshes who have gone overseas—but on the average, the leakage across to interstate would be negligible, so I think you would be to capture a fantastic set of data that would largely reflect the Australian experience, because it is such a common operation.[259]

A State or National Registry

The issue of whether the South Australian Government should implement a state-based registry for all types of implantable mesh devices was raised during the inquiry. The Committee heard from witnesses who advocated for a state registry as well as those who consider that a national approach would be more appropriate.

Dr Simonis advised in her oral evidence to the Committee, as patients may move from state to state, it is important that a register of implantable mesh devices is maintained at a national level:

> I think it's important that it not be just a state-run thing. I think the recommendation was, from the Senate inquiry, that it be a national register because patients do move, they don't stay in one area. Much like the cancer registry that we have, it used to be state run and now it's nationally run for those same reasons, so that we can actually have a better idea of the numbers.[260]

Nationally consistent approach

According to Professor Ahern CQRs have become recognised as a valuable way to measure "clinical variation" and initiate quality improvement in products and services. CQRs can collect a minimum data about a procedure or device from multiple hospitals or clinics. The data entered must be identical to ensure consistency. Professor Ahern explains:

> Consistency is ensured through the use of identical definitions and data collection procedures. The information is then aggregated and regularly analysed to review quality of care and outcomes. The results are fed back in the individual reports to clinicians and their hospitals as well as public annual reports, in peer reviewed publications, in conferences and other society meetings.[261]

The MTAA advised that CQRs should be established on a national rather than state level and should "be set up and operated in accordance with the principles, guidelines and standards for Australian Clinical Quality Registries."[262, 263] Dr Herkes commented that linkages between different data collection systems across jurisdictions has been limited in the past:

> As you probably know, within the states and territories there are incident monitoring systems, where clinicians report these sort of complications into the state system, and what hasn't happened so far is that the systems transmit that information to the TGA. The Commonwealth and State systems are now working out how they might integrate.[264]

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[259] Professor Guy Maddern, *Hansard*, 30 November 2020: 210.

[260] Dr Magdalena Simonis, *Hansard*, 21 September 2020: 168.

[261] Professor Susannah Ahern, *Hansard*, 27 April 2020: 55.

[262] See ACSQHC: https://www.safetyandquality.gov.au/publications/framework-for-australian-clinical-quality-registries/

[263] MTAA, *Written submission No. 39*, 13 September 2019: 6.

[264] Dr Robert Herkes, *Hansard*, 1 June 2020: 94.

The Federal Government's response to the Senate Inquiry states in relation to the CQR Strategy, the work "complements and builds upon" the ACSQHC Framework for Australian Clinical Quality Registries and "will consider ways to provide a nationally consistent approach to the selection, funding, implementation, management and performance of CQRs to improve health outcomes."[265]

As a result, this is a matter for the National Cabinet Reform Committee (Health), and in the Department of Health's written submission (October 2019), the Federal Government advised that the former COAG (National Cabinet Reform Committee) would consider the draft National CQR Strategy in 2020.[266]

SA Health Transvaginal Pelvic Mesh Audit 2018

SA Health's Transvaginal Pelvic Mesh Audit 2018 (the TVM Audit) examined the records of 230 patients from seven SA Health sites, from 2003 until 2018, which resulted in the review of seventy-nine medical records.[267]

SA Health provided the following list of hospitals involved in the TVM Audit, as well as those which were not:

> The 7 hospitals involved in the TVM Audit, which performed mesh implants from 2003 to 2018 were:[268]

1. Murray Bridge Hospital 2. Mt Gambier Hospital 3. Riverland Hospital (Berri) 4. Port Pirie Hospital	5. Modbury Hospital 6. Lyell McEwin Hospital 7. Noarlunga Hospital

SA Health was queried in relation to the methods used in the auditing process, as it was not clear in the TVM Audit Report why only some hospitals were selected as participants in the audit and not others.

SA Health's response detailed issues with the records management processes within the Department for Health and Wellbeing (DHW) over the indicated timeframe, as well as problems in obtaining data from procurement systems. SA Health advised:

> It is important to note that these hospitals were not the only hospitals that performed mesh implants from 2003 to 2018 but were instead those hospitals that performed mesh implants from 2003 to 2018 and had the SA Health electronic procurement system (ORACLE iProcurement solution) as the source for all procurement data.
>
> It should be noted that other hospitals who did performed mesh implants from 2003 to 2018 were not able to participate in the audit as they did not have the ORACLE iProcurement solution in place.

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265 Australian Government, *Australian Government Response to the Senate Community Affairs References Committee Report: Number of women in Australia who have had transvaginal mesh implants and related matters*, October 2018: 7.

266 Australian Government, *Written submission No. 66*, 22 October 2019: 4.

267 SA Health, *Transvaginal Mesh Audit 2018 Report Summary*, received 8 September 2020: 5.

268 SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 28.

The other SA public hospital recording a gynaecology procedure that may have included the implantation of pelvic mesh include: [269]

1. Angaston	10. Kangaroo Island	19. Northern Yorke
2. Balaklava	11. Kapunda	20. Port Augusta
3. Bordertown	12. Loxton	21. Port Lincoln
4. Ceduna	13. Meningie	22. RAH
5. Clare	14. Millicent	23. Renmark
6. CYP Maitland	15. Mt Barker	24. RGH
7. FMC	16. Mt Pleasant	25. South Coast
8. Gawler	17. Murray Bridge	26. Southern Districts
9. Jamestown	18. Naracoorte	

Of the 79 medical records audited:

> […] it indicated there were 29 (37%) patient re-presentations following the TVM procedure – with either SUI and/or POP symptoms. Applying the audit findings, it is expected that approximately 3774 (34%) of the 10,989 procedures (Hospital Activity data) had a mesh implant […] it is estimated that:
>
> - approximately 1386 (37%) of patients who had a mesh implant have or will re-present with either SUI or POP symptoms
> - annually 92 women, calculated on those re-presenting over the 15-year period of the data set, will re-present with SUI or POP symptoms post their mesh procedure. [270]

Evidence regarding the TVM Audit claims the audit reviewed transvaginal mesh procedures that have been undertaken in SA public hospitals to:

> *> ascertain the potential cohort of women affected by mesh implants*
> *> inform the development of clinical pathways to effectively support clinicians and affected woman in the management of these women with complications.* [271]

SA Health also stated in evidence that:

> The Transvaginal Mesh Audit did not include the review of specific mesh implantation, native tissue repair or other such non-mesh procedures. These criteria were out of scope for the audit.
>
> The Transvaginal Mesh Audit did scope the occurrence of pelvic mesh complications in the audit i.e. Page 2 Transvaginal Mesh Audit Summary –
>
> *"The agreed purpose of the audit was to:*
>
> *a. Ascertain an estimate of the number of women in SA public sector who have been exposed to transvaginal mesh.*
>
> *b. Ascertain the estimate of the number of women in SA public sector who have documented possible 'mesh' complications.*

[269] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 28.

[270] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 8; 29.

[271] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 29.

c. Using the above information ascertain an estimated number of women that are likely to be referred to the Pelvic Mesh Clinic, (proposed for a major metro site) in the first year following establishment."[272]

While the TVM Audit was a response to the Senate Inquiry, the data from the TVM Audit is incomplete, which suggests a limited application. As advised by SA Health, the TVM Audit did not include records where other POP or SUI procedures may have been indicated, including those procedures performed abdominally with mesh, or those performed with biological, or native tissue. The other limitation, as provided by SA Health is the exclusion of the majority of hospital sites, twenty-six, as a result of the differing procurement systems.

Further, the Committee was concerned to learn, of the total [33] hospitals listed as possibly having undertaken pelvic mesh implantation procedures during 2003 to 2018, *all continue* to provide services for procedures involving the implantation of mesh.[273]

Given the differing procurement systems, incomplete hospital patient records, and a lack of traceability of the mesh that has been implanted, the results from the TVM Audit indicate there is a need for the DHW to investigate the development of more robust policies and procedures for patient record-keeping. It was noted by the Committee that the TVM Audit did not contain any data extracted from reports made subject to the *Patient Incident Management and Open Disclosure Policy Directive.*

Australian Government

The Australian Government has undertaken an extensive consultation process, according to Ms Tracey Duffy. It is evident from the submissions of the Department of Health (DoH) and the TGA, including the representations made by Ms Duffy, that despite considerable discussion amongst consultation stakeholders, the registry will be prospective as there is difficulty in retrospective data collection.[274]

The investigations made by the DoH show that there is a lack of accurate data being available from any one source, or sources combined. The other main issue is the timeframe for which medical records are kept, generally for a period of seven years.[275] It appears that at best, a retrospective registry would be able to provide limited and imprecise data for the last seven years, or back to 2013.

According to the DoH the APFPR has progressed after experiencing significant delays due to COVID-19. The update on the registry provided by Ms Duffy revealed the registry would proceed to testing in January 2021 with the participation of 22 health sites across Australia.[276]

The hospitals participating in the initial phase is an approximate 50:50 mix of public and private sites with three in South Australia. These include the Queen Elizabeth Hospital (QEH), Royal Adelaide Hospital (RAH), and the Calvary North Adelaide Hospital (CNH) with Flinders Medical Centre showing interest.[277]

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[272] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 29.

[273] SA Health, *Responses to Questions on Notice, Hansard*, 7 September 2020, received 3 November 2020: 28.

[274] Ms Tracey Duffy, *Hansard*, 7 December 2020: 217.

[275] Ms Tracey Duffy, *Hansard*, 11 May 2020: 72.

[276] Ms Tracey Duffy, *Hansard*, 7 December 2020: 214.

[277] Ms Tracey Duffy, *Responses to questions on notice*, 18 December 2020. *Hansard*, 7 December 2020: 214. Received 1 February 2021: 1.

These hospital sites will provide data to the register initially for six to nine months on a voluntary basis. The registry will collect and evaluate the data about patients who present with new or revision surgery for SUI as well as revisions and explantation procedures for POP, or for including mesh removals.[278]

According to Ms Duffy, following the initial rollout, the registry will continue to on board sites, identifying high volume public and private sites in each state. It is not clear at this stage if the QEH, RAH and CNH will continue as 'on board' hospitals for implementation of the register. Ms Duffy advised that in the implementation phase:

> APFPR clinicians in these jurisdictions will approach these units/specialists in the first instance. The APFPR project team will work with site's Head of Departments to introduce the registry through lunchtime seminars/forums and other appropriate hospital meetings. Registry staff will also invite sites to participate through an Expression of Interest process via the college Communiques in 2021 and the APFPR website.[279]

The APFPR became operational in February 2021.[280]

South Australian Government

The Minister for Health and Wellbeing (the Minister) advised in a written submission that the new Commonwealth regulatory framework for surgical mesh devices, approved in October 2017, including the reclassification of implantable mesh devices, is expected to "provide greater traceability of devices across the new system."[281]

The Minister did not provide a submission regarding the prospect of a dedicated South Australian mesh device recipient registry however, it is understood the SA Government supports the implementation of the national APFPR for recipients of pelvic mesh devices. The Committee did not receive any evidence the SA Government would be supportive of pursuing a state-based register for *all* implantable mesh device recipients.

Unique Device Identification System

In the written submission to this inquiry, the Commonwealth Department of Health (DoH) advised consultation was underway for the establishment of a Unique Device Identification (UDI) system in Australia.[282] The proposed UDI will align with the International Medical Device Regulators Forum (IMDRF) UDI Application Guide. If established, the UDI has the potential to code medical devices from the point of manufacture, extending to the use by the recipient, so that each device is trackable through the system.

The benefits of such a system are obvious, but the DoH advised that the benefits could "be significantly enhanced if adopted in the Australian health system more broadly, including by registries, hospital systems and the MyHealth Record."[283]

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[278] Ms Tracey Duffy, *Hansard*, 7 December 2020: 214.

[279] Ms Tracey Duffy, *Responses to questions on notice*, 18 December 2020. *Hansard*, 7 December 2020: 214. Received 1 February 2021: 1.

[280] See Australasian Pelvic Floor Procedure Registry, *Communique #2 – February 2021* https://apfpr.org.au/wp-content/uploads/2021/02/20210218_APFPR_Communique_2.pdf

[281] Hon. Stephen Wade MLC, Minister for Health and Wellbeing, *Written submission No. 65*, 15 October 2019: 2 – 3.

[282] Department of Health, *Written submission No. 66*, 31 October 2019: 6.

[283] Department of Health, *Written submission No. 66*, 31 October 2019: 6.

According to the consultation paper issued by the DoH, the UDI in Australia will potentially provide significant benefits throughout the supply chain, including:

- enhanced effectiveness of post-market safety-related activities, such as faster and more accurate identification of problems
- improved functionality in the reporting of incidents and adverse events; and more effective management of medical device recalls
- a more robust pre-market assessment of medical devices due to the availability of better-quality evidence-based data that is presented consistently and which includes post-market data and analysis
- a reduction in medical and surgical procedural errors by allowing healthcare professionals and others to quickly trace a device and obtain vital information about its characteristics
- enhanced analysis and research through the uniform documentation of devices in electronic health records, clinical information systems, registries, and other data sources
- a more robust and secure global distribution chain, which helps to tackle diversion and counterfeiting, and facilitates preparation for medical emergencies
- better sharing of medical device information around the world. [284]

Some of the issues identified by the Health Consumers' Alliance of SA relate to the notification of the system by the DoH to the medical device recipient:

> Information about the device, be provided to the consumer (in a form accessible to them) prior to use/procedure of the;
>
> - Evidence of incidents/adverse events associated with the device (eg vaginal mesh)
> - In the case of an incident or adverse event related to the medical device, consumers can be notified in a timely manner.
> - Risks associated with use of the specific device (eg evidence-based date on surgical errors) including options for alternative devices
> - Open disclosure by health practitioners/services of any 'kick-backs' or incentives received by the practitioner/service by using the device
> - Access to current research information
> - Public access to information, in a form accessible by consumers (the public) about all devices (i.e plan language, accessible online portals (eg TGA website) and other formats, provision of information at health consultation etc
> - Access to a central body to raise formal concerns, issues or queries (patient reported measures and experiences) in relation to a specific device that has been used in their treatment (eg the UDI regulatory body).[285]

Other considerations include costing the system, the interoperability with other Australian systems and registries (linkages between the Australian Register of Therapeutic Goods (ARTG)), and consistency with international jurisdictions, in particular the United States and European Union.[286]

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[284] Department of Health, *Consultation: Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia*, January 2019: 6 - 7. Accessed 7 December 2020 https://www.tga.gov.au/sites/default/files/consultation-proposal-introduce-unique-device-identification-udi-system-medical-devices-australia.pdf

[285] Health Consumers' Alliance of SA, *Response to TGA Consultation - Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia*, 22 January 2019: 4. Accessed 5 January 2021 https://www.tga.gov.au/sites/default/files/submissions-received-proposal-udi-system-medical-devices-hca.pdf

[286] Department of Health, *Submissions received: Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia*. Accessed 5 January 2021 https://www.tga.gov.au/submissions-received-proposal-introduce-unique-device-identification-udi-system-medical-devices-australia

Ms Tracey Duffy advised the Committee that the Federal government approved the TGA to access $7.7 million of the TGA held reserve fund, accumulated through fees and charges on industry in order to establish the UDI database. Ms Duffy advised the scoping work for the UDI system is under way and that the project will be undertaken over a four-year period. [287]

Before progressing the UDI project further however, changes would be needed to be made to the *Therapeutic Goods Act 1989* (TG Act), to enable the UDI to be implemented. Ms Duffy stated the changes had been laid before Australian Parliament at the end of 2020.[288]

The DoH states, the proposed first actions once the amendments have been made to the TG Act and the Therapeutic Goods (Medical Devices) Regulations 2002 will be to:

- allow the designation of Issuing Agencies (or Issuing Entities) and provide these with the power to issue Unique Device Identifiers
- prescribe requirements for the placing of Unique Device Identifiers on a device, its labelling and packaging
- establish the AusUDID and link it to the Australian Register of Therapeutic Goods.[289]

While changes to the legislation awaits assent through the parliament, there is still work to do on the UDI database itself and the DoH has engaged with state and territory public hospitals and private hospital, about how information will be made available.

There will also be an "in-panel" version the database and a public version of the database which the DoH was considering will likely operate similarly to the US FDA's version of the UDI database. [290]

Committee's View

The evidence presented to the Committee shows there is a great need for a register of all implanted mesh devices which includes details of the patient, medical practitioners, devices used and adverse events. The Committee considers such a register should be based on the Clinical Quality Register framework produced by the ACSQHC's National Strategy 2019-20. The Committee also considers, based on evidence that shows capturing data via a national register, rather than a state register, is likely to be most robust.

The register the 2018 Senate Inquiry recommended to be developed by the APFPR Steering Committee and Monash University, which is now being trialled across several states, has the benefit of being modelled on several other registers of medical devices, administrated by Monash University. The Committee understand the APFPR has been built to a best-practice standard, which increases the veracity of the data which is able to be captured.

On this basis, the Committee supports the State Government in continuing to work collaboratively with the Federal Government and the states and territories in ensuring the APFPR is fully implemented and continues into the future. The Committee would also like to see, on the basis of identified need for a hernia mesh register, scoping work undertaken for a register to be developed for other implantable surgical mesh devices.

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[287] Ms Tracey Duffy, *Hansard*, 7 December 2020: 215.

[288] Ms Tracey Duffy, *Hansard*, 7 December 2020: 215 - 216.

[289] Department of Health, *Consultation: Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia*, January 2019: 9.

[290] Ms Tracey Duffy, *Hansard*, 7 December 2020: 216.

Recommendations

The Minister for Health and Wellbeing:

3. Provide support through the National Cabinet Reform Committee (Health), for the progression of the National Clinical Quality Register (CQR) Strategy, including specifically a CQR for hernia mesh, and other mesh devices or a full mesh register, using the Australasian Pelvic Floor Procedure Registry as a model.

4. Continue to provide support through the National Cabinet Reform Committee (Health) for the progression of the Unique Device Identification system and associated research necessary to implement such a reporting system through the Therapeutic Goods Administration.

(c) identifying the current role of South Australian medical practitioners in reporting medical mesh associated adverse outcomes and the consequences of nonmandatory reporting

In many of the submissions to this inquiry, in relation to systems for reporting of adverse events involving medical mesh, witnesses and submitters raised questions that had repeated themes. Some of these centred around questions such as "Who is responsible for reporting to the relevant regulatory bodies under current practices?" "When a problem arises or a defect is found with a medical device or when an implant doesn't do what it should do, or causes unwanted side-effects, where does a patient go?" "From whom does the patient seek advice and remedy?" "What redress is there if something goes catastrophically wrong with a surgically implanted medical device, such as mesh?"

Along with these questions, came the repeated and despairing claims from people injured by medical mesh that "[Their] General practitioner did not know what was causing their symptoms." "The surgeon denied anything was wrong, that it wasn't the TVT." [Their] Gynaecologists repeatedly told [them] they didn't have 'mesh', it was a 'tape' and nothing could go wrong with 'tape'." "It was [their] fault, they are the only one out of many successful surgeries who has had an issue." This was found to be the case for several recipients of hernia mesh as well as for a number of pelvic mesh recipients.[291, 292, 293]

The Therapeutic Goods Administration (the TGA) provides the following list of adverse events that may be associated with urogynaecological meshes:

- punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel (these may require surgical repair)
- transitory local irritation at the wound site
- a 'foreign body response' (wound breakdown, extrusion, erosion, exposure, fistula formation and/or inflammation)
- mesh extrusion, exposure, or erosion into the vagina or other structures or organs
- as with all foreign bodies, mesh may potentiate an existing infection
- over-correction (too much tension applied to the tape) may cause temporary or permanent lower urinary tract obstruction
- acute and/or chronic pain
- voiding dysfunction
- pain during intercourse
- neuromuscular problems including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area
- recurrence of incontinence
- bleeding including hemorrhage, or haematoma
- seroma
- urge incontinence / urinary retention
- urinary frequency
- adhesion formation
- atypical vaginal discharge
- exposed mesh may cause pain or discomfort to the patient's partner during intercourse
- mesh migration
- allergic reaction
- abscess
- swelling around the wound site

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[291] Name confidential, *Written submission No. 15*, 11 September 2019: 2.

[292] Name confidential, *Written submission No. 33*, 13 September 2019: 1.

[293] Name confidential, *Written submission No. 64*, 8 October 2019: 1.

- recurrent prolapse
- contracture
- scarring
- excessive contraction or shrinkage of the tissue surrounding the mesh
- vaginal scarring, tightening and/or shortening
- constipation/defecation dysfunction
- granulation tissue formation. [294]

This list is not a list of symptoms which are experienced in isolation, or one at a time; some who gave evidence to this inquiry have several of these symptoms, others have had many. Most of the women who provided evidence to this inquiry spoke of having multiple symptoms- all of them on the TGA's list, and which, impact their lives on a day-to-day basis. Some of the women have endured these symptoms for years, and continue to endure them, despite having been counselled, in some cases that their pain is not real. Some, despite continuing believing they will be able to have the mesh removed, continue to wait.

Kim, a survivor of failed pelvic mesh, representative of the South Australian Pelvic Mesh Support Group and consumer member of the SA Pelvic Mesh Consumer Advisory Group with the SA Health SA Pelvic Mesh Clinic, commented:

> I believe—and this is my personal opinion—the voice of mesh-injured women still isn't being listened to. I believe that the medical profession in the clinic don't understand the type or severity of the pain. They are still not believing women. It was cited to me that a woman with a particular type of mesh wouldn't feel that type of pain. It doesn't matter if mesh is in the right place or not, it still causes life-changing, extremely debilitating pain. Most, not all, of these women have delivered babies themselves. They know what pain is. They are strong, resilient women who are often at their wits' end.[295]

Written submission 44 told the Committee that for her abdominal hernia repair in 2016, no other options were given to her by her surgeon and no complications discussed pre-operation:

> On one occasion prior to surgery, I asked Dr […] if any of his patients had had any complications from this type of surgery and he indicated only one, however the patient was reportedly elderly and was suffering other health issues.
>
> Three and a half years post-surgery, I still experience physical pain/discomfort from my mesh, ranging from the feeling of many, many needle pricks to pulling in the abdominal area. I reported my pain to my surgeons on a few occasions following my surgery and I was told to give it time, keep up with the exercise and that it would settle. I even visited Dr […] in short succession following a spate of negative media stories regarding patient complications with transvaginal/uterine mesh implants. On that occasion, Dr […] reassured me that it was a completely different situation to my abdominal mesh implantation and that my pain would improve, particularly with exercise. While my physical pain levels have improved, I am not pain-free. Aside from my strong disappointment with myself for not conducting more thorough research into the implications of mesh insertion, psychologically, I have suffered as a result of the implantation of my medical mesh. I find it extremely distressing to think that I could have to manage my pain/discomfort for the rest of my life and that mesh removal is not a physically possibility at present as the mesh is embedded in my tissue matter. My consistent pain/discomfort is a constant reminder of the futility of my situation.[296]

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[294] TGA, *Urogynaecological surgical mesh complications,* "TGA urges reporting of adverse events", August 2016. Accessed 31 May 2019 https://www.tga.gov.au/alert/urogynaecological-surgical-mesh-complications#:~:text=Adverse%20events%20that%20may%20be,these%20may%20require%20surgical%20repair)

[295] Kim, oral evidence, *Hansard*, 30 November 2020: 194.

[296] Name confidential, *Written submission No. 44*, 13 September 2019: 1 – 2.

In several submissions, witnesses relayed how they were advised by their treating surgeon or gynaecologist that their complications were "very rare", "the pain wasn't normal", it just needed a "little snip" or that they were just experiencing "anxiety" which was causing the problems.[297, 298, 299, 300]

Written submission 19, who had a TVT-O for SUI in 2008, and suffered numerous medical conditions and incorrect diagnoses following the implant stated:

> I was dismissed by doctors and specialists as suffering from anxiety and that nothing I was feeling was anything I could die from.
> I was judged and made to feel like a hysterical female and a hypochondriac.
> It was suggested I could benefit from therapy.
> My husband was furious at the lack of empathy and literally dragged me out of two appointments saying there was no point in being there as they were not listening and had made up their minds that there was nothing wrong with me.[301]

Other witnesses claimed their treating surgeons refused to see them again or did not answer their telephone calls.[302] Several other written submissions detailed how witnesses had reported their adverse events to their surgeon, hospital or the TGA, only to continue to be told their complications could not be from their mesh implant. In all cases, these witnesses appear to have had their symptoms minimised or dismissed.[303, 304, 305]

In Written submission 42 (WS 42), the Committee was provided with a detailed chronology of events, which describe how this witness endured years of complications and fruitless visits to GPs and specialists. This account is synonymous with many of the other witness accounts of their complications with mesh. The Committee heard and read many accounts by witnesses of the repeated visits to GPs, specialists and gynaecologists, without much effect. The following account is provided to show how the consequences of a lack of mandatorily reported and verifiable information concerning mesh complications, can affect one person. WS 42 writes that initially it took several years for her diagnosis and treatment offered was mesh:

> In April of 2009, I had a prolapse and sought assistance from my local GP. After 2 years of prolapse and bladder infection issues, I was finally referred to Dr […] on 27 January 2011. Dr […] felt that the reason I was getting repeated infections was due to the ongoing prolapses that were occurring. Upon his recommendation I was scheduled for surgery to have the Mesh implant to support everything to stop the prolapses and help stop the repeated infections.[306]

After surgery, WS 42 writes that while initially there were problems including bleeding and bladder infections things "settled down", although she continued to have the infections, for which antibiotics had stopped working. WS 42 provides the following chronology, abridged for this report:

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297 Name confidential, *Written submission No. 10*, 10 September 2019: 1 – 2.

298 Name confidential, *Written submission No. 25*, 13 September 2019: 2.

299 Name confidential, *Written submission No. 26*, 12 September 2019: 1 - 2.

300 Name confidential, *Written submission No. 46*, 13 September 2019: 1.

301 Name confidential, *Written submission No. 19*, 12 September 2019: 2.

302 Name confidential, *Written submission No. 53*, 13 September 2019: 1.

303 Name confidential, *Written submission No. 11*, 10 September 2019: 2.

304 Name confidential, *Written submission No. 31*, 13 September 2019: 1

305 Name confidential, *Written submission No. 47*, 13 September 2019: 1.

306 Name confidential, *Written submission No. 42*, 13 September 2019: 1 - 2.

- **June 2011** – Surgery - major anterior elevate mesh repair for vaginal prolapse. In hospital for 3 days.
- Follow up appointment due to bleeding - advised 'to be expected' but to return if it continued.
- Reoccurring bladder infections, often on antibiotics prescribed by new local GP.

  ……..
- **February 2017** - Sharp pain in right side and rash with no attributable cause.
- Visits to local GP roughly every 2 months during 2017 to monitor situation.
- Ongoing bladder infections. Urine changed and smell of rotting plastic.
- **March 2018** - Local GP sent referral to […] Hospital to get bladder infection under control.
- **October 2018** - Appointment at […] Hospital. Advised of 12 months wait for follow up surgery or repeated visit. Notes from appointment took 4 months to be sent back to local GP.
- Appointment with local GP - advised right kidney was smaller than left and a shadow near lowest right rib.
- **November 2018** – Further bladder infection and prescribed antibiotics not working.
- New GP as regular GP unavailable. Requested referral to Dr […] (original surgeon). Advised by GP "there is nothing more she can do."
- Changed GP again.
- New GP more understanding and suggested trying alternative medications.
- Appointment with Dr […] (original surgeon) made for 28 February 2019.
- **28 February 2019** - Appointment with Dr […] (original surgeon) cancelled and rescheduled to 7 March 2019due to Dr […] (original surgeon) on holiday.
- **7 March 2019** - Appointment with Dr […] (original surgeon) advised nothing wrong but had acquired a prolapsed bowel as well. Advised day surgery would be required to have a further look and repair. Advised would be 3 to 4 months wait for appointment. Surgery scheduled for July 2019.
- **9 May 2019** - GP ordered X-rays and CT Scan done to assist resolving issues.
- **May 2019** - Five GP appointments
- **June 2019** – Four GP appointments
- **16 July 2019** - Day surgery with Dr […] (original surgeon).
- Post-operative follow-up appointment scheduled for 27 August 2019 with Dr […] (original surgeon).
- **27 August 2019** – Appointment results from exploratory surgery not available. Dr […] (original surgeon) provided no information on exploratory surgery. Further appointment scheduled for 17 October 2019.
- **17 October 2019** - Appointment with Dr […] (original surgeon] and was advised the mesh had fused with insides and unable to be removed. Bladder flushed out at appointment. On waiting list for a date for exploratory bowel surgery and referral required for heart problems.

Written submission 48 (WS 48) had a "tape" implanted following a hysterectomy. Ten days after her surgery she experienced bleeding and visited her surgeon. She was advised at this appointment that she had an infection and "it's not uncommon" and she was prescribed antibiotics. At her 6-week follow up appointment, WS 48 told her surgeon she was still in pain, however he advised her it "might take a few months to calm down" but she could recommence sexual relations with her husband.[307] WS 48 offered the following account of how her symptoms got worse over time, but was told repeatedly she was the only patient the surgeon had operated on who had these complications:

> The first time my husband and I tried to have sex, my husband was stabbed in the penis, grazing it, and frightening the heck out of him. I assumed it must have been a "stitch" left in there, so organised a follow up consult with the gynaecologist. I was examined and although he couldn't see anything, he said he could feel something, and thinks I might have "erosion" of the tape through my vagina. He said he'd heard of it, but none of his patients had ever experienced it. I was SOO unlucky.
>
> He prescribed some oestrogen cream to be dispensed into my vagina daily. […] I dispensed the cream daily, and occasionally checked or had my husband check to see if he could feel anything sharp down there. A few weeks on, we could still feel a sharp protrusion. So again we went back to the gynaecologist and his nurse, who checked and said I had erosion that would need to be trimmed and sewn over. He reassured me that I was VERY unlucky and that it was a simple operation, and I'd have no further complications. He was wrong. I had two revision surgeries, followed by trial surgery for removal and then removal surgery. In between I had many other consultations, CT scans and medications. […]
>
> It wasn't until I appeared in the local paper with my story, to shed some light on mesh awareness, that I found out that I had been lied to. Another mum from my child's school approached me and told me she was suffering from similar complications since a similar surgery. She went on to tell me that her surgeon, the hospital, the procedure, and the date of her surgery, were all the similar to mine, occurring a couple of months after mine. She said she had seen the same surgeon and was told that he had never had this happen before with any of his patients (same story I was told) and that she too was SOOO unlucky. […]
>
> I researched and found that the surgeons do not have to mandatorily report complications or adverse reactions to implants; in fact they are supposed to tell the manufacturer of the product, and the manufacturer is supposed to mandatorily report same to the TGA. When I reported my complications to the TGA, I assumed they would "match" up my product number to the report made by my surgeon. But there wasn't a report placed by my surgeon, nor the manufacturer.[308]

The Committee was concerned that the problems with medical mesh continues to impact the lives of South Australian women and men, and that there continues to be a lack of knowledge and understanding of these issues amongst GPs, gynaecologists and treating surgeons, despite the exposure gained from the Senate Inquiry. Of significance, and what is evident from the submissions presented, is where a patient has not been able to receive appropriate care and treatment from their medical practitioners, in the event of complications from medical mesh, they cannot possibly expect the very same medical professionals to report the adverse effects of medical mesh to the TGA or any other regulatory organisation.

Legislation and Governance of Clinical Practice in Hospitals and Day Surgery Centres

In South Australia, and across the states and territories, public and private hospitals and day surgery centres are governed by a number of different statutes and governance instruments which provide frameworks for the management of patient related adverse events, including with medical devices.

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[307] Name confidential, *Written submission No. 48*, 13 September 2019: 1 – 2.

[308] Name confidential, *Written submission No. 48*, 13 September 2019: 2 – 3.

National Safety and Quality Health Service Standards

The Australian Commission on Safety and Quality in Health Care (the ACSQHC) is responsible under the Commonwealth *National Health Reform Act 2011* for developing standards for health care safety and quality and for the Australian Health Service Safety and Quality Accreditation (the AHSSQA) Scheme. In support of these functions sit the National Safety and Quality Health Service Standards (the NSQHS Standards) (Second edition ACSQHC 2019b), under which all public and private hospitals, day procedure services are required to be accredited.

The NSQHS Standards are comprised of eight safety and quality standards which provide for protection of the public and determine the quality of care the public can expect.[309] The ACSQHC administers the NSQHS and is responsible for the states and territories compliance with the standards. The NSQHS Standards provide "[…] primary aims of the NSQHS Standards are to protect the public from harm and to improve the quality of health service provision."[310] Of particular importance is the Clinical Governance Standard which:

> […] aims to ensure that there are systems in place within health service organisations to maintain and improve the reliability, safety and quality of health care. This standard, together with the Partnering with Consumers Standard, set the overarching requirements for the effective implementation of all other standards. The Clinical Governance Standard recognises the importance of governance, leadership, culture, patient safety systems, clinical performance and the patient care environment in delivering high quality care.[311]

All hospitals and day surgery centres must meet the requirements set down in the NSQHS Standards, submitting reports for accreditation throughout an assessment cycle. The purpose of the assessment is to make sure that safety and quality systems are in place and reviewing compliance with the NSQHS Standards. Organisations are encouraged to utilise the PICMoRS method of self-assessment as part of their assessment process.[312] The PICMoRS is used for gathering evidence from clinicians, managers, other members of the workforce, representatives of the governing body and consumers.

Throughout the assessment process, assessors confirm each safety and quality system is in place by assessing compliance with the NSQHS Standards, determining compliance by collating information and comparing findings with the requirements of the NSQHS Standards. The Assessors then report their preliminary findings to the health organisation to address and then to accrediting agencies, the ACSQHC and any other regulatory organisations as to whether there are any risks.[313]

SA Health Patient Incident Management

SA Health advised that the SA Health policy 'Safety Learning System Reporting Framework' (the SLS Reporting Framework), guides staff in the reporting of all adverse events, including those associated with all medical mesh implants.[314]

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309 AIHW, *Safety and Quality of Health Care*. Accessed 12 January 2021 Safety and quality of health care - Australian Institute of Health and Welfare (aihw.gov.au)

310 ACSQHC, *Implementation of the NSQHS Standards.* Accessed Implementation of the NSQHS Standards | Australian Commission on Safety and Quality in Health Care

311 ACSQHC, *Clinical Governance Standard* Clinical Governance Standard | Australian Commission on Safety and Quality in Health Care

312 PICMoRS is an acronym for Process, Improvement strategies, Consumer participation, Monitoring, Reporting, Safety and quality systems. See Fact Sheet 12: Assessment Framework for Safety and Quality Systems, December 2020

313 ACSQHC, *Assessment Framework for Safety and Quality Systems*. See Fact Sheet 12: Assessment Framework for Safety and Quality Systems, December 2020

314 SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 8.

The SLS Reporting Framework covers the SA Health *Patient incident management and open disclosure Policy Directive,* which requires all SA Health employees or persons who provide health services on behalf of SA Health to comply with the policy directive.[315] The policy directive states:

> **incident (patient incident)** means: any event or circumstance which could have (near miss) or did lead to unintended and/or unnecessary psychological or physical harm to a consumer/patient that occurs during an episode of health care. Incident types are harmful incident, cluster incident, near miss, no harm incident and adverse incidents
> […]
> **incident management** means: all the activities involved in the reporting, notification or documentation of an incident or near miss, including the review, investigation and analysis of the individual incident, and the analysis of groups of incidents, or data arising, for the purpose of improvement of the safety and quality of the health service and the care provided.[316]

The policy directive also refers to 'Open disclosure' as a process of providing "an open, consistent approach to communicating with patients/consumers, their family, carer and/or support person following a patient incident. This process includes expressing regret or saying sorry."[317]

The Committee acknowledges the policy and procedures in place within SA Health to provide for open disclosure and patient incident reporting (*Patient Incident Management and Open Disclosure Policy Directive* or *PIR*). The PIR policy is mandatory for SA Health staff employed in an SA Health facility.[318]

However, it is not clear whether the *Patient Incident Management and Open Disclosure Policy Directive* has been utilised as a way of recording incidents that have occurred in patients with mesh implants, or if the policy directive has been utilised for determining how many such incidents have been reported. The Committee did not receive evidence as to how the PIR policy and procedures have been monitored or reviewed for improvements, or if the PIR policy is applied in the SA Pelvic Mesh Clinic.

For example, Dr Watson advised the Committee that there are women who present to the general gynaecology clinics within SA Health who require treatment for mesh related issues, but who do not necessarily go on to be admitted to the SA Pelvic Mesh Clinic. It is not clear if reports are made in the PIR system by the gynaecology clinics, who is responsible for reporting or when such a report is likely to be recorded for patients in this cohort:

> […] we are still seeing people with mesh complications in the general gynaecology clinics as well. They don't all end up in the mesh clinic. If we think they require the services of the mesh clinic, then we will refer them on to there, but for a lot of people it is a tiny, small erosion of mesh that can be dealt with by a general gynaecologist and we will deal with it.[319]

In-line with the TGA's advice that a mesh related complication, or adverse event is considered, amongst other things to be:

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[315] SA Health, Safety and Quality, System Performance and Service Delivery. *Patient incident management and open disclosure Policy Directive V2.2,* 29 September 2017:7.

[316] SA Health, *Patient incident management and open disclosure Policy Directive V2.2*, 2017:7.

[317] SA Health, *Patient incident management and open disclosure Policy Directive V2.2*, 2017:6.

[318] SA Health, *Patient incident management and open disclosure Policy Directive V2.2, 2017*: 6.

[319] Dr Roy Watson, *Hansard*, 1 February 2021: 240.

- a 'foreign body response' (wound breakdown, extrusion, erosion, exposure, fistula formation and/or inflammation)
- mesh extrusion, exposure, or erosion into the vagina or other structures or organs[320]

the TGA encourages health professionals and consumers to report these adverse events through the TGA's Incident Reporting and Investigation Scheme (IRIS).

The SA Pelvic Mesh Clinic has assisted in the lodgement of forty reports to the TGA, while there is a "backlog" of a further thirty awaiting finalisation and lodgement.[321] It is not clear if these adverse events have also been recorded in the SA Health's own PIR system.

Review of Medicines and Medical Devices Regulation Panel

In 2015, the Review of Medicines and Medical Devices Regulation Panel (the MMDR Panel) undertook a review for the Australian Government, of the Regulatory Framework for Medicines, Medical Devices. In reviewing the processes for reporting on adverse effects of medical devices and the effectiveness of post-market regulation of such devices, the MMDR Panel recommended earlier communication in the reporting of risks to improve post-marketing scheme. The MMDR Panel also found that where a device was in a higher risk class, the scheme should be mandatory:

> The Panel is of the view that an early post-marketing risk communication scheme for therapeutic goods should be implemented to encourage adverse event reporting for new therapeutic goods. The Australian NRA should develop inclusion criteria for which products should be captured by the scheme in consultation with relevant stakeholders. However, the Panel recommends that the scheme be mandatory for all products granted provisional approval under the new Pathway Three for either medicines or medical devices, as it will be particularly important to encourage adverse event reporting by consumers and health practitioners for these products.[322]

In the report on the *Regulatory Framework for Medicines, Medical Devices*, the MMDR Panel advised:

> No regulatory system can ever be 100 per cent effective for catching all risks and no medical device can be guaranteed to be 100 per cent safe. The iterative nature of medical devices means that many are approved on the basis of their design and the manufacturer's compliance with quality standards, rather than on the basis of detailed clinical trials as are required for medicines. As a result, timely and effective post-market monitoring of the performance of medical devices in the real world is an essential element of an effective regulatory system.

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[320] TGA, *Urogynaecological surgical mesh complications,* "TGA urges reporting of adverse events", 2016. Accessed 31 May 2019 Urogynaecological surgical mesh complications | Therapeutic Goods Administration (TGA)

[321] Dr Roy Watson, *Responses to Questions on Notice*, *Hansard*, 1 February 2021: 241. Received 12 February 2021: 2.

[322] Emeritus Professor Lloyd Sansom AO, Mr Will Delaat AM, Professor John Horvath AO. Review of Medicines and Medical Devices Regulation, *Report on the Regulatory Framework for Medicines, Medical Devices,* March 2015: 159. Accessed 20 November 2020 Review of Medicines and Medical Devices Stage One Report.pdf (health.gov.au)

Reporting adverse events to the TGA

According to the TGA, in every year the TGA receives around 5 500 incident reports relating to one million medical devices that are in use across Australia.[323] As part of an application to receive entry into the ARTG, clinical trials of a medical device are evidence of efficacy of the device. In the case of transvaginal mesh, it was reported in the Senate Inquiry that there was a lack of clinical trials undertaken on those devices, which resulted in there being a complete lack of evidence to support claims made by injured mesh recipients.[324]

The 2018 Senate Inquiry's Recommendation No. 1

In its report on the *Number of women in Australia who have had transvaginal mesh implants and related matters*, the Senate Community Affairs References Committee (the Senate Inquiry) recommended that because the reporting of adverse events from medical devices to the Therapeutic Goods Administration (TGA) was so vital for post-market surveillance, the Federal Government in consultation with relevant stakeholders, should review the existing system for reporting, with the view to implementing mandatory reporting by medical practitioners.[325]

The Senate Inquiry found that it was "inappropriate to rely on estimates to determine the quality and safety of mesh devices" and referred to a previous report by the Senate Community Affairs References Committee on the regulatory standards for approval of medical devices.[326] The Senate Committee noted that the then Australian Government's response to the need to increase reporting was one of support; encouraging greater participation in the reporting system by the medical profession. The Senate Inquiry importantly observed:

> […] 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. [*]
>
> 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.[327]

The Senate Committee in 2018, raised concerns that the apparent laxness of reporting by the medical profession could give rise to failures in the post-market regulation of devices:

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[323] TGA, *Progress update: Improving post-market monitoring and surveillance of medical devices*. Accessed 21 December 2020 https://www.tga.gov.au/progress-update-improving-post-market-monitoring-and-surveillance-medical-devices

[324] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 89 – 90.

[325] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: viiii; 57.

[*] Senate Community Affairs References Committee, *Inquiry Report*, "*The Regulatory Standards for the Approval of Medical Devices in Australia"*, November 2011, Recommendation 8, p. 102. Cited at Reference 103 in Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 57.

[326] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 57.

[327] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 57.

> […] the current system appears to allow significant scope for medical practitioners and device sponsors to determine whether an event should be reported…this has led to inconsistency in the reporting of events…"; the Committee was particularly concerned by the "…level of underreporting of adverse events to the TGA…and that…post market regulation is reliant on voluntary reporting by medical professionals.[328]

Further, it was reported that the Senate Committee had received "…a significant amount of evidence recommending that reporting of adverse events should be mandatory for medical practitioners."[329] Recommendation 1 of the Senate Inquiry report provides (bold added):

> Recommendation 1
> 5.55 Noting the vital role of adverse reporting in post-market surveillance, the committee recommends that the Australian Government, in consultation with the states and territories and the Medical Board of Australia, **review the current system of reporting adverse events to the Therapeutic Goods Administration to:**
>
> - **implement mandatory reporting of adverse events by medical practitioners;**
> - provide guidance on what constitutes an adverse event for use by consumers, medical practitioners and device sponsors;
> - improve awareness of the reporting system; and
> - examine options to simplify the reporting process;[330]

The Australian Government Response and Actions taken

In response to the Senate Inquiry findings and recommendations, the Australian Government advised it had "in principle" support for mandatory reporting by medical practitioners and that the Department of Health (DoH), through the TGA had commenced a range of reforms aimed at improving the processes for the reporting of adverse events concerning medical devices.[331] The DoH advised the Action Plan consists of three key strategies:

> The Action Plan aims to strengthen Australia's regulatory system whilst continuing to be patient focused and have greater transparency. It outlines actions that continue to improve the safety, performance and quality of medical devices in Australia and improve health outcomes for consumers who require medical devices.
>
> The Action Plan is underpinned by three strategies which will build on current work to:
>
> - improve how new medical devices obtain entry to the Australian market;
> - strengthen post-market monitoring and follow up of devices already in use; and
> - improve the provision of medical device information to patients about the devices they use.[332]

Consultation by TGA for Mandatory Reporting by Healthcare Facilities

As part of the program of reforms, Strategy 2 of the *Action Plan for Medical Devices* (the Action Plan) proposes strengthening the monitoring of devices already in use, including the proposal to

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[328] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 57.

[329] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 57.

[330] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: viiii.

[331] Australian Government, *Progress Report on the Australian Government Response to the Senate Community Affairs References Committee Report: Number of women in Australia who have had transvaginal mesh implants and related matters*, October 2019: 5.

[332] Australian Government, Department of Health. *Written submission No. 66*, 31 October 2 019: 7.

make reporting of adverse events by healthcare facilities mandatory.[333, 334, 335] This proposal was released on public consultation after approval by the Federal Government in April 2019. In December 2020, the TGA finalised the first stage of consultation on the reforms proposed by the Action Plan, including a mandatory reporting process for health care facilities and medical practitioners.[336] The DoH advised that:

> Although sponsors of medical devices have mandatory legal obligations to report adverse events to the TGA, healthcare practitioners, health institutions and consumers only report adverse events associated with medical devices on a voluntary basis. Consequently, adverse event data held by the Department is incomplete. This compromises systematic data tracking through the device supply chain so that development of a comprehensive profile of implantable devices is challenging.[337]

Ms Duffy advised that improvements to the reporting framework were continuing:

> […]part of our public consultation process, which is scheduled this year to do, is to look at all potential improvements to how adverse event reporting occurs in Australia. That is one of the limitations of our current system, and we would expect that a request for further granularity could be something that comes through from our consultation. That has to be balanced with the burden. We used to require more information as part of our adverse event reporting requirements and had to scale it back to try to increase the numbers, because consumers and others were saying that we wanted too much information. It's a real balance, and I think if we are going to improve information sharing between the states and territories and the TGA, we have to have be able to record the information that makes sense to the states and territories so they can also understand what is happening in their own jurisdictions.[338]

On 7 December 2020, Ms Tracey Duffy provided the Committee with an update on actions completed by the TGA as part of the *Action Plan for Medical Devices*. Ms Duffy advised that although consultation on making reporting mandatory for medical practitioners was to proceed to a second round, improvements had been made to the information available to GPs, specialists, surgeons and patients.

Following this, and as a result of the 2018 Senate Inquiry, improvements have also been made to the online reporting forms to make them easier and quicker for medical practitioners to use.[339]

Issues for Mandatory reporting

Submissions to this inquiry show that the TGA online reporting system for recording adverse outcomes for mesh implantation has been difficult for health professionals to use, highlighting both the lack of compliance in reporting and the need for system improvements.

Dr Ian Tucker commented that population movement is a critical issue for databases that cross jurisdictions and says in support of mandatory reporting, that:

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333 Australian Government, *Progress Report on the Australian Government Response to the Senate Community Affairs References Committee Report: Number of women in Australia who have had transvaginal mesh implants and related matters*, October 2019: 5 – 6.

334 Australian Government, Department of Health. *Written submission No. 66*, 31 October 2019: 15.

335 See also: Medical devices reforms: Enhancements to post-market monitoring | Therapeutic Goods Administration (TGA)

336 TGA, Accessed 7 January 2021 https://consultations.health.gov.au/tga/copy-of-test-2-adverse-events-reporting-for-medica/

337 Department of Health, *Written submission No. 66*, 31 October 2019: 5.

338 Ms Tracey Duffy, *Hansard*, 11 May 2020: 73.

339 Department of Health, *Written submission No. 66*, 31 October 2019: 5.

> It is vitally important that information be transmitted to the original surgeon […] for audit and continuing understanding of the progress of that patient.[340]

Another for issue pointed out by Dr Ian Tucker is that the data-entry involved in reporting in registries is time consuming and there are times when, after completing a busy surgery list, it is difficult to then sit down and do all the data entry required.[341]

However, Dr Tucker also intimated that making a registry for the collection of data on all mesh surgeries mandatory would be a way to ensure the data entry gets completed.[342]

Professor Guy Maddern provided the following observation on another register that had been successful as a mandatory reporting system:

> I think if it's not mandatory, our experience is that you lose a lot of really important information. For example, some years ago—a long time ago in fact—we did some work for the TGA where we looked at the introduction of abdominal aortic aneurysm repairs, which were done through the groin where a piece of plastic was put into the aorta to stop an aneurysm. We collected that data—initially it was mandatory. You could not get an MBS payment—this was inside the MBS—unless you reported your outcomes. Most of the problems were, of course, in that early peri-operative period. There was a lot of political pressure and the surgeons at the time said, 'It shouldn't be mandatory, we'll do this voluntarily.' So they started to do it voluntarily and we saw a dramatic drop in the number of deaths. What was happening, we suspect, was that people were not so forthcoming to share their bad outcomes but wanting to do their good ones, so that is a dilemma. We have evidence that that is what occurs.[343]

Dr Magdalena Simonis commented that imposing mandatory reporting would be "difficult":

> To date, reporting of adverse events for complications from mesh implantation is voluntary and nonmandatory for doctors. It would be difficult to impose a mandatory reporting requirement on all medical practitioners, especially those not directly involved in the surgical implantation of mesh.[344]

In her article for RACGP however, Dr Simonis writes that GPs *should* report all adverse events to the TGA:

> All [pelvic mesh] revisions and complications should be reported to the TGA, the process of which has been simplified for doctors to easily log in and report adverse events […] GPs need to be mindful that women who have had mesh inserted and are exhibiting symptoms need to be listened to, taken seriously […][345]

While Dr Tucker offered:

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340 Dr Ian Tucker, *Written submission No. 69*, 7 December 2020: 5.

341 Dr Ian Tucker, *Hansard*, 7 December 2020: 224; 233.

342 Dr Ian Tucker, *Hansard*, 7 December 2020: 224; 233.

343 Professor Guy Maddern, *Hansard*, 30 November 2020: 205.

344 Dr Magdalena Simonis, *Parliament of South Australia Mesh Enquiry 21.09.2020 Social Development Committee Submission by Dr Magdalena Simonis - RACGP representative MBBS FRACGP DRANZCOG MHHS*, 21 September 2020: 4.

345 Dr Magdalena Simonis, *Transvaginal mesh implants inquiry: What GPs need to know*, 26 April 2018: 2. Accessed 24 August 2020 https://www1.racgp.org.au/newsgp/clinical/transvaginal-mesh-implants-inquiry-what-gps-need

> The complications are obviously under-reported, and that is I think a fault of people like myself and other clinicians. We forget to, as an admission of guilt. We are time-constrained, but really, realistically, we should be reporting every complication, and whether making that mandatory would be worthwhile is obviously what you are here about. It does take a lot of time and there are a lot of pros and cons about that, which I probably mentioned later in the submission. There are a lot of things you have to think about.[346]

Dr Samantha Pillay commented that for some surgeons, if a complication is within an "expected range" the surgeon may not consider reporting the complication as an adverse event is required:

> If there was something that was considered unusual or unexpected or new, that would be usually when a clinician would be thinking of reporting to the TGA, but if it was within the reported and expected rates of the identified complications that occur with all procedures, I think that's where they wouldn't have been reported.[347]

Committee's View

The issues raised highlight the importance of the doctor- patient relationship and of continuity of practice. It also places importance on doctors making sure they are appropriately informed about what the TGA regards as an adverse event for mesh devices. While the TGA relies on the latest scientific and medical research to inform decisions concerning ARTG approvals for medical devices, the TGA is also informed by consumer/patient input, which provides a perspective that some medical practitioners may not have access to, or be aware of from their own research methods.

The Committee understands that if mandatory reporting to the TGA, of adverse events concerning mesh devices was in place, it might allow for a greater breadth of information to be captured about a patient, allowing for all doctors involved in the treatment of a patient to have a better understanding of the issues.

Recommendations

The Minister for Health and Wellbeing:

5. Through the National Cabinet Reform Committee (Health), advocate for the introduction of mandatory reporting by health care organisations and health professionals of adverse events associated with medical mesh implantable devices to the Therapeutic Goods Administration.

[346] Dr Ian Tucker, *Hansard*, 7 December 2020: 224.

[347] Dr Samantha Pillay, *Hansard*, 15 June 2020: 104.

(d) assessing the usefulness of current patient information provided prior to surgery, including options for non-surgical treatment, possible adverse outcomes and fully informed consent

The Committee was concerned to learn from witnesses during the inquiry, that there were many instances where medical practitioners had not obtained 'informed consent' prior to implantation of medical mesh. More alarming were the examples provided where medical practitioners had not even sought to obtain basic consent per se.

A number of examples were provided to the Committee where witnesses told of how they were implanted with medical mesh without their knowledge, as already referred to in this report. The majority of examples from witnesses told of how they were provided with some, often cursory information, about the procedure recommended to them, but were not informed of all of the 'material risks' involved, nor of alternative treatments. There were no examples provided by witnesses, where the full facts of the proposed surgery to implant medical mesh were given prior to the surgery.

The Committee finds this deeply alarming, given the potential for adverse outcomes, and that even when medical mesh was first introduced as a treatment for Stress Urinary Incontinence (SUI) and Pelvic Organ Prolapse (POP), that disclosure of the facts involving the lack of clinical trials and longitudinal data on the efficacy of certain meshes in the treatment of POP and SUI[348,349] was withheld, or was simply not mentioned.

While it is noted that there are many factors involved in the relaying and receiving of information, in the patient / medical professional relationship, there is what is considered to be a standard of care and therefore of information, to be divulged by a medical professional to a patient, in the process of diagnosis and treatment.

In light of the number of witnesses who stated they were not informed appropriately or adequately prior to the implantation of medical mesh, this section of the report gives consideration to some of the legal, as well as ethical obligations incumbent upon medical professionals to comprehensively inform and consult with their patients. This is followed by discussion of some of the information that was given to witnesses by their GPs, surgeons or specialists at varying stages in their treatment process.

The Committee has also reviewed the steps taken to improve the types of information available for patients, medical professionals and health services as a result of the Senate Inquiry.

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[348] Cathryn MA Glazener, Suzanne Breeman, Andrew Elders, Christine Hemming, Kevin G Cooper, Robert M Freeman, Anthony RB Smith, Fiona Reid, Suzanne Hagen, Isobel Montgomery, Mary Kilonzo, Dwayne Boyers, Alison McDonald, Gladys McPherson, Graeme MacLennan, John Norrie "Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT)", *The Lancet,* Vol 389 January 28, 2017: 382.

[349] The PROSPECT trials found: Results of previous studies showed a benefit from the use of synthetic mesh and biological graft on objective prolapse stage. However, there are important methodological limitations in aggregating the evidence from these studies using meta-analysis, including the quality of the evidence, the failure to differentiate between primary and secondary repairs, and paucity of patient-centred, validated prolapse-specific outcomes, or quality of life. Our large, rigorous study offers strong, clinically relevant evidence for the alternative view: that mesh or graft are unlikely to be useful in terms of improving any symptoms of pelvic-floor dysfunction or women's quality of life up to 2 years after surgery. Some women had treatment for mesh complications, although most mesh exposures were small and asymptomatic. Further long-term follow-up will ultimately determine whether the use of mesh or graft in vaginal prolapse repair provides any long-term benefits. (See above reference p. 382)

The Committee provides some recommendations for further improvements, particularly in relation to the respect of an individual's right to choose a certain medical treatment and in respect of the communication processes that exist in the medical professional / patient relationship.

Medical Practitioners' Duty of Care and Consent

In Australia, Common law, establishes that all 'competent' adults can consent to, or refuse medical treatment. Accordingly, a patient has the right to not be subjected to an invasive procedure without first providing their consent, unless there is other lawful justification, such as an emergency. However, even in these circumstances it is considered best practice to obtain consent.

The *Australian Charter of Health Care Rights* (the Australian Charter) also provides guidance on the rights of patients and other people using the Australian health system. The Charter makes the rights of patients and others essential, to ensure that, "wherever and whenever care is provided, it is of high quality and is safe".[350] The Australian Charter provides:

What can I expect from the Australian health system?	
MY RIGHTS	**WHAT THIS MEANS**
Access I have a right to health care.	I can access services to address my healthcare needs.
Safety I have a right to receive safe and high-quality care.	I receive safe and high-quality health services, provided with professional care, skill and competence.
Respect I have a right to be shown respect, dignity and consideration.	The care provided shows respect to me and my culture, beliefs, values and personal characteristics.
Communication I have a right to be informed about services, treatment, options and costs in a clear and open way.	I receive open, timely and appropriate communication about my health care in a way I can understand.
Participation I have a right to be included in decisions and choices about my care.	I may join in making decisions and choices about my care and about health service planning.
Privacy I have a right to privacy and confidentiality of my personal information.	My personal privacy is maintained and proper handling of my personal health and other information is assured.
Comment I have a right to comment on my care and to have my concerns addressed.	I can comment on or complain about my care and have my concerns dealt with properly and promptly.

Fig. 5 Australian Charter of Health Care Rights, 2008[351]

[350] ACSQHC, *Australian Charter of Health Care Rights*. 1st edition, 2008: 1. Accessed https://www.safetyandquality.gov.au/publications-and-resources/resource-library/australian-charter-health-care-rights-first-edition

[351] ACSQHC, *Australian Charter of Health Care Rights*. 1st edition, 2008: 1. Accessed Australian Charter of Health Care Rights (first edition) | Australian Commission on Safety and Quality in Health Care

In South Australia, the *Charter of Health and Community Services Rights* under the *Health and Community Services Complaints Act 2004,* provides patients with rights in relation to services received in the South Australian health system, and are adopted from the Australian Charter (above).

They include a person's right to: health care access, safety, quality, respect, information, participation and comment, in health services received. [352] These legislative and governance mechanisms provide that people seeking or having medical treatment in South Australia have the right to:

- decide whether or not to undergo medical treatment after receiving a reasonable and timely explanation of what the treatment involves and the risks associated with the treatment
- be treated with reasonable care and skill by the health care provider
- have medical information and treatment kept confidential.[353]

Accordingly, if consent is not given by a patient, before a medical procedure or treatment, there may be legal consequences for medical practitioners who fail to meet consent requirements.[354]

'Informed consent' thus refers to consent to medical treatment on the basis that a patient has received enough information about the risks and benefits involved in a treatment, in order to be able to make an informed choice about giving their consent.[355] This means patients need to be supported to make a decision about their treatment, by having all of the relevant facts about a proposed treatment provided to them.

Medical practitioners must, therefore, provide information on all material risks of a proposed treatment as part of their duty of care. In the case of *Rogers v Whitaker [1992] HCA 58*, the medical practitioner involved was found by the High Court of Australia to have failed to warn his patient of a 'material risk' involved in certain ophthalmological surgery (known as the 'failure to warn principle').[356]

As such, the failure to warn a patient of the material risks in a proposed treatment, may lead to civil liability for an adverse outcome, even if the treatment itself was not negligent.[357] Judge Gaudron in *Rogers v Whitaker* described the duty of care required of a medical professional as "a single comprehensive duty covering all the ways in which a doctor is called upon to exercise his skill and judgment" and "[…] it extends to the examination, diagnosis and treatment of the patient and the provision of information in an appropriate case."

However, it was also found that it should not be incumbent upon the medical professional nor the medical profession to determine what is or is not to be included as relevant information to be provided to a patient, in order to meet that duty of care.[358]
Rather:

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[352] Health and Community Services Complaints Commissioner*, Know your rights when receiving a health or community service*. Accessed 19 January 2021 https://www.hcscc.sa.gov.au/wp-content/uploads/2013/10/h_know_you_rights_charter_brochure.pdf

[353] Legal Services Commission of South Australia, *Patients' Rights*. Accessed on 2 February 2021 Patients' Rights (lawhandbook.sa.gov.au)

[354] Australian Government, Australian Law Reform Commission, *Informed consent to medical treatment*. See Informed consent to medical treatment | ALRC

[355] Australian Law Reform Commission, *Informed consent to medical treatment*. See Informed consent to medical treatment | ALRC

[356] *Rogers v. Whitaker [1992] HCA 58 175 CLR 479,* 19 November 1992. Accessed 19 January 2021 Rogers v Whitaker [1992] HCA 58 - BarNet Jade - BarNet Jade

[357] Australian Law Reform Commission, *Informed consent to medical treatment*. See Informed consent to medical treatment | ALRC

[358] *Rogers v. Whitaker [1992] HCA 58 175 CLR 479*, 19 November 1992: 3 – 4.

> […] the doctor-patient relationship […] gives rise to a duty to provide information and advice. That duty takes its precise content, in terms of the nature and detail of the information to be provided, from the needs, concerns and circumstances of the patient. A patient may have special needs or concerns which, if known to the doctor, will indicate that special or additional information is required. In a case of that kind, the information to be provided will depend on the individual patient concerned. In other cases, where, for example, no specific enquiry is made, the duty is to provide the information that would reasonably be required by a person in the position of the patient.
>
> Whether the position is considered from the perspective of the individual patient or from that of the hypothetical prudent patient [the patient who asks questions of the medical professional] and unless there is some medical emergency or something special about the circumstances of the patient, there is simply no occasion to consider the practice or practices of medical practitioners in determining what information should be supplied. However, there is some scope for a consideration of those practices where the question is whether, by reason of emergency or the special circumstances of the patient, there is no immediate duty or its content is different from that which would ordinarily be the case.
>
> Leaving aside cases involving an emergency or circumstances which are special to the patient, the duty of disclosure which arises out of the doctor-patient relationship extends, at the very least […], to information that is relevant to a decision or course of action which, if taken or pursued, entails a risk of the kind that would, in other cases, found a duty to warn. A risk is one of that kind if it is real and foreseeable, but not if it is "far-fetched or fanciful".[359]

The duty to warn, as cited in this case, refers to other matters such as the duty to alert the patient to bodily abnormality, the failure of the patient's ailment to respond to the doctor's ministrations, limitations to be observed for his or her welfare, precautionary therapy for the future and the need for or appeal for alternative treatment which might provide greater benefit.[360]

In South Australia, medical practitioners also have a duty of care and consent, under the *Consent to Medical Treatment and Palliative Care Act 1995* (the CMTPC Act). The CMTPC Act states that medical treatment means the provision by a medical practitioner of physical, surgical or psychological therapy to a person, including the provision of therapy for the purposes of preventing disease, restoring or replacing bodily function in the face of disease or injury, or improving comfort and quality of life and prescription or supply of drugs.[361] The Objects of the CMTPC Act provide a legal right:

> (i) to allow persons of or over the age of 16 years to decide freely for themselves on an informed basis whether or not to undergo medical treatment; and
>
> (iii) to provide for the administration of emergency medical treatment in certain circumstances without consent;[362]

Section 15 of the CMTPC Act states that a medical practitioner, in the treatment of a person, has a duty to ensure that the person understands the treatment, risks and outcomes of the proposed treatment as well as any alternatives to the treatment.

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[359] *Rogers v. Whitaker [1992] HCA 58 175 CLR 479*, 19 November 1992: 7.

[360] *Rogers v. Whitaker [1992] HCA 58 175 CLR 479*, 19 November 1992: 7.

[361] Part 1—Preliminary, Section 4—Interpretation, *Consent to Medical Treatment and Palliative Care Act 1995.* Version: 29.3.2015: 4. Accessed 19 January 2021 Consent to Medical Treatment and Palliative CareAct 1995 (legislation.sa.gov.au)

[362] Part 1—Preliminary, Section 3—Objects, *Consent to Medical Treatment and Palliative Care Act 1995.* Version: 29.3.2015: 2.

Section 15 reads:

15—Medical practitioner's duty to explain

A medical practitioner has a duty to explain to a patient (or the patient's representative), so far as may be practicable and reasonable in the circumstances—

(a) the nature, consequences and risks of proposed medical treatment; and
(b) the likely consequences of not undertaking the treatment; and
(c) any alternative treatment or courses of action that might be reasonably considered in the circumstances of the particular case.[363]

There are exclusions on the duty under section 16, which provide that the medical practitioner is not liable in either a civil or criminal capacity, if the circumstances meet certain criteria. Those criteria include:

(a) with the consent of the patient or the patient's representative or without consent but in accordance with an authority conferred by this Act or any other Act; and
(b) in good faith and without negligence; and
(c) in accordance with proper professional standards of medical practice; and
(d) in order to preserve or improve the quality of life.[364]

The often-cited case in the Supreme Court of South Australia, *F v. R. (1983) 33 SASR*, whereby a case of negligence was brought against a treating surgeon, Judge King found the duty to disclose information to a patient is not a question of whether a medical practitioner's conduct is in accordance with professional standards, but whether their care is within the standard of the law.[365]

In referring to this, in *Rogers v Whittaker*, the Judges found, bearing in mind where there is no basis for application of therapeutic privilege (for example, in a medical emergency or in consideration of the patient's ability to receive, comprehend and properly evaluate the significance of the information),[366] that:

> The law should recognize that a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.[367]

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[363] Part 3—Provisions governing medical practice, Division 1—Medical practice generally, Section 15—Medical practitioner's duty to explain, *Consent to Medical Treatment and Palliative Care Act 1995.* Version: 29.3.2015: 11.

[364] Part 3—Provisions governing medical practice, Division 1—Medical practice generally, Section 16—Protection for medical practitioners etc, *Consent to Medical Treatment and Palliative Care Act 1995.* Version: 29.3.2015: 11.

[365] *F v. R. [1983] 33 SASR, p 194. Cited in Rogers v. Whitaker [1992] HCA 58 175 CLR 479*, 19 November 1992: 4.

[366] See *Rogers v. Whitaker [1992] HCA 58 175 CLR 479,* 19 November 1992 at page 9 for discussion on "therapeutic privilege." Accessed 19 January 2021 Rogers v Whitaker [1992] HCA 58 - BarNet Jade - BarNet Jade

[367] *Rogers v. Whitaker [1992] HCA 58 175 CLR 479,* 19 November 1992: 6. Accessed on 19 January 2021 at Rogers v Whitaker [1992] HCA 58 - BarNet Jade - BarNet Jade

This view is consistent with the 'patient-centred' approach to healthcare, relative to consent.[368] Notwithstanding, while a medical practitioner may have regard to the overall effect on a patient of the disclosure of material risks, the patient has a legal right to be informed of those risks, to be advised of alternative treatments that exist and to decide for him or herself whether or not to proceed with the treatment being proposed.[369]

What is 'Fully Informed Consent'?

As a result of recent studies undertaken by the ACSQHC, the updated information on 'informed consent' provided by the ACSQHC for clinicians, states:

Informed consent[370]

Informed consent is a person's decision, given voluntarily, to agree to a healthcare treatment, procedure or other intervention that is made:

- following the provision of accurate and relevant information about the healthcare intervention and alternative options available; and
- with adequate knowledge and understanding of the benefits and material risks of the proposed intervention relevant to the person who would be having the treatment, procedure or other intervention.

Ensuring informed consent is properly obtained is a legal, ethical and professional requirement on the part of all treating health professionals and supports person-centred care. Good clinical practice involves ensuring that informed consent is validly obtained and appropriately timed.

Informed consent is integral to the right to information in the Australian Charter of Healthcare Rights and recognised in Professional Codes of Conduct. Additionally, the National Safety and Quality Health Service Standards require all hospitals and day procedures services to have informed consent processes that comply with legislation, lawful requirements and best practice.

The ACSQHC explains that there is a need to obtain informed consent at different stages of a "treatment pathway", including before commencement of treatment or undertaking a medical examination. The ACSQHC advises that: [371]

- Medical practitioners have a duty to warn their patients about the material risks of the treatment, procedure or other intervention as part of obtaining a patient's consent. Accordingly, Failure to adequately warn a patient of these risks is a breach of the medical practitioner's duty of care;

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368 ACSQHC, *Australian Charter of Healthcare Rights* (2nd ed.). Accessed Australian Charter of Healthcare Rights (second edition) - A4 Accessible | Australian Commission on Safety and Quality in Health Care

369 *Rogers v. Whitaker [1992] HCA 58 175 CLR 479*, 19 November 1992: 4.

370 ACSQHC, *Fact sheet for clinicians: Informed consent in healthcare*, 2020: 1. Accessed 19 January 2021 Fact Sheet for clinicians- Informed consent in health care (safetyandquality.gov.au)

371 ACSQHC, *Fact sheet for clinicians: Informed consent in healthcare*, 2020: 1.

- a person has the right to refuse treatment (with some legislated exceptions) or withdraw consent previously given prior to treatment; and
- medical practitioners should make contemporaneous records of their discussions around consent with their patient and include written consent forms (where appropriate) in the person's healthcare record.

Professional Codes of Conduct

Royal Australasian College of Surgeons

The Royal Australasian College of Surgeons (RACS) provided evidence that the *RACS Code of Conduct* requires surgeons to "fully inform the patient and obtain consent before employing a new intervention, technique or prosthesis", and that:[372]

> Surgeons should assist patients in their selection of the form of treatment most appropriate to their particular situation. Where any form of surgery is planned information should be provided which outlines the anticipated benefits of the intervention along with any potential risks. Discussion is expected to be more specific where the proposed procedure is more controversial or of higher risk.[373]

The RACS Professional Development and Standards Board provides the *Informed Consent* position paper, which states:

> […] patients are entitled to make their own decisions about treatment. To do so they need access to appropriate and readily understandable information about treatment options, associated risks and the expected outcomes. Surgeons should give advice, with no coercion. Disclosure of information and discussion is best performed by the surgeon who will be conducting the treatment. The patient should be free to accept or reject the advice offered. The process of Informed Consent has legal ramifications.[374]

Outlined in the position paper are a set of principles to which surgeons should adhere, in accordance with the *RACS Code of Conduct*:

> **Principles**
>
> 1. **Open dialogue:** An open dialogue between surgeons and patients is crucial for informed consent discussions. High importance should be given to patients and their families on receiving such information about their health and their concerns in a frank and honest way.
> 2. **Information for Patients:** Information concerning the medical condition, investigation options, treatment options, benefits, possible adverse effects of investigations or treatment, and the likely result if treatment is not undertaken, should be provided. Complete information on predicted outcomes and risks cannot be determined with absolute certainty.
> 3. **Respect and Clarity:** Sensitivity should be given when patients may be sick, injured or traumatised, or along with their relatives, feel anxious about a procedure. Clarity and simplicity in language is recommended. Respect must be given to a competent patient making their own decisions about their medical treatment and their right to grant, withhold or withdraw consent before or during examination, investigation, or treatment.
> 4. **Legality:** Whilst RACS produces policies and guidelines that may be consulted in disciplinary or civil proceedings to help decide whether the surgeon has behaved

[372] RACS, *Written submission No. 62*, 8 October 2019: 4.

[373] RACS, *Written submission No. 62*, 8 October 2019: 4.

[374] RACS, *Informed Consent 2019*. Accessed 29 October 2020 https://www.surgeons.org/en/about-racs/position-papers/informed_consent_2019

> reasonably in giving information, it is ultimately the role of the courts, tribunals or commissions to decide the reasonableness of the surgeon's behaviour in any given case. The legal duty to warn patients of risks is covered under common law.[375]

Dr Samantha Pillay of RACS, commented in her oral evidence to the Committee that incontinence has been an area that until recently has not received widespread attention in the community, by GPs or in an education setting. Since the 2018 Senate Inquiry, there has been a lot of awareness created amongst the community and GPs regarding the condition and the treatment options.[376]

Dr Pillay stated that the ACSQHC information documents produced as a result of the Senate Inquiry are the go-to documents for anyone wanting information on the treatment options for SUI. Dr Pillay commented further that following on from the Senate Inquiry, medical practitioners recommending surgery as a first-line treatment for SUI could be considered "ill-advised":

> The information brochure […] from the Australian Commission on Safety and Quality in Health Care on stress incontinence lists the non-surgical options. So, anyone using any of that information, when they go through that document, will have to go through all those options. I would think that in the current climate it would be unusual and probably ill-advised for people to be recommending surgery without discussing treatment options, including non-surgical treatment options, and providing patients with the information available.[377]

Dr Pillay suggests that individual surgeons, whilst being bound by professional codes of conduct and the law, have their own processes for providing patients with information about treatments. This, according to Dr Pillay is very difficult to track and determine where non-compliance exists:

> […] we don't have information on what individual surgeons do—because it is not recorded anywhere—to be able to report to you what an individual does. I can only speculate with that. For example, in my individual practice I will have a preoperative checklist that I go through, I will have the various written information from various surgical societies, the government and my own-produced, and I'll have online resources. But I can only speak for my practice; I don't personally know what other practices do.[378]

Royal Australian and New Zealand College of Obstetricians and Gynaecologists

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) submitted in their evidence that in accordance with guidance from the ACSQHC, their organisation, recommends non-surgical treatment as first-line management of POP and SUI which, includes lifestyle changes, pelvic floor muscle training, pessaries, and estrogen supplement.[379]

It was not clear from the evidence how long this has been the accepted policy, but it is assumed that surgery as the first-line of treatment has never been the case, even before mesh was introduced.

RANZCOG has produced a number of patient information pamphlets on POP and SUI which include information on alternative management options, surgical procedures and complications with mesh and non-mesh procedures.[380, 381]

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375 RACS, *Informed Consent 2019*. Accessed 29 October 2020 https://www.surgeons.org/en/about-racs/position-papers/informed_consent_2019

376 Dr Samantha Pillay, *Hansard*, 15 June 2020: 107.

377 Dr Samantha Pillay, *Hansard*, 15 June 2020: 107.

378 Dr Samantha Pillay, *Hansard*, 15 June 2020: 107.

379 RANZCOG, *Written submission No. 45*, 13 September 2019: 2.

380 RANZCOG, *Written submission No. 45*, 13 September 2019: 12.

381 For RANZCOG information pamphlets see Stress-Urinary-Incontinence-KK19.pdf (ranzcog.edu.au) and Pelvic-Organ-Prolapse-KK19.pdf (ranzcog.edu.au)

RANZCOG advised that RANZCOG members also use Urogynaecological Society of Australasia patient information leaflets on conservative treatment options as well as surgical treatment for SUI. RANZCOG members have available to them information pamphlets on SUI, anterior vaginal repair, posterior vaginal wall repair and vaginal repair with mesh, produced by the International Urogynaecological Association.[382]

Consistent with other medical professional associations and societies, RANZCOG stated in their written submission that there should be verbal discussions between surgeons and patients as well as any written information, in order for patients and consumers' needs to be met:

> Irrespective of the written information provided, all surgeons should engage in a detailed conversation with their patients prior to surgery. This conversation should cover the individual patient's health and lifestyle priorities, concerns and expectations, the treatment options available and the potential benefits and risks of these treatments.[383]

In order to receive certification with RANZCOG, specialist gynaecologists and urogynaecologists must complete the RANZCOG training. The RANZCOG Curriculum, 3rd edition (the Curriculum), provides several modules for specialists training in gynaecology and sub-specialty urogynaecology, for gaining patient consent.[384]

Other modules in the Curriculum relate to engendering and practicing professional attitudes and conduct, and the specialist's responsibilities to their patients and under law.

Annotation of the relevant curriculum competencies is provided below and demonstrates that all RANZCOG certified gynaecological specialists have at a minimum completed some training in matters that concern obtaining informed consent from patients.

Learning Module 3 of the Curriculum outlines the profile of a specialist gynaecologist, with reference to their professional qualities:

> The societal expectation is that specialists dedicate their distinct body of knowledge, skills and professional qualities towards improving the health and well-being of others and commit themselves and their collegiate bodies to the highest possible standards of clinical care and ethical conduct. This involves an ongoing commitment to reviewing and updating practices. It also includes showing respect for differing cultural perspectives regarding healthcare and understanding the ways in which these might interact with traditional practices.[385]

Learning Module 4 relates to knowledge and application, with Chapter 4B on clinical knowledge and management skills. Module 4B. B.3 General Surgical Principles, provides that gynaecological specialist trainees must demonstrate an understanding of, and prepare a specific patient for a specific operation by being able to:

- Demonstrate knowledge of risks, outcomes, alternatives, potential complications and their incidence […] and;
- ensure understanding and obtain specific informed consent, including consent for audit, research and new procedures where appropriate […][386]

Module 4C refers to contextual knowledge, with Module 4C C.1 on women's health and cultural issue. Learning outcomes to achieve include:

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382 RANZCOG, *Written submission No. 45*, 13 September 2019: 12.

383 RANZCOG, *Written submission No. 45*, 13 September 2019: 12.

384 RANZCOG, *RANZCOG Curriculum*, 3rd edition, Melbourne, 2016: 58.

385 RANZCOG, *RANZCOG Curriculum*, 3rd edition, Melbourne, 2016: 12.

386 RANZCOG, *RANZCOG Curriculum*, 3rd edition, Melbourne, 2016: 58.

- Customise care according to the individual needs and wishes of women in their care, taking into account their personal beliefs, experiences, and social, economic and cultural background […] and:
- advocate on behalf of all patients, particularly those who are vulnerable and those with special needs […]
- Understand the major objections and complaints that women make about the delivery of obstetric and gynaecological services. Consider and develop means of addressing these objections and complaints, for example, the importance of an apology when a patient has been inconvenienced or where her treatment has proved to be suboptimal. Understand the variety of perspectives that health professionals, women and women's advocate groups have on health and disease, particularly with regard to pregnancy and how these affect their choice of healthcare and their decision making. Endeavour to sympathetically accommodate those views where possible when planning individual care or health services […][387]

Module 4C C.2 refers to ethics, ethical attitudes and conduct. Specialist trainees must be able to:

- Deliver the highest quality healthcare with integrity, honesty and compassion
- practise medicine that is ethically responsible and consistent with the obligations of a self-regulating profession
- recognise patient autonomy and legal and moral duties to women in their care
- be familiar with the RANZCOG Code of Ethics and its framework for practice in obstetrics and gynaecology
- be familiar with the concepts of Beneficence, Non-maleficence, Autonomy, Justice, Dignity and Truthfulness in the application of medical ethical principles […][388]

Module 4C C.3 is about Law and provides that specialist trainees must be able to exhibit ethical attitudes […] be able to describe:

- The development of duty of care in common law
- contemporary understanding of the duty of care in medicine
- breach of duty of care/standard of care
- important cases in the development of the duty of care a doctor owes to a patient
- gaining consent […]
- know how to respond to complaints and use complaints to improve their practice.[389]

Module 4C C.4 provides specialist trainees with skills in management and professional practice. Specialist trainees must be able show knowledge of patient care and risk management:

- Ensure that staff communicate clearly, (verbally and in writing), with women in one's care
- understand and utilise where appropriate the principle of "open disclosure"
- be available to discuss complaints and sub-optimal outcomes with women in one's care
- risk management is not about blame
- primary role of risk management as a tool for improving quality of care, not litigation avoidance […][390]

[387] RANZCOG, *RANZCOG Curriculum*, 3rd edition, Melbourne, 2016: 66.

[388] RANZCOG, *RANZCOG Curriculum*, 3rd edition, Melbourne, 2016: 68.

[389] RANZCOG, *RANZCOG Curriculum*, 3rd edition, Melbourne, 2016: 69.

[390] RANZCOG, *RANZCOG Curriculum*, 3rd edition, Melbourne, 2016: 71 - 72.

Urological Society of Australia and New Zealand

The Urological Society of Australia and New Zealand (USANZ) advised that there has been much done in terms of producing and/or updating information sheets for patients by the United States Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction, the American Urogynacologic (Sic) Society, USANZ and the UroGynaecological Society of Australasia (UGASA). These are on top of the information prepared by the ACSQHC.[391]

In their written submission, USANZ advise that NSW Health through the Agency for Clinical Innovation have produced a "Decision toolkit" for women suffering from SUI.[392] The *Decision aid for women experiencing stress urinary incontinence* (the toolkit), provides a more "personal approach" to the information available to women with SUI.[393]

The toolkit has brought together the expertise of a number of organisation representatives, clinicians and consumers to provide for what NSW Health describes as "clinical innovations across the NSW public health system to change the way that care is delivered."[394]

USANZ also commented that some clinicians provide product information to the patient by giving them the batch and serial number of the product implanted.[395]

Dr Ian Tucker, is a Urogynaecologist in private practice in Adelaide and is closely associated with the RANZCOG and the UGSA. Dr Tucker made the following observations in his written submission that in the past, some Medical practitioners failed in the provision of information to women prior surgery:

> There is now a considerable amount of documented evidence available by practitioners themselves and their associated Colleges. There is a huge amount of evidence available on the internet but unfortunately this is not always correct. It is the responsibility of every medical practitioner to fully explain a particular problem, the options for treatment and the risks of not treating v's the complications of medical or surgical intervention in a manner well understood by the patients. This I believe failed in the mesh situation as many practitioners were coerced, or decided to use the mesh for primary procedures when there was a large body of evidence from the beginning that
>
> - mesh should only be used for recurrent prolapses when it was clear that the native tissue was too deficient to provide adequate support.
> - There was also evidence and advice that trans-vaginal mesh should not be placed in the posterior vaginal wall.
> - […] this was also often ignored.
>
> Clearly many patients were not advised of these recommendations, many clinicians ignored them and some companies encouraged the mesh use in primary repairs.[396]

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391 Urological Society of Australia and New Zealand (USANZ), *Written submission No. 59*, 25 September 2019: 2.

392 USANZ, *Written submission No. 59*, 25 September 2019: 2.

393 USANZ, *Written submission No. 59*, 25 September 2019: 2.

394 NSW Government, Agency for Clinical Innovation, *Decision aid for women experiencing stress urinary incontinence*, November 2019: 16. Accessed 29 January 2021 ACI-Urology-Stress-urinary-incontinence-women-decision-aid.pdf (nsw.gov.au)

395 USANZ, *Written submission No. 59*, 25 September 2019: 2.

396 Dr Ian Tucker, *Written submission No. 69*, 7 December 2020: 5.

Royal Australian College of General Practitioners

Dr Magdalena Simonis, considers, to ensure vital information is given to patients at the start of their treatment process, behaviour change in the medical profession is much needed:

> I think, coming back to educating GPs and getting behaviours to change and dissemination of these wonderful tools that we have actually taken the time to create, I agree with you, there is no specific education program around this that heralds its importance and its significance in the community. I think that it's a stepwise process. The first part of the process was actually having the women make the complaint. The second part of the process was the Senate inquiry and the federal government to agree to a national steering committee on this and subsequently development of tools. Things, unfortunately, don't always flow very freely or quickly, so getting that information out again—I think that it does require repetition and that's where we are at. The problem has not gone away and women are still presenting with these issues, therefore we need to be aware of that. That's going to be through upgrading the RACGP teaching modules. That's also going to be through departments like yours requesting that the RACGP take action.[397]

Concerns raised by the Committee on numerous occasions with representatives of the various professional societies and associations was that information provided to or by the professional bodies to their members appeared to fail to reach patients. By way of example, information concerning mesh complications was not disseminated in the surgeries of GPs for patients to see.

It was concerning to the Committee to hear from mesh injured advocates that it is believed some patients having a pelvic mesh implant recently have done so without informed consent. The following evidence provided by Kim, representative of the SA Pelvic Mesh Support Group, advised in November 2020 that information about mesh procedures was in some cases still not being provided to patients by medical practitioners.[398]

> […] I believe that women, to this day, still are not getting fully informed consent. I have had a number of conversations recently where women have given consent for mesh implantation, but when I have asked them a few questions as to what they know about that procedure, they can't give me any information and they haven't been given any information. […] At present, most of the surgeons only consider that this is for the large pelvic organ prolapse meshes and it doesn't pertain to stress urinary incontinence mesh, but it should be all of them. […] I still believe that there is not enough information out there. Many GPs still don't know what mesh is, they don't know where to get the information, and women are still educating their doctors. There is still a huge problem with credentialling and there's a number of doctors in South Australia that are performing removals and partial removals without the appropriate credentials.[399]

It is now widely accepted that in the treatment of POP and SUI, the first line of treatment should be conservative in approach.

Surgical intervention should only be considered where other more conservative approaches are unsuitable or have failed. In her advocacy work for women who have been injured as a result of failed mesh implants, Kim commented:

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[397] Dr Magdalena Simonis, *Hansard*, 21 September 2020: 171.

[398] Kim, *Hansard*, 30 November 2020: 196.

[399] Kim, *Hansard*, 30 November 2020: 196.

> Many of those who have been implanted with medical mesh were offered medical mesh as a first-line treatment without any consideration to nonsurgical techniques of dealing with problems of pelvic organ prolapse, stress urinary incontinence and hernia—for example, pelvic floor exercises or pessaries for POP. Women are still being offered these implants as a first-line intervention. They are not being given true informed consent. They are not informed of the possible complications that are available on the TGA website that states that there are many possible complications. These are supposed to be given to women prior to this surgery and, ideally, with an explanation.[400]

Evidence was provided that many women who are older or have limited skills with technology may not access the internet in order to have access to the literature available on the websites of the ACSQHC or the TGA. In relation to the dissemination of information about the complications of mesh in POP, SUI and hernia, the Committee proposed that information be displayed in GP practices. However, it was suggested that this was an impractical option due to the large amount of health-related literature requiring display in GP surgeries.[401]

SA Health

SA Health provided evidence in relation to the practices within SA Health Local Health Network hospitals regarding information provided to SA Health hospital patients and materials for informing General Practitioners (GPs).

SA Health Consent to Medical Treatment and Health Care Policy Guideline

In accordance with the National Safety and Quality in Health Service Standards (NSQHS Standards), SA Health has in place the *Consent to Medical Treatment and Health Care Policy Guideline* (SA Health Consent Policy), which is applicable to all medical practitioners in the provision of medical, surgical and dental treatment as well as some other medical practices and some services provided by other health practitioners.[402, 403] The SA Health Consent Policy contributes to meeting:

- NSQHS Standard 1: Governance for Safety and Quality in Health Care
- NSQHS Standard 2: Partnering with Consumers; and
- NSQHS Standard 6: Clinical Handover.[404]

A medical practitioner is responsible for obtaining consent and under the SA Health Consent Policy, the medical practitioner should, wherever possible, avoid assigning the task of obtaining consent from a patient.[405] Because the SA Health Consent Policy makes provision for avoiding delegating obtaining consent from a patient, it reflects the degree of responsibility placed on the medical practitioner and the importance of patients giving their consent to receive treatment.

The SA Health Consent Policy provides for circumstances where certain aides are required in order to obtain consent, such as in cases of English as a second language or where there are specific cultural requirements.

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400 Kim, *Hansard*, 2 March 2020: 21.

401 Dr Magdalena Simonis, *Hansard*, 21 September 2020: 172

402 Department for Health and Wellbeing, SA Health, *Consent to Medical Treatment and Health Care Policy Guideline*, V.2, December 2014: 3.

403 See SA Health, *Consent to Medical Treatment* https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+programs+and+practice+guidelines/end+of+life/consent+to+medical+treatment+for+health+professionals

404 SA Health, *Consent to Medical Treatment and Health Care Policy Guideline*, V.2, December 2014: 15.

405 SA Health, *Consent to Medical Treatment and Health Care Policy Guideline*, V.2, December 2014: 4.

The SA Health Consent Policy unequivocally states:

> Except in the case of an emergency where the patient is incapable of giving consent and the patient's representative is not available, a medical practitioner has a duty to warn the patient of each material risk associated with the medical treatment.
>
> ***The duty imposed on medical practitioners by the Consent Act should be followed by all health practitioners when seeking to provide medical treatment and or health care to persons.***[406]

Process of obtaining consent by a medical practitioner

The SA Health Consent Policy provides a number of ways in which a patient is able to provide either their express or implied consent. These include:

- non-verbal consent through giving a bodily action, or lack of action;
- verbal consent or
- written consent.[407]

The SA Health Consent Policy clearly states that where treatments are of a serious nature or have inherent risks or complications, there must be written consent from the patient.[408]

Consent must be obtained prior to any medical treatment being administered, and the SA Health Consent Policy is unambiguous in its instructions for the recording of written and non-written, or non-verbal consent, and discussions between medical practitioners and patients, including discussions of the risks involved in a medical treatment:

> **4.1.6 Recording consent and documenting consent**
>
> It is proper practice for the health practitioner to document the patient's consent to medical treatment in the medical records as well as having the patient complete and sign the consent to medical treatment form, including a Substitute Decision-Maker or Person Responsible. This will ensure there is no ambiguity as to whether the patient has consented to the medical treatment. Wherever possible, discussions between the health practitioner and the person should be documented in the person's medical record, including the risks and consequences of proceeding with a medical treatment and specifically any concerns raised by the person.[409]

[406] SA Health, *Consent to Medical Treatment and Health Care Policy Guideline*, V.2, December 2014: 4.

[407] SA Health, *Consent to Medical Treatment and Health Care Policy Guideline*, V.2, December 2014: 5.

[408] SA Health, *Consent to Medical Treatment and Health Care Policy Guideline*, V.2, December 2014: 5.

[409] SA Health, *Consent to Medical Treatment and Health Care Policy Guideline*, V.2, December 2014: 6.

Obtaining a valid consent

The SA Health Consent Policy provides that for a consent from a patient to a medical treatment to be valid, it must be voluntary and clear, and the patient giving consent must have decision-making capacity.[410]

Consent where a patient is unable to give their consent

The SA Health Consent Policy provides that in circumstances where a patient is unable to give consent, a substitute decision-maker, Guardian, prescribed relative or in some cases a close friend, is required to give or withhold consent for them.[411] There are several relevant statutes and policies that apply including principally, the *Consent to Medical Treatment and Palliative Care Act 1995.*[412]

Other statutes and instruments include the *Guardianship and Administration Act 1993, the Advance Care Directive Act 2013,* the *Mental Health Act 2009.* The SA Health *Providing assessment and or medical treatment where patient consent cannot be obtained Policy Directive* provides guidelines for medical practitioners to obtain consent from a patient in circumstances where the patient consent is unable to be obtained from them personally.[413]

Reporting

The SA Health Consent Policy provides that reporting to the Department for Health and Wellbeing on compliance and non-compliance with the guideline must be undertaken. Reporting through the Safety Learning System must also be undertaken for instances where consent was not effectively obtained or incorrect processes for obtaining consent were undertaken. The SA Health Consent Policy also provides that consumer experiences in relation to consent should be regularly reported.[414]

SA Health Pelvic Mesh Clinic

In response to questions on notice during oral evidence given by representatives of SA Health, the Committee was advised that women attending the SA Health Pelvic Mesh Clinic are supported in making an adverse event report to the Therapeutic Goods Administration (TGA):

> Pelvic mesh Nurse supports patient to complete the documentation and make the report. Pelvic Mesh Nurse secures consent from the pelvic mesh patient to release information on her behalf to the TGA adverse event reporting framework SA Health Pelvic Mesh website provides information to the consumer in how to report the adverse event to the TGA. The Pelvic Mesh Nurse Consultant encourages each patient to personally complete a 'adverse event due to a medical device' incident report. This is in line with TGA recommendation found at https://www.tga.gov.au/node/4580 The SA Health Pelvic Mesh webpage provides a direct link for the consumer to report an adverse event to the TGA if they have not been involved and prompted by the Pelvic Mesh Clinic.[415]

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410 SA Health, *Consent to Medical Treatment and Health Care Policy Guideline*, V.2, December 2014: 4.

411 See SA Health, *Changes to Consent Factsheet*, June 2014. Accessed Changes to Consent Act Factsheet (sahealth.sa.gov.au)

412 SA Health, *Consent to Medical Treatment and Health Care Policy Guideline*, V.2, December 2014: 7 – 10.

413 SA Health, *Consent to Medical Treatment and Health Care Policy Guideline*, V.2, December 2014: 9.

414 SA Health, Consent to Medical Treatment and Health Care Policy Guideline, V.2, December 2014: 14.

415 SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 2.

SA Health also advised the SA Pelvic Mesh Clinic website contains information for GPs and it is understood the Central Adelaide Local Health Network (CALHN) undertook a communications plan for medical professionals to highlight the issues around mesh.[416]

> The Pelvic Mesh Clinic has developed a revised Pelvic Mesh Clinic Communication Plan aimed at refreshing information for consumers and clinicians involved in women's pelvic floor care and the operation of the Pelvic Mesh Clinic at the Royal Adelaide Hospital. The intended primary audience is GPs and medical specialists with a reminder of the Pelvic Mesh Clinic referral process requirements. Due to COVID-19 and media attention, the Pelvic Mesh Clinic Communication Plan was delayed until October 2020.[417]

According to the SA Health response to questions on notice submission, the SA Health Gynaecology Advisory Group, Transvaginal Mesh Clinical Reference Group, and Executive Consumers Group assisted in the development and approval of initial content for the SA Pelvic Mesh Clinic website, which contains information for patients and GPs in relation to deciding whether to have a mesh implant and the complications of mesh for women.[418]

SA Health advise the current website content has been revised as part of the CALHN revision of the SA Health website content.[419]

Documents on the SA Health Pelvic Mesh Clinic containing information on pelvic mesh for medical practitioners include:

- Transvaginal mesh information for General Practitioners Newsletter
- Pelvic Mesh Clinic KPIs, report on the calls from GPs to the Infoline
- Pelvic Mesh Clinic local referral pathway flowchart
- Information Sheet: SA Health Pelvic Mesh Clinic
- Draft Communications Plan for the Pelvic Mesh Clinic.[420]

Dr Roy Watson, Gynaecologist with CALHN advised:

> I think the work that was done early on in getting publicity out to patients through consumer groups and also on the SA Health website and the information that was sent out to GPs, getting it as part of their software packages and so forth, have definitely helped the awareness of these problems among general practitioners.[421]

However, in February 2021, Dr Watson advised the communication plan is still under review. Dr Watson commented that the SA Pelvic Mesh Clinic was at the time, without a lead clinic nurse[422] and that:

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[416] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 3.

[417] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 4.

[418] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 3.

[419] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 3.

[420] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 3 - 4.

[421] Dr Roy Watson, *Hansard*, 7 September 2020: 156.

[422] Dr Roy Watson, *Hansard*, 1 February 2021: 242.

> The workload of the clinic nurse in the latter half of 2020, due largely to clinics being rearranged to accommodate our locum and COVID restrictions, was such that this work was not completed. I have had a discussion regarding this and have received an undertaking to have this completed by April.[423]

SA Health further advised the ACSQHC Care Pathway has been used to model the development of a local referral pathway flowchart that has been communicated to all SA GPs and gynaecologists. The ACSQHC Service Model Framework is also utilised to inform the SA Health Pelvic Mesh Clinic model of care.[424]

Private Hospitals

The Committee did not receive any evidence causally related to informed consent and the policies and practices of individual South Australian private hospitals. This was the case for both pelvic mesh and hernia mesh implantation surgeries. However, like public hospitals, private hospitals must comply with the National Safety and Quality Health Service Standards (NSQHS Standards), which require them to credential medical staff.

Accordingly, this aligns with a practitioner's scope of clinical practice, experience and qualifications to the service requirements for the practitioner's role and the capability of the organisation.[425]

Medical Board of Australia

The Medical Board of Australia provides the *Good Medical Practice: A Code of Conduct for Doctors in Australia* (the Good Medical Practice Code), which defines what is expected of all medical practitioners registered to practice in Australia. This includes the public and private sectors. It contains a set of principles that describes what good medical practice is and is explicit about the standards of ethical and professional conduct expected of medical practitioners in their practice to the community.[426]

In reviewing the evidence concerning the manner in which witnesses, and submitters referred to both the conduct and assistance provided by medical practitioners before they had mesh implanted, and after when adverse events were experienced, the Committee considers it is a good opportunity to refer to some of the pertinent requirements of the Medical Board's Good Medical Practice Code, for this term of reference.

The following passages are extracts from the Good Medical Practice Code.

The Good Medical Practice Code describes professional behaviour of medical practitioners as including, and encompassing the following attributes and behaviours:

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[423] Dr Roy Watson, *Responses to Questions on Notice*, *Hansard*, 1 February 2021, received 12 February 2021: 2.

[424] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 4.

[425] Ms Nonnie Oldham, Executive Officer, ACSQHC, Email, *RE: Query in relation to AHSSQA Scheme and Private Hospital Senior Medical Professional Credentialling*, 9 October 2020: 1.

[426] Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia,* March 2014: 4. Accessed on 3 February 2021 Medical-Board---Code-of-conduct.PDF

1.4 Professional values and qualities of doctors [427]

Doctors have a duty to make the care of patients their first concern and to practise medicine safely and effectively. They must be ethical and trustworthy.
[…]
Doctors have a responsibility to protect and promote the health of individuals and the community. Good medical practice is patient-centred. It involves doctors understanding that each patient is unique, and working in partnership with their patients, adapting what they do to address the needs and reasonable expectations of each patient. […]

The Good Medical Practice Code provides guidelines for medical practitioners in communicating with their patients, including informing patients of the nature of, and need for, all aspects of their clinical management. The guidelines describe what is necessary for medical practitioners to "partner" with their patients to ensure quality, effective, professional and compassionate health care.

This requires a high standard of professional conduct from the medical practitioner, and recognition that there is a power imbalance in the medical practitioner and patient relationship, which requires that a medical practitioner does not exploit his or her patients as a consequence.[428]

Guideline 3.3 provides for ways in which medical practitioners should conduct themselves in communications with their patients and states:

3.3 Effective communication[429]

An important part of the doctor–patient relationship is effective communication. This involves:

3.3.1 Listening to patients, asking for and respecting their views about their health, and responding to their concerns and preferences.

3.3.2 Encouraging patients to tell you about their condition and how they are currently managing it.
[…]
3.3.4 Discussing with patients their condition and the available management options, including their potential benefit and harm.
[…]
3.3.6 Ensuring that patients are informed of the material risks associated with any part of the proposed management plan.

[427] Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia*, March 2014: 5.

[428] Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia*, March 2014: 8.

[429] Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia*, March 2014: 8.

Guideline 3.5 refers to informed consent and provides:

3.5 Informed consent[430]

Informed consent is a person's voluntary decision about medical care that is made with knowledge and understanding of the benefits and risks involved. The information that doctors need to give to patients is detailed in guidelines issued by the National Health and Medical Research Council. Good medical practice involves:

3.5.1 Providing information to patients in a way that they can understand before asking for their consent.

3.5.2 Obtaining informed consent or other valid authority before you undertake any examination, investigation or provide treatment (except in an emergency), or before involving patients in teaching or research.

3.5.3 Ensuring that your patients are informed about your fees and charges.

3.5.4 When referring a patient for investigation or treatment, advising the patient that there may be additional costs, which patients may wish to clarify before proceeding. […]

Guideline 3.10 describes the responsibilities a medical practitioner has in addressing adverse events that occur as a result of their treatment or medical intervention. It states that medical practitioners have a responsibility to be open and honest in their communication with a patient where an adverse event has occurred.

The Guideline advises that when something has gone wrong the medical practitioner should seek advice, to review what has occurred and to report it appropriately:

3.10 Adverse events[431]

Good medical practice involves:

3.10.1 Recognising what has happened.

3.10.2 Acting immediately to rectify the problem, if possible, including seeking any necessary help and advice.

3.10.3 Explaining to the patient as promptly and fully as possible what has happened and the anticipated short-term and long-term consequences.

3.10.4 Acknowledging any patient distress and providing appropriate support.

3.10.5 Complying with any relevant policies, procedures and reporting requirements.
[…]
3.10.7 Reporting adverse events to the relevant authority, as necessary.

3.10.8 Ensuring patients have access to information about the processes for making a complaint.

[430] Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia*, March 2014: 9.

[431] Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia*, March 2014: 10.

Guideline 6.2 refers to a medical practitioner's duty to minimise risk and to address issues appropriately and ethically as they arise, including addressing where an adverse effect has occurred as a result of their treatment or medical intervention.

These responsibilities extend to a duty to protect patients where a medical practitioner is aware there may be risks posed by a treating colleague:

6.2 Risk management[432]

Good medical practice in relation to risk management involves:

6.2.1 Being aware of the importance of the principles of open disclosure and a non-punitive approach to incident management.

6.2.2 Participating in systems of quality assurance and improvement.

6.2.3 Participating in systems for surveillance and monitoring of adverse events and 'near misses', including reporting such events.

6.2.4 If you have management responsibilities, making sure that systems are in place for raising concerns about risks to patients.

6.2.5 Working in your practice and within systems to reduce error and improve patient safety, and supporting colleagues who raise concerns about patient safety.

6.2.6 Taking all reasonable steps to address the issue if you have reason to think that patient safety may be compromised.

6.3.4 Taking steps to protect patients from risk posed by a colleague's conduct, practice or ill health.

6.3.5 Taking appropriate steps to assist your colleague to receive help if you have concerns about a colleague's performance or fitness to practise.

6.3.6 If you are not sure what to do, seeking advice from an experienced colleague, your employer, doctors' health advisory services, professional indemnity insurers, the Medical Board of Australia or a professional organisation.

The Good Medical Practice Code states that medical practitioners should conduct themselves in a manner that engenders trust and respect in the community. This includes observing and practising the principles of ethical conduct and maintaining a high level of medical competence and professional conduct.[433]

The conduct of medical practitioners should be of the highest standard and model behaviours that engender best practice in health care. This is particularly important in addressing the concerns of patients when something goes wrong with the chosen treatment.

[432] Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia*, March 2014: 16.

[433] Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia*, March 2014: 6; 18.

Accounts from Mesh Injured Witnesses and Submitters

Despite the best intentions of the many policies and safeguards being in place, the experience of many of the witnesses with mesh implants does not support their observance or effectiveness.

The Committee found, the majority of the written submissions from individuals who had mesh implants, relayed consistent accounts of medical practitioners, including GPs, gynaecologists, and surgeons, failing to provide adequate information to them prior to surgery, or to obtain informed consent. This was evidenced in both the public and private hospital sectors and include the:

- absence of providing detailed information on the proposed surgery to the patient
- failure to disclose risks and possible complications involved in mesh implantation
- failure to disclose and discuss other non-surgical treatment options
- failure to investigate risk factors with patients to assess suitability for a mesh implant
- failure to disclose that mesh was being used in the surgical procedure
- failure to identify that "slings", "hammocks" and "tapes" were in fact mesh products
- failure to advise mesh was not designed to be removed.

The Committee received numerous written submissions in which the submitters stated that, prior to having surgery, they were told incomplete, incorrect or inappropriate information by the specialist or surgeon, such as, "complications are very rare", "no amount of physio will help", "it's a new beaut treatment", "it's better than sliced bread", "it will make you feel like a virgin again" or "it's the gold standard treatment."[434, 435, 436]

Several submitters wrote that they were told so few details about the proposed treatment, or why they even needed to have surgery as a first-line treatment. They were not given other options to explore such as physiotherapy, pelvic floor exercises, pessaries or estrogen:

> [The gynaecologist] suggested this new beaut way of doing it with tape! Would never need it repeated again, was permanent! It wasn't explained to me that my bladder was perfectly ok, just this would solve the problem! Looking back now I should have gone to a physiotherapist that specialized in this area but wasn't suggested as a try this first before surgery. **I was not informed this was mesh and trusted my doctor this was safe!**[437]

One submitter wrote to the Committee that she explicitly told the gynaecologist she did not want to have surgery, but was pressured into it:

> […] I sought a Routine Pap Smear. During the pap smear out of embarrassment I said "if you put pressure on my bladder I may leak". Instantaneous my new gynaecologist diagnosed USI - 'Urinary Stress Incontinence' (Sic) a condition I'd never heard off – considering I'd never complained or sought treatment. He said "I can fix it' in what he trivialized "a simple, safe effective non-invasive 20 min. procedure". I didn't want surgery but he warned "if you don't proceed your symptoms will deteriorate and then you will be too old to have it done".[438]

Several submitters advised there was never any discussion as to whether or not they were in fact a suitable candidate for a mesh implant, only to be told when the implant failed that it was their fault:

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[434] Name confidential, *Written submission No. 7*, 10 September 2019: 1.

[435] Name confidential, *Written submission No. 10*, 10 September 2019: 2.

[436] Name confidential, *Written submission No. 46*, 13 September 2019: 1.

[437] Name confidential, *Written submission No. 20*, 12 September 2019: 1.

[438] Name confidential, *Written submission No. 5*, 9 September 2019: 1.

> I was implanted with a TVT in September 2010 at the […]. At follow up in 7 weeks I explained to them I'd had no improvement in my SUI and was told that the reason for that was because of my obesity and my lifestyle. I was gob smacked, I had fully disclosed that I was a smoker and had a bad diet and that didn't prevent them implanting, now that it isn't working it's my fault!!![439]

Some submitters told of how their gynaecologist or surgeon advised them the surgery would involve the insertion of a "sling" or a "tape" but did not disclose that these products were made from mesh.[440, 441, 442]

Others were advised they would get a mesh implant, but not told how much mesh would be used or that it would be much larger than was advised.[443]

In one case, the submitter was shown a small piece of mesh material during the initial consultation however, it was only after years of complications, followed by removal surgery performed in the United States, she found out instead of the small sample size she was shown, it was in fact over 10 times larger and covered many organs:

> In a conversation with [the surgeon], he showed me an innovative surgery of inserting mesh into the pelvis via a small incision in my vagina. He showed me a small piece of mesh about the size of my finger, and said "after about 6 weeks rest "I would be right to go, there was no discussion re possible complications. As he was a Doctor that I had worked with while I had trained as a Registered Nurse, I trusted this medical professional […] the mesh that was taken out it was approximately 25cms long, and attached to my bladder and rectum, bowel and numerous muscles of my pelvic floor, it had also eroded through the wall of my vagina in several places. I have extensive scaring to my whole pelvic floor, and my vagina.[444]

In one case the submitter advised the surgeon who was to perform a hysterectomy on her told her he would fit a transvaginal "tape" at the same time, in case she developed incontinence later on. Although the hysterectomy was performed through open abdominal surgery, the surgeon still chose to implant the SUI mesh via the vagina.

Following the surgery, and after repeated denials of there being anything wrong, the surgeon told this submitter the complications she was experiencing were because of her weight; however, he also advised he wouldn't charge her the gap fee "under the circumstances":

> In 2008 I was having problems with endometriosis and adenomyosis with cancer cells and was recommended to have a hysterectomy, I was informed by my gynaecologist that sometimes after a hysterectomy that women have urinary stress incontinence (Sic) so he suggest that he put in a transvaginal tape which was new on the market and that he could do it at the same time. […] I asked the Doctor why I was in so much pain in the vagina and groin he said from the TVT mesh. I was confused because my hysterectomy was done abdominally to make sure they got all the endometriosis and made sure no cancer found elsewhere. So I thought if I was cut open from hip to hip why stitch me up and do the TVT vaginally. I was never informed of how the TVT mesh or tape was being implanted or of any risks or complications. […]

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439 Name confidential, *Written submission No. 10*, 10 September 2019: 2.

440 Name confidential, *Written submission No. 12*, 10 September 2019: 1.

441 Name confidential, *Written submission No. 25*, 12 September 2019: 1.

442 Name confidential, *Written submission No. 40*, 13 September 2019: 1.

443 Name confidential, *Written submission No. 14*, 11 September 2019: 1.

444 Name confidential, *Written submission No. 26*, 12 September 2019: 1; 2 – 3.

> Over the 6-week period I had gone back to see my gynaecologist claiming of pain and problems sitting and he kept saying its inflammation it would settle down. After 8 weeks I had gone back again and I was told it would still settle and a scan was done and he informed me scan was ok. He then said that he had trouble when putting in the TVT on the left side due to my weight at that stage I was only 92 kilo and I'm 5ft 10 inches tall. He said that under the circumstances he wouldn't charge me a gap for the procedure of the mesh.
> I asked why not do it when he had me opened he said that the TVT was the best method to go with and I was never given any other method in fact probably didn't really need the procedure at all.[445]

Many of the submissions showed doctors did not provide any written or verbal details of what the potential adverse effects of mesh were.[446, 447, 448, 449, 450]

> [The] Gynocologist (Sic) informed me that there was a new procedure that was less invasive and very successful in relieving incontinence. He explained that it involved a mesh tape introduced via the vagina and looped up into the abdomen to pull the urethra into place. I was not told of any side effects and believed it was a minor procedure […] I cannot remember receiving advice of long term adverse outcomes.[451]

The majority of these submitters stated that had they been made aware prior to mesh surgery, they would have chosen against having mesh implanted:

> I have only recently found out that it is mesh that is causing my problems. Before joining the dots I thought it was 'just me' and my age, but have since found out that this is not the case. […] I think many women feel the same as I have. I was not informed of the dangers of mesh or of the risk of adverse events during my consult with the implanting surgeon. I was not informed that previous adverse events had been found to occur in USA and in Australia regarding pelvic vaginal mesh prior to my operation. I believe if I had known this I would not have agreed to mesh surgery.[452]

A number of the witnesses who had TVT-O mesh for SUI, were not advised by their doctors that "trocars", titanium hooks that thread the mesh through the patient's flesh, would be used as part of the surgery procedure, or that they would have metal hooks attached to the mesh and their bones or ligaments, which would hold the mesh suspended in the pelvis:[453]

> I was 30 years old when I had a laparoscopic sacrocolpopexy, anterior and posterior vaginal mesh repair and a TVT O. The majority of this surgery was not necessary. I have lived with the consequences since that day. I did not go into the operation with a full understanding of what the surgeon was going to do. I did not know the extent of how much mesh would be used, how it would be attached to my sacral promontory and I certainly did not have a full understanding of the risks of using mesh.[454]

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[445] Name confidential, *Written submission No. 56*, 20 September 2019: 1.

[446] Name confidential, *Written submission No. 5*, 9 September 2019: 2.

[447] Name confidential, *Written submission No. 54*, 20 September 2019: 1.

[448] Name confidential, *Written submission No. 21*, 12 September 2019: 1.

[449] Name confidential, *Written submission No. 19*, 12 September 2019: 1.

[450] Name confidential, *Written submission No. 28*, 13 September 2019: 1.

[451] Name confidential, *Written submission No. 1*, 8 August 2019: 1.

[452] Name confidential, *Written submission No. 21*, 12 September 2019: 1.

[453] Name confidential, *Written submission No. 33*, 13 September 2019: 1.

[454] Name confidential, *Written submission No. 47*, 13 September 2019: 1.

Several submitters wrote they did not need the mesh implant, but received it as a matter of course.[455, 456, 457]

For other submitters, they were simply not told they would be having mesh implanted and were implanted without giving their consent.[458]

This was also the case for the few submissions received from witnesses in relation to hernia mesh and in the case of one submission received concerning the use of mesh for a rectal prolapse.[459, 460] In one case, the submission stated in relation to having a mesh implant for a hernia, that the submitter was told there was no other option for her:

> On the 20/8/18 I apparently had an incarcerated inguinal hernia of 1cm. I was admitted for emergency surgery. In the ward they told me they use mesh to fix it and I refused as I had issues with autoimmune already. In the ward I signed paperwork to have sutures as he told me everyone has their beliefs. That all changed when I got to theatre. I was petrified the female surgeon told me I had to have the mesh even though I told her about my previous health problems and autoimmune disorders, she didn't care. She told me I could die if they don't fix it and mesh was the only option.[461]

Advocates for Mesh victims

Mesh Injured Australia (MIA) consider high rates of adverse events are as a result of the over-use of mesh as a 'first-line' treatment, rather than a 'last-resort'. As such, MIA recommend that a "Restricted Access Protocol" be introduced to ensure that other Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI) treatments are explored first.[462] MIA advised the Committee:

> Many of our community report they were not given true and informed consent prior to their implant as they weren't made aware of the following:
>
> - It was a permanently implantable device that was meant to create scar tissue, inflammation and was never designed to be removed (and removal is another story);
> - The types of complications that "may" occur aren't minor, and indeed catastrophic to lives; and
> - That it was made of the same material as plastic chairs.[463]

Health Consumers' Alliance SA (HCASA) advised in their written submission that patients frequently told of their surgeon telling them about the proposed procedure after they believed they had consent. There were also stories of surgeons disclosing procedure details to patients while they were waiting to go into surgery or once they were being wheeled from their ward into theatre.

HCASA also told the Committee there was concern that consent for one type of procedure or mesh product was being taken as consent for other types as well:

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455 Name confidential, *Written submission No. 5*, 9 September 2019: 1.

456 Name confidential, *Written submission No. 47*, 13 September 2019: 1.

457 Name confidential, *Written submission No. 56*, 20 September 2019: 1.

458 Name confidential, *Written submission No. 15*, 11 September 2019: 1.

459 Name confidential, *Written submission No. 14*, 11 September 2019: 1.

460 Name confidential, *Written submission No. 63*, 11 October 2019: 1.

461 Name confidential, *Written submission No. 14*, 11 September 2019: 1.

462 Mesh Injured Australia Inc., *Written submission No. 49*, 13 September 2019: 3 – 4.

463 Mesh Injured Australia Inc., *Written submission No. 49*, 13 September 2019: 3 – 4.

> Consumers have experienced that consent for surgery does not currently routinely allow for them to have time to research other options and make fully informed consent. Consumers report that consent is sought prior to any disclosure by the medical practitioner about medical mesh implantation. Further, consent can often be subject to lack of definitive parameters. For example, consent by a consumer for the use of a 2cm piece of medical mesh does not provide consent for any amount of medical mesh.[464]

International Comparison - Scottish Independent Review, 2017

The 2017 *Scottish Independent Review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women* (the Scottish review), found that there should be a minimum standard of information provided to women considering pelvic surgery.

In 2014, the Scottish review recommended implementation of a New Care Pathways, specifically aimed at women who require complicated surgery for POP and SUI and for women who have suffered mesh complications. The New Care Pathways produced a "new patient information and consent booklet for SUI", which is publicly available and outlines the risks associated with this procedure and the alternatives available before women make a decision about pelvic surgery.[465]

The 2017 Scottish review found that training by professional organisations was important and recommended training in gaining consent be specifically provided to new specialists:

> **2.2 Guidance for surgery (National Institute for Health Care and Excellence (NICE) and professional bodies)** [466]
>
> As part of the surgical training for gynaecologists, urologists and urogynaecological subspecialists there is a need to be familiar with the range of procedures to offer as treatment when discussing symptoms with patients. These procedures include the options noted above, some of which will be initially tried in General Practice before a referral to a specialist. The specialist will be aware of the range of professional advisory documents on the procedures that can be offered. In NHS Scotland it is obligatory to use the guidance from the NICE Interventional Procedures Programme. This programme includes a range of procedures from 2005 to 2016 for both SUI and POP.
>
> In addition, NICE published a detailed clinical guideline in 2006 with updates in 2013 and 2015 on urinary incontinence management in women which can be used when arranging services in NHS Scotland. The professional societies including British Society of Urogynaecology (BSUG4), the British Association of Urological Surgeons (BAUS5) and the Royal College of Obstetricians and Gynaecologists (RCOG6) provide specialist training and professional guidance, plus a method of recording activities and patient information and consent information.

[464] Health Consumers Alliance of SA Inc., *Written submission No. 23*, 13 September 2019: 6.

[465] Scottish Government, *Scottish Independent Review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women*, March 2017: 16.

[466] Scottish Government, *Scottish Independent Review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women*, March 2017: 16.

Conclusion 3[467]

Informed consent is a fundamental principle underlying all healthcare interventions. Extensive work was carried out by the Expert Group prior to the establishment of the IR [Independent Review], with leadership by both patients and clinicians. This has resulted in an information leaflet on Synthetic Vaginal Mesh Tape Procedure for the Surgical Treatment of Stress Urinary Incontinence in Women and consent form. Following on from this, the IR concludes that additional work is required to ensure that this work is extended to include all appropriate SUI and POP procedures and that the existing SUI leaflet is reviewed in the light of this work and other recent developments. This should be addressed by the Expert Group as a matter of urgency.

Other points highlighted by the IR include the provision of adequate time for discussion and reflection. Patients should be provided with the information they need in order to make informed choices. Patients also require appropriate information, which must include device identification, to allow them to report adverse events if these occur.

Senate Inquiry Findings 2018

The Social Development Committee (the Committee) recalls the views of the Community Affairs References Committee on the practices of the medical profession and the lack of informed consent that was evidenced during the 2018 Senate Inquiry:

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.[468]

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.[469]

[467] Scottish Government, *Scottish Independent Review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women*, March 2017: 92

[468] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 84.

[469] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 85.

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.[470]

The Community Affairs References Committee noted the resources that were being put together at that time by the ACSQHC and was interested in seeing how women seeking advice on POP and SUI treatment would fare, particularly where there were barriers to accessing the ACSQHC website or the internet in general.[471]

The Community Affairs References Committee also noted the detailed information and education documents put together by the various colleges and associations to assist specialists and surgeons in communicating with patients in the consent process.

However, the Community Affairs References Committee went on to conclude that "despite the availability of detailed guidance and patient information leaflets […] many women appear to have received little or no information to assist them to make a decision or provide their informed consent.[472]

The Committee notes evidence received during this inquiry shows that an effective consent process must involve a dialogue between the medical practitioner and the patient and must be tailored to the need of the individual patient.

Recommendation 6 of the Community Affairs References Committee recommended the ACSQHC develop and publish guidance material on effective informed consent processes.[473] These would assist in achieving dialogue to occur between a medical practitioner and their patient prior to any treatment.

The guidelines were recommended to include the following for medical practitioners to adopt in their discussions with patients, and the resultant ACSQHC documents are discussed below:

- Clarification of the rationale for the proposed treatment;
- discussion of the range of alternate treatment options available and their attendant risks and benefits;
- discussion of the likely success and potential complications of the recommended treatment as they relate to the individual patient;
- provide an opportunity for the patient to ask questions; and
- confirm that the individual patient has understood the information discussed.[474]

[470] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 85.

[471] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 102.

[472] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 102.

[473] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 102 – 3.

[474] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 103.

Australian Commission on Safety and Quality in Health Care

The Australian Commission on Safety and Quality in Health Care (ACSQHC) have produced information sheets on treatment pathways for Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI).[475, 476] The information sheets are available on the ACSQHC website and links to them are provided on various other organisation websites, including the SA Health Pelvic Mesh Clinic website.

Dr Robert Herkes, Chief Medical Officer with the ACSQHC, advised the Committee in his oral evidence to this inquiry that in 2017, as a result of a large-scale national consultation process concerning the issues of pelvic mesh, the ACSQHC reviewed relevant scientific evidence and feedback from the consultation process to identify the most pressing issues for Australian women.[477]

This process coincided with the Senate's 2018 Inquiry and the outcomes of both processes were analogous in their findings. Key safety and quality issues identified by the ACSQHC were:

- concerns raised by women regarding the level of informed consent prior to surgery and pain and suffering following implantation of the transvaginal mesh;
- the lack of data on the number of procedures involving transvaginal mesh in Australia;
- the outcomes and complications as a result of implantation and the number of women having mesh removed;
- the complexity of the process for reporting adverse events for both patients and clinicians;
- the need for greater clarity regarding patient selection for pelvic organ prolapse and stress urinary incontinence procedures and care pathways for both pelvic organ prolapse and stress urinary incontinence;
- the need for more accessible information concerning the potential complications resulting from transvaginal mesh procedures and the recognition of these complications by general practitioners and specialists;
- the need for information, training support and credentialing for clinicians involved in transvaginal mesh implants and their removal; and
- guidance for health service organisations and consumers on the essential components of a service model for mesh removal and complications.[478]

The ACSQHC also developed patient information on mesh complications and removal; information targeted at clinicians and health care organisations was also developed in relation to care pathways, informed consent, hospital senior medical practitioner credentialling and mesh removal.[479, 480, 481]

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[475] ACSQHC, *Treatment options for pelvic organ prolapse*, 2018. Accessed 5 November 2019 Treatment Options for Pelvic Organ Prolapse (POP) | Australian Commission on Safety and Quality in Health Care

[476] ACSQHC, *Treatment options for stress urinary incontinence*, 2018. Accessed 5 November 2019 Treatment Options for Stress Urinary Incontinence (SUI) | Australian Commission on Safety and Quality in Health Care

[477] Dr Robert Herkes, *Hansard*, 1 June 2020: 90.

[478] Dr Robert Herkes, *Hansard*, 1 June 2020: 90.

[479] Dr Robert Herkes, *Hansard*, 1 June 2020: 90.

[480] See ACSQHC Transvaginal Mesh | Australian Commission on Safety and Quality in Health Care

[481] See ACSQHC, *Fact sheet for clinicians: Informed consent in healthcare*, 2020: Fact Sheet for clinicians-Informed consent in health care (safetyandquality.gov.au)

In 2018, information about the "suite of guidance resources" was widely distributed and made available on the ACSQHC's website. Dr Herkes stated, the ACSQHC regularly seeks advice from the states and territories regarding the accuracy of information on its service model webpage and updates this as required.[482]

Dr Herkes also commented that there is much better availability of information and resources for consumers, patients and health professionals and that the ACSQHC has ensured the information has had a wide distribution. Dr Herkes advised:

> The documents were distributed widely. They were sent to all the states and territories, all the jurisdictional health departments, all the private hospital groups. They were distributed to the consumer health forums and the consumer groups. They were distributed to the colleges and specialist societies that oversee doctors and they were sent to AHPRA, the registration organisation for doctors, nurses and allied health personnel. We have been assured by the states and territories that they have commenced credentialling to our credentialling guidance so that specialists who are credentialled to implant or explant mesh have appropriate education, have followed their patient's journey, have appropriate skills at assessing a patient for mesh implantation or removal and have appropriate skills at explaining and gaining informed consent.[483]

Adjunct Professor Kathy Mileady, Stream Director, ACSQHC added:

> […] our interactions with and input that we received from the consumer advocacy groups around the country after the resources were distributed indicated that they were also having that second wave of distributing and making sure that their networks were aware of the resources, but […] we don't have any quantitative information about how far that has spread. In the short time following the release of the resources, we certainly did receive some favourable feedback about the resources, but it was more about the content and the nature of the resources rather than perhaps how far the utility of those had gone at the time.[484]

In relation to the issue of informed consent Dr Herkes offered that during the review and consultation process undertaken by the ACSQHC, issues were identified concerning availability of information for patients and consumers on the role of consent in the treatment process. Dr Herkes advised:

> […] when we did our investigation, it was clear that consent processes didn't involve distribution of very useful consumer information historically. Both these resources and resources that the TGA have developed with their patient card, which informs patients who are going to get mesh of the nature of the mesh and the potential pros and cons of that, should help improve communication and understanding from patients. I would hope more recently, people are better informed than historically.[485]

Dr Herkes also commented that because there are now resources available on consent, he believes the processes around consent won't be "quite so one-sided."[486] While Adjunct Professor Mileady offered:

> […] ensuring in terms of informed consent that the resources are widely profiled so that the medical practitioners offering the informed consent and going through the options of non-surgical and surgical options are utilising resources and supporting the women as much as possible with that industry information.[487]

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[482] Dr Robert Herkes, *Hansard*, 1 June 2020: 91.

[483] Dr Robert Herkes, *Hansard*, 1 June 2020: 92.

[484] Adjunct Professor Kathy Mileady, *Hansard*, 1 June 2020: 92.

[485] Dr Robert Herkes, *Hansard*, 1 June 2020: 92.

[486] Dr Robert Herkes, *Hansard*, 1 June 2020: 95.

[487] Adjunct Professor Kathy Mileady, *Hansard*, 1 June 2020: 95.

Dr Herkes stated he considered at a state level it was important that the credentialling of senior medical practitioners in hospitals is working; and making sure that the doctors who are being credentialled are using the appropriate informed consent and are able to consider both surgical and non-surgical techniques.[488]

Therapeutic Good Administration Mesh Hub

In the Department of Health (DoH), Therapeutic Goods Administration's (TGA) written submission, the TGA advised that from 1 December 2018, sponsors of urogynaecological meshes are required to provide a patient implant card with the device as a condition of inclusion in the Australian Register of Therapeutic Goods (ARTG), along with a patient information leaflet by December 2020.[489]

The information will provide consumers with the details of the device that has been implanted and is a written record of those details for future reference. The DoH advised

> This information, when provided by those reporting adverse events, will assist the TGA to enhance the accuracy of adverse event monitoring and the ability to take appropriate action. Similarly, conditions of inclusion in the ARTG also require patient information leaflets to be provided either electronically or in hard copies with the urogynaecological mesh devices. The information in the leaflet must be written in a way that is readily understood by patients and include a description of the intended purpose, operating instructions, risks, precautions, contraindications, expected lifetime of the device, materials used, when to contact a health professional and advice to report adverse events to the manufacturer and to the TGA. Such information will assist health practitioners and patients to discuss risks and ensure informed consent pre-operatively, and to identify symptoms and signs of an adverse event post-operatively.[490]

The DoH advised the information contained in the patient implant card must include:

> […] the name of the device; the model of the device; the batch code, lot number or serial number of the device; the unique device identifier of the device (if any) and the manufacturer's name, address and website. When an adverse event is reported, such information is essential for accurate adverse event monitoring and hazard alert purposes.[491]

The DoH stated that in order for the patient implant cards and patient information leaflets to be effective, they need to be provided to patients by their treating practitioner and discussed as part of the process of patient decision-making and informed consent.[492]

Ms Tracey Duffy advised that the TGA had been consulting with a consumer working group to develop a patient information sheet titled *'Five questions to ask your health professional before you get a medical implant'*. The consumer information sheet was drafted with all the consumer groups involved and is available on the TGA website.[493, 494]

The information sheet provides people who are considering whether a medical device implant is the right treatment option for them, to consider a number of matters and put those to their treating medical practitioner before consenting to the treatment.

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488 Dr Robert Herkes, *Hansard*, 1 June 2020: 95.

489 Australian Government, Department of Health, *Written submission No. 66*, 31 October 2019: 5 – 6.

490 Australian Government, Department of Health, *Written submission No. 66*, 31 October 2019: 5 – 6.

491 Australian Government, Department of Health, *Written submission No. 66*, 31 October 2019: 12.

492 Australian Government, Department of Health, *Written submission No. 66*, 31 October 2019: 13.

493 Ms Tracey Duffy, *Hansard* 7 December 2020: 214.

494 See TGA https://www.tga.gov.au/community-qa/five-questions-ask-your-health-professional-you-get-medical-implant

Ms Duffy also informed the Committee that there were a series of consultations undertaken between the TGA and consumers in relation to the TGA reviewing the post-market definitions, to have consistency worldwide. This was in order to improve consistency in device information so that if an issue flagged in another country, information could be shared in Australia and with TGA regulators outside Australia.[495]

Another of five proposals looked at by the TGA was enhancing communication via the TGA with consumers of medical devices. Ms Duffy advised this project was ongoing and would continue into 2021.[496]

In October 2019, the Australian Government, in providing an update to its response to the 2018 Senate Inquiry recommendations advised that on top of the existing improvements made in the information available to consumers, prospective patients and medical professionals, work was being done to determine how to include device information in MyHealth Record.

Further, the submission stated in relation to distribution of the TGA's information for consumers, that the TGA managed awareness-raising activities through social media and the transvaginal mesh hub website:

> The TGA continues awareness raising activities including through social media to increase patients, consumers and healthcare practitioners' awareness of the importance of reporting adverse events associated with implantable medical devices. The TGA established a transvaginal mesh hub on its website to provide a central source for consumers and health practitioners to access information about resources, support services and other useful information: https://www.tga.gov .au/hubs/transvaginal-mesh.[497]

DoH further advised that Strategy 3 in the TGA's *Action Plan for Medical Devices* was about partnering with consumer groups to co-design a range of improvements which seek to provide more information to patients about the devices they use and enhancing consumer awareness.[498] Ms Duffy commented in relation to raising awareness and the limitations of web-based approaches:

> […] we do identify to consumer organisations representing consumers that they be aware of any consultation, particularly these consultations, and I guess spread the word through their channels. What we have heard also is that patients and consumers are more likely to be in touch with representative groups that represent their interests as opposed to engaging directly with the TGA or watching the TGA website.[499]

The role of medical device sponsors

Sponsors of medical devices included in the ARTG must comply with their responsibilities under the medical devices regulatory framework. Sponsors' responsibilities include:

- reporting adverse events
- maintaining distribution records
- assisting the TGA in investigations of incidents
- taking corrective action when necessary (such as recalling devices)

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[495] Ms Tracey Duffy, *Hansard* 7 December 2020: 215.

[496] Ms Tracey Duffy, *Hansard* 7 December 2020: 215.

[497] Australian Government, *Progress Report on the Australian Government Response to the Senate Community Affairs References Committee Report: Number of women in Australia who have had transvaginal mesh implants and related matters*, October 2019: 6.

[498] Australian Government, *Progress Report on the Australian Government Response to the Senate Community Affairs References Committee Report: Number of women in Australia who have had transvaginal mesh implants and related matters*, October 2019: 6.

[499] Ms Tracey Duffy, *Hansard*, 7 December 2020: 218.

- informing the TGA of any overseas regulatory actions and investigations undertaken by the manufacturer, such as further clinical studies and reviews of adverse events
- obtaining information requested by TGA from the manufacturer(s). [500]

As part of the post-market monitoring and surveillance, the TGA has implemented many changes to the regulatory framework for which sponsors of medical devices must comply, commencing with amendments to the Therapeutic Goods (Medical Devices) Regulations 2002.[501] This includes compliance with the reclassification of medical mesh as a class 3 device, and the inclusion of the patient implant cards and patient information leaflets.

Johnson & Johnson response

In their written submission to this inquiry, Johnson & Johnson Medical Pty Ltd (JJM) cited the changes to the medical devices regulations requiring consumer information leaflets to be provided with all implantable medical devices from 1 December 2019:

> As noted in the Federal Government's response to the Senate Inquiry, this information will include the device name and model, intended purpose of the device and information about how to use the device safely. The information is required to be updated as new evidence emerges of safety issues, side effects, warnings and risks associated with the medical device. It will also give guidance on how to advise health professionals and/or the TGA and manufacturers.
> JJM also notes the Federal Government has directed the TGA to work with the Australian Commission on Safety and Quality in Health Care on guidance materials for patients to better inform discussions with health professionals in relation to implantable medical devices.[502]

Committee's View

In the absence of any procedure to be able to audit individual medical practitioners and their practices in obtaining consent from their patients, there is no way to ensure patients are receiving best practice advice, collaboration and counselling about treatment options, and about the act of giving consent to a particular treatment.

While there are mechanisms in place to support compliance with the relevant state and Commonwealth laws, the NSQHC Standards, hospital codes of conduct, or with the ethical and procedural standards administered by the professional colleges and associations, much rests on the conduct of the individual doctor.

The Committee found that although there were reported instances of patients being denied the opportunity to provide fully informed consent prior to the surgical procedure to have mesh implanted in both public and private hospitals, there needs to be greater transparency from doctors in both sectors in relation to patients giving consent.

As part of this inquiry, representatives of SA Health's Pelvic Mesh Clinic and senior SA Health Governance Officers gave oral evidence to the Committee and provided further answers to questions on notice. One of those questions taken on notice concerned whether SA Health public hospitals had implemented the recommendations of the Senate Inquiry in relation to fully informed consent.

SA Health advised the Committee in evidence to this inquiry, SA Health has implemented the Australian Commission on Safety and Quality in Health Care recommended procedures to obtain fully informed consent from prospective mesh implant patients.

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[500] Australian Government, Department of Health, *Written submission No. 66*, 31 October 2019: 13.

[501] Ms Tracey Duffy, *Hansard*, 11 May 2020: 74.

[502] Johnson & Johnson Medical Pty Ltd., *Written submission No. 30*, 13 September 2019: 7.

SA Health advised:

> SA Health sites secure informed consent from prospective mesh implant patient in accordance with the SA Health Consent to Medical Treatment and Health Care Policy Guideline.[503]

SA Health also provided an update on the progress of SA Health public hospitals implementing the "patient information leaflet" and "patient implant card", which are now required by the TGA to be adopted by manufacturers of mesh products, and which must be supplied to patients when they are implanted with a mesh device. SA Health advised:

> From 1 December 2018, manufacturers of all new permanently implantable or active implantable medical devices are required to make available to patients, patient information leaflets with the device. All Local Health Networks are required, in line with TGA requirements to provide the patient information as part of the consent process and document clearly in the medical record that the information has been provided and the details of the implantable device, recorded.[504]

Despite what appears to be the best intensions of the professional organisations and the best efforts of the Federal and State Governments, it is clear to the Committee that there are still failures in the practices of medical professionals, to ensure that patients have the information they need, that they feel supported to make a decision that they feel is the right decision for them, and that they are supported after any surgery in continuity of care. The evidence from the individual submitters and witnesses are testament to that.

The Committee formed the view, in spite of the complications women with failed mesh implants have faced, evidenced from years of unmonitored mesh implantations, the issues faced by this group of the community are still not being comprehended by medical professionals, nor discussed in partnership with their patients in an adequate fashion.

Recommendations

The Minister for Health and Wellbeing:

6. Undertake an audit to determine how South Australia is tracking with the newly implemented patient information leaflets and patient implant cards for pelvic mesh.

7. Provide funding for an education campaign to be targeted at SA Health facilities, to ensure that all patients considering a medical mesh device implant, receive adequate information prior to making a decision, and giving consent.

8. In relation to increasing the awareness of mesh-related injury and improving visibility of treatment options for mesh injured patients, as soon as practicable, undertake to:

    (a) Continue to urgently progress the SA Health Pelvic Mesh Clinic Communications plan for General Practitioners and ensure that the communications plan is published in the relevant medical associations and colleges' newsletters to their members, through the assistance of the Royal Australian College of General Practitioners; and that the plan include direct mail to doctors.

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[503] SA Health, *Responses to Questions on Notice, Hansard,* 7 September 2020, received 3 November 2020: 9.

[504] SA Health, *Responses to Questions on Notice, Hansard,* 7 September 2020, received 3 November 2020: 9.

(b) That SA Health, as a matter of urgency, pursue avenues to ensure South Australian women be included in the Australasian Pelvic Floor Procedure Registry pilot.

(c) Give consideration to undertaking a further audit of women in South Australia, who having had urogynaecological surgery in the course of the last three years followed by a sequence of three year blocks going back to 2006, within both the private and public hospital systems, including day surgery centres, and notify them of the issues that have been identified concerning pelvic mesh implants, and where they may seek advice and assistance.

9. Provide funding for an education campaign across SA Health regarding issues that may occur with medical meshes for hernia, which could extend to the private sector, through partnering with the Royal Australian College of General Practitioners and the Royal Australasian College of Surgeons.

(e) the credentialing of medical practitioners conducting implantation and the removal of medical mesh

The Social Development Committee (the Committee) received a number of written and oral submissions indicating there were concerns about the expertise, training or techniques of medical practitioners who had performed mesh implantation surgery, where a device had subsequently failed.

Several issues were identified from the evidence received in relation to the credentialing of medical practitioners in South Australia who perform mesh implants, mesh excisions, partial removals and eventually full removals.

It was identified that at the time of writing, there is not a properly trained, credentialed urogynaecologist in the South Australian public health system who can perform full mesh removal surgery. This raises the issue of South Australia being unable to provide women with failed mesh devices the option of a full mesh removal.

More broadly, it raises issues for the provision of a speciality mesh removal surgical team, as it is understood full mesh removals often require a number of different surgeons, such as a colorectal or plastic surgeon.

Concerns exist also in relation to the nursing staff and other support staff who are needed to provide care to women with failed mesh who are seeking a full mesh removal. All of the members of a mesh removal team require appropriate training and skills to support the women in need of this service.

SA Health advised the Committee, as a result of not having a credentialed gynaecologist to undertake full mesh removals, there are also no specialist education programs to train the multidisciplinary team on the "comprehensive care requirements to be afforded the woman having full pelvic mesh removal."[505] SA Health further stated:

> It is acknowledge (Sic) that the care required for the woman having full pelvic mesh removal is much more complex than post op care of POP implantation as it is highly likely to involve more health disciplines that the POP. These could include, urologist, neurologist, orthopaedic surgeon, pain specialist, colorectal surgeon, pelvic floor physiotherapist, and psychologist. It is very rare that the woman having had a POP requires access to such an extensive list of specialist to assist / manage her care. When CALHN has secured a credentialed Gynaecologist to undertake full pelvic mesh removal a comprehensive education strategy will be mobilised to:
>
> - communicate the commencement of the new surgery to all key stakeholders
> - ensure there is a co-ordinated approach to the new care pathway
> - educate all health disciplines involved in the care / management
> - ensure the clinical areas designated to accommodate the woman having full pelvic mesh removal is fully equipped to manage this care
> - ensure all health disciplines involved in the care / management are aware of the care pathway for the woman having full pelvic mesh removal
> - ensure all clinician involved in the care / management of the woman having full pelvic mesh removal have the appropriate clinical competencies
> - ensure escalation of care pathways are determined for the woman having full pelvic mesh removal and these are communicated and made aware to the clinicians involved.[506]

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[505] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 24.

[506] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 24.

Dr Ian Tucker commented:

> There is no doubt there have been mistakes, and you have to own what mistakes you make, don't you? That is an important part of it. It is even more complex than that, though, because not all the mesh insertion was bad. Some of the techniques might be criticised as well, because if people are poorly trained to do a procedure as complex as inserting mesh then you are going to be more likely to have problems. I have no doubt that that possibly happened. So I think better training would be an important factor. Again, I have accepted the apology point of view, but I think better training would be very important, because not all mesh was bad, we know that. […][507]

Ms Julia Overton of the Health Consumers Alliance of South Australia (HCASA) advised HCASA "strongly supported rigorous credentialing of medical practitioners undertaking removal of medical mesh" and that any medical practitioners implanting mesh needed to be credentialed to do so:

> Medical practitioners involved in implantation of medical mesh also need to be credentialed but this needs to be within a framework of 'medical mesh as a last resort' and with a clinically determined, with consumer input, decision matrix that records the use of medical mesh and the clinical rationale for its us. The current process of training surgeons in new techniques of 'see one, teach one, do one' for medical mesh removal is putting consumers already impacted by the adverse health outcomes of medical mesh at risk of further, potentially prolonged, complications. So our recommendations are that there is an implementation of a focused and targeted research program for surgical and non-surgical alternatives to the use of medical mesh and that consumers be involved in developing the credentialing process for removal and implantation of medical mesh.[508]

Dr Tucker further commented:

> The training is important. […] Once mesh is there, there is the chance it could prove to be a problem way down the track. Tissues don't get better with time, do they? They weaken. […] Will we in 10 years find more problems with mesh that have been implanted 15 years before, we don't know, do we? So that is a big issue and we have to be cognisant of that and we have to be prepared for it. […][509]

Credentialing, Certification and Scope of Clinical Practice

The process of credentialing and defining the scope of clinical practice of medical practitioners is a responsibility of the employing hospital or day procedure centre. The states and territories have obligations to ensure their public hospitals meet all relevant requirements under relevant laws, policies and charters as well as the requirements of the National Safety and Quality in Health Service Standards (NSQHS Standards).

Individual organisations in the private hospital sector are also required to meet the NSQHS Standards and their credentialing processes are determined by individual organisation by-laws.

The process of credentialing and defining the scope of clinical practice in health care organisations is listed under the NSQHS Standard 1, Clinical Governance.[510]

Credentialing refers to the formal process used to verify the qualifications, experience, and professional standing of clinicians for the purpose of forming a view about their competence,

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[507] Dr Ian Tucker, *Hansard*, 7 December 2020: 231.

[508] Ms Julie Overton, *Hansard*, 23 March 2020: 43.

[509] Dr Ian Tucker, *Hansard*, 7 December 2020: 232.

[510] ACSQHC, *NSQHS Clinical Governance Standard*. Accessed 9 February 2021 Clinical Governance Standard | Australian Commission on Safety and Quality in Health Care

performance and professional suitability to provide safe, high quality health care services within specific organisational environments.[511, 512]

Credentialing of medical practitioners ensures a health organisation is committed to the observation and practice of meeting national standards in clinical governance, safety and quality in health care and accountability. Credentialing is undertaken by a committee who has responsibility to verify the information provided by an applicant, and to determine the credentials and scope of clinical practice for their employment. The ACSQHC recommends that credentialing committees:

> […] should include, and preferably be led by, representatives from the professional group whose scope of clinical practice is being determined.[513] […] policies should be developed by the organisation's credentialing committee (or the relevant decision maker) and may also include the requirements set out by a relevant college or professional body.[514]

Credentials refer to the formal qualifications, professional training, clinical experience, continuing professional development and training and experience in leadership, research, education, communication and teamwork that contribute to a medical practitioner's competence, performance and professional suitability to provide safe, high quality health care services.[515]

Certification or Accreditation is the process of a medical practitioner obtaining and meeting the graduate training and professional requirements expected by a relevant specialty college or association. In order to be registered as a specialised medical practitioner, compliance of 'Continuing Professional Development' requirements must be met, as determined by the Australian Health Practitioner Registration Agency and National Boards (AHPRA).[516]

Scope of clinical practice refers to the boundaries imposed by the health care facility on the medical practitioner in what they can and can't do in their employed position. A practitioner's scope of clinical practice is defined by the health service organisation, and is dependent on the practitioner operating within the bounds of their qualifications, education, training, current experience and competence, and within the capability of the facility or service in which they are working.[517]

According to the ACSQHC, credentialing a medical practitioner involves "the demonstrated competence of the practitioner." This includes, but is not limited to, qualifications obtained from a

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511 Hon. Stephen Wade MLC, Minister for Health and Wellbeing, *Written submission No. 65*, 15 October 2019: 3.

512 Department for Health and Wellbeing, SA Health, *Credentialling and Defining the Scope of Clinical Practice for Medical and Dental Practitioners Policy Directive*, V. 2, Adelaide, 6 August 2018: 29. Accessed https://www.sahealth.sa.gov.au/wps/wcm/connect/b82dca004e8840fa8f588f3a30168144/Directive_Credentialling+and+Defining+the+Scope+of+Clinical+Practice_Apr2015.pdf?MOD=AJPERES&CACHEID=ROOTWORKSPACE-b82dca004e8840fa8f588f3a30168144-lYyu3nE

513 ACSQHC, *Credentialing health practitioners and defining their scope of clinical practice: A guide for managers and practitioners*, Sydney, 2015: 26. Accessed on 10 February 2021 Credentialing-health-practitioners-and-defining-their-scope-of-clinical-practice-A-guide-for-managers-and-practitioners-December-2015.pdf (safetyandquality.gov.au)

514 ACSQHC, *Credentialing health practitioners and defining their scope of clinical practice: A guide for managers and practitioners*, Sydney, 2015: 14.

515 SA Health, *Credentialling and Defining the Scope of Clinical Practice for Medical and Dental Practitioners Policy Directive*, V. 2, Adelaide, 6 August 2018: 29.

516 Australian Health Practitioner Registration Agency and National Boards, *Continuing Professional Development*, 3 July 2020. Accessed on 10 February 2021 Australian Health Practitioner Regulation Agency - Continuing Professional Development (ahpra.gov.au)

517 ACSQHC, *Credentialing health practitioners and defining their scope of clinical practice: A guide for managers and practitioners*, 2015: 8.

recognised training organisation relevant to the position, and subsequent work experience in the specific areas for which the practitioner seeks to be credentialed to perform work.[518]

Further, the ACSQHC describes the 'core scope' of clinical practice as referring to "[…] those aspects of clinical practice that can reasonably be expected to be undertaken by all practitioners holding a particular qualification […]"[519]

Organisations can choose to have 'core' or 'specific' scope of clinical practice definitions. Accordingly, specific credentialing and specific scope of clinical practice is required where the medical practitioner's qualifications do not include the specific competency and thus will require additional training, and/or experience, to meet the specific requirements.[520] The ACSQHC advises:

> To be granted specific scope of clinical practice in a specific area of clinical practice, a practitioner's training and competence in that procedure should match the requirements for that specific clinical practice, as set out in the policies. These policies should be developed by the organisation's credentialing committee (or the relevant decision maker) and may also include the requirements set out by a relevant college or professional body.[521]

The ACSQHC states that in relation to new procedures and treatments, health care organisations must ensure that a medical practitioner's training and competence in a specific procedure should match the requirements for that specific clinical practice, as set out in the organisation' relevant policies.[522] The ACSQHC provides:

> […] what constitutes a competent practitioner with regards to new clinical procedures, technologies or treatments […]

And

> Decisions about the introduction of new clinical procedures are the responsibility of the health service management, not the credentialing committee. The process for introducing a new procedure into the organisation should be addressed within the policies of the organisation.[523]

National Safety and Quality in Health Services Standards

The National Safety and Quality in Health Services Standards (NSQHS Standards) provide a "nationally consistent and uniform set of measures of safety and quality for application across a wide variety of health care services."[524]

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[518] ACSQHC, *Credentialing health practitioners and defining their scope of clinical practice: A guide for managers and practitioners*, Sydney, 2015: 8.

[519] ACSQHC, *Credentialing health practitioners and defining their scope of clinical practice: A guide for managers and practitioners*, 2015: 14.

[520] ACSQHC, *Credentialing health practitioners and defining their scope of clinical practice: A guide for managers and practitioners*, 2015: 14.

[521] ACSQHC, *Credentialing health practitioners and defining their scope of clinical practice: A guide for managers and practitioners*, 2015: 14.

[522] ACSQHC, *Credentialing health practitioners and defining their scope of clinical practice: A guide for managers and practitioners*, 2015: 14.

[523] ACSQHC, *Credentialing health practitioners and defining their scope of clinical practice: A guide for managers and practitioners*, 2015: 22.

[524] SA Health, *Credentialling and Defining the Scope of Clinical Practice for Medical and Dental Practitioners Policy Directive*, V. 2, 6 August 2018: 28.

Accordingly, the Clinical Governance Standard requires that health care organisations have in place a clinical governance framework in order that patients and consumers receive safe and high-quality health care.[525]

Standard 1.10 – refers to a health organisation's requirement to implement the NSQHS Standards, with Action item 1.23 relates to a health organisation's duty to provide credentialing and scope of clinical practice for their medical practitioners:

> The health service organisation has processes to:
> - Define the scope of clinical practice for clinicians, considering the clinical service capacity of the organisation and clinical services plan
> - Monitor clinicians' practices to ensure that they are operating within their designated scope of clinical practice
> - Review the scope of clinical practice of clinicians periodically and whenever a new clinical service, procedure or technology is introduced or substantially altered[526]

Action item 1.24 health organisations to endure credentialing processes are in place and monitors compliance with the processes, including assessing when improvement are needed:

> The health service organisation:
> - Conducts processes to ensure that clinicians are credentialed, where relevant
> - Monitors and improves the effectiveness of the credentialing process.[527]

Senate Inquiry 2018 and the Australian Commission on Safety and Quality in Health Care Credentialing Guidance

The 2018 Senate Community Affairs References Committee's Inquiry on the *Number of women in Australia who have had transvaginal mesh implants and related matters* (the Senate Inquiry), found that guidance for the credentialing of medical practitioners was urgently required to be given by the Australian Commission on Safety and Quality in Health Care (ACSQHC) in relation to transvaginal mesh surgery. The Community Affairs References Committee commented that:

> […] the committee noted concerns regarding the knowledge and skill of surgeons practicing transvaginal mesh procedures. Based on the evidence of personal accounts received from individual women, the committee considers that there is a need to improve the awareness of medical practitioners, especially General Practitioners, of symptoms associated with surgical mesh devices. There is also a clear need to improve the communication skills of some medical practitioners to ensure that they are communicating effectively with, and listening to patients.[528]

Following this, the Community Affairs References Committee recommended this be undertaken by the states and territories seeking such guidance material from the ACSQHC.

> **Recommendation 9 of the Senate Inquiry:**
> The committee recommends that the Commonwealth, state and territory health Ministers require that guidance developed by the Australian Commission on Safety and Quality in Health Care for the credentialing of medical practitioners who perform transvaginal mesh

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525 ACSQHC, *NSQHS Clinical Governance Standard*. Accessed Clinical Governance Standard | Australian Commission on Safety and Quality in Health Care

526 ACSQHC, *NSQHS Clinical Governance Standard. Action item 1.23.* Accessed Action 1.23 | Australian Commission on Safety and Quality in Health Care

527 ACSQHC, *NSQHS Clinical Governance Standard. Action item 1.24.* Accessed Action 1.24 | Australian Commission on Safety and Quality in Health Care

528 Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 105.

> procedures should underpin credentialing processes in all public hospitals and work with private hospitals to encourage the adoption of a similar requirement.[529]

As a result, the ACSQHC in consultation with the Royal Australasian College of Surgeons (RACS), the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), the Urological Society of Australia and New Zealand (USANZ), the Transvaginal Mesh Reference Group and state and territory health departments, developed guidance documents for the credentialing of senior medical practitioners for the implantation of mesh and also for the removal of mesh.

The documents set out the experience and qualifications that senior medical practitioners need to be credentialed to implant and remove mesh for treatment of POP and SUI, and recommends that state and territory health departments adopt the guidance.[530]

Ms Tracey Duffy from the TGA commented, the four mesh devices still approved by the TGA, will require a greater level of scrutiny by regulators, including by way of medical practitioner credentialing processes. As such, for the approved mesh devices:

> […] there has to be express provision of patient-informed consent; that there needs to be a supply of patient information materials; that they can only be used by suitably credentialled health professionals, consistent with the guidelines previously issued by the safety and quality commission; and that there will be increased reporting obligations, including of incident rates of adverse events, which we have indicated could be published on our website, so a greater level of transparency. […] As at 1 December and also as at today, there are no mesh devices approved for supply in Australia that treat pelvic organ prolapse, and only those devices can be accessed through the special access scheme now.[531], [532]

Accordingly, all mesh devices for the treatment of POP, and unapproved mesh devices for the treatment of SUI, may now only be used in accordance with approval from the TGA under the Special Access Scheme, such as for clinical trials.[533] The TGA states on its Mesh Hub website:

> The TGA's approval for some other types of transvaginal mesh remains in place because the use of these devices continues to be well supported by evidence. Mid-urethral slings for the treatment of stress urinary incontinence can still be supplied in Australia. Transvaginal meshes that are inserted through the abdomen (rather than the vagina) can also be supplied in Australia.[534]

In her evidence to the Committee in December 2020, Ms Duffy added:

> As at 1 December, there were 13 mesh devices that were required to do two things: firstly, they had to have their class III conformity assessment certificate assessed and issued and they also had to apply for inclusion as a class III device into the ARTG. As at 1 December, only four devices have been approved by the TGA and the rest have been cancelled. […] the four

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[529] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 108.

[530] See ACSQHC https://www.safetyandquality.gov.au/our-work/health-conditions-and-treatments/transvaginal-mesh/resources-consumers-clinicians-and-health-service-organisations-transvaginal-mesh#guidance-for-hospital-credentialing-of-senior-medical-practitioners-to-implant-and-remove-transvaginal-mesh

[531] Ms Tracey Duffy, *Hansard*, 7 December 2020: 216.

[532] See also TGA, *Special Access Scheme* https://www.tga.gov.au/form/special-access-scheme

[533] Ms Tracey Duffy, *Hansard*, 7 December 2020: 216.

[534] TGA, *Transvaginal (urogynaecological) surgical mesh hub*. Accessed online Transvaginal (urogynaecological) surgical mesh hub | Therapeutic Goods Administration (TGA)

> devices that have been approved are only for the treatment of stress urinary incontinence (SUI), and the approval is based on a number of conditions and post-market obligations.[535]

The ACSQHC advised in relation to the credentialing guidance:

> These resources have taken into account recent changes to the registration of a number of transvaginal mesh devices on the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA). While registration of transvaginal mesh products for treatment of POP has been cancelled, there is still potential for clinicians to use these devices with the necessary approvals. For this reason, the Commission has continued to produce guidance documents for POP.[536]

The Royal Australasian College of Surgeons (RACS) stated in RACS' written submission that, RACS does not provide specific training / re-training or consent advice on every specific procedure. RACS also stated that the responsibility of being appropriately informed on all of the aspects of continuing education, through the lifetime of surgical practice, must remain with each individual surgeon.[537] However, in reference to the credentialing guidance material developed by the ACSQHC, RACS provided:

> The development of credentialing guidance by an agency is a departure from existing processes where typically the profession – in conjunction with the Australian Medical Council (AMC) – outline the terms of its credentialing processes. RACS encourages ongoing review of this process in conjunction with our specialty societies to ensure this process is beneficial.[538]

RANZCOG advised that with the guidance documents developed by the ACSQHC coming into effect, there would be implications for hospitals' resourcing:

> The resource implications including the capacity, membership and infrastructure, of implementing these credentialing guidelines by hospital credentialing committees requires careful consideration and investment from state government departments of health.[539]

RANZCOG advised that it supported the service model framework guidelines also developed by the ACSQHC and advocated for a multi-disciplinary approach to the care of women affected by mesh.[540]

ACSQHC Guidance for Credentialing - Mesh Removal

The ACSQHC's *Guidance for Hospital Credentialing of Senior Medical Practitioners to Undertake Transvaginal Mesh Implant Removal Surgery* provides that the guidance document is designed for use in the credentialing of senior medical practitioners in the "substantial removal" of pelvic mesh.[541]

The guidance document states that the document does not apply to procedures involving "initial adjustment of a mesh implant with the purpose of retaining it as a functioning device but improving

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[535] Ms Tracey Duffy, *Hansard*, 7 December 2020: 216.

[536] ACSQHC, *Resources for consumers, clinicians and health service organisations - Transvaginal Mesh* Accessed on 5 November 2019 Resources for consumers, clinicians and health service organisations - Transvaginal Mesh | Australian Commission on Safety and Quality in Health Care

[537] RACS, *Written submission No. 62*, 8 October 2019: 5.

[538] RACS, *Written submission No. 62*, 8 October 2019: 5.

[539] RANZCOG, *Written submission No. 45*, 13 September 2019: 12.

[540] RANZCOG, *Written submission No. 45*, 13 September 2019: 12.

[541] ACSQHC, *Guidance for Hospital Credentialing of Senior Medical Practitioners to Undertake Transvaginal Mesh Implant Removal Surgery*, 2018: 2.

its functionality and/or the patient experience associated with it."[542] Nor is the guidance document for use involving removal of smaller amounts of exposed mesh with the purpose of retaining it as a functioning device to improve its functionality and/or the patient experience associated with it.

The ACSQHC makes clear however, that any further adjustments for removal of mesh should be considered as "substantial removal":

> […] any second or subsequent adjustment of a mesh device involving an individual patient, regardless of the amount of mesh to be removed or the time interval between adjustment procedures, is to be considered a "substantial removal" for the purposes of this Guidance. This is irrespective of whether the same or different medical practitioners undertook the initial implantation and/or the initial adjustment of the device.[543]

The guidance document contains details for the training, patient care and professional requirements for medical practitioners who will be employed in a hospital in the capacity of removing pelvic mesh, as summarised:

1. Core training and experience for senior medical practitioners who have not previously independently performed transvaginal mesh removal surgery as the primary operator
2. Transitional provision – senior medical practitioners who currently independently perform transvaginal mesh removal surgery as primary operator
3. Skills maintenance and review
4. Patient Outcome Monitoring and Reporting
5. Local institutional role and facilities.[544]

Health Care Act 2008

The *Health Care Act 2008* establishes a legal obligation on South Australian public hospitals to have in place certain policies and processes for credentialing of medical practitioners and defining a scope of clinical practice. Section 100(2)(j) of the Health Care Act provides that the Health Care Regulations 2008, may outline how any policies and processes will be carried out:

(2) Without limiting the generality of subsection (1), the regulations may—

[…]

(j) provide for the establishment and operation of policies, protocols or practices in order to assess the clinical competencies of any health care provider and to determine the appropriate scope of a health care provider's practice in a particular setting or circumstance; […]

Part 7 of the Health Care Regulations provides that the Chief Executive may meet the requirements set out in section 100(2)(j) in Regulation 29:

Part 7—Clinical competencies and scope of practice prescribes:

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[542] ACSQHC, *Guidance for Hospital Credentialing of Senior Medical Practitioners to Undertake Transvaginal Mesh Implant Removal Surgery*, 2018: 3.

[543] ACSQHC, *Guidance for Hospital Credentialing of Senior Medical Practitioners to Undertake Transvaginal Mesh Implant Removal Surgery*, 2018: 3.

[544] ACSQHC, *Guidance for Hospital Credentialing of Senior Medical Practitioners to Undertake Transvaginal Mesh Implant Removal Surgery*, 2018.

29—Clinical competencies and scope of practice

For the purposes of section 100(2)(j) of the Act—

(a) the Chief Executive may establish policies or protocols that set out practices in order to assess the clinical competencies of, and to determine the scope of the clinical practice of, specified classes of health care providers in specified settings or circumstances (including before a person is engaged as a health care provider) (being policies or practices that may be varied or substituted, and have effect, from time to time and according to their terms); and

(b) the Chief Executive may establish committees to undertake practices associated with assessing the clinical competencies of, and to determine the scope of the clinical practice of, specified classes of health care providers under any policy or protocol established under paragraph (a); and

(c) an incorporated hospital and SAAS, and any person engaged in connection with the Act, must comply with, and apply, any policies, protocols or practices established under paragraph (a); and

(d) an incorporated hospital or SAAS may establish policies, protocols and practices that are secondary or subordinate to (and consistent with) any policies, protocols or practices established under paragraph (a).

SA Health Credentialling and Scope of Clinical Practice

The process of credentialing and defining the scope of clinical practice for medical practitioners being recruited to or working in SA Health public hospital facilities is determined in accordance with the SA Health *Credentialling and Defining the Scope of Clinical Practice for Medical and Dental Practitioners Policy Directive* (the SA Health Credentialing and Scope of Clinical Practice Policy).

The SA Health *Credentialling and Scope of Clinical Practice Policy*[545] is established under Regulation 29 of the Health Care Regulations 2008 and provides:

> '**scope of clinical practice**' means: the extent of an individual Practitioner's Clinical Practice within a particular organisation (health care service or Local Health Network) based on the individual's credentials, competence, performance and professional suitability, and the needs and the capability of the organisation to support the Practitioner's scope of clinical practice.[546]

The SA Health *Credentialling and Scope of Clinical Practice Policy* states that it makes explicit what is required for defining and reviewing the credentials and scope of clinical practice for medical practitioners working in SA Health facilities, and "it is a fundamental part of ensuring high quality health care services and to protect the community from harm."[547]

Each Local Health Network (LHN) within SA Health has a 'Credentialing and Scope of Clinical Practice Committee', responsible within each specialty, for determining, reviewing and verifying the credentials of all medical practitioners who provide clinical services at a specific LHN health facility.

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[545] SA Health, *Credentialling and Defining the Scope of Clinical Practice for Medical and Dental Practitioners Policy Directive*, V. 2, 6 August 2018: 4.

[546] SA Health, *Credentialling and Defining the Scope of Clinical Practice for Medical and Dental Practitioners Policy Directive*, V. 2, 6 August 2018: 31.

[547] SA Health, *Credentialling and Defining the Scope of Clinical Practice for Medical and Dental Practitioners Policy Directive*, V. 2, 6 August 2018: 4.

The SA Health *Credentialling and Scope of Clinical Practice Policy* states that "Specific criteria for Defining the Scope of Clinical Practice must be developed by the Committee to ensure consistency and equity in decision-making."[548]

Medical practitioners practicing in the South Australian public health facilities must have relevant specialty college certification as part of the credentialing and scope of clinical practice processes:

> Just as graduation from a university indicates attainment of a minimum standard of qualification, attainment of professional/vocational accreditation or endorsement from a medical/dental college provides evidence that a Practitioner has completed a minimum standard of training in a particular speciality. Medical/dental college accreditation/endorsement is considered in the process of Credentialling and Defining the Scope of Clinical Practice for a Practitioner, together with other training, experience, professional references and any other factors deemed relevant to assist the accreditation process […].[549]

The SA Health *Credentialling and Scope of Clinical Practice Policy* also states, where the relevant credentialing committee suspects a medical practitioner is unable to meet the scope of clinical practice required of them, and:

> If the Committee remains in doubt about the competence of the Practitioner to perform a particular clinical service, procedure or intervention, the Committee may:
>
> - request a specific evaluation of the Practitioner's performance by an external or internal peer
> - place restrictions on the time period or Scope of Clinical Practice granted, and/or
> - require the Practitioner to be supervised or to attend further training.[550]

The SA Health *Credentialling and Scope of Clinical Practice Policy* is consistent with the recommendations of the ACSQHC, where the implementation of new treatments or procedures requires medical practitioners to meet further credentialing and scope of clinical practice directives:

> As new procedures and treatment modalities are developed or introduced to a Health Care Facility, Practitioners need to have their Scope of Clinical Practice amended to provide these interventions. In addition, clinical requirements or minimal level of clinical competency (as informed by relevant SA Health clinical practice guidelines/standards) may change for particular situations or procedures. This may also result in Practitioners needing to have their Scope of Clinical Practice amended or a probationary period, training or supervisory requirements defined.[551]

According to the written submission of the Minister for Health and Wellbeing (the Minister), SA Health has undertaken a review of the credentialing processes in practice within the SA Health LHNs.

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[548] SA Health, *Credentialling and Defining the Scope of Clinical Practice for Medical and Dental Practitioners Policy Directive*, V. 2, 6 August 2018: 9.

[549] SA Health, *Credentialling and Defining the Scope of Clinical Practice for Medical and Dental Practitioners Policy Directive*, V. 2, Adelaide, 6 August 2018: 4

[550] SA Health, *Credentialling and Defining the Scope of Clinical Practice for Medical and Dental Practitioners Policy Directive*, V. 2, Adelaide, 6 August 2018: 15.

[551] SA Health, *Credentialling and Defining the Scope of Clinical Practice for Medical and Dental Practitioners Policy Directive*, V. 2, 6 August 2018: 16.

The Minister advised:

> A credentialing process review is currently being undertaken in SA Health to identify system expectations and limitations of the current credentialing system. This process is occurring under the auspice of a Steering Committee, and I have asked that consideration be given to the feasibility of credentialing for practitioners conducting implantation and removal of medical mesh.[552]

In other evidence provided by representatives of SA Health, and representatives of the SA Health Pelvic Mesh Clinic, the Committee was advised that all staff employed at the SA Pelvic Mesh Clinic who practice gynaecology would be credentialed to perform mesh excision and partial removals of mesh. Further submissions from SA Health state:

> SA Health utilised the ACSQHC Credentialling of Hospital Senior Medical Practitioners to inform the gap analysis undertaken of the SA Health document: *Credentialing and Scope of Clinical Practice System for Medical and Dental Practitioners* to ensure SA Health sites were supported.[553]

And:

> […] each LHN has their own credentialing processes managed by a designed (Sic) committee that includes ensuring the implantation of mesh devices. (Sic)

Details of the gap analysis were not supplied as evidence to this inquiry however, the Committee was advised by SA Health that there are:

> "111 Gynaecologists in SA – credentialed with FRANZCOG and are credentialed to undertake the implant and excision / partial removal procedures."[554]

The Committee has presumed that this means there are 111 gynaecologists who have completed training in implantation, excision and partial removal procedures of mesh, and are therefore 'certified' with RANZCOG, rather than there being 111 gynaecologists who are credentialed within a private or public hospital to perform these procedures.

The Committee was also advised that in the process of setting up the SA Health Pelvic Mesh Clinic, SA Health established is a transvaginal reference group, which is a clinical group, underneath the maternal gynaecological group. SA Health advised this clinical reference group has been responsible for developing the clinical pathways of care, training and credentialing, and patient decision support in relation to pelvic mesh complications.[555]

However, no evidence was provided in relation to what the training and credentialing requirements are, how many SA Health employed surgeons will be credentialed and what the terms of the credentialing will be.

Another issue raised by Dr Samantha Pillay of the RACS, was how the State can ensure there are enough surgeons credentialed to perform mesh related surgeries.

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[552] Hon. Stephen Wade MLC, Minister for Health and Wellbeing, *Written submission No. 65*, 15 October 2019: 4.

[553] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 4.

[554] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 5.

[555] Ms Michele McKinnon, *Hansard*, 7 September 2020: 150.

Dr Pillay commented that the notion of dealing with this through the issuing of quotas for specialist surgeons or an "isolated procedure" raised many questions from an operational perspective:

> Relying on quotas alone for credentialing has limitations. Quotas for an isolated procedure don't evaluate a surgeon's skill set or their ability to operate beyond that particular procedure. For example, if performing a mesh sling, how familiar are the surgeons with the surrounding structures—bladder, urethra, bowel? Have they performed other operations? Can they recognise an injury, prevent it or repair it and manage a complication if it occurs?

Further, Dr Pillay questions how senior surgeons are to meet annual quotas as they transition to teaching and supervision to train younger surgeons and are then only involved in more complex cases.[556] This was an issue also raised by Dr Ian Tucker.[557]

Dr Pillay informed the Committee that there is also the issue of *quality* to consider. Dr Pillay advised that the training of surgeons can vary widely and the overall surgical experience between those surgeons who are trained as a Fellow through the College of Surgeons and those surgeons who are not a Fellow with RACS, varies considerably. Dr Pillay goes on to say:

> The College of Surgeons overseas training and ongoing CPD for its members that is not procedure-specific. A quota alone may make it hard for credentialing committees, colleges or other jurisdictions to act on a poorly performing surgeon who still meets the quotas. The surgeon with the highest number of procedures could, in fact, have the highest complication rate. Relying on just a quota would be akin to wearing a mask during the COVID-19 pandemic but not following any other precautions and then assuming you were safe.[558]

The Urological Society of Australia and New Zealand (USANZ) stated in their written submission that USANZ supports the guidance documents of the ACSQHC but considers that credentialing is a complex process. USANZ also refer to credentialing by quota as problematic and that 'competency-based' credentialing is more important than 'quota-based credentialing'.[559]

International Comparison – New Zealand

In June 2019, the Aotearoa New Zealand Ministry of Health initiated a restorative justice review to examine the harm caused by surgical mesh use in New Zealand (the NZ review).[560] The project determined there was a need for the provision of a national framework for assessing and credentialling the technical competence of surgeons to insert, repair, renew or remove mesh.

Similar to the consumer focussed workshops undertaken by the ACSQHC, the NZ review proposed that a working group be set up to make recommendations to the Ministry of Health on mesh related issues. The NZ review proposed consideration be given to how a national credentialing framework might be co-designed with consumers.[561]

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556 Dr Samantha Pillay, *Hansard*, 15 June 2020: 100.

557 Dr Ian Tucker, *Hansard*, 7 December 2020: 229.

558 Dr Samantha Pillay, *Hansard*, 15 June 2020: 100 - 101.

559 USANZ, *Written submission No. 59*, 25 September 2019: 3.

560 Wailling, J., Marshall, C., and Wilkinson, J., The Diana Unwin Chair in Restorative Justice, Victoria University of Wellington. *Hearing and responding to the stories of survivors of surgical mesh: Ngā kōrero a ngā mōrehu – he urupare* - A report for the Ministry of Health, New Zealand, 2019: 5. Accessed 6 August 2020 https://www.health.govt.nz/publication/hearing-and-responding-stories-survivors-surgical-mesh

561 Wailling, J., Marshall, C., and Wilkinson, J., *Hearing and responding to the stories of survivors of surgical mesh: Ngā kōrero a ngā mōrehu – he urupare*, 2019: 44.

The NZ review also sought the views of medical practitioners, surgeons and other clinicians about what credentialing should involve:

> Clinicians stressed that credentialling should involve more than an assessment of a surgeon's technical ability to perform surgery. It should also encompass holistic models of care, patient experience and collegial behaviours, and be incorporated into professional standards that were regularly assessed […][562]

The NZ review concluded there was a need to establish a 'credentialing committee', which would recommend national standards for individual practitioners and services for urogynaecology procedures. Minimum standards would be required for surgeons performing mesh insertion, renewal, repair and removal surgery and there would also be requirements for native tissue repairs. Further, the credentialing framework would include requirements for informed consent.[563]

> Clinicians working with mesh injured patients expressed distress at the lack of acknowledgement and ownership of the problem by some of their colleagues. They believed responsibility rested with the original surgeon. Two respondents suggested that accepting responsibility for treatment injury should be mandated in professional standards. Others thought that would be unnecessary, as it was simply a matter of "*doing the right thing"*.[564]

Recommendations

The Minister for Health and Wellbeing:

10. Review the 'comprehensive education strategy' proposed by CALHN and the SA Pelvic Mesh Clinic for staff at the Royal Adelaide Hospital (RAH) to ensure that once an experienced credentialed Urogynaecologist surgeon is recruited to the SA Pelvic Mesh Clinic, the RAH is appropriately staffed to support South Australian women undergoing full and partial mesh removals, including post-operative staff. Further, that the existence of the SA Pelvic Mesh Clinic be widely communicated throughout the RAH and other SA Health facilities.

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[562] Wailling, J., Marshall, C., and Wilkinson, J., *Hearing and responding to the stories of survivors of surgical mesh: Ngā kōrero a ngā mōrehu – he urupare*, 2019: 36.

[563] Wailling, J., Marshall, C., and Wilkinson, J., *Hearing and responding to the stories of survivors of surgical mesh: Ngā kōrero a ngā mōrehu – he urupare*, 2019: 44; 45.

[564] Wailling, J., Marshall, C., and Wilkinson, J., *Hearing and responding to the stories of survivors of surgical mesh: Ngā kōrero a ngā mōrehu – he urupare*, 2019: 37.

(f) identifying the extent to which there exists a need for physical and psychological support, including family members, following adverse outcomes

> The incontinence is so much worse now than it ever was and I have regular accidents which is humiliating and isolating. To have an outing means I need to know where restrooms are and bring along change of clothes in the event of an accident. Travel is added stress and pain so I have lost interest which is unfair on my husband and family. […] It has been a very difficult time for my husband and myself as a couple and it has affected us mentally, physically, emotionally and financially. The ongoing problems continue to cause us stress and has changed our relationship. There is no intimacy due to the pain and that is very hard to accept when before mesh we had an active and loving relationship. We are not as settled as we once were and there is a lot of tension and frustration that we have to deal with now. There has been family conflict at times because of the changes in me and the difference in how I need to approach day to day activities which are not always understood or appreciated. The loss of what I was capable of, to what I can manage now, has had a huge impact in every area of our lives. All this needs to be taken into consideration when looking at the effects on a person and all around them.[565]

Mesh Adverse Outcomes and the Psychological Impact

In discussion of terms of reference (b), the Committee referred to a number of submissions by women and men who had provided evidence indicating that the complications from their mesh implants had also caused mental ill-health. Several of these submissions referred to suicide or assisted dying as the only viable options left available as symptoms worsened.[566]

The vast majority of written and oral submissions from people who have had mesh implanted and have had adverse effects, have also, along with the devastating physical symptoms, described a myriad of other causally related problems. These include the ripple effects of complications that have had detrimental consequences affecting their families, relationships, self-esteem and identity, children, finances and income, quality of life, productivity, social lives, friendships, opportunities, hobbies, fitness, health and living arrangements. Some of these are outlined in the accounts below.

The Senate Inquiry and the UK Inquiry, *First Do No Harm,* both examined the way in which women were made to feel belittled and sometimes even paranoid because health professionals refused to believe their symptoms would or could be caused by their mesh implants.[567, 568]

The accounts of mesh affected people and their families during this inquiry also demonstrate that the medical professionals actively dissuaded their patients in believing their health complications were the result of the mesh implants they had. This has already been discussed in previous chapters.

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[565] Name confidential, *Written submission No. 19*, 12 September 2019: 4 – 5.

[566] Names confidential, *Written submission No. 43*, 13 September 2019: 1; *Written submission No. 44*, 13 September 2019: 2; *Written submission No 50*, 13 September 2019: 1; *Written submission No. 52*, 15 September 2019: 2; *Written submission No. 53*, 16 September 2019: 1; *Written submission No. 55*, 20 September 2019: 1; *Written submission No. 61*, 8 October 2019: 1; *Written submission No. 64*, 8 October 2019: 1; *Written submission No. 67*, 1 May 2020: 1.

[567] Senate Community Affairs References Committee, *Inquiry Report*, March 2018: 77 - 79.

[568] Independent Medicines and Medical Devices Safety Review, *First Do No Harm*, United Kingdom, July 2020: 17 – 18; 139. Accessed 4 August 2020 https://www.immdsreview.org.uk/Report.html

However, the Committee has noted especially the impact and toll that 'not being believed' has had on the psychological welfare of the women who have experienced injuries as a result of pelvic mesh, and to a lesser extent for people with injuries from hernia mesh. The UK Inquiry noted:

> The consequences of not being believed and not being listened to are far reaching. It immediately sets the tone for a patient-clinician consultation that is far from equal and precludes any form of shared decision-making around future care and treatment. The patient is vulnerable and feels unable to challenge and question. The patient is ignored and feels belittled.[569]

It is not surprising that constantly having convince doctors and specialists a set of symptoms do exist, might result in damage to a person's sense of self, reality and importance. The Committee was deeply concerned by the accounts of the survivors of mesh injuries, who have continued to try and over-come their injuries and trauma, on top of mental ill-health some of which may be attributed to their struggle to be believed and have legitimacy given to their claims.

Accounts from Mesh Injured People, their Families and Friends

Written submission 3 stated that following several complicated and damaging procedures for hernias, which were caused as a result of the surgical removal of cancer and pollops in his bowel, [Name confidential] is still unable to do everyday things such as sitting down to watch tv for any length of time:

> I got 3 hernias so they decided to wrap them up in mesh. Things went from bad to worse. The mesh broke and I had such pain I was in bed all the time as I could not sit up and walking was really bad. I was taking (Sic) Oxynorm and Lyrica every 4 hours. So Dr […] sent me to see Dr […] in […] . [Dr] said another op 3-6HRs Because of all the scar tissue it had to be picked bit by bit. The hernia had spread up into and past my rib cage and [Dr] found it growing into the mesh, bowel and stoma […] I am still not able to sit and watch t.v. anymore than 1 hour same if we go out too. Standing up I have to stand still and let everything settle back into place. Its been bloody hell right since the beginning and its never going to get better.[570]

Written submission 43 describes how her life was full of activities with her family before her mesh implant. After mesh, she describes the way it reduced her life to a limited existence where simply walking is a painful thing to do:

> My life now is miserable living with this poison in my body. I used to run 25km a week and be fit healthy, but now I cant go for a simple walk as every step I take is painful. I take regular pain relief medication to take the edge off the pain when its at its worst. Family days out are non existent unless it does not involve anything physical. I cant say anymore too upsetting.....writing this is sending me into the deep dark hole I fight every day to keep out of.....[571]

The mental and emotional strain of living with mesh complications is significant and includes conditions that also come with physical symptoms. It was very troubling to the Committee to read the accounts of mesh affected women and men who felt that they were in some way to blame for what had happened to them.

The written submissions indicated that mesh injured people can often suffer from feelings of guilt along with a sense of shame. Feelings of hopelessness were very common in the accounts, as were accounts of depression, anxiety and Post-Traumatic Stress Disorder (PTSD).

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[569] Independent Medicines and Medical Devices Safety Review, *First Do No Harm*, United Kingdom, July 2020: 18. Accessed 4 August 2020 https://www.immdsreview.org.uk/Report.html

[570] Name confidential, *Written submission No. 3*, 4 September 2019: 1 – 2.

[571] Name confidential, *Written submission No. 43*, 13 September 2019: 1.

Impacts of mesh on people's mental health, described in the submissions, include:

- depression
- Suicidal ideation
- Feelings of hopelessness
- Stress and anxiety
- fatigue
- brain fog
- fibromyalgia
- PTSD
- opioid dependency
- feelings of humiliation
- feelings of uselessness
- feelings of guilt and shame
- feelings of the loss of sexuality
- feelings of the loss of gender identity i.e. femininity or masculinity

Written submission 44 describes a "strong disappointment" with herself for not doing more "thorough" research into the implications of hernia mesh before she had a mesh implant to repair an abdominal hernia. She relays that the "consistent pain/discomfort is a constant reminder of the futility of [her] situation', causing her distress at the thought of having to manage the pain and discomfort caused by hernia mesh for the rest of her life.[572] She is 47 years old and has entertained euthanasia as an option to end her pain:

> My level of distress is such that I am unable to read detailed reports regarding mesh complications without feeling physically sick. I refer them to my husband first for him to gauge whether I will be able to stomach reading the material myself. Furthermore, I have communicated to some family members and friends that I would consider euthanasia if my pain/discomfort levels ever became unbearable.[573]

Written submission 50 describes how "Mesh has wrecked my life":

> Today I am in so much pain and have been ready to end it all.
> if it wasn't for my 10 year old daughter.
> I am suicidal due to the way a Tvto has wrecked my life.
> I am 50 years old and feel like I am 90.
> Some days I don't even think I can go on.[574]

Kim told the Committee in her experience as an advocate for women injured by pelvic mesh, the women's lives the lives of their families are irrevocably changed for the worse:

> I help administer several online support groups of approximately 1300 women and this number grows daily. Some days this page brings me to tears, women unable to work, enduring so much pain they are unable to leave their homes. I see women battle to come to terms with the physical, mental and emotional harm caused to them by an operation that they were assured had low risks , and was and effective treatment option "ideal for busy Mums" Women unable to intimate with their partners/husbands due to pain, many of whom then see their partners/husbands walk away unable to physically or emotionally support their wives /partners.[575]

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[572] Name confidential, *Written submission No. 44*, 13 September 2019: 2.

[573] Name confidential, *Written submission No. 44*, 13 September 2019: 2.

[574] Name confidential, *Written submission No. 50*, 13 September 2019: 1.

[575] Kim, Administrator, South Australian Pelvic Mesh Support Group, *Written submission No. 29*, 13 September 2019: 1.

Many submissions to this inquiry came from mesh injured women and men who referred to the detrimental impacts of mesh on relationships, family and children. A number of submissions were also received from family members of mesh victims. The impacts on families include:

- family members having to take on full-time or part-time caring roles
- children witnessing their parent in pain
- family members feeling hopeless at not being able to help their suffering loved one
- children suffering the loss of a once active and engage parent
- children experiencing and witnessing marriage or intimate partner breakdowns
- children witnessing their parent on drugs of dependence
- children witnessing their parent suffer humiliating physical conditions i.e soiling oneself
- intimate partners seeking other intimate partners, having "affairs"

The issues faced by single parents are raised in several submissions where everyday activities are made harder because of the pain, discomfort and immobility caused by mesh injuries.

Written submission 60 commented on the way pelvic mesh has diminished her capacity to work and care for her three children since she had the implant in 2006:

> As a single mother of 3 children with autism, the symptoms I experience is making it difficult to reestablish my career which I have been forced to do to be able to keep a roof over my children's heads and to pay their school fees. I'm am always exhausted and am grateful to make it to the end of the work day. As I am sick and/or exhausted most of the time, I miss out on valuable and precious time with my children. I often skip social events as I don't feel up to going. And being a single parent I am always behind on everything as I don't have the energy to do what I need to do.[576]

Written submission 64 described how his relationship with his wife collapsed following hernia mesh implantation. At 43 years of age, he now suffers from anxiety and depression, whilst continuing to care for his daughter:

> Living like this has caused undue extra stress on my health in General, Impacted my work life, Relationship with my wife failed and I suffer with Anxiety & Depression. I am only 43 Year Old and a single dad of a daughter 15 yrs old.[577]

Written submission 58 describes the guilt he experienced when his wife experienced adverse events from the mesh she had implanted for SUI. He describes, as a result of her injuries, he had to work more, as she could no longer; this meant leaving his son to do caring duties:

> There were times I'd return home from work to find her curled up in pain on the floor unable to move. She became so helpless that even lifting the kettle exasperated pain. She stopped socialising and became bedbound and isolated which caused depression, and when in extreme pain she'd contemplate suicide. She became so incapacitated she couldn't be left alone but since she couldn't work my workload doubled. I felt so guilty witnessing my sons cry in despair at their mother's suffering. My youngest sons grades flumped when he had to take time off University to care for her, a horrifying and embarrassing ordeal to shower and dress his mother.[578]

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[576] Name confidential, *Written submission No. 60*, 27 September 2019: 1.

[577] Name confidential, *Written submission No. 64*, 8 October 2019: 1.

[578] Name confidential, *Written submission No. 58*, 24 September 2019: 1.

A family member wrote about the depression, PTSD and loss of quality of life her mother suffered, following pelvic mesh implantation:

> PTSD, depression and anxiety caused prolonged sleep disorder leaving [Mum] mentally and emotionally traumatised. It was very distressing to witness her struggle and try smile through the pain for the sake of family when she felt she was dying. Shameful to witness a strong, confident, active, fun loving woman reduced to severe helplessness and left unable to walk, humiliated, degraded and permanently urine soaked. It was appalling and traumatic for all concerned.[579]

Families told of how the financial burden caused the loss of their houses, quality of life and opportunities for themselves and their mesh injured loved ones. A common occurrence in the evidence given is the accumulation of debt and loss of income for mesh affected people and their immediate families. Impacts of financial burden include:

- loss of income from employment or busines ownership
- loss of superannuation
- loss of equity in property or loss of property
- increased debt
- loss of future financial security and prosperity

Written submission 51 tells of the decline in health and fitness; followed by loss of employment and social activities, which has damaged relationships within the family as a result of his wife's mesh injuries:

> My wife was previously a fit, healthy and engaged woman. She now has not worked since May 2019. […] As a partner, I have watched my wife invest much time and money to pursue a full-time career she trained for but can no longer do as a result of mesh injury. She is now unable to make commitments due to chronic, ongoing pain, fatigue, sleep deprivation and anxiety. […] This has had a flow on impact to her work, social engagements, and attending of appointments, such as medical, our kids' school and others. This has led to social isolation. The loss of income we've experienced has now involved myself working longer hours and harder, and this has taken a huge toll on me physically and mentally. Our intimacy has been adversely impacted. […] The domino effect of Mesh injuries reaches much further than the mesh injured themselves. The trauma is compounded in the impacts on partners, children, family and friends. Where do we go for help?[580]

Written submission 33 describes that like other mesh injured people, she borrowed money to have her TVT-O mesh removed over-seas, and to undergo specialist treatment which she could not have done in Australia. She is no longer able to work because of the damage done by the mesh:

> I'm still on opioids and have nerve blocks with my pain specialist every three months. That's after borrowing heavily to fly to the US to have a full removal in 2017. I made this decision based on reported removal results in Australia by other women. Results were terrifying and invariably only partials were being undertaken as surgeons here do not have removal expertise. I also flew to France for excruciating nerve decompression surgery. All this could have been avoided and I could still be employed if informed consent, meaning full disclosure of the procedure, was given.[581]

Written submission 58 recalls having to access savings which were being kept for their children's education and their own retirement to pay for his wife's mesh removal:

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[579] Name confidential, *Written submission No. 61*, 8 October 2019: 1.

[580] Name confidential, *Written submission No. 51*, 13 September 2019: 1 - 2.

[581] Name confidential, *Written submission No. 33*, 13 September 2020: 1.

> Thankfully my wife has […] had her mesh fully removed costing in access (Sic) of $30.000, funds saved for the children's future education and our retirement. […] Today my wife is endowed with grey hair and looks like she has aged 10 years in 3. She remains in pain and most days bedbound as any activity causes more pain. She is also left fully incontinent and must wear bulky adult nappies destroying her dignity, confidence and femininity. […] My wife's life, my life and my entire families' lives remain in tatters; destroyed because of a surgery she was told would greatly improve her quality of life. But mesh ruined our lives.[582]

Many submissions to this inquiry detailed the social impacts on mesh injured people and their families. Some of these impacts include:

- giving up work, paid and volunteer
- reducing amount of time spent outside of the house
- not going out for food and entertainment
- giving up recreational activities and hobbies
- self-isolating and self-neglect
- not wanting to be seen by family and friends.

Written submission 36 details the story of her friend "May" who nearly died from a septic abscess caused by her pelvic mesh and her resistance to antibiotics from many infections. "May" had a 30cm piece of mesh implanted, for SUI, and for which she had not given consent. She only found out about the mesh when she obtained her medical records through Freedom of Information:

> "May" cried for days when she found out she had been implanted with mesh […] This mesh implant ruined not only her life but the lives of her husband & children who suffered greatly as a result. When I think of her injuries and the years of suffering she endured I become teary and cannot process how this is allowed happen today […] It's sad but all I can do is support May, help her through her pain and warn others against MESH.[583]

Chelsea describes the trauma of watching her mother being dragged down a "horrific path" and the impact felt by the family because of the mesh injuries her mother sustained:

> Since the implantation of medical mesh, it is an understatement to say that my mother has never been the same person. Her positivity has declined rapidly with each ongoing health issue she faces day in and day out, not to mention the increasing amount of new problems that surface on a regular basis. Most recently, my mother has been trialled on so many different types of pain medication to keep her chronic pain level somewhat at bay, but her memory, energy, mental state and physical abilities are declining rapidly each and every day, which is unfair on her and also us as a family because it makes each of us more helpless in the sense that there is no definite solution to this problem.[584]

Chelsea's stepsister, Ebony also comments on witnessing her stepmother decline and feeling powerless to help:

> Some days I see her and I just wish that I could take it away from her. She is not the person that she used to be and, unfortunately, she can't do the things she wants and once used to do with no troubles at all. I can see the pain in her when she walks, sits or even moves, and it is not fair for anyone.[585]

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[582] Name confidential, *Written submission No. 58*, 24 September 2019: 1.

[583] Name confidential, *Written submission No. 36*, 13 September 2019: 1 – 2.

[584] Chelsea, Oral evidence, *Hansard*, 20 July 2020: 131.

[585] Ebony, Oral evidence, *Hansard*, 20 July 2020: 129.

> The physical symptoms that go with mesh injuries are numerous and overwhelming. Every written submission and every oral presentation from mesh affected people and their families contained accounts of severe, often chronic pain associated with mesh. This included some accounts of suffers who had no visible or obvious injuries, but experienced terrible pain. Most commonly accounts from women with pelvic mesh told of urinary tract infections, leg and groin pain, nerve pain, Dyspareunia, pain in the uterus, pelvic pain, and pain caused by mesh erosion into the vagina. Several submissions made by those suffering from hernia mesh told of pain in the abdomen and groin.

Some of the physical injuries and symptoms of mesh were cited in the evidence as:

- sharp abdominal pain
- pain with sitting down
- nerve compression, spasm or damage
- mesh erosion
- groin pain
- chronic inflammation
- dyspareunia
- incontinence
- pelvic pain
- vaginal pain
- urinary tract infection
- infection with odour
- sepsis
- limited mobility
- immune suppression
- foreign body reaction
- bladder perforation

The Committee understands women who are accepted as patients of the SA Health Pelvic Mesh Clinic have access to specialist consultants to deal with physical and psychological symptoms of mesh injury, but the threshold for admittance to the clinic is very high and waiting times are very long. Mesh injury has been seen to cause a number of ongoing conditions, and the Committee is concerned for the patients who are not able to be seen by the clinic, as well as for those who are accepted but are still waiting for services.

While the SA Mesh Clinic attempts to assist with appointments close together, women from regional South Australia often have to make a number of trips (sometimes in significant pain) for appointments with health professionals.

Queensland Pelvic Mesh Service – Person-Centred Care and 'Hub and Spoke' Pelvic Mesh Service Model

The Queensland Pelvic Mesh Service website (QPMS) acknowledges of the suffering that women with pelvic mesh complications have experienced and continue to endure:

> Queensland Health acknowledges the pain and distress caused to women who have experienced transvaginal mesh procedure complications. Our service has been designed collaboratively with consumers and clinicians to provide holistic care for all women who attend the Service.[586]

[586] Queensland Government, Queensland Pelvic Mesh Service, 2020. Accessed https://www.qld.gov.au/health/services/specialists/pelvic-mesh-service

The Committee heard evidence from Associate Professor Dr Malcolm Frazer, Urogynaecologist and Clinical Lead, and Ms Nicolle Germano, Consumer Representative, from the QPMS. The QPMS in collaboration with consumer representatives, principally Ms Germano and Ms Michelle Kennedy, produced a guideline for implementing, monitoring and improving patient centred services at the QPMS.[587]

A Person-Centred Care Approach in the Treatment of Mesh Injured Women, created by the QPMS Mesh Advisory Group of which Ms Germano is Lead, is a guideline for integrating a set of service standards in accordance with a quality assurance framework for the QPMS. The framework covers the areas of clinical governance, quality improvement systems, partnering with patients and health literacy. [588]

Queensland Health initially made provision for an annual budget of $3.14 million for the QPMS for a period of two years, which according to Assoc. Prof Dr Frazer, was enough when the clinic had approximately one hundred and twenty three patients, but as patient numbers increase, so does the need for more funding.[589]

In March 2020, Queensland Health mailed out some 20 000 letters to women who had undergone pelvic surgery since the year 2000. According to Assoc. Prof. Dr Frazer, the mailout was an "honest and a sincere attempted to contact women who may have had mesh complications and were suffering in silence."[590]

The Committee also heard that the service has done a lot of work to clarify the large numbers of women being identified as mesh affected in the mailout. Assoc. Prof. Frazer advised, also as a result of the mailout, the large numbers indicated the initial assumptions of the numbers in Queensland need to be "drastically revised upwards."[591]

Since commencing in 2019, the QPMS has received 965 referrals to October 2020. Approximately 25 per cent of these have been deemed not eligible. Thirteen patients have withdrawn their referrals and the QPMS has triaged 239 mesh affected patients since April 2019.[592] The QPMS categorises patients into three types following triage. Assoc. Prof. Dr Frazer advised:

> Category 1 there is vaginal bleeding or an offensive vaginal discharge which is related, or presumed to be related, to mesh exposure. We find this quite uncommon in the numbers we have.
>
> Category 2 is things like recurrent urinary tract infections or unexplained blood in the urine potentially related to the presence of mesh in the bladder. Category 3 is a situation where there is stable mesh-related pelvic or vaginal pain, including pain on intercourse. That would be a large number of the patients we would be referred.
>
> Category 1 and 2 patients are contacted within about a week by a clinical nurse to obtain information, including surgical details and a history of mesh insertion, including, if possible, the prosthetic device label if it is available—and many of these ladies do actually carry their own notes, which is very useful for us. If necessary, the clinic will obtain hospital or practice notes to guide us but, of course, this all takes time.[593]

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[587] Ms Nicolle Germano, *Hansard*, 16 November 2010: 182.

[588] Queensland Pelvic Mesh Service, Ms Nicolle Germano and Ms Michelle Kennedy, *A Person-Centred Care Approach in the Treatment of Mesh Injured Women,* 2018: 4. Received 25 November 2020.

[589] Associate Professor Dr Malcolm Frazer, *Hansard*, 16 November 2020: 180.

[590] Associate Professor Dr Malcolm Frazer, *Hansard*, 16 November 2020: 180.

[591] Associate Professor Dr Malcolm Frazer, *Hansard*, 16 November 2020: 180.

[592] Associate Professor Dr Malcolm Frazer, *Hansard*, 16 November 2020: 181.

[593] Associate Professor Dr Malcolm Frazer, *Hansard*, 16 November 2020: 181.

The Committee heard, the QPMS has 66 patients who have undergone mesh excision surgery after their initial appointment and for 46 of these patients, the excision of the mesh was "complete."[594] According to Assoc. Prof Dr Frazer, this represents 70 per cent of the total number of patients seen for mesh excision.[595] The QPMS has undertaken 80 planned partial excisions, three "fairly simple" sling divisions, and (at the time of oral evidence) there were 13 patients on the waiting list for an excision.[596]

The Person-Centred Care Approach in the Treatment of Mesh Injured Women, advises staff of the QPMS that Mesh injured women using the service "will expect that full, safe removal of their mesh, with a surgeon extensively experienced in full removals, will be an option available to them."[597] It also stats that partial removals should not be deferred to as a first option for resolution of a mesh affected person:

> No partial removals should be offered unless there are extenuating circumstances. These procedures must only be performed with full, informed consent from the consumer, as per Recommendation 6 of the Australian government's response to the Senate inquiry.

Person-centred care approach

The Committee was impressed with the 'Person-centred care approach' to the treatment of mesh injured women that the QPMS has adopted.[598] Ms Germano advised that the QPMS was developed in conjunction with Health Consumers Queensland and Queensland Health. Ms Germano was the consumer representative during the development of the QPMS and worked with other consumers to develop the person-centred approach. Ms Germano commented:

> Initially, as the only consumer I felt the pressure of speaking for many and asked for additional consumers to be added to the project. One consumer voice cannot be the voice of an entire community. Following this, Michelle Kennedy was brought on as the second consumer, and five other women were later asked to make up the QPMS mesh advisory group. Michelle and I authored a person-centred care approach in the treatment of mesh-injured women. This was shared with everyone on the project, and it formed the foundation of what we believed as consumers should be the clinic's ethos. It was also used as part of empathetic training for staff.[599]

Ms Germano also advised that the QPMS is able to respond to the needs of its patients because it is co-managed by health professionals and consumers, and adapts as situations change. Ms Germano commented that consumer input into the service-model is an "essential" part of the service:

> The QPMS was co-designed, but now we are entering a new phase of co-management. As the service grows and expands it's really important, especially as new staff come on board, not to lose sight of why this service was established. Consumer involvement is essential to keep the needs of its patients front and centre, to monitor community feedback and to push for the service to be a part of the solution, like ongoing research, providing repairs not just removals, and the reporting of all complications to the TGA. Our service is an ever-evolving service.[600]

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[594] Associate Professor Dr Malcolm Frazer, *Hansard*, 16 November 2020: 182.

[595] Associate Professor Dr Malcolm Frazer, *Hansard*, 16 November 2020: 182.

[596] Associate Professor Dr Malcolm Frazer, *Hansard*, 16 November 2020: 182.

[597] Queensland Pelvic Mesh Service, Ms Nicolle Germano and Ms Michelle Kennedy, *A Person-Centred Care Approach in the Treatment of Mesh Injured Women,* 2018: 4. Received 25 November 2020.

[598] Ms Nicolle Germano, *Hansard*, 16 November 2020: 182.

[599] Ms Nicolle Germano, *Hansard*, 16 November 2020: 182.

[600] Ms Nicolle Germano, *Hansard*, 16 November 2020: 183.

As with the SA Pelvic Mesh Clinic, the QPMS was established in response to the 2018 Senate Inquiry Recommendation 13, and provides a multidisciplinary service to women affected by pelvic mesh. The QPMS provides services in urology, gynaecology, psychology, physiotherapy, pharmacy services, access to the state-wide chronic pain service and has an administrative team.[601]

One of the services provided to patients by the QPMS, which is not offered in South Australia, is access to a social worker. The QPMS advises that the QPMS social worker can advocate and negotiate on behalf of patients to assist in linking them to other services and resources. Other services include welfare information, disability support, psychoeducation and other community support organisations which can assist in providing patients with help around employment and income.[602]

As referred to above, Ms Germano referred to the space in which mesh research is "evolving" and that the QPMS has a dedicated research section to inform the service.[603] The *Person-Centred Care Approach in the Treatment of Mesh Injured Women* action item for partnering with patients in their own care provides that, the health service organisation uses a charter of rights that is consistent with the *Australian Charter of Healthcare Rights* and has processes for the QPMS to identify the capacity of a patient to make decisions about their own care.[604] The QPMS guideline also states:

> The governance body, and the operational and clinical teams, must recognise that trans vaginal mesh complications and treatment, is an evolving field of research. Treatment options should not be ruled out because clinicians aren't yet aware of supporting evidence. Above all else, clinicians must operate from a consumer-centred approach to the treatment and care of mesh injured women; including trusting and valuing a consumers' desired treatment option.[605]

Another service provided by the QPMS, which has not been fully explored by the SA Pelvic Mesh Clinic is the development of a 'Peer workforce of consumer advocates.'[606] The QPMS *Person-Centred Care Approach in the Treatment of Mesh Injured Women* describes the functions of the Peer workforce as providing support and advocacy for patients throughout the course of the patient's treatment and recovery journey. This includes assisting patients with appointments and providing the QPMS with feedback on how patients are doing.

The *Person-Centred Care Approach in the Treatment of Mesh Injured Women* advises that continuity of support is "[…] crucial to appropriately and effectively supporting mesh injured women using the service."[607]

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601 Queensland Pelvic Mesh Service, *About the Queensland pelvic mesh Service* Accessed 22 February 2021 https://www.qld.gov.au/health/services/specialists/pelvic-mesh-service/services-and-support/about-queensland-pelvic-mesh-service

602 Queensland Pelvic Mesh Service, *Our Team*. Accessed 22 February 2021 https://www.qld.gov.au/health/services/specialists/pelvic-mesh-service/services-and-support/our-team

603 Ms Nicolle Germano, *Hansard*, 16 November 2020: 183.

604 Queensland Pelvic Mesh Service, Ms Nicolle Germano and Ms Michelle Kennedy, *A Person-Centred Care Approach in the Treatment of Mesh Injured Women,* 2018: 7. Received 25 November 2020.

605 Queensland Pelvic Mesh Service, Ms Nicolle Germano and Ms Michelle Kennedy, *A Person-Centred Care Approach in the Treatment of Mesh Injured Women,* 2018: 7. Received 25 November 2020.

606 Queensland Pelvic Mesh Service, Ms Nicolle Germano and Ms Michelle Kennedy, *A Person-Centred Care Approach in the Treatment of Mesh Injured Women,* 2018: 10. Received 25 November 2020.

607 Queensland Pelvic Mesh Service, Ms Nicolle Germano and Ms Michelle Kennedy, *A Person-Centred Care Approach in the Treatment of Mesh Injured Women,* 2018: 10. Received 25 November 2020.

> First of all, acknowledging that they have a problem is really important. These women have traipsed around from doctor to doctor for a decade or more and they have been told that it's their imagination, or there's nothing you can do, or it can't be undone, or whatever they have been told—and I have been guilty of having these conversations, too, so don't think for a minute that I'm excusing myself. I think acknowledgement that they have a problem is immensely important psychologically. I'm not saying it will cure their pain, but they will feel a hell of a lot better.[608]

In an article published by Assoc. Prof. Dr Malcolm Frazer and Dr J Oliver Daly in 2014, both doctors advised that the unrestrained use of transvaginal mesh in Australia (and elsewhere around the World) was undertaken without regard for (the lack of) adequate clinical trials and scientific evidence on mesh's efficacy in either POP or SUI:

> If we look back critically and honestly at the introduction of TVM, we can perhaps admit to ourselves that we were too easily persuaded about mesh benefit when the evidence was clearly incomplete and sadly remains so to this day. When the next innovation emerges we can at least ensure we and our patients are better prepared to meet and benefit from it.[609]

In his oral evidence to the Committee, Assoc. Prof. Dr Frazer commented that it is important that whatever service is set up for providing assistance to mesh affected women, there must be acknowledgement from the service that mistakes were made:

> When you ask, 'Do we need to acknowledge this?' the answer is yes. Is it uncomfortable for clinicians, particularly senior, old, white guys like me? Absolutely. […] If you had asked me […] five years ago I would have said […], 'Oh, it's a problem, but it's not as big a problem as you would imagine,' because none of us want to admit that. It's uncomfortable admitting it. I feel happier that I've admitted it.[610]

Ms Germano added:

> […] acknowledging the problem is huge. It goes a long way to breaking down the barriers and re-establishing trust, but it's continuing that dialogue the whole way through the service that is, I think, almost even more important. It's okay to say, 'I'm sorry this happened. I'm sorry there was a systemic failure and you're a part of that failure,' but it has to carry through the service. It has to carry through with every person you meet through the service, from the clinicians to the physios to the admin. It's something that I think patients continue to need to hear, not just at the beginning.[611]

As already discussed, the QPMS has a person-centred model of care in place which allows the patient to have a voice through not only the model of service-delivery, but also through consumer-advocate representation. The consumer-advocates are mesh-affected women themselves, which provides a direct linkage to the experiences mesh affected women have been through.

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608 Associate Professor Dr Malcolm Frazer, *Hansard*, 16 November 2020: 186.

609 Dr J Oliver Daly and Associate Professor Dr Malcolm Frazer. "Decline and Fall: Lessons learned from the troubled history of transvaginal mesh kits", *O&G Magazine*, Autumn 2014: 3. https://www.ogmagazine.org.au/16/1/decline-and-fall/

610 Associate Professor Dr Malcolm Frazer, *Hansard*, 16 November 2020: 186.

611 Ms Nicolle Germano, *Hansard*, 16 November 2020: 186.

The ACSQHC advises in the publication ACSQHC, *Patient-Centred Care: Improving Quality and Safety Through Partnerships with Patients and Consumers*, that there is an "increasing body of research on the association between patient experience and perception of care", which highlights improved health and service satisfaction outcomes when the concerns of patients are provided for. These include matters such transparency, respect, communication and collaboration.[612]

Hub and Spoke Mesh Clinic Services

Assoc. Prof. Dr Frazer advised the Committee that the QPMS was examining the potential for implementing a 'hub and spoke' model of service across Queensland to ensure that mesh affected women in country and rural areas, as well as those in urban and city centres are able to access adequate services, without prolonged waiting times.[613] Assoc. Prof. Dr Frazer commented:

> […] the main impetus for developing this was the large number of referrals that came on the back of the mailout. It hasn't been set up yet. The whole idea is to have a secondary service closer to Brisbane which would deal with a number of patients and then other services on the Sunshine Coast, just north of Brisbane, and another one in North Queensland where a certain number of surgical interventions and a certain number of assessments can be made without necessarily the full gamut of complex surgical removal, fistula repairs and all the other things we've been doing on the Gold Coast. The idea is to try and give a way to get into the service for some women and at least begin their journey without having to wait for the clinicians down on the Gold Coast to see them.

The 'hub and spoke' model of service-delivery is characterised by a primary service centre, as identified above by Assoc. Prof. Dr Frazer, with other smaller 'satellite' services in places of greatest need. One definition provides:

> The hub-and-spoke model, as applied in healthcare settings, is a method of organization involving the establishment of a main campus or hub, which receives the heaviest resource investments and supplies the most intensive medical services, complemented by satellite campuses or spokes, which offer more limited service arrays at sites distributed across the served market.[614]

Committee's View

The Committee considers it will be beneficial to continue the campaign to educate members of the medical system, the GPs, specialists, surgeons and allied health practitioners of the devastating consequences a person may experience as a result of mesh injuries.

The Committee would also like to see the SA Pelvic Mesh Clinic adopt a more 'patient-centred' approach to delivery of its services and considers the Clinic could achieve this through:

- recruiting advocates with lived experience to partner with patients and the clinic
- adopting a 'hub and spoke' model to deliver services to patients in country areas of the state.

The SA Pelvic Mesh Clinic could also offer more services to assist mesh affected women and their families to process and overcome the psychological, social and financial impacts of mesh. This could be achieved through the clinic recruiting a Social Worker and providing access to more sessions with psychologists.

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[612] ACSQHC, *Patient-Centred Care: Improving Quality and Safety Through Partnerships with Patients and Consumers*, Sydney, 2011: 9 – 10.

[613] Associate Professor Dr Malcolm Frazer, *Hansard*, 16 November 2020: 186.

[614] James K. Elrod and John L. Fortenberry Jr. "The hub-and-spoke organization design revisited: a lifeline for rural hospitals", *BMC Health Services Research*, 17 (Suppl 4), 2017: 795.

Recommendations

The Minister for Health and Wellbeing:

11. Investigate the potential for developing a 'hub and spoke' model of services, similar to the one being developed by the Queensland Pelvic Mesh Service, with the primary Centre of Excellence located in the SA Pelvic Mesh Clinic in Adelaide. This would benefit SA regional and rural mesh injured patients who have no choice but to travel long distances on numerous occasions for treatment in Adelaide.

12. Urgently raise for discussion at the earliest convenience, through the National Cabinet Reform Committee (Health), a proposal to urgently develop a 'hub and spoke' model for the full surgical removal of pelvic mesh for women across the States and Territories, whose mesh removals are considered to be the most complicated, and will require the most experienced urogynaecological surgeons in Australia.

(g) any other related matter

SA Health Pelvic Mesh Clinic

The SA Health Pelvic Mesh Clinic is established as a service for women with 'complex' or 'complicated' adverse effects of transvaginal and other types of pelvic mesh, as recommended by the 2018 Senate Inquiry into the *Number of women in Australia who have had transvaginal mesh implants and related matters* (the Senate Inquiry).[615] The SA Pelvic Mesh Clinic currently operates on a budget of $810 000, of which $410 000 is for clinic activity and $400 000 is held centrally to support women at the clinic to access mesh removal, as well as for "additional growth in the clinic."[616]

The 2019-20 Pelvic Mesh Clinic budget was allocated to the following staffing and business areas:[617]

Corporate Costs		Ongoing
Nurse Consultant	RN 3.1	1.0 FTE
Pelvic Floor Physio	AHP303	0.13 FTE
Pain Management Consultant	MD029G	0.05 FTE
Pain Psychologist	AHP303	0.13 FTE
Gynaecology Consultant	MD029G	0.25 FTE
Urology Consultant	MD029G	0.05 FTE
Colorectal Consultant	MD029G	0.05 FTE

Since its establishment in December 2018, the SA Pelvic Mesh Clinic has not had an appropriately trained, experienced and credentialed urogynaecologist who can perform full mesh removals for patients of the clinic seeking this service.

The Committee was informed of the dire lack of properly trained and credentialed urogynaecologist surgeons in Adelaide, or indeed South Australia, who can perform the surgery mesh affected patients require, and that the difficulty of recruitment has been an issue which has been ongoing for a number of years.[618]

The Committee was advised SA Health via Central Adelaide Local Health Network (CALHN) has undertaken "an extensive recruitment strategy in their attempts to secure an urogynaecologist surgeon to the SA Pelvic Mesh Clinic.[619] In February 2021, Dr Roy Watson, Head of Gynaecology with CALHN, advised CALHN was negotiating with a urogynaecologist who has been an associate professor of pelvic floor surgery in New York and has been spending time at the Royal Women's Hospital, Melbourne in order to become a subspecialist in Australia. Dr Watson advised,

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615 Ms Michele McKinnon, *Hansard*, 7 September 2020: 150.

616 Dr Roy Watson, *Responses to Questions on Notice*, *Hansard*, 1 February 2021, received 12 February 2021: 1.

617 SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 32.

618 Dr Ian Tucker, *Hansard*, 7 December 2020: 231 – 232.

619 SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 27.

The urogynaecologist should be able to commence on 1st July 2021 and will be able to perform full mesh removal on all but the most complicated cases. Dr Watson stated:

> We anticipate employing her at 0.6 FTE, and she is keen to maintain a working relationship with RWH during the rest of her time. I therefore envisage that we will be able to perform most mesh removals at RAH but utilise the MoU with RWH for the most complex cases, whilst also upskilling this urogynaecologist by her being involved in the cases at RWH.[620]

While the twenty-seven patients continue to wait for this vital and much needed service to be implemented at the SA Pelvic Mesh Clinic, SA Health advise that:

> The women awaiting assessment in consideration of requiring a full mesh removal procedure are supported with a range of strategies including:
>
> - Care plan to actively manage their symptoms
> - Referral for alternate surgery to relieve symptoms
> - Increase frequency of PMC appointments to increase assessment
> - Wait list data and activity reports are managed daily and reported monthly – report 3/12 to Pelvic Mesh Specialist Group.[621]

Accessibility

The SA Pelvic Mesh Clinic functions within a case management model with the Pelvic Mesh Clinic Triage nurse the critical point of contact for patients attending the clinic. SA Health advised that as referrals to the clinic are based on the complexity of a patient's case, not everyone is able to attend the clinic. Ms Bonnie Fisher from the SA Maternal Neonatal and Gynaecology Community of Practice, SA Health, offered the following clarification:

> […] the clinic is really set up for those women who have complex conditions. It's not for those who have an early onset of maybe minor conditions because the GP is well versed to be able to manage that, if not the gynaecologist who in fact undertook the surgery. The clinic is set up for more complex patients.[622]

Ms Fisher also advised that patients who may not have been aware their condition is mesh related, are likely to have "[…] a few years of dealing with those minor conditions that have turned more complex."[623]

The Pelvic Mesh Clinic Triage Nurse collates the clinical information of a referred patient and undertakes a case conference with the Pelvic Mesh Clinical Gynaecologist to ascertain the most suitable site / clinic to manage the referred patient's presenting symptoms.[624]

SA Health advised the following details in relation to the categorisation of a patient's symptoms for the purpose of accepting the patient into the clinic:

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620 Dr Roy Watson, *Responses to Questions on Notice*, *Hansard*, 1 February 2021, received 12 February 2021: 2.

621 SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 22.

622 Ms Bonnie Fisher, *Hansard*, 7 September 2020: 155.

623 Ms Bonnie Fisher, *Hansard*, 7 September 2020: 155.

624 SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 15.

> 'Major' complication(s) are assessed when the woman's symptoms or complications are at risk of causing / or have caused a significant deterioration in her health and quality of life (a Quality of Life Scale assessment is used to assist this determination).
>
> 'Less' complex complications are deemed as those having minimal impact on their quality of life (a Quality of Life Scale assessment is used to assist this determination) and are highly likely to have resolution of these symptoms with conservative management and requires limited access to the multidisciplinary team and can easily be managed by the GP or referring Medical Officer.
>
> Women who present with minor clinical complications / symptoms are referred to their GP or referring Medical Officer for local management that does not include the Pelvic Mesh Clinic.[625]

SA Health advise that an 'initial' appointment is the appointment a patient has once a referral has been received from the patient's General Practitioner (GP) and the patient has been 'triaged'.[626] Dr Watson at the SA Pelvic Mesh Clinic advised that the process is generally as follows:

1. the referral from the patient's GP is received at the SA Pelvic Mesh Clinic
2. there is a process of needing to gather information, which is often lengthy. This includes the patient's medical records and so forth
3. once all the information relating to the patient's condition has been collated, the referral is triaged and the patient gets the 'initial' appointment
4. from receipt of referral to the 'initial' appointment is 111 days
5. from triaging to 'initial' appointment is 67 days.[627]

The Pelvic Mesh Clinic Triage nurse consults the patient referred to the Pelvic Mesh Clinic and her referring medical officer during the process to secure the above information prior to the patient receiving their initial appointment.

Patients are accepted to be treated by the SA Pelvic Mesh Clinic based on assessment of the following criteria by the SA Pelvic Mesh Clinic Triage nurse and Clinical Gynaecologist:

- a documented history of a pelvic mesh implant
- had an active clinical management plan aimed at reducing the adverse health outcomes or treat the presenting symptoms
- consented and / or secured the relevant medical record(s) related to the implanted mesh
- commenced the clinical assessments to assist diagnosing and/ or the appropriate clinical management plan for her
- secured referrals to the multidisciplinary team to assist her manage her symptoms / complications.[628]

SA Health stated that patients who are referred to the clinic that do not meet the criteria as above will not be appointed to the Pelvic Mesh Clinic.[629]

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[625] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 11 - 12.

[626] Ms Alex Emerson, *Hansard*, 7 September 2020: 154.

[627] Dr Roy Watson, *Hansard,* 1 February 2021: 242.

[628] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 11.

[629] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 11.

Concerns for mesh affected patients who do not meet the criteria were raised in evidence, as GPs continue to be mis-informed by the symptomology of mesh injuries.[630] Kim advised:

> I still believe that there is not enough information out there. Many GPs still don't know what mesh is, they don't know where to get the information, and women are still educating their doctors. There is still a huge problem with credentialling and there's a number of doctors in South Australia that are performing removals and partial removals without the appropriate credentials.[631]

SA Health Pelvic Mesh Clinic waiting lists

SA Health advised the Committee in November 2020 that the SA Health Pelvic Mesh Clinic (SA Pelvic Mesh Clinic) has 133 women on their case lists as women who have been seen by the clinic between December 2018 and October 2020.[632]

One hundred and twelve patients have had an 'additional' appointment (an appointment on top of their initial appointment) 'booked' during this time. According to the data provided by SA Health there were 76 patients awaiting an initial appointment with the clinic in 2020, while there are a further five booked so far for 2021.[633]

The Committee is disappointed in noting that the SA Pelvic Mesh Clinic TVM Audit from 2018 ascertained that approximately 150 women would require the services of the clinic in the first year of operation, yet the clinic has not seen half that many in the two years it has been operational.[634, 635]

SA Health advised that as of 1 February 2021, the SA Pelvic Mesh Clinic has twenty-seven or twenty-eight women waiting for an assessment of full mesh removal.[636]

As there is not a credentialed urogynaecologist employed by the SA Pelvic Mesh Clinic, these women are waiting for the MOU with the Royal Women's Hospital (RWH) Melbourne to be enacted, in order to be assessed for a full removal of their mesh in Victoria.

Accordingly, the Committee understands that once the MOU is in place, the RWH Melbourne will have capacity to treat up to 5 women seeking a full removal per year.[637] The written submission from one member of the SA Pelvic Mesh Consumer Advisory Group sums up the disappointment many of the mesh affected patients feel:

> I have been a member of the Trans Vaginal Mesh Consumer Advisory Group as part of the SA Health Trans Vaginal Mesh Project and continue to have a role as a consumer on the RAH Pelvic Mesh clinic committee. I am disappointed with the outcome of this project. Too little is still being done. While efforts have been made to help woman in need in South Australia much still needs to be done. Extensive waiting times for appointments, lack of appropriate

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630 Kim, *Hansard*, 30 November 2020: 196.

631 Kim, *Hansard*, 30 November 2020: 196.

632 SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 10.

633 SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 10.

634 SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 10.

635 Ms Bonnie Fisher, *Hansard*, 7 September 2020: 151.

636 Dr Roy Watson, *Hansard,* 1 February 2021: 236.

637 Ms Bonnie Fisher, *Hansard*, 7 September 2020: 165.

> medical practitioners, access to psychological support and above all the lack of acceptance in the gynaecological community that MESH is a problem.[638]

The Committee was advised in November 2020, that three women are awaiting an excision of their pelvic mesh, six women are awaiting an assessment for a partial removal of their pelvic mesh and one woman is awaiting a partial removal procedure.[639]

The Committee understands that there are (at the time of writing), thirteen women on a waiting list to be triaged, who are awaiting the return of their medical records to the SA Pelvic Mesh Clinic.[640] SA Health also advised the current waiting time as at November 2020, for a partial removal or excision of mesh through the SA Pelvic Mesh Clinic was 3 months as per all 'Category 2 surgical cases'.[641]

Elective Surgery

The SA Health Elective Surgery Policy Framework and Associated Procedural Guidelines (SA Health Elective Surgery Policy) provides for the categorisation of surgical procedures and states that the policy goal is:

> To ensure optimal management of elective surgery admissions across the public hospital system in order to minimise waiting times, maximise patient satisfaction and promote health outcomes for individual patients and the community in general.[642]

The SA Pelvic Mesh Clinic is required to follow the SA Health Elective Surgery Policy.
The policy provides that treatment of patients from the elective surgery booking list is *based on prioritisation according to clinical need*, and acknowledges that this process may be complex and influenced by a range of factors. These factors are listed in the SA Health Elective Surgery Policy as the following:

> **4.2.2 Prioritisation within clinical urgency categories**
> Within each clinical urgency category, a number of factors should be considered in selecting patients from the booking list:
>
> - Waiting time
> - Priority for admission must be given to patients who have waited longer than the recommended time for their assigned urgency category Previous postponements
> - Patients whose surgery has previously been postponed for clinical or hospital-related reasons will be given priority and should be rescheduled as soon as practical, based on clinical need. Social and geographic circumstances
> - Social and geographic circumstances of a patient will be taken into consideration. For example, if a patient is a carer, the hospital should try to accommodate them and their personal circumstances although they might not be the longest waiting patient.

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638 Name confidential, *Written submission No. 47*, 13 September 2020: 1.

639 SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 17 – 18.

640 SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 11.

641 SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 18.

642 SA Health, *Elective Surgery Policy Framework and Associated Procedural Guidelines*, February 2018: 8. Accessed 22 February 2021 https://www.sahealth.sa.gov.au/wps/wcm/connect/07cd7280482dfb079467f47675638bd8/Elective+Surgery+Policy+Framework_Amended_+29032018.pdf?MOD=AJPERES&CACHEID=ROOTWORKSPACE-07cd7280482dfb079467f47675638bd8-niQ4u7Z

Other factors that may influence selection of patients from the elective surgery booking list include:

- type of surgery and post operative care required
- complexity of case and length of operating time patient co-morbidities
- medication requirements
- patient social and community support availability
- appropriateness of day surgery
- the need for other treatments while awaiting surgery
- teaching requirements for junior doctors.[643]

The SA Health Elective Surgery Policy also describes the categories for Clinical urgency categorisation, based on National clinical urgency categories, and which, is used to ensure access to surgery is "provided in an equitable manner with priority for those who have the greatest clinical need and then to those who have waited the longest"[644]:

4.1.1 Clinical urgency categorisation
The clinical urgency categories are:

Patients ready for care
Category 1 – Urgent: very early admission for a condition that has the potential to deteriorate quickly to the point that it may become an emergency or is life threatening (Admission within 30 days desirable)

Category 2 – Semi-Urgent: admission within 90 days for a condition causing some pain, dysfunction or disability which is not likely to deteriorate quickly or become an emergency (Admission within 90 days desirable)

Category 3 – Non-Urgent: admission at some time in the future for a condition causing minimal or no pain, dysfunction or disability, that is unlikely to deteriorate quickly and that does not have the potential to become an emergency (Admission within one year desirable).[645]

The following advice in the policy states that scheduling should be carried out ahead of a patient's operation, within the designated categories, with category 2 requiring a date of operation to be scheduled within 60 days of being placed on the bookings list:

4.2.3 Scheduling surgery
Category 1 – Urgent
It is desirable that an operation date be allocated for all urgent patients at the time of the initial outpatient appointment. If an operation date is not given at the initial outpatient appointment, then the patient must receive an operation date within 5 working days to ensure they are treated within 30 days of being placed on the booking list.

Category 2 and 3 – Semi-urgent and non-urgent
Category 2 patients must be assigned a date within 60 days of being placed on the booking list and Category 3 patients must be assigned a date by 10 months. A minimum of two weeks notice (a month is desirable) should be provided for Category 2 and 3 patients when planning their admission date. The exception is in the circumstance of a hospital postponement when rescheduling should be to the next available booking.[646]

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643 SA Health, Elective Surgery Policy Framework and Associated Procedural Guidelines, February 2018: 14 – 15.

644 SA Health, Elective Surgery Policy Framework and Associated Procedural Guidelines, February 2018: 13.

645 SA Health, Elective Surgery Policy Framework and Associated Procedural Guidelines, February 2018: 13.

646 SA Health, *Elective Surgery Policy Framework and Associated Procedural Guidelines*, February 2018: 15.

Patient and Consumer Engagement

The Committee received evidence from a number of witnesses and written submissions that the chief complaint regarding the SA Pelvic Mesh Clinic was that the Clinic could not offer patients a full mesh removal service because of the lack of an appropriately trained, experienced and credentialed urogynaecologist.[647, 648]

Other serious concerns were raised by some of the witnesses and written submissions, which included that waiting times are too long with so many mesh affected women in pain with debilitating symptoms; others, that patients were not treated with respect or dignity and felt that their voices were not being heard.[649] Some advised they have not had had a positive experience with the SA Pelvic Mesh Clinic, or that they feel misunderstood or hopeless at the treatment options available to them.[650]

> The SA Health has reluctantly started the RAH Pelvic Mesh Clinic. Unfortunately, the uptake from women has not been positive. Part of the problem is that women have been fobbed off for so long and are not trusting of the SA Health Minister, Public Health System and SA Gynaecologists in general as a majority have not been supportive and they simply do not trust the service being offered. The service was also initially communicated that you could get into the Clinic and see all the people you needed to see in one trip to Adelaide over 1-2 days – this is not the case and patients continue to have to make numerous trips for appointments which for country people especially is not practical, expensive, impacts work (for those left who can work) and travel for any mesh patient is an issue as sitting in 99% of cases for any length of time in extremely unbearable. [651]

One submitter told of how her "case" for full mesh removal was discussed by a "committee" yet she was not included in the discussions.[652]

Other witnesses claimed that they were disparaged by the SA Pelvic Mesh Clinic employing gynaecologists who had performed their mesh implantation and felt a sense of betrayal of their interests and health care needs.[653]

Kim advised the Committee in her oral evidence that as the consumer representative for the SA Pelvic Mesh Clinic Advisory Group, she was invited to participate in the forums around setting up the clinic in the initial stages of its development however, as time progressed she was increasingly left out of meetings:

> I sat on the initial committee that set up the mesh clinic. I was a consumer introduced by Health Consumers Alliance of South Australia, which is a governing body that now doesn't exist in South Australia. I sat on a committee with numerous other medical professionals but I really did feel—and I had brought it up a couple of times to health consumers—that they really weren't listening to someone with lived experience. That's how I felt. I felt that if I expressed my opinion on what my lived experience had been they just pretty much ignored it or pooh-poohed it. I don't think they felt that I was an equal. I kept saying to them, 'I am not only the voice of other women in South Australia, I'm the voice of a woman who has had lived experience of this.'[654]

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[647] Kim, *Hansard*, 30 November 2020: .

[648] Name confidential, *Written submission No. 31*, 13 September 2019: 2;

[649] Name confidential, *Written submission No. 31*, 13 September 2019: 2;

[650] Name confidential, *Written submission No. 15*, 11 September 2019: 3;

[651] Name confidential, *Written submission No. 31*, 13 September 2019: 2;

[652] Name confidential, *Written submission No. 10*, 10 September 2019: 4.

[653] Name confidential, *Written submission No. 61*, 8 October 2019: 1.

[654] Kim, *Hansard*, 30 November 2020: 197 – 198.

The Committee heard that many of the mesh injured women who gave evidence, need the multiplicity of issues they suffer to be recognised and given legitimacy by the medical profession.[655]

The ACSQHC advises in *Patient-Centred Care: Improving Quality and Safety Through Partnerships with Patients and Consumers*, that in a patient-centred care approach, the contribution of patients to their own health care treatment assists in benefiting the health system, providing safer outcomes and greater satisfaction for patients and health services employees.[656] This was also acknowledged in recent research undertaken by the Centre for Education & Workforce Development, NSW Health, where some barriers to patient-centred care were identified as attitudes that patients don't have the choice about where they get treated.[657] Further, the ACSQHC states:

> [while] [t]here are clear differences in the processes that empower individuals to contribute to improving the safety and quality of health care, and the processes that enable the public to hold the health system to account. […] without engaging patients in making decisions about their own care and in improving the safety and quality of the health system as a whole, consumer engagement can be seen as little more than tokenistic.[658]

Many of the witnesses who gave evidence to the Committee during this inquiry also told of the losses they had experienced in relation to their careers, employment opportunities, hours able to be worked, loss of income and loss of fulfillment employment provided in their lives.[659]

> There just seems to be brick walls standing in the way of many other avenues that we need help and support with now : for example disability pensions, healthcare packages, carers pension for the many partners who are trying to adjust also, access to our super regarding the mesh nightmare that many of us live with now everyday of our lives.[660]

A number of written submissions called for assistance for mesh affected women to be supported in making applications to Federal Government agencies such as Centrelink and the National Disability Insurance Scheme.[661]

Rebuilding Trust in the Health System

The Committee heard evidence that many of the sufferers of adverse effects from medical mesh, and the families of mesh affected people, believe there is a need for the Government of South Australia to apologise for the harm that has occurred from medical mesh. There were numerous written

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655 Names confidential, *Written submission No. 5*, 9 September 2019: 3; *Written submission No. 11*, 10 September 2019: 2; 4; *Written submission No. 17*, 11 September 2019: 2; *Written submission No. 22*, 12 September 2019: 1; *Written submission No. 53*, 16 September 2019: 1.

656 ACSQHC, *Patient-Centred Care: Improving Quality and Safety Through Partnerships with Patients and Consumers*, 2011: 9.

657 Bradley Lloyd, Mark Elkins and Lesley Innes, "Barriers and enablers of patient and family centred care in an Australian acute care hospital: Perspectives of health managers", *Patient Experience Journal*, Volume 5, Issue 1 – 2018: 59

658 ACSQHC, *Patient-Centred Care: Improving Quality and Safety Through Partnerships with Patients and Consumers*, 2011: 17.

659 Name confidential, *Written submission No. 10*, 10 September 2019: 4; Name confidential, *Written submission No. 15*, 11 September 2019: 2.

660 Name confidential, *Written submission No. 15*, 11 September 2019: 3.

661 Name confidential, *Written submission No. 56*, 20 September 2019: 2.

submissions from mesh affected women and men who stated that they no longer had any trust in the health system, or with their doctors and other health professionals.[662]

There has been widespread attention given to the catastrophic injuries and suffering caused by medical mesh, around the world. As already referred to in this report, inquiries have been undertaken by the governments of New Zealand, 2019, the United Kingdom, 2020, Scotland, 2017, the United States, 2019 and Canada, 2019. Of these, NZ, the UK and Scotland have recommended their respective governments make an apology to victims of mesh.

On 10 October 2018, the Federal Minister for Health, the Hon Greg Hunt, made a public apology to the victims of transvaginal mesh in Australia. The apology was recognised as a symbolic step forward in addressing the concerns of the women and families affected by transvaginal mesh, but it was equally noted, that there is still more to be done to truly compensate the women who are suffering and restore trust in the health system:

> The trust has been lost in surgeons and GPs as they failed to acknowledge adverse effects as they began to manifest themselves, and to inform patients before implanting once those complications had been known. […] Trust has been lost in our regulators as they haven't done as we, as a community, expect them to do. Trust has been lost in the federal government. […]
>
> We need to believe that we can again trust the health system. At the moment, it is a health industry, and while it's an industry the pressure to put profit first will always undermine patient safety and will adversely affect families like mine. This committee—and by extension, the government of South Australia in cooperation with the federal government—needs to find a way to re-establish lost trust. Otherwise, everything that is being done presently will be for nothing.[663]

The State of South Australia has an opportunity to exercise diligence in being a model of restorative justice, by issuing an apology and following up that apology with further meaningful actions to provide more much-needed services to all mesh affected people in the State.

ACSQHC Open Disclosure in Health Services

As part of a review on open disclosure in health services in Australia (2012), which was undertaken by the Australian Commission on Safety and Quality in Health Care (ACSQHC), the ACSQHC advised that in the event of an adverse health outcome from a service provider, an apology is part of an open disclosure system which engenders the trust of patients.

Although the guidance document *Saying sorry: A guide to apologising and expressing regret during open disclosure* is intended for health clinicians in health care organisations, it provides a template for recognition and action following adverse events:

> One of the principal aims of open disclosure is to restore patient trust in clinicians and the healthcare system. A key element of achieving that aim for patients is early acknowledgement of harm by providers and clinicians and an apology or expression of regret for the harm

[662] Name confidential, *Written submission No. 15*, 11 September 2019: 4; Name confidential, *Written submission No. 19*, 12 September 2019: 2; Name confidential, *Written submission No. 24*, 12 September 2019: 1; Name confidential, *Written submission No.58*, 24 September 2019: 1; Name confidential, *Written submission No. 61*, 8 October 2019: 1.

[663] Jared, Oral evidence, *Hansard*, 2 March 2020: 24.

> endured. Apologising and expressing regret are key components of open disclosure, but also the most sensitive. 'Saying sorry' requires great care.[664, 665]

Health service organisations are required to implement open disclosure as part of the Clinical Governance Standard of the National Safety and Quality Health Service Standards (NSQHS Standards), 2nd edition (Standard 1, Criterion 1.16).[666] The ACSQHC provides:

> Open disclosure describes the way clinicians communicate with and support patients, and their family and carers, who have experienced harm during health care. Open disclosure is a patient right, is anchored in professional ethics, considered good clinical practice, and is part of the care continuum. Over the past two decades, open disclosure has been recognised as a practice that can benefit patients and clinicians involved in adverse events. Open disclosure is inherently complex, and is challenging and difficult for all participants. However, its systematic practice can assist health service organisations to manage adverse events compassionately and provide broader benefits through improved clinical communication and systems improvement.[667]

As part of the review undertaken by the ACSQHC, all states and territories resolved to enact 'apology legislation'. South Australia's *Civil Liability Act 1936*, under Division 12, section 75, provides for this, with the limitation of liability where an apology is made by or on behalf of a person in connection with a matter alleged to have been caused by the person.

The apology does not constitute an express or implied admission of fault or liability by the person in connection with that matter. An apology under the Civil Liability Act means:

> ***apology*** means an expression of sympathy or regret, or of a general sense of benevolence or compassion, in connection with any matter, whether or not the apology admits or implies an admission of fault in connection with the matter.[668]

The Committee received evidence that witnesses were faced with numerous difficulties in accessing their hospital records or obtaining information from hospitals and medical practitioners about the procedures they had undergone.[669]

Not only are the instances described in the evidence contrary to the values and behaviours evinced in the NSQHS Standards, they underline a lack of willingness more broadly on the part of the health system, to recognise and help redress the damage caused to some patients by medical mesh.

Kim who appeared on behalf of the SA Pelvic Mesh Support Group commented if there were an apology given to South Australians regarding mesh, they might feel that they were listened to and had been heard. This, Kim said, "[…] may go some of the way to helping them feel that there is some hope for them moving forward and their problems are acknowledged."[670] And:

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664 ACSQHC, *Saying sorry: A guide to apologising and expressing regret during open disclosure*, Sydney, 2013: 4. Accessed 17 February 2021 Australian Open Disclosure Framework: Saying sorry - A guide to apologising and expressing regret during open disclosure | Australian Commission on Safety and Quality in Health Care

665 See also ACSQHC, *Australian Open Disclosure Framework,* Accessed 17 February 2021 The Australian Open Disclosure Framework | Australian Commission on Safety and Quality in Health Care

666 ACSQHC, *Australian Open Disclosure Framework,* Sydney, 2013: 8. Accessed 17 February 2021 Australian Open Disclosure Framework (safetyandquality.gov.au)

667 ACSQHC, *Australian Open Disclosure Framework*, 2013: 10. Accessed 17 February 2021 Australian Open Disclosure Framework (safetyandquality.gov.au)

668 *Civil Liability Act 1936* Division 12, 75—Effect of apology on liability

669 Name confidential, *Written submission No. 68*, 17 June 2020: 1.

670 Kim, *Hansard*, 30 November 2020: 201.

> The Federal health minister gave an apology to mesh-affected women. I actually think that should happen here in South Australia. They should acknowledge that there is a problem and they should also acknowledge that they are here to give those men and women the respect and care that they do deserve—and it is a problem.[671]

In 2020, the UK Inquiry report of the Independent Medicines and Medical Devices Safety Review recommended that the English Government apologise for the pain and suffering of women affected by pelvic mesh:

> Our Terms of Reference required us to investigate whether the response of the healthcare system was sufficiently robust, speedy and appropriate. In the following chapters we will show that it was not, resulting in avoidable harm. […] The system and those that oversee it, need to acknowledge what has gone so badly wrong.
>
> Recommendation 1: The Government should immediately issue a fulsome apology on behalf of the healthcare system to the families affected by […] pelvic mesh.[672]

Likewise, in New Zealand the review on medical mesh undertaken in 2018 by the Diana Unwin Chair in Restorative Justice, Victoria University of Wellington found participants of the review process, including mesh victims, health professionals and government agencies were supportive of an apology being issued, which recognised the harm that had occurred:

> A distinction was made between *acknowledgement* and *apology*. MDU [Mesh Down Under] conveyed the preference of their members that a formal apology from the government should come at the end of the process, after a commitment to reparative actions has been taken.[673]

The ACSQHC recommends an apology be given, on behalf of the health service, with all the known facts provided to the patient. This is to enable a dialogue between health service and the patient as it acts as a communication tool.

The respect that a formal apology shows was identified in the New Zealand review, where rebuilding trust through dialogue was considered an important outcome of an apology:

> All participants consider it critically important to include the mesh community and clinicians in transparent and inclusive dialogue in order to rebuild trust and secure lasting change. It is only through the restoration of institutional relationships characterised by trust and partnership that wellbeing can be restored, actions implemented, and future harm reduced or prevented.[674]

To inform services provided by the SA Pelvic Mesh Clinic, initiate a review to be led by people with Lived Experience of mesh injuries and contributed to, by a Consumer Advisory Group, of the available services and continuity of care for mesh affected patients who have had a full mesh removal but still experience chronic pain associated with mesh and mesh related injuries. Whilst a 'hub and spoke' model is being considered, implement a program of 'mobile services' to regional and rural mesh injured patients on a twice-yearly basis. Patients should have access to all services they would ordinarily have access to when they attend clinics in Adelaide, with SA Health providing for specialist consultants to visit regional and rural patients in situ.

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671 Kim, *Hansard*, 30 November 2020: 198.

672 Independent Medicines and Medical Devices Safety Review, *First Do No Harm*, United Kingdom, July 2020: 9. Accessed 4 August 2020 the Independent Medicines and Medical Devices safety Review - Oral hearings (immdsreview.org.uk)

673 Wailling, J., Marshall, C., and Wilkinson, J.*, Hearing and responding to the stories of survivors of surgical mesh: Ngā kōrero a ngā mōrehu – he urupare*, 2019: 43.

674 Wailling, J., Marshall, C., and Wilkinson, J.*, Hearing and responding to the stories of survivors of surgical mesh: Ngā kōrero a ngā mōrehu – he urupare*, 2019: 43.

Australian Class Actions involving Pelvic Mesh Manufacturers

Johnson & Johnson Medical Pty Ltd / Ethicon

On 21 November 2019, Shine Lawyers' class action against Johnson & Johnson Medical Pty Ltd (J&J) and its subsidiary company, Ethicon was won in the High Court of Australia for faulty urogynaecological meshes, the largest women's health action of its kind in Australian history.[675]

One of the claims made against J&J, Ethicon in the case was that the risks described in the product information and the warnings to medical professionals and patients were "defective and negligent", as they did not properly advise of the risk of complications, the types of complications that might arise and the severity and the duration of complications if they were to occur.[676] The J&J, Ethicon urogynaecological mesh products that were the subject of the court case are:

- Gynecare Prolift Pelvic Floor Repair Systems (Anterior, Posterior and Total);
- Gynecare Prosima Pelvic Floor Repair Systems (Anterior, Posterior and Combined);
- Gynecare Prolift+M Pelvic Floor Repair Systems (Anterior, Posterior and Total);
- Gynecare TVT;
- Gynecare TVT - Abbrevo;
- Gynecare TVT – Secur;
- Gynecare TVT Exact;
- Gynecare TVT - Obturator; and
- Gynecare Gynemesh PS Nonabsorbable polypropylene mesh.[677]

Ms Bridget Cook, Senior Associate, Shine Lawyers advised, the allegations proven were:

1. the complications needed to be warned about and were inadequately warned about
2. the complications were caused by the mesh devices
3. the severity and the magnitude of the complications were not insignificant
4. Johnson & Johnson knew or had knowledge about the complications.[678]

Her Honour Justice Katzman found that the warnings in the patient and medical practitioner product material was misleading and did not adequately disclose the number of matters, including the full extent of complications, the incidence and severity of complications and the duration of complications if they did occur.

Her Honour made orders requiring J&J to incorporate warnings and other information consistent with her findings, into the product information provided with the mesh devices still available on the market.[679] Since the High Court judgement in November 2019, there have been subsequent hearings with J&J appealing the court's decision. The appeal was heard by the Full Court of the Federal Court in Sydney. The Federal Court dismissed the appeal by J&J. The decision was handed down on Friday, March 5th, 2021.[680]

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675 Shine Lawyers, *Johnson and Johnson/ Ethicon Class Action*. Accessed 1 March 2021 https://www.shine.com.au/service/class-actions/johnson-johnson-ethicon-class-action

676 Ms Bridget Cook, *Hansard*, 29 June 2020: 115.

677 Shine Lawyers, *Johnson and Johnson/ Ethicon Class Action*. Accessed 1 March 2021 https://www.shine.com.au/service/class-actions/johnson-johnson-ethicon-class-action

678 Ms Bridget Cook, *Hansard*, 29 June 2020: 115.

679 Ms Bridget Cook, *Hansard*, 29 June 2020: 115.

680 Shine Lawyers, *Johnson and Johnson/ Ethicon Class Action*. Accessed 1 March 2021 https://www.shine.com.au/service/class-actions/johnson-johnson-ethicon-class-action

American Medical Systems

Shine Lawyers are currently in the process of mounting a class action against American Medical Systems (AMS) for urogynaecological meshes. As with the case against J&J, Ms Cook advised, that the content of materials provided to medical professionals and patients in the AMS product information is also subject to one of the claims in the AMS class action.[681]

Shine Lawyers provides the meshes manufactured by AMS, which are subject to the Action on their website as the following:

- Perigee Transobturator Anterior Prolapse Repair System;
- Apogee Vaginal Vault and Posterior Prolapse Repair System;
- Elevate Anterior and Apical Prolapse Repair System;
- Elevate Apical and Posterior Prolapse Repair System;
- SPARC Sling System;
- MONARC Subfascial Hammock System;
- MiniArc Single-Incision Sling System;
- MiniArc Precise Single-Incision Sling System;
- MiniArc Pro Single-Incision Sling System;
- RetroArc Retropubic Sling System.[682]

Recent United States of America Lawsuits

The Committee notes with interest, since 2016, several states in the United States of America including California, Washington, West Virginia and Oregon have all filed lawsuits against Johnson & Johnson / Ethicon over false and deceptive marketing. Along with these matters, an action undertaken by 41 American states and the District of Columbia, was filed against Johnson & Johnson, and which, was settled for an aggregated total of US$117 million in 2019.[683]

Most recently, according to the Californian Department of Justice, on 30 January 2020, the San Diego Superior Court affirmed that Johnson & Johnson knew about the potential risks and side effects of their pelvic mesh products prior to their release onto the market.

Johnson & Johnson were found to have deliberately hidden that the mesh products were known to potentially cause serious and irreversible complications, which could result in a devastating impact on overall quality of life. The Court issued the judgment which requires Johnson & Johnson to pay US$343.99 million in penalties.[684]

This follows an out of court settlement by Johnson & Johnson in April 2019 with Washington State, for US$9.9 million for similar claims. The Washington State Attorney General claimed that Johnson & Johnson omitted known risks from their mesh devices' marketing materials for patients and

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681 Shine Lawyers, *American Medical Systems Mesh Class Action*. Accessed on 1 March 2021 https://www.shine.com.au/service/class-actions/american-medical-systems-mesh-class-action

682 Shine Lawyers, *American Medical Systems Mesh Class Action*. Accessed on 1 March 2021 https://www.shine.com.au/service/class-actions/american-medical-systems-mesh-class-action

683 Reuters, *Johnson & Johnson agrees to pay about $117 million to settle U.S. states' mesh probe,* 18 October 2019. Accessed 23 March 2021 https://www.reuters.com/article/us-johnson-johnson-settlement-mesh-idUSKBN1WW2EK

684 State of California Department of Justice, Attorney General, *Attorney General Becerra Secures nearly $344 Million Judgment Against Johnson & Johnson for Endangering Patients through Deceptive Marketing of Pelvic Mesh Products*, 30 January 2020. Accessed 1 March 2021 https://oag.ca.gov/news/press-releases/attorney-general-becerra-secures-nearly-344-million-judgment-against-johnson

Instructions for Use for doctors. It was also stated that Johnson & Johnson's conduct was egregious, and the payout will go towards providing the women who were harmed and their families with relief.[685]

Committee's View

The Committee considers reporting of mesh related incidents into the SA Health PIR system is something SA Health could address with clinical and nursing staff into the future. This could be achieved by an education and training campaign to raise awareness and develop staff skills in identifying mesh related adverse incidents.

The Committee understands CALHN has provided some assistance to women who do not meet the criteria to be admitted to the SA Pelvic Mesh Clinic. A number of those patients have been referred as an outpatient to the various specialists who work within the CALHN outpatient services.[686] Other patients not meeting the criteria have been referred back to their GPs for treatment and care.

While the SA Pelvic Mesh Clinic has resources available for GPs and has developed several initiatives to inform GPs about mesh issues, there is a case to argue that the specificity of mesh injury calls for a more specialised continuity of care.

The Committee considers it would be beneficial for the SA Pelvic Mesh Clinic in collaboration with CALHN, to continue to provide some support and treatment to the cohort who do not meet the criteria for admittance to the SA Pelvic Mesh Clinic. This could be in the form of psychologist sessions, physiotherapy and pain management. It is noted that this would require increased funding to implement and continue.

The Committee considers that the addition of a social work position within the SA Pelvic Mesh Clinic would be very beneficial to patients with needs in the areas of employment, relationships, income, and advocacy in dealing with agencies around access to disability support services.

Recommendations

The Minister for Health and Wellbeing:

13. On behalf of the Government of South Australia, consider issuing a public apology to the women and their families affected by medical mesh in South Australia, for the systemic failures of the Healthcare system in detecting and acting promptly on issues around medical mesh, and for continuing to implant mesh in the public hospitals, despite a lack of robust clinical and longitudinal research data on the efficacy and safety of medical mesh.

14. In relation to funding identified by SA Health for mesh injured women in South Australia undertake to:

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[685] Washington State Office of the Attorney General, *Johnson & Johnson Will Pay $9.9 Million For Failing To Disclose The Risk Of Its Surgical Mesh Devices*, 22 April 2019. Accessed 1 March 2021 https://www.atg.wa.gov/news/news%E2%80%90releases/johnson%E2%80%90johnson%E2%80%90will%E2%80%90pay%E2%80%9099%E2%80%90million%E2%80%90failing%E2%80%90disclose%E2%80%90risk%E2%80%90its%E2%80%90surgical%E2%80%90mesh

[686] SA Health, *Responses to Questions on Notice*, *Hansard*, 7 September 2020, received 3 November 2020: 20.

(a) Urgently develop a policy to release existing funding (that has been previously identified for approved Mesh Clinic patients to travel to Victoria for assessment for full removal of their mesh implants under a Memorandum of Understanding (MOU) with the Royal Women's Hospital), so that these patients may seek care and surgery in Victoria without additional suffering.

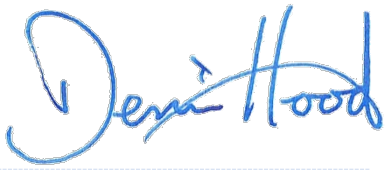
(b) Following the successful establishment of an MOU, those women who were, or are, on the SA Pelvic Mesh Clinic waiting list for full mesh removal surgery and have proceeded with surgery, be assessed for compensation so they are not financially disadvantaged.

(c) As soon as practicable commit additional funding to the SA Pelvic Mesh Clinic so that the Clinic can increase the services the clinic can provide to mesh affected women. This funding could provide for additional staff including: urogynaecologist surgeon(s); nurse consultant; physiotherapist(s); counsellor(s); lived experience advocates; social worker(s); pain management professionals to provide services to mesh injured women and assist with lodgement of adverse events reports to the Therapeutic Goods Administration. Further, in determining a suitable funding increase, consideration should be given to lowering the threshold or level of complexity for acceptance to the clinic and the access to the specialist services it offers.

15. Provide funding for the SA Pelvic Mesh Clinic to re-establish the Consumer Advisory Group of the Clinic to be led by appropriately remunerated lived experience staff.

16. Whilst a 'hub and spoke' model is being examined, urgently consider implementing a program of 'mobile services' to regional and rural mesh injured patients on a twice-yearly basis. Patients should have access to all services they would ordinarily have access to when they attend clinics in Adelaide, with SA Health providing for specialist consultants to visit regional and rural patients in situ.

17. To inform services provided by the SA Pelvic Mesh Clinic, initiate a review to be led by people with lived experience of mesh injuries and contributed to, by a Consumer Advisory Group, of the available services and continuity of care for mesh affected patients who have had a full mesh removal but still experience ongoing pain associated with mesh and mesh related injuries.



Hon Dennis Hood MLC
Presiding Member

25 May 2021

Written Submissions

001 Name withheld
002 Name withheld
003 Name withheld -
004 Health and Community Services Complaints Commissioner
005 Name withheld
006 Australian Commission on Safety and Quality in Health Care
007 Name withheld
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023 Health Consumers Alliance of SA Inc
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027 Name withheld
028 Name withheld
029 South Australian Pelvic Mesh Support Group
030 Johnson and Johnson Medical Pty Ltd
031 Name withheld
032 Name withheld
032 Name withheld
033 Name withheld
034 Name withheld

035 Name withheld

036 Name withheld

037 Name withheld

038 Name withheld

039 Medical Technology Association of Australia

040 Name withheld

041 Australasian Pelvic Floor Procedure Registry Steering Committee

042 Name withheld

043 Name withheld

044 Name withheld

045 Royal Australian and New Zealand College of Obstetricians and Gynaecologists

046 Name withheld

047 Name withheld

048 Name withheld

049 Mesh Injured Australia Inc

050 Name withheld

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056 Name withheld

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058 Name withheld

059 Urological Society of Australia and New Zealand

060 Name withheld

061 Name withheld

062 Royal Australasian College of Surgeons

063 Name withheld

064 Name withheld

065 Minister for Health and Wellbeing

066 Medical Devices & Product Quality Division, Health Products Regulation Group, Department of Health

067 Name withheld

068 Name withheld

069 Dr Ian P Tucker

Oral Evidence Hearings and Witnesses

The Committee held hearings of evidence at Parliament House, Adelaide, as follows:

Monday, 17 February 2020
Individuals
Alicia
Franciszka
Penny
Robert
Tracey

Monday 2 March 2020
Individuals
Kim
Jared

SA Pelvic Mesh Group
Ms Kim Blieschke
Anne

Monday 23 March 2020
Health Consumer Alliance of South Australia
Ms Julia Overton, Chief Executive

Monday, 27 April 2020
Australasian Pelvic Floor Procedure Registry Steering Committee
Professor Helen O'Connell, Chair
Professor Susannah Ahearn, Primary Chief Investigator

Monday, 11 May 2020
Department of Health
Ms Tracey Duffy, First Assistant Secretary, Medical Devices and Product Quality Division

Monday 1 June 2020
Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Dr Christopher Bennes, Chair
Dr Steve Robson, Immediate Past President

Australian Commission on Safety and Quality in Health Care
Dr Robert Herkes, Chief Medical Officer
Assoc Professor Kathy Meleady, Stream Director

Monday 15 June 2020
Royal Australasian College of Surgeons
Dr Samantha Pillay

Monday 29 June 2020
Shine Lawyers
Ms Jan Saddler, Head of Litigation and Loss Recovery
Ms Bridget Cook, Senior Associate, Class Action Team

Monday 20 July 2020
Individuals
Chelsea
Ebony
Elsie
Eunice
Gordon
Jacob
John
Sarah
Sharon

Monday 7 September 2020
SA Health
Ms Michele McKinnon, Executive Director, Provider Commissioning and Performance
Ms Bronwyn Masters, Executive Director, Operations, Central Adelaide Local Health Network
Dr Roy Watson, Head of Gynaecology, Central Adelaide Local Health Network
Dr Meredith Craigie, Specialist Pain Medicine Physician, Central Adelaide Local Health Network
Ms Bonnie Fisher, Principal Project Manager, SA Maternal Neonatal and Gynaecology Community of Practice
Ms Alexandra Emerson, Nurse Consultant, SA Pelvic Mesh Clinic

Monday 21 September 2020
Royal Australian College of General Practitioners
Dr Magdalena Simonis

Monday 16 November 2020
Queensland Pelvic Mesh Service
Prof. Malcolm Frazer, Head of Unit
Ms Nicolle Germano, Consumer Rep. QPMS Committee

Monday 30 November 2020
Ms Kim Blieschke

SA Health
Professor Guy Maddern, Director of Research, Basil Hetzel Institute for Translational Health Research

Monday 7 December 2020
Department of Health
Ms Tracey Duffy, First Assistant Secretary, Medical Devices and Product Quality Division

Dr Ian Tucker, Gynaecologist and Certified Urogynaecologist

Monday 1 February 2021
SA Health
Dr Roy Watson, Head of Gynaecology, Central Adelaide Local Health Network