On 28 March 2018 the Australian Senate Community Affairs References Committee issued its final report on transvaginal mesh devices. It found these devices have caused unnecessary physical and emotional pain and suffering to thousands of women who were not told by their doctors of the objective material risks associated with their use. The Senate Committee concurred with the description by the Public Health Association of Australia of the complications resulting from transvaginal mesh implants as constituting a serious public health issue requiring a response at both an individual and at a population level, including counselling, public education, clinical interventions and long-lasting protective mechanisms. The committee’s inquiry highlighted significant shortcomings in Australia’s reporting systems for medical devices, with flow-on consequences for the health system’s ability to respond in a timely and effective way. Among other recommendations, the Senate Committee backed the establishment on a cost recovery basis of a national registry of high-risk implantable devices linked to a system of mandatory reporting of adverse events.

Keywords: transvaginal mesh; Senate Committee; adverse events; fiduciary duty

DEVELOPMENT OF TRANSVAGINAL MESH AND ITS APPROVAL FOR USE IN AUSTRALIA

The Australian Senate Community Affairs References Committee released its final report on transvaginal mesh implants late in March 2018.1 The Committee made significant recommendations concerning the education of medical practitioners about their responsibilities to patients to avoid conflicts of interest in their interaction with corporate device manufacturers.

Transvaginal mesh devices were manufactured from the late 1990s to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI) in women. Prolapse can occur after birth when the pelvic organs such as the bladder and bowel bulge into the vaginal wall.2 The mesh is inserted as a mid-urethral sling or tension-free vaginal tape and anchors hold the mesh in the hips. The mesh is composed of polypropylene; 45 million metric tons of this material are produced annually for use in packaging, automotive, electrical, household and manufacturing applications.3 The mesh device was also used for urinary incontinence and if performed successfully, the patient was able to lead a normal life.4 Use of transvaginal mesh appeared to be equivalent to or better than existing procedures and involved shorter

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3 The Project, Transvaginal Mesh Implants (26 April 2017) TenPlay.

surgery and recovery time. It soon became the most frequently performed surgical procedure for the treatment of SUI and POP.

Early published data were relatively supportive of the safety and efficacy of the use of mesh in the treatment of POP. However, there was a considerable lag before data from Randomised Control Trials (RCTs) became available. The first RCTs on the use of mesh devices for the treatment of prolapse were not published until five to seven years after the devices came into use. This is not abnormal with implantable medical devices as, unlike pharmaceuticals, they cannot readily or ethically be trialled on animals or groups of volunteers.

The first Australian adverse event from transvaginal mesh was reported in 2006. Complications associated with mesh procedures were soon found to range from mild discomfort to debilitating pain and could become evident immediately or might not manifest for some years after surgery. The devices were found to have “more problems than benefits” and “women who underwent the operation had high rates of needing repeat surgery due to mesh exposure, bladder injury and urinary incontinence”. Complications could be severe and catastrophic and were not limited to pain, impaired mobility, incontinence/frequent urination as well as related relationship/marriage difficulties, sexual difficulty, loneliness/social withdrawal, recurring infection, lethargy and depression. Physical symptoms were closely linked with psychological symptoms and could be lifelong and irreversible in some cases.

The Cochrane Review headed by Dr Christopher Maher investigated the issue and found reasons why transvaginal mesh devices were implanted so widely. The Review discovered that the devices had been “marketed aggressively” by corporate manufacturers to doctors and that companies provided free education and training for the meshes that did not deal objectively with the material risks or alternatives. Critically, it was found that many authors of clinical studies showing positive results had financial ties to mesh manufacturers.

Mesh devices were cleared for use in Australia in 2005. They were not classified as high-risk devices because previously they had been used to treat hernias. The Therapeutic Goods Administration (TGA), however, received 99 adverse event reports between 2012–2016 and found that the most frequently reported were “pain and erosion”. The mesh was then classified as a high-risk device. The TGA recommended that further clinical trials were needed and should have the highest practical level of evidence and be appropriately designed to ensure safety and that the device performs its purpose.

Consumers and health professionals were urged to report “any adverse events experienced in association with these medical devices”. It was erroneously thought not compulsory for health professionals or consumers to report adverse events. An adverse event, however, presumptively puts a patient in a position of extreme vulnerability. Arguably it was and remains part of the legal obligations of doctors to report all adverse events promptly to which they have or should have direct

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5 Maher, n 4.
7 C Maher et al, “Transvaginal Mesh or Grafts Compared with Native Tissue Repair for Vaginal Prolapse” (2016) 2 Cochrane Database of Systematic Reviews 10.
8 The Australian Pelvic Mesh Support Group, Homepage (27 March 2017) Facebook <https://www.facebook.com/groups/AustralianPelvicSupportGroup/>.
knowledge. This represents a logical extension of the categories of extreme vulnerability which the High Court in *Breen v Williams* ((1996) 186 CLR 71) recognised created fiduciary obligations in doctor-patient relations.

The TGA completed a review of the mesh implants in 2014 and highlighted the importance of: “appropriate patient selection, surgeon experience and the need for fully informed patient consent.” They found that the evidence used in literature to support the use of mesh devices was of a very poor quality and that their overall effectiveness “is not established”. Poor training of surgeons and inadequate experience were found to be factors that increased complications. The TGA assured the public that the “medical devices regulatory framework was now significantly more mature than it was at the time the early mesh devices were assessed”.

Under-reporting of problems became a significant issue due to very private nature of the surgery and the awkwardness many women felt when they talk about it. The Royal Australian and New Zealand College of Obstetrics and Gynaecology (RANZCOG) ceased recommending that the mesh be used “as the first line treatment of any vaginal prolapse”. RANZCOG encouraged clinicians to have an “extensive discussion regarding other options and referral for a second opinion”. In 2015 a National Health Service (NHS) working group in the United Kingdom found the level of risk associated with transvaginal mesh insertion was unacceptable.

In 2015 Senator Derryn Hinch initiated the call for a Senate Inquiry stating that transvaginal mesh implants were “one of the greatest medical scandals and abuses of mothers in Australia’s history”. Senator Hinch likened this issue to thalidomide as he said that device manufacturers had put “money before morality” and had put “profit before pain”. Senator Hinch stated that the TGA was “letting victims down” and that is was a “national disgrace”. The emotive language used by Senator Hinch was a factor in establishing an inquiry but so was investigative reporting by journalist Joanne McCarthy. This revealed for example that a major hospital had no prior knowledge and had given no ethics approval for transvaginal mesh surgery that took place on its premises.

At the crux of this story were the patients organised in support groups led by activists such as Caz Chisholm. Many of them underwent suffering they could have avoided had they been told (as required by norms of medical ethics, common law and international human rights) of the objective and subjective material risks associated with the implant. It is important to acknowledge, though, that many women successfully received this surgery with no long-term adverse effects.


15 Therapeutic Goods Administration, n 14.

16 McCarthy, n 17.


18 Mesh Working Group, n 13.


23 Scottish Independent Review, n 6, 2.
INTERNATIONAL PERSPECTIVES ON TRANSVAGINAL MESH

Transvaginal mesh devices have been approved for use in many nations. Yet in many jurisdictions, the volume and nature of complaints received by regulators has spurred investigative commissions and class action litigation.

The United States approved mesh implants for use in 2002. Manufacturers developed “kits” for clinicians and meshes were used widely as it was believed they were better than native tissue repairs. However, much like Australia, complaints soon were received and the Food and Drug Administration (FDA) investigated the devices. The FDA stressed that improved training was needed for surgeons to be able to use the meshes correctly and it considered complications to be rare.24 Nevertheless, complications continued to be reported. In 2011 the FDA retracted their statement that serious complications were rare and reported that “there was no compelling evidence” for the use of mesh devices. The mesh was reclassified into a higher risk category which meant that greater premarket evaluations needed to occur before the device was allowed on the market.25 Over 40,000 lawsuits were commenced in the United States alone.26 In Australia class actions have been commenced against mesh manufacturers Johnson & Johnson and American Medical Systems. Globally the damages sought have been estimated at US$20 billion.27

Scotland undertook review of transvaginal mesh implants in 2015. The review found there was a need for improved governance around the introduction of new procedures.28 It is likely that these findings will be replicated in an Australian context. This review shows that it is important that women who are selected for this procedure are appropriate candidates. The review uncovered that the current state of evidence was insufficient in establishing the long-term impacts of the mesh devices.29 Importantly, patients felt that their complaints had been sidelined and dismissed. Due to this lack of care by regulators and doctors, 32% of the women who responded said that they had lost faith in medical professionals and the health care system.30

The Mesh Working Group was established by the NHS in 2015 to address concerns over the use of mesh devices. The Group found that patients were not told that the mesh can be impossible to remove. Patients were also not given enough time to consider their options.31 Doctors hold the balance of power in the doctor–patient relationship and patients need to be given information and time to make fully informed decisions.32

The European Commission’s Scientific Committee on Emerging and Newly Identified Health Risks suggested that a certification system should be introduced for surgeons to ensure that they have received appropriate training.33 The Committee recommended that implant registries be developed in order to track the progress of the implants and that greater training of doctors was needed.34 The Committee recommended that studies be commissioned to investigate the long-term effects of transvaginal meshes because the evidence was currently lacking.35

24 Scottish Independent Review, n 6, 2.
25 Scottish Independent Review, n 6, 2.
30 Scottish Independent Review, n 6, 14.
31 Scottish Independent Review, n 6, 12.
32 Scottish Independent Review, n 6, 12.
34 Scientific Committee on Emerging and Newly Identified Health Risks, n 33.
35 Scientific Committee on Emerging and Newly Identified Health Risks, n 33.
The Australian TGA decided on 28 November 2017 to remove transvaginal mesh products whose sole use is the treatment of POP via transvaginal implantation from the Australian Register of Therapeutic Goods (ARTG). It stated “this follows a review by the TGA of the latest published international studies and an examination of the clinical evidence for each product included in the ARTG and supplied in Australia. Based on this new information, and since the publication by the TGA of the Results of review into urogynaecological surgical mesh implants, the TGA is of the belief that the benefits of using transvaginal mesh products in the treatment of pelvic organ prolapse do not outweigh the risks these products pose to patients”.36

THE LACK OF DISCLOSURE OF MATERIAL RISK AND ITS CONSEQUENCES

Disclosure of objective and subjective material risks by a doctor to a patient prior to a procedure is an integral part of the comprehensive civil law duty of care.37 This duty allows patients to make informed choices about what the best option is for them. It also limits the liability of the medical professional and is central to the trust necessarily implicit in the doctor–patient relationship.

Many patients have said that they were not fully informed of the risks of receiving a mesh implant. One woman was not told that the mesh implant was permanent and could not be removed. Caz Chisholm, the founder of the Australian Pelvic Mesh Support group said: “If you’ve not consented to what is going to happen to you, and you wake with serious complications, you’re not only dealing with the physical impacts of mesh but the emotional trauma of feeling violated. … It is a violation of your body to have something in there that you didn’t consent to.” The mesh is implanted in a private and sensitive area and this increases the feelings of assault and violation that these women experience.

The women’s stories highlight the failure of the TGA to appropriately assess the safety of the devices and the failure of doctors to give fully informed consent. One patient, Kim Blieschke, said: “Not once was I told it was permanent. I was shown a little piece of gauze-like curtain material … the problem is when you implant it into bodies it goes as hard as cement within weeks.” She spent US$50,000 flying to the United States to find a surgeon to remove the mesh as there was not a doctor in Australia who could perform the operation.38

The final report of the Senate Committee was heavily critical of the disclosure of material risk undertaken by doctors about transvaginal mesh implants:

[T]he committee notes evidence to the inquiry about the inconsistent and at times cursory manner in which consent has been obtained from patients undergoing transvaginal mesh procedures. The committee is deeply concerned by reports that some medical professionals have not provided patients with detailed guidance and patient information leaflets. The committee is particularly concerned by the evidence of the APMSG that guidance prepared by RANZCOG has not been used to guide the process of informed consent in many cases.39

As but one example, Dr Richard Reid from New South Wales was the subject of many complaints in this regard, being the subject of related proceedings in the Supreme Court and the New South Wales Health Care Complaints Commission.40 One of his patients, Barb Jobson, has said that Dr Reid gave her prior to the procedure he performed “no indication that there was going to be any problems”. She was left with immense pain and unable to lead a normal life.41

37 Rogers v Whitaker (1992) 175 CLR 479.
39 Australian Senate Community Affairs References Committee, n 1, [5.83].
CONFLICTS OF INTEREST AND THEIR IMPACT ON PATIENT OUTCOMES

The Senate Committee was concerned that evidence before it suggested doctors might have been improperly influenced by device manufacturers:

The committee heard a range of evidence regarding the interactions between device manufacturers or sponsors and medical practitioners. Such concerns ranged from questions over the presence of sponsor representatives in the surgical theatre to the possibility of financial inducements to medical practitioners to use specific products.42

Many studies supporting mesh devices are flawed by apparent and real conflicts of interests between doctors and manufacturers. Dr Reid, as detailed in a report by Joanne McCarthy of the Newcastle Herald, disclosed he “received financial support from the manufacturer, developer, distributor of the Surgisis device”.43

Another Australian doctor, Dr Petros, developed the IVS Tunneller which was used to support the safety and efficacy of other mesh devices. It was suggested to Dr Petros in court that his financial interest may have prevented him from fully explaining the risks of the device as he received AU$15 in royalties for each mesh device used. The judge stated that “the defendant did not, it would seem, and apparently still does not, believe there was or is any real detriment associated with ‘his’ procedure”.44

In 2010 the United States introduced the Physician Payments Sunshine Act 2010 (US) where all financial interactions between clinicians and companies are entered into a public database. This could be introduced in Australia. The relationship between doctors and pharmaceutical companies is overseen by the RANZCOG’s Code of Ethical Practice which reminds doctors that any relationship they have with pharmaceutical companies cannot come into conflict with their ultimate duty of care to their patients.45 The Cochrane Review suggested that doctors should seek approval and guidance from an ethics committee when using new devices.

ANALYSIS OF SENATE COMMITTEE RECOMMENDATIONS

Below is an analysis of the recommendations from the Senate committee’s Final Report.

Recommendation 1

The Senate Committee recommended 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 TGA 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.

Medical practitioners are used to mandatory reporting requirements (ie child abuse, notifiable infectious disease). Mandating reporting of adverse events is congruent with basic professional responsibilities as found, for example, in the Australian Medical Council Guidelines on Good Medical Practice. The reporting system will need to be a streamlined online system where notification takes no longer than 10 minutes. Doctors should be able to bill Medicare or Private Health insurer for filling out

42 Australian Senate Community Affairs References Committee, n 1, [5.124].
44 McCarthy, n 27.
45 RANZCOG, n 19, 8.
such an adverse event notification. The TGA should be able to recover costs for reviewing each such adverse event notified from the relevant manufacturer.

As long ago as 2005, an article in this journal made the case that: “It may now be time for the courts to consider that the doctor-patient relationship involves a fiduciary element equally as troubling for a vulnerable patient as sexual or financial abuse. This concerns the obligation on a treating doctor to disclose with reasonable promptness adverse events that have occurred in relation to her or his patient. The obligation requires disclosure to the patient concerned or their guardian. The common law doctrine of disclosure of material risk protects the rights of patients to obtain information prior to proceeding with medical treatment. It seems equally important for the law to ensure that patients have rapid access to information that may suggest that a medical procedure or treatment has involved a mistake or adverse event, even if no causally related damage can yet be substantiated. Without the assurance that such information will be disclosed as a part of a doctor’s (fiduciary) duty, patients may end up compromising their rights under new, restricted statutory periods of limitation. They may also be prevented from seeking additional necessary treatments, or change of treating doctor or institution, or properly evaluating the risks and benefits in relation thereto”[46]

**Recommendation 2**

The Senate Committee recommended that the TGA and the Australian Commission on Safety and Quality in Health Care develop an information sheet to be provided to recipients of implantable devices providing guidance on appropriate action to take in the event of an adverse event, including guidance on seeking appropriate treatment and support and on reporting the event.

Provision of such information in such form (capable of being taken home by the patient and considered) is surely already part of the standard of care for provision of information about objectively likely material risks of all surgery, but in particular all surgery involving implanting devices.

The Australian Pelvic Mesh Support Group has called for mesh devices to stop being used until good clinical data is provided.[47] The statement released by RANZCOG in 2016 urges clinicians to be cautious with these devices. It recommends that mesh should not be the “first line treatment of any vaginal prolapse”.[48]

Currently there is no credentialing process that ensures doctors are trained correctly. The Urogynaecological Mesh Working Group (UDWG)’s report released in 2014 wrote that “ultimately decisions to use mesh are made individually by surgeons based on the needs to their particular patients. The amount of training completed prior to using any particular urogynaecological mesh device is an individual decision of the surgeon”. RANZCOG would be the most appropriate body to establish a training system.[50]

The UDWG found that Australian data for mesh devices were inadequate and difficult to come by because the Medicare Benefits schedule statistics do not differentiate between primary and secondary repair “nor mesh and native tissue repair”. Differentiation of numbers could be a cost-effective solution to establishing a registry which would keep track of patients who had implants, which would allow for easier data collection.[51] The UDWG document states that surgeons do “not have a strong awareness

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of Australia’s adverse event reporting systems”. The TGA needs to investigate ways in which their procedures can be transparent and accessible so that reporting rates increase. Gai Thompson, a woman who endured serious and permanent complications following mesh surgery in 2008, wrote a complaint to the TGA. It took the TGA three years to respond to a point where it communicated that the incident had been investigated. Mrs Thompson has expressed outrage: “They’re supposed to be the regulator. They’re supposed to be the ones protecting the public but they’ve done nothing. … Why is it up to the women who are the victims of this whole thing to be the watchdog as well?”52 Patients need to be empowered with the knowledge to know where they can report, or their surgeons need to be obliged to make reports of adverse findings.

**Recommendation 3**

The Senate Committee recommended 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.

This is an excellent idea, particularly if the registry is open to the medical profession, regulators and the public and includes information on which medical practitioners were utilising which type of devices. It should apply to all implantable devices. If an adverse event occurs, such a registry notification of it would allow better tracing and patient care as well as correlation of individual adverse event notifications to create automatic red flag notifications.

**Recommendation 4**

The Senate Committee recommended that the Medicare Benefits Schedule Taskforce prioritise release of the report of the Gynaecology Clinical Committee for consultation.

It is hard to understand what public benefit is to be obtained in not making this report visible.

**Recommendations 5 and 11**

The Senate Committee recommended that the Australian Government prioritise the establishment of a more comprehensive postmarket monitoring scheme and provide to the Senate by 29 November 2018 a progress report on work undertaken to date. The Senate Committee recommended that Commonwealth, States and Territory governments commission the Australian Commission on Safety and Quality in Health Care to undertake an audit of transvaginal mesh procedures undertaken and their outcomes since the introduction of transvaginal mesh devices for use in the Australian market.

Postmarketing surveillance and audits especially are critical to safety of medical devices, as it is not possible to implement the various stages of clinical trials that are feasible with pharmaceuticals. For instance, surgeons cannot ethically (or probably practically) place implants in animals and they cannot trial them on small groups of volunteers.

**Recommendation 6**

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

- clarify the rationale for the proposed treatment;
- discuss the range of alternate treatment options available and their attendant risks and benefits;
- discuss the likely success and potential complications of the recommended treatment as they relate to the individual patient;

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• provide an opportunity for the patient to ask questions; and
• confirm that the individual patient has understood the information discussed.

This recommendation in effect says no more than that doctors should do what medical ethics and health law already requires them to do.

Recommendation 7
The Senate Committee recommended that treatment guidelines developed by the Australian Commission on Safety and Quality in Health Care should clearly indicate that transvaginal mesh implantation should only be undertaken with fully informed consent and as a last resort when other treatment options have been properly considered and determined unsuitable.

Such a recommendation itself shapes the standard of care for both professional responsibility and medical negligence. It would be advisable for doctors performing transvaginal mesh implants in future to videorecord each one of the series of material risk discussions. This would include those in which the pamphlet including the objective material risks was handed over to be considered, as well as patients raising particular subjective concerns and having them answered.

Recommendations 8 and 9
The Senate Committee recommended that the medical professional specialist colleges and societies ensure that processes are in place to draw their members’ attention to the resources released by the Australian Commission on Safety and Quality in Health Care and implement arrangements which require members to consider the resources in their practice. The Senate Committee also recommended that the Commonwealth, State and Territory Health Ministers require that guidance developed by the Australian Commission on Safety and Quality in Health Care for the credentialing of medical practitioners who perform transvaginal mesh procedures should underpin credentialing processes in all public hospitals and work with private hospitals to encourage the adoption of a similar requirement.

The need for such recommendations highlight the extent to which this is not happening now. They emphasise to medical indemnity lawyers that failure of a doctor undertaking such implant surgery without reference to such resources and credentialing represents conduct falling outside the requisite standard of care.

Recommendation 10
The Senate Committee recommended that medical professional colleges and specialist societies implement governance arrangements for transvaginal mesh procedures which require that their members:

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

Medical colleges ought to have been doing this already.

Recommendation 12
The Senate Committee recommended that the Department of Health work with the Medical Technology Association of Australia and the Medical Board of Australia to review the systems in place within the device manufacturing industry and the medical professions to support consistent, high ethical standards, with a specific emphasis on systems in place to prevent the payment of inducements by device manufacturers to medical professionals and teaching hospitals.

The role of medical device manufacturers inducing doctors to insert their products is a critical part of the whole Senate Committee investigation. It is unlikely that such a review will achieve anything. If
it does not produce a policy equivalent to the National Medicines Policy. 53 What we need in Australia, however, is a version of the False Claims Act 1863 (US) by which whistleblowers about fraud on the government purse in such area are entitled to 15–30% of the triple damages the government proves when its joint investigation with the whistleblower’s lawyers substantiates the fraud allegation. 54

**Recommendation 13**

The Senate Committee recommended that State and Territory governments continue to work with the Australian Commission on Safety and Quality in Health Care to review the provision of services for the use and removal of transvaginal mesh devices. In particular, the Committee recommended that consideration be given to the establishment of:

- information and helplines that women who have received transvaginal mesh implants can contact for advice on the availability of treatment and support services, including financial support programs, in their state;
- specialist counselling programs, to assist women who have sustained injuries following transvaginal mesh procedures;
- specialist multidisciplinary units for the assessment and management of complications associated with transvaginal mesh procedures, comprising:
  - comprehensive diagnostic procedures, including relevant diagnostic imaging facilities and expertise;
  - specialist pain management expertise; and
  - high level expertise in the partial or full removal of transvaginal mesh;
- advice and practical assistance for women who are seeking to access their medical records; and
- the provision of further guidance for medical professionals on recording the use of implantable devices on medical records and reporting adverse events to the Therapeutic Goods Administration.

These are all valuable recommendations, although they highlight a significant failing in medical professional regulatory systems if a Senate Committee is the best clinical governance mechanism to bring them to light.

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