HCASA
Health Consumers Alliance of SA Inc

Consumers at the centre of health in South Australia

# Parliament of South Australia –
## Social Development Committee

## Surgical Implantation of Medical Mesh in South Australia

## September 2019

## Contents



HCASA acknowledges the Traditional Custodians of Country. We pay respect to Elders past and present, and recognise that their cultural heritage, beliefs and relationship to Country are important for sustaining health and wellbeing.

## Executive Summary

Health Consumers Alliance of SA Inc (HCASA) is the peak body for health consumers in South Australia. We are a member-based, independent, not-for-profit organisation. We work with consumers and health services to position consumers at the centre of care. Health consumers are people who use, or are potential users of health services, including their family and carers.

HCASA's mission is to engage consumers and health services to achieve high quality, safe, consumer-centred care for all South Australians. We seek to promote and strengthen the voices, wellbeing, rights and leadership of health consumers.

We advocate that consumer engagement policy and practice is embedded across the SA health care system. This includes public, private and non-government health service providers.

We believe that consumer engagement results in better planning and policy-making. This leads to better health outcomes and community wellbeing.

## HCASA submission

Health Consumers Alliance (HCASA) was invited to provide a written and/or oral submission. As the health consumer peak body in South Australia, we are well placed to work with our consumer, community and organisational partners to respond to more detailed questions from the Committee and welcome any Committee request to do so.

This document provides an initial consumer perspective to the Committee's deliberations. It has been informed by:

- A specially convened consumer focus group comprising consumers and representatives with experience of surgical implantation of medical mesh in South Australia
- Ongoing advice from the HCASA *Consumer Advocates Network*, a state-wide group of over 200 Consumer Advocates trained and supported to represent the perspective and experience of their lived experience and community groups
- HCASA's long-standing role in health consumer representation in a wide range of health system inquiries and health service consumer engagement strategies
- HCASA's role as Chair of the *TransVaginal Mesh Consumer Advisory Group* and as a member of the *TransVaginal Mesh Executive Advisory Group* formed by the Department for Health and Wellbeing to deliver on the recommendations of the '*Senate Inquiry: Community Affairs References Committee on transvaginal mesh implants and related matters 2018'* (concluded 30 June 2019)
- HCASA's everyday work, which sees us interacting with consumers with lived experience and their representatives, community leaders and representatives, regarding their needs, goals, values and preferences in the delivery of safe, quality health care for all South Australians

## Introduction

HCASA welcomes the opportunity to contribute information to the Social Development Committee about the 'Surgical Implantation of Medical Mesh in South Australia'.

We provide the following comments, informed by consumers with lived experience of surgical implantation of medical mesh.

## Response to the Terms of Reference

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

HCASA strongly supports the need to obtain accurate data on the number of people in South Australia adversely affected following the implantation of medical mesh. We believe that this needs to commence with investment in determining the number of people who have mesh implanted, for treatment of any condition.

The experience obtained through our involvement in the SA Health response to the '*Senate Inquiry: Community Affairs References Committee (Senate Committee) on transvaginal mesh and related matters 2018*' final report recommendations, recognises the current process for recording use of mesh in a procedure is adhoc and not systemic. The process for the audit undertaken in South Australia to gain a snapshot of likely numbers of people affected by transvaginal mesh was to locate health services that had ordered mesh and then manually search patient records to locate patients who had medical mesh implanted. Reporting adverse events in relation to medical mesh will need to consider the following:

- Many consumers are not aware that they have medical mesh implanted and the range of adverse outcomes that has been shown to be linked to medical mesh implantation has not been universally understood by health practitioners responsible for recording adverse outcomes.
- Consumers may experience initial positive outcomes from medical mesh implantation this outcome can change over time and consumers have reported developing serious adverse health outcomes many years later that are not initially recognised by medical practitioners as related to the mesh implantation.
- There are no accurate, easily accessible consumer records or reporting data about who has had medical mesh implanted and who has experienced adverse outcomes from medical mesh implantation
- The Department for Health and Wellbeing has undertaken some auditing of use of medical mesh within public hospitals to gain an appreciation of the scale of the situation.

- However, anecdotally there is a view that surgical procedures using medical mesh has and is being undertaken more frequently in private hospitals. This data is not reported on or available.
- There is also a view that surgical implantation of medical mesh has and is being undertaken more frequently in regional and remote areas as a 'quick fix' than in metropolitan hospitals (where access to other health interventions is more readily available including physiotherapy).

**Recommendations:**

1. Establish a retrospective registry of medical mesh implantation in South Australia in both the public and private health services including ongoing, long-term monitoring of adverse health outcomes.
2. Public and private hospitals and medical practitioners be required to, and accountable for, providing appropriate information to consumers about the known possible risks associated with medical mesh implantation and provide them with clear alternative treatments including surgical procedures that do not require implanting medical mesh.
3. Transparent and proactive notification to consumers who are/have been implanted with medical mesh so that they can determine if they have been adversely affected and have access to a process to gain assistance and medical treatment if they start to experience any symptoms previously linked to adverse outcomes of medical mesh implantation.

(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;

HCASA supports the establishment of a South Australian Medical Mesh Register and believes this will benefit consumers, clinicians and the health system.

Consumers will benefit by being clearly informed:

- that they have had medical mesh implanted
- what occurred during their procedure (as there are still many consumers who do not know that they have had medical mesh implanted)
- what occurred during their treatment (as many consumers have had poor experiences in trying to determine what occurred during their treatment and this has had negative outcomes for their mental health)
- that their experiences of poor health outcomes from medical mesh implantation are recognised and acted upon by the health system

Clinicians will benefit by:

- having a clear process for supporting consumers who have medical mesh implanted and being able to respond to meet each individual consumer needs
- being better informed about the possible adverse health outcomes directly attributable to medical mesh implantation

The health system will benefit by:

- having a process that focuses on safety and quality outcomes through continuous improvement and monitoring of health outcomes of people with medical mesh implanted
- a more complete picture of the scale and extent of medical mesh implants in South Australians
- the use of this data to develop clear strategies to support consumers and address future health issues arising from medical mesh implantation

Consumers believe that A Medical Mesh Register should contain, as a minimum, the following elements:

- Name of the Medical Practitioner who implanted the medical mesh
- Type of procedure
- Date of implantation
- Clinical rationale for use of medical mesh
- Record of adverse health outcomes
- Date of when adverse health outcomes began to be experienced
- Consumer outcomes of treatment following implantation of medical mesh – both positive and negative

**Recommendations:**

4. Development of systems and processes for undertaking prospective and retrospective audits of medical mesh implantation across the public and private health sectors
5. Ongoing monitoring of outcomes post medical mesh implantation
6. The Medical Mesh Register should focus on quality improvement and accountability and be established using the core principle of supporting a health system that is transparent and focussed on raising awareness through open communication with consumers.

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

Consumers stressed the importance of medical practitioners working with a commitment to integrity and honesty. When medical practitioners undertake to partner with consumers in

this way, they will more effectively listen to consumers who are adversely affected by medical mesh and identify appropriate treatment to address these adverse outcomes

Consumers continue to report variable acceptance by health practitioners (including from general practitioners, medical specialists and allied health and other providers) of the adverse outcomes of medical mesh implantation. Further, consumers report that health practitioners continue to recommend medical mesh implantation despite the increasing evidence about the adverse outcomes in many cases.

One consumer stated "if we knew the risks we would never have agreed". Consumers are concerned that even though the risks are better understood medical practitioners are not informing consumers of those risks and not enabling consumers to be part of a shared decision making process about their treatment options. The issue of informed consent therefore, requires careful consideration by the Committee.

**Recommendations:**

7. The implementation of a clear policy directive outlining the obligation of health practitioners to provide consumers with clear information about the known adverse outcomes of medical mesh implantation in collaboration with consumers
8. Alternative treatment (including surgical alternatives) to medical mesh implantation be provided for consumers to inform their decision-making
9. Support for medical practitioners to be better informed/educated in identifying and reporting adverse outcomes so they know what to report

(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;

HCASA support the need for current consumer information resources about medical mesh (routinely provided prior to surgery) being co-designed with consumers. Consumers stress that information provided must include options for non-surgical treatment and possible/known adverse health outcomes to ensure truly informed consent.

Consumers also believe that information should be provided about alternative surgical options that do not involve medical mesh implantation. These treatments, for example Burch techniques of native tissue repairs, were routinely performed prior to the introduction of medical mesh products but are now performed sporadically, potentially leading to a loss of skill in the surgeons performing these procedures.

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.

**Recommendations:**

10. Co-design of information resources be in relation to medical mesh surgical procedures, including options for alternative surgical methods, non-surgical treatment, known possible adverse outcomes and informed consent
11. Clinicians be better trained in surgical and non-surgical alternatives to the use of medical mesh
12. Consent processes for surgical procedures for use of medical mesh be genuine and transparent

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

HCASA strongly supports rigorous credentialing of medical practitioners undertaking removal of medical mesh. 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 use.

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.

Recommendations:

13. Implementation of a focused and targeted research program for surgical and non-surgical alternatives to the use of medical mesh
14. Consumers to be involved in developing the credentialing process for removal and implantation of medical mesh

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

HCASA supports the allocation of resources to providing physical, emotional and psychological support for consumers, their family and carers experiencing adverse health outcomes related to implantation of medical mesh.

Clinicians need to be educated in the lifelong and life altering impact of medical mesh implantation for those consumers experiencing adverse health outcomes and consider providing their support to consumers attempting to access financial assistance through various means. For example access to the disability pension for people effected by medical mesh implantation has been limited due to the lack of recognition about the severity of the

physical, emotional and psychological and impact of adverse and the debilitating nature of these impacts.

The TransVaginal Mesh Clinic at the Royal Adelaide Hospital now provides access for women to psychological support and consumers are reporting that this has been beneficial. This support is not however, provided for family members or carers.

**Recommendations:**

15. Consumer participation and involvement in identifying the extent of need for physical, emotional and psychological support for consumers, families and carers following adverse health outcomes through medical mesh implantation
16. The eligibility criteria for the disability pension be examined to ensure that consumers adversely effected by medical procedures involving medical mesh implantation are supported

(g) any other related matter.

Consumers have identified the financial burden they incur associated with treatment for remedial action for those people experiencing adverse health outcomes as a direct result of medical mesh implantation in both private and public health services. This burden includes costs associated with treatment, travel, parking, accommodation and is often over multiple days. For consumers who are in pain this is particularly problematic.

The South Australian response to the '*Senate Inquiry: Community Affairs References Committee (Senate Committee) on transvaginal mesh and related matters 2018*' recommendation includes financial support for travel and treatment however it fails to recognise the commitment of time taken to attend numerous appointments, further exacerbated for people living in regional and remote areas. The Patient Assisted Transport Scheme has eligibility criteria and is a subsidy program not a full reimbursement process.

Currently, treatment for medical mesh complications is not recognised as an item in Total and Permanent Disability insurance cover and only some Income Protection policies cover this injury. Consumers have also reported lack of success in accessing the disability pension despite being unable to work due to their injuries following medical mesh implantation.

**Recommendations:**

17. The need for State Government advocacy for the recognition of medical mesh injuries as a Total and Permanent Disability and as eligible for Income Protection
18. The need for State Government advocacy for recognition of medical mesh injured people as eligible for the Disability pension and support through the National Disability Insurance Scheme
19. Development of a communication strategy regarding the known complications and impact of medical mesh implantation and options available for people experiencing adverse health outcomes following implantation.

## Recommendations:

1. Establish a retrospective registry of medical mesh implantation in South Australia in both the public and private health services including ongoing, long-term monitoring of adverse health outcomes.
2. Public and private hospitals and medical practitioners be required to, and accountable for, providing appropriate information to consumers about the known possible risks associated with medical mesh implantation and provide them with clear alternative treatments including surgical procedures that do not require implanting medical mesh.
3. Transparent and proactive notification to consumers who are/have been implanted with medical mesh so that they can determine if they have been adversely affected and have access to a process to gain assistance and medical treatment if they start to experience any symptoms previously linked to adverse outcomes of medical mesh implantation.
4. Development of systems and processes for undertaking prospective and retrospective audits of medical mesh implantation across the public and private health sectors
5. Ongoing monitoring of outcomes post medical mesh implantation
6. The Medical Mesh Register should focus on quality improvement and accountability and be established using the core principle of supporting a health system that is transparent and focussed on raising awareness through open communication with consumers.
7. The implementation of a clear policy directive outlining the obligation of health practitioners to provide consumers with clear information about the known adverse outcomes of medical mesh implantation in collaboration with consumers
8. Alternative treatment (including surgical alternatives) to medical mesh implantation be provided for consumers to inform their decision-making
9. Support for medical practitioners to be better informed/educated in identifying and reporting adverse outcomes so they know what to report
10. Co-design of information resources be in relation to medical mesh surgical procedures, including options for alternative surgical methods, non-surgical treatment, known possible adverse outcomes and informed consent
11. Clinicians be better trained in surgical and non-surgical alternatives to the use of medical mesh
12. Consent processes for surgical procedures for use of medical mesh be genuine and transparent
13. Implementation of a focused and targeted research program for surgical and non-surgical alternatives to the use of medical mesh
14. Consumers to be involved in developing the credentialing process for removal and implantation of medical mesh

15. Consumer participation and involvement in identifying the extent of need for physical, emotional and psychological support for consumers, families and carers following adverse health outcomes through medical mesh implantation
16. The eligibility criteria for the disability pension be examined to ensure that consumers adversely effected by medical procedures involving medical mesh implantation are supported
17. The need for State Government advocacy for the recognition of medical mesh injuries as a Total and Permanent Disability and as eligible for Income Protection
18. The need for State Government advocacy for recognition of medical mesh injured people as eligible for the Disability pension and support through the National Disability Insurance Scheme
19. Development of a communication strategy regarding the known complications and impact of medical mesh implantation and options available for people experiencing adverse health outcomes following implantation.

## Conclusion

SA Health has demonstrated commitment to supporting women adversely effected through implantation of medical mesh through the work to implement the recommendations from the '*Senate Inquiry: Community Affairs References Committee (Senate Committee) on transvaginal mesh and related matters 2018*'. However, there is still a long way to go to ensure that all South Australians adversely effected by implantation of medical mesh are supported physically, emotionally, psychologically and financially.

High performing health and community services support consumers to be self-determining and self-managing, so people can achieve what matters to them and respect and share decision-making at all levels: individual health care, services and policy.

Engaging consumers (and their carers and families) in improving health care safety and quality means creating effective partnerships between those who provide care and those who receive it. A partnership approach allows consumers to access the health care and outcomes they need, want and value through consumer influence on the design, delivery and value placed on health and community services.