

For the good of the many – HIC submission to the Senate Inquiry



FOR THE GOOD OF THE MANY

Submission to the Senate Inquiry into the number of women in Australia who have had transvaginal mesh implants and related matters

Curated by the Health Issues Centre on behalf of the 1,900 women who shared their lived experience



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“It takes a thousand voices to tell a single story.”

– Native American proverb

One of a thousand:

“The mesh has ruined my life, my career, my marriage and my daughters can't remember NOT seeing their Mum in pain.”

This submission has been produced to ensure that the women whose lives have been impaired and in many instances ruined as a consequence of gynaecological mesh implants, will be heard and helped and that the systemic failures that led to their suffering be held to account.

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Survey sponsored and supported by Health Consumers Queensland, Health Consumers' Council (WA), Health Consumers Alliance of SA, Health Care Consumers Association (ACT), Health Consumers New South Wales

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EXECUTIVE SUMMARY

Over six weeks in April and May 2017, the Health Issues Centre (HIC) conducted survey research specifically to inform this Inquiry as to the number of women in Australia who have undergone vaginal mesh implants and the proportion of these that have experienced adverse outcomes. At the time of writing we have received over 1,900 survey responses with 58% of respondents claiming that the procedure failed to resolve their health concerns and 65% of these describing their ongoing pain as severe (23%), debilitating (31%) or unendurable (12%). (Full survey results Appendix 5.)

Our research methodology was shaped by our conviction that adverse impacts had been dramatically under-reported for a variety of reasons but most importantly because many surgeons failed to accept the claims of their patients that their symptoms were mesh related. In addition many women have been left so shattered that they do not wish to add the further stress of public disclosure to their private pain.

This submission is entirely based on the lived experiences of these women. Each statement represents a unique individual and we have made no attempt to editorialise their comments other than to de-identify their stories and remove references to specific names and circumstances.

While HIC is party to a joint submission of all state peak health consumer bodies and supports all of its recommendations, we felt it was important to submit these testimonials as a stand-alone submission because these women deserve to have their voices heard without further intrusion into their private and intimate pain.

And there is another reason. Much of the debate about the severity of this problem has been framed in terms of the good outcomes for the many outweighing the unfortunate experiences of a few. Health spokespeople continue to refer to TVM as the “gold standard” in dealing with prolapse.

Our health system is built on social equity values such as a universal duty of care, not on a cost/benefit analysis that accepts the unavailability of collateral damage. We present the lived experience of our respondents to collectively remind us of the human dimensions of this tragedy and to ensure that our sense of humanity is not subordinated to a statistical dispute over acceptable failure rates.

While it may fall outside the terms of reference of this inquiry we cannot avoid drawing attention to the broader implications of this issue, namely the systemic failure of the regulatory institutions and processes established to guarantee the safety and quality of health care in Australia.

This whole of system failure implicates Commonwealth and State health authorities, their instruments and in particular the Australian Commission for Safety and Quality in Health Care (ACSQHC), the Therapeutic Goods Administration (TGA), the various state and federal complaints commissions, a large number of surgeons and GPs conducting or referring mesh implant surgery and the various specialist colleges and professional associations that represent them. These stakeholders have all been asleep at the wheel while this tragedy has unfolded. Their collective failures include:

- failure to adequately evaluate the safety and efficacy of medical devices and procedures;

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- failure to establish a comprehensive register of mesh products and procedures;
- failure of adverse reporting systems to accurately represent health consumer outcomes;
- failure to enforce adherence to the principles of informed consent;
- failure to adopt a patient centred approach to health service delivery;
- failure to apply precautionary principles in the face of mounting evidence of adverse outcomes.

The failure of the health system to protect the women whose lives have been ruined by mesh implants is a catastrophic failure and justifies a more comprehensive inquiry into safety and quality regimes throughout Australia and into their data collection practices.

But this is not just a system failure – it is also indicative of cultural failure. Despite the lessons we should have learned from the under reporting of rape and domestic violence and child sexual abuse we continue to repeat fundamental mistakes.

We choose denial rather than acknowledge system failure. We put the burden of proof on the shoulders of victims who have already been shattered by their experiences. We discredit the victims until they doubt their own lived experience. We shift blame from party to party. We look for closure through expressions of regret rather than genuine repentance. And we obfuscate until the pressure of public outrage forces genuine reform.

To build an effective safety regime we must firstly admit that our current system has failed us. It is only by accepting that this crisis evaded all radar that we can begin the task of rebuilding a safety regime that acts decisively with foresight rather justifies its inaction through hindsight.

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INTRODUCTION

Health Issues Centre (HIC) first became aware of adverse outcomes associated with gynaecological mesh implants in late 2016 through contact with our peer state based consumer organisations and through the mesh reference group convened by the Australian Commission for Safety and Quality in Health Care (ACSQHC).

We assisted the Commission to recruit and facilitate a Melbourne based consultation with eight women who were prepared to speak publicly about the negative impact they had experienced from mesh implants. Their lived experiences were unique but they shared in common the devastating impact mesh had on their lives.

Our contact with these courageous women set in motion a chain of inquiry that convinced us that adverse outcomes had been severely under reported most likely due to women declining to make their private and intimate suffering a matter of public disclosure.

It was decided that in our role as consumer health advocate, we would attempt to reach out to as many affected women as possible to determine whether this was a case of a few unfortunate outliers, or something greater.

In mid-April we launched a survey inviting women to share their experiences (good and bad) to help us quantify the extent of adverse outcomes. In six weeks we received almost 2,000 responses and these form the basis of this submission.

To the evident question as to why a small community based organisation could succeed in documenting nearly 2,000 case studies in six weeks where far better resourced institutions (including the TGA) had failed over a far longer time span we offer two factors:

We provided respondents with identity protection;

We went looking for them.

We believe this patient centred approach holds the key, not only to our success in establishing a comprehensive data set, but to providing a model of how our safety institutions could more effectively protect the public interest by focussing on patient experience than relying on clinician reporting .

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METHODOLOGY

In considering the underreporting of adverse outcomes a number of factors were identified:

- Many women were unaware that they had received a mesh implant either because it had been otherwise referred to as a “sling”, “hammock” or “tape”;
- Many women were unaware or unsure if they had had an implant;
- Many women had been disabused by their health specialist of the possibility that their symptoms were mesh related;
- Many health professionals believed (contrary to their patients testimonials) that the procedure had been successful and therefore did not warrant reporting;

But most importantly

- Most affected women having had their physical and psychosocial wellbeing shattered did not wish to deal with the further pain of public disclosure.

It was apparent to HIC that adverse event reporting and the standard complaints lodgement process had failed as instruments to measure the extent of the problem. We determined to reach out to effected women and to provide them with the opportunity to document their lived experience without self-identifying.

Based on previous successful research carried out through social media, HIC established a conversation page (Understanding Pelvic Mesh Implants and Impacts) through Facebook inviting women to anonymously document their experiences through a short and long answer on-line survey.

Participants were required to link to the survey through their own Facebook account (thus assuring the authenticity of contributions) but were de-identified once they reached the survey.

The conversation was then “boosted” (advertised) taking advantage of Facebook’s algorithms to target women who had potentially been mesh recipients. Facebook enables targeting on the basis of defined “interest” allowing us to reach out to women who had experienced urinary incontinence, pelvic prolapse, vaginal surgery or had referenced these issues without necessarily associating their symptoms with mesh.

Most questions in the survey were quantitative questions with the exception of Question 12 which invited the respondents to add any other comments or information. Respondents were also invited to elaborate information in Question 5 (adverse impacts) beyond the four options that were given.

Thematic analysis was used to analyse the comments made in these two sections of the survey. The analysis was conducted by a nurse with experience in social research.

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The data was analysed using a three stage approach: data immersion, coding and then creating categories. The qualitative research program Nvivo was used to collate and code the data. The first stage of data immersion involved the researcher reviewing the responses to Q5 and Q12 to provide an overall sense of the issues raised by respondents. The second stage involved the researcher coding responses that were seen as similar in nature. Once all responses were coded the data was grouped into categories (stage three). In stage three a deductive process was applied to determine if the codes could be categorised into the four key areas:

1. Outcome of the surgery: includes comments on the immediate outcomes of the surgery.
2. Secondary surgical interventions - includes descriptions of subsequent surgical procedures required resulting from the mesh implants.
3. Impact of the surgery on quality of life: describes women's descriptions of how mesh has affected their lives, both the overall impact and the various symptoms/complications experienced.
4. Understanding of the implications of surgery involving mesh implants: Perceptions of level of information given about mesh prior to surgery and experiences of support from health professionals with complications that have occurred post surgery.

1564 unique-individual comments were coded. Most responses included information that fitted with multiple categories and these were given multiple coding.

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SUMMARY OF FINDINGS

Respondents were given the opportunity to provide open-ended answers for two questions, 5 and 12. Under question 5 they were invited to elaborate on adverse impacts they had experienced. 335 out of 654 respondents to this question chose to leave a comment.

Under question 12 respondents were invited to leave further general comments about their experiences. 821 respondents chose to leave a statement.

The following categorisations were selected as best representing the two sets of comments received. Because not all respondents chose to leave comments but many comments fell into multiple categories, the number of references in each category do not necessarily correlate with the proportionate results represented in the survey.

The entire log of comments received categorised under the four categories have been included as appendices. While they are listed as appendices they are the basis of this submission and we commend them to members of the Inquiry as integral to this submission.

Category	Code	Description	Number of References
Outcome of the surgery	Surgery resolved my problems	Surgery resolved their symptoms and they were happy/satisfied with the outcome. It should be noted that many women indicated that overtime their symptoms had returned. Some women in this category also indicated that they had other symptoms but were unsure if they were related to the mesh implants.	121
	Surgery resolved symptoms but caused other issues	Surgery fixed their prolapsed problem but other issues caused by the surgery were far worse than the symptoms experienced with the prolapse.	23
	Symptoms persist post surgery	The procedure had little or no impact on symptoms includes women who indicated that their symptoms were worse following the surgery.	115
Secondary surgical interventions	Needed multiple procedures to correct problems	The need for multiple surgical procedures to try and rectify problems related to the mesh implant, in many cases four or more operations. Most indicated that these surgeries had not rectified the problems.	130
	Mesh removal	Attempts to have the mesh removed with varied outcomes. Some had not been able to find a doctor who would agree to remove it; many were told it was not possible to remove the mesh. Most of those that reported having partial removal indicated that it had not resolved their symptoms. A small number of women (n=10) reported that they had gone to USA/UK to have the mesh removed; most of these indicated that symptoms had improved.	51

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Impact of the surgery on quality of life	Major social and physical impact on my life	Major social and or physical impact on quality of life often described as life being ruined/destroyed. Not being able to undertake routine daily tasks, care for their children, financial hardship and emotional distress were frequently mentioned. Some women indicated that they had suicidal thoughts and were scared for the future.	160
	Affected my ability to work	No longer able to work or having to significantly reduce working hours.	34
	Depression/ Anxiety	Mental health issues usually attributed to the impact of the physical problems caused by the mesh implants.	36
	Relationship Issues	Physical complications impacting on family relationships and friendships. Feelings of guilt related to not being able to care for their family. Financial strain cause by multiple surgeries and not being able to work impacting relationships. Some indicated that their marriage/partnerships had ended as a result of the impact of complications.	110
	Sexual problems	Painful sexual intercourse often resulting in avoiding all sexual activity with their partner. Abrasions to the penis from the mesh protruding the vaginal wall. Women spoke of the added distress of having their concerns about this ignored or brushed aside when they tried to discuss them with their doctor.	88
	Pain	Pain featured in the majority of the responses it was frequently described as being constant, and debilitating. Other impacts included; unable to function normally, diminished ability to enjoy life, unable to walk or sit for any length of time due to back and leg pain. Some described the pain as unbearable.	237
	Urinary Problems	Urinary problems such as incontinence and persistent UTIs were the most frequent issues. Others indicated that the surgery had fixed their incontinence but they now had problems related to not being able to urinate or to empty their bladder fully and for some this required self catheterization.	187
	Complications due to erosion of vagina, adhesions or nerve damage	A range of issues related to the mesh eroding the vaginal wall resulting in infections, discharge and adhesions to the bowel and bladder. Issues of nerve damage in pelvic region were also commonly mentioned resulting in pain, loss of feeling and movement in the legs.	130
	Experienced Autoimmune Response	Autoimmune responses included – fibromyalgia, chronic fatigue, arthritis, blood conditions and allergic reactions.	34
	Bowel Problems	Faecal incontinence as a consequence of the erosion problems and/or extreme pain with bowel actions.	34
Understanding of the implications of surgery involving mesh	Did not feel fully informed about mesh surgery and/or regret having the surgery	Not being fully informed about what the surgery involved and/ or not being told about the potential complications. Many of these women explicitly stated that they regretted having the surgery. A large number of the respondents commented that mesh should be banned as they did not want others to suffer as they had.	120

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implants	Felt well informed about the surgery	Felt they had had the procedure clearly explained to them.	12
	Doctors dismissed my symptoms	Feeling distressed because symptoms could not be explained/believed. Being made to feel that their symptoms were not real and/ or unrelated to the mesh implant and in some cases being made to feel they were to blame for their problems. Difficulty obtaining information from health professionals about possible side effects of mesh.	54
	Unsure if problems are related to mesh implants	Significant symptoms following surgical procedures for prolapse but unsure if they had had mesh implants or they knew they had mesh implants but were unsure if their symptoms were due to this.	60

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TERMS OF REFERENCE

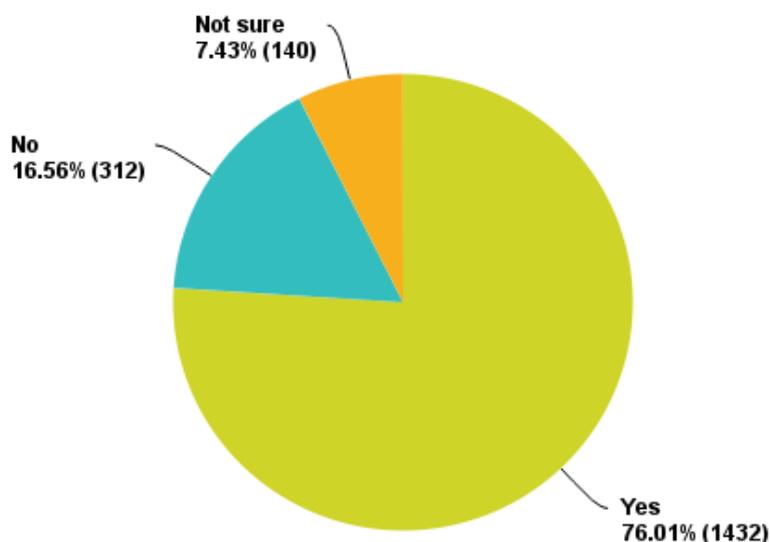
1. The number of women in Australia:

a. who have had transvaginal mesh implants;

Of 1,910 respondents 76% (n = 1,431) reported that they had undergone a mesh implant. Another 7.4% (n = 140) were unsure because they had not been specifically informed of the nature of procedures they had undergone. This in itself is cause for concern and further reflects on the multiple failings of surgeons to obtain informed consent.

Q1 Have you undergone a transvaginal mesh, tape or sling implant as treatment for urinary incontinence or pelvic organ prolapse?

Answered: 1,884 Skipped: 28



Sample responses

“My surgeon didn't even tell me he was going to use mesh”

“I was Not informed by my Gynecologist that I was being implanted with Any Mesh...I have [REDACTED] and [REDACTED] [REDACTED].I have been mutalated and raped by this barbaric unacceptable procedure...Why do Doctors Still implant Anyone with this Toxic Fishing Line...polythene mesh????:

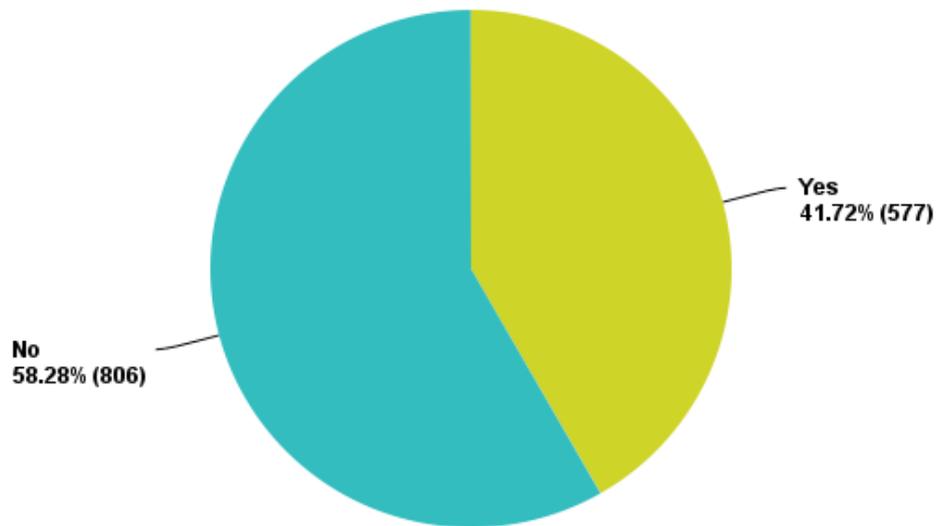
“I was not given any information on the product i was implanted with. I didn't know what mesh was!!!”

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b. who have had transvaginal mesh implants who have experienced adverse side effects;

Q4 Did the procedure satisfactorily resolve your health concerns?

Answered: 1,383 Skipped: 529



and c. who have made attempts to have the mesh removed in Australia or elsewhere.

Attempts to have the mesh removed with varied outcomes. Some had not been able to find a doctor who would agree to remove it; many were told it was not possible to remove the mesh. Most of those that reported having partial removal indicated that it had not resolved their symptoms. A small number of women (n=10) reported that they had gone to USA/UK to have the mesh removed; most of these indicated that symptoms had improved.

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Sample responses

“I have already had 1 surgery to attempt to remove the mesh - that surgery was agony in itself but the mesh has again eroded into my vagina and I suspect my bowel given the pain. My greatest fear is that it will turn septic and kill me.”

“Erosion into bladder and urethra, excruciating pain like a serrated edge knife in vaginal/bladder area, laser surgery x 2 to remove mesh from inside bladder, constant pain for 9 years and for the rest of my life”

“Mesh found its way out of the vagina. Had to be cut off then another operation to remove”

“Multiple uti some drug resistant. Erosion. Two surgery to remove part of mesh. Pelvic floor damage with bowel dysfunction. Multiple days of work. Chronic pain. Severe hip pain walking with a limp. Untreated incontinence worse than when it started.”

“Had to have second procedure to remove mesh leaving me scarred vaginally, impacting on my sexual relationship with my husband. Painful intercourse, incontinence, and loss of sensation (no longer able to have satisfactory orgasm)”

“System rejected tape and became infected resulting in surgery to remove”

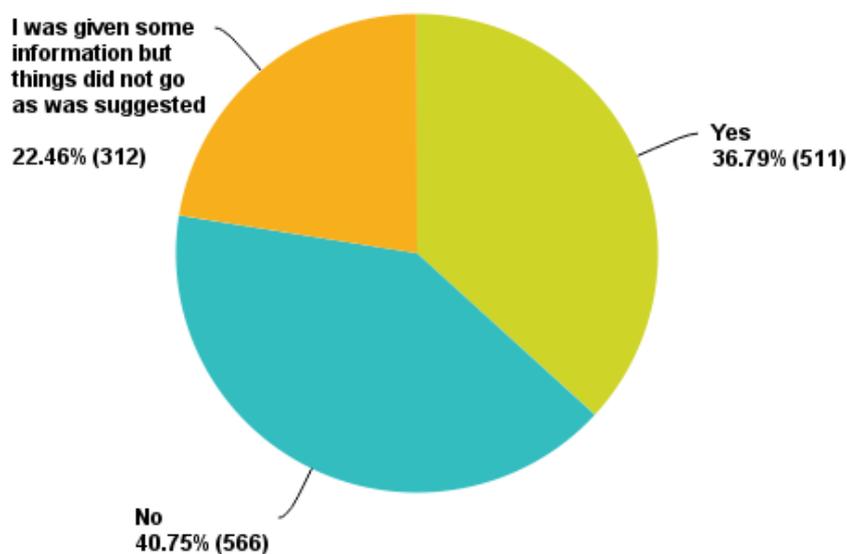
“Some bleeding. Numerous times having to have mesh/wires cut out in Dr's surgery, and public hospitals.”

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2. Information provided to women prior to surgery about possible complications and side effects.

Q3 Do you feel you were fully informed before agreeing to the procedure?

Answered: 1,389 Skipped: 523



Name	Description	No of References
Regret having the surgery and or not informed	Women spoke of not being fully informed about what the surgery involved and or not being told about the potential complications. Many of these women explicitly stated that they regretted having the surgery. Many claimed that they were not informed that they would be undergoing a mesh procedure until after the event.	120

Sample responses

“Poorly informed, most questions were shun aside making me feel silly and making me feel that dr knows all and am not having faith in her. Wish it knew then what I learn later, would never have it done.”

“believe I was not given enough information regarding adverse effects of the mesh. I was told it was being discontinued but not why it was being discontinued.”

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“I had a prolapse mesh implanted, I was not told of the size of this mesh. Was not told it was made of polypropylene.

“Was told a small piece of tape.”

“I wish I didn't have this surgery, I was not fully informed”

“I would not advise any person to have this done ,it recks your life ,so many women have had this done ,it is not some thing that can be fixed easy ,I so wish I never had it done

“Had I know the possible side effects I would have seeked other opinions..

“I was given a printed sheet with information, but not the all the adverse consequences of the operation.

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3. Information provided to doctors regarding transvaginal mesh implants and possible complications and side effects.

Name	Description	No of References
Doctors dismissed my symptoms	Many women spoke of the distress of being made to feel that their symptoms were not real and or unrelated to the mesh implant and in some cases being made to feel they were to blame for their problems. They also talked about having difficulty obtaining information from health professionals about possible side effects of mesh.	54

Sample responses

“had the surgery in April, 2003. [redacted] mesh was inserted. The experience was traumatic and its effects will remain for the remainder of my life. I am fortunate in that my persistent severe abdominal pain is well managed by taking a long-acting Tramadol daily which continues to enable me to live a full life. If however, a dr decides one day that this is all 'in my head' and refused to continue to prescribe the medication, then my quality life will deteriorate to being unbearable. I do not believe that I am addicted to the Tramadol as I have tried other medication with some positive outcome though not as comprehensive and non-intrusive as Tramadol is. I have not needed to increase the dosage since I began it in 2004. The doctors who did the original surgery when the mesh was inserted as well as the ones who performed the subsequent surgeries to remove it, were arrogant, rude, dismissive and protective of the medical personnel involved far above my health or well-being concerns. Thankyou for providing the opportunity to complete this survey. Until my daughter sent me the link to the ABC interview about this, I thought that I was the only one with this problem. PS. I am currently being treated for a supra-pubic abscess which arose without prior symptoms 2 weeks ago. The surgeon managing this for me is of the opinion that it could be the mesh that has worked its way to the surface and causing local inflammation and infection. Treatment is continuing in the form of MANY antibiotics and repeat surgery may be required. We don't have answers at this stage. I feel the past has returned to haunt my health!”

“It has reached a stage that no medical professionals seem to believe I'm in such pain. I am consulting a new general practitioner Thursday with hope. I have no life outside my lounge and constant medical appointments. I cannot be a wife to my husband for the last 2 years. I live off pain killers and have recently been informed by the general practioner that I am leaving I am nothing but a whinger. I was a very energetic person and loved life, did volunteer work. This has all to be given away. Since April 2016 I have done nothing in spiral further and further downhill and all I want are answers.”

“One of the biggest problems is finding a doctor who is sympathetic to these issues and who is willing to try to help fix or alleviate the severity of the pain issues”

“I found it disturbing that before surgery I really liked my gynaecologist as he appeared to be a gentleman but when the surgery didn't go according to plan and injuries occurred he changed from a gentle Dr. Jekyll to an alter ego Mr. Hyde as put up a defensive barrier, took no responsibility and refused to be held accountable. In

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fact in a report to my GP he even blamed me for my slow progress because I refused to learn self-cauterization, thus taking the onus off himself and surgical mistakes”.

4. Any financial or other incentives provided to medical practitioners to use or promote transvaginal mesh implants.

No information on this matter was sought from respondents and this submission does not address the question.

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5. The types and incidence of health problems experienced by women with transvaginal mesh implants and the impact these health problems have had on women’s lives.

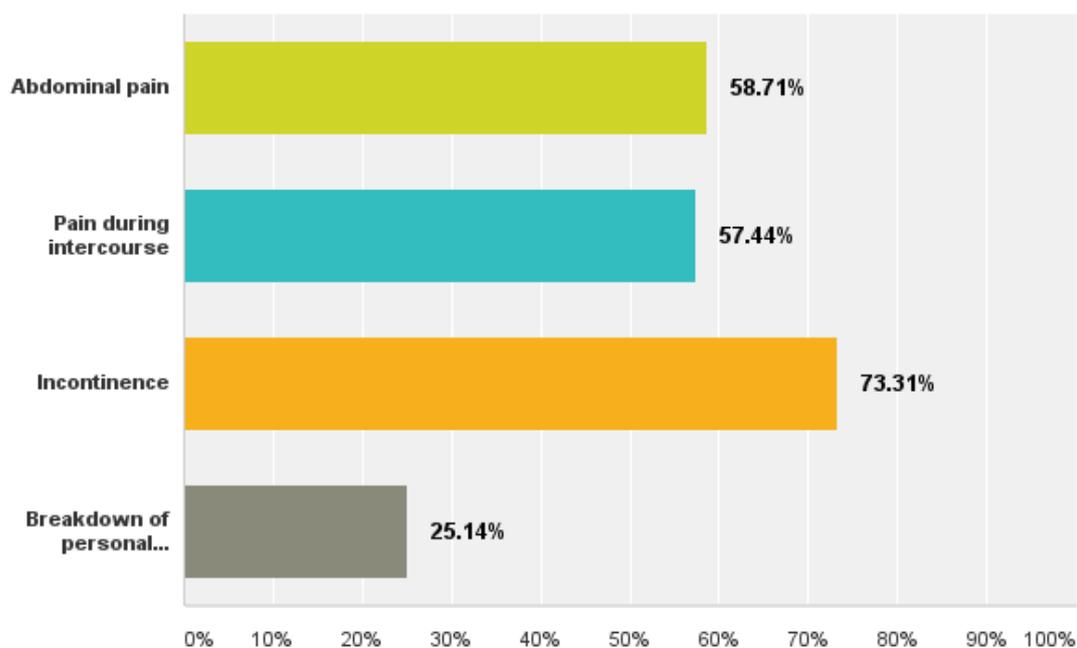
Associated Health Problems

613 women responded to the question: **“Could you specify any adverse impacts you may have experienced?”**

They were given four options predetermined on the basis of existing anecdotal information:

Q5 Could you specify any adverse impacts you may have experienced?

Answered: 712 Skipped: 1,202



Answer Choices	Responses
– Abdominal pain (1)	58.79% 418
– Pain during intercourse (2)	57.52% 409
– Incontinence (3)	73.28% 521
–	25.18%

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Answer Choices–	Responses –
Breakdown of personal relationships (4)	179
Total Respondents: 711	

Respondents were also given the opportunity to provide additional information on adverse impacts. 381 took up this option and their responses have been categorised below and illustrated with representative examples:

Name	Description	No of References
Pain	Pain featured in the majority of the responses. Many women talked of their pain as being constant, and debilitating. They described it as limiting their capacity to function normally and their ability to enjoy life. Many women spoke of being unable to, walk or sit for any length of time due to back and leg pain. Many indicated that they were unable to find any medications to relieve the pain. Some described the pain as unbearable.	237

Sample responses

“Someone should be held accountable for pain and suffering as I have mesh left behind in my bladder which can't be removed and stones keep forming there. I have something also left in my body that feels like a knife digging into me if I lay on my left side wakes me through the night with excruciating pain.”

“Day to day acute pain since 3 operations last feb-march 2016”

“Constance pain in pelvic region which has at times effected my ability to function in walking . When I sit and bend forward it feels like a rod across my lower abdomen. The pain has now radiated to my hips. My bowel movements at times I get a severe stabbing pain in lower abdomen to a point where I want to pass out. I have burning sensations at the side of my inner thighs. I generally just feel so unwell.”

“Pain in both hips/groin, continual, ranging from very mild to not being able to walk.”

“Discharge, pain in bottom, pain in groin, can't walk without pain.”

“Since the day I was implanted its too painful to have intercourse. I avoid functions as its very painful to sit for long in restaurants or functions, painful to walk far on a beach, park or shopping in supermarket. Extreme pain after vacuuming or mopping floors. Unable to work if I have to sit or stand for long periods.”

“Pelvic, groin, vaginal and lower back pain. Quality of life has dramatically changed. I can't interact with my kids or do daily tasks like grocery shopping.”

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Name	Description	No of References
Urinary Problems	A very large number of women spoke of urinary problems. Incontinence and persistent UTIs were the most frequent issues. Others indicated that the surgery had fixed their incontinence but they now had problems related to not being able to urinate or to empty their bladder fully and for some this required self catheterization.	187

Sample responses

“U.T.Is consistently with severe pain and live on antibiotics”

“Retention. Urgency. Spasms. Can no longer sit down to void.”

“Organ perforation, tissue erosion, abscess, fistula, biofilm infection, complete urinary retention.”

“Constant bladder infections.”

“Total incontinence, mesh broke down, implanted itself throughout my abdomen. Many surgeries!”

“The tape was put in incorrectly, I couldn’t pass urine and had problems with my bowels, as tape was pulling my bladder backwards onto my bowel and kinked up my urethra”

“Bladder left with 300mls after emptying so have to cathertise twice a day”

“pain to go to the toilet, every time, uti's all the time. multiple surgery's to try to fix problems. It digs in to me, it has torn through my virginal wall twice. the list goes on”.

Name	Description	No of References
Sexual problems	Many women indicated that they had been unable to have intercourse since surgery as it was unbearably painful. A number of women described sex as being very painful for both them and their partners as the mesh was protruding the vaginal wall and causing abrasions/lacerations to the penis with intercourse. Women spoke of the added distress of having their concerns about this ignored or brushed aside when they tried to discuss them with their doctor.	88

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Sample responses

“This has ruined my life, my relationship, my financial security my physical well being.”

“As a result of pain and discomfort not only is my confidence gone but also my sex life.”

“Infection. Return of prolapse. Fiscal at wound sites. Erosion of sling mesh. Three surgeries. Ongoing pain and pelvic weakness and and extensive scaring. Internal examinations very painful. No sex life.”

“sexual intercourse is not possible”

“sharpness inside vaginal wall, not good for partner.”

“I was not able to have sex again and told I was too old anyway!”

“My mesh partly protruded from my vagina, so some was removed, the rest is pushing into my bladder causing awful problems. My husband was aware of the mesh with intercourse and when I visited my specialist about that he just said "get your husband to have a penile reduction"! No care, no responsibility and just a joke to him. I have suffered awfully since 2004.”

“Mesh protruded and cut my partners penis during intercourse”

“Loss of sex life due to pain”

“Bleeding, inability to walk long distances, problems going to the toilet, mesh scratching my partner”

Name	Description	No of References
Experienced Autoimmune Response	Women reported a range of autoimmune responses that they believed or had been told by doctors are related to their mesh implants. Conditions included – fibromyalgia, chronic fatigue, arthritis, blood conditions and allergic reactions.	34

Sample responses

“One year after undergoing surgery I developed scleroderma, a serious autoimmune disease. I put out a general enquiry to women through the scleroderma website and have found that this my experience is not uncommon.

My rheumatologist has said to me she is at a loss to understand why I have this disease, my medical history has no risk factors. I have 7 siblings including a twin sister none of whom have any associated medical history to indicate a pre disposition to auto immune diseases.”

“Was diagnosed with Chronic Fatigue Syndrome in 2014 with symptoms starting post surgeries in 2012.”

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“I have [redacted] my surgeon implanted this in me posteriorly and [redacted] mesh anteriorly. I have chronic pain in both hips and both knees pain in both hands, back, neck, elbows. Auto immune diseases- Pernicious Anemia, diverticulitis, IBS, Fibromyalgia, chronic urinary tract infections, mesh infections, erosion of mesh in vagina, foreign body response. Blurred vision, sweats, headaches. Reactive Osteoarthritis and suppressed immune system. Vaginitis naturopathy. Nerve pain. Brain fog, PTS, anxiety, depression. Over the years many hospital admissions due to pain and Diverticulitis and infections. I have been unable to have sex since first surgery in 2007.”

Name	Description	No of References
Complications due to erosion of vagina, adhesions or nerve damage	Large numbers of women reported a range of issues related to the mesh eroding their vaginal wall resulting in infections, discharge, adhesions to the bowel and bladder. Issues of nerve damage in pelvic region were also commonly mentioned resulting in pain, loss of feeling and movement in the legs.	130

Sample responses

“3 pelvic abscesses, 2 leading to more surgery with nothing resolved,. Left with 2 areas of 'exudate' filled areas of fibrous scar tissue. Intermittant Bowel pain, especially when going to the toilet, Issues for surgery Still basically there... has been made worse actually”

“Vaginal bleeding, intercourse pain during and after sex, husbands penis cut, mesh erosion into vagina, crippling pain affecting walking, sitting, driving. Pain even when laying down. Continuous pain 24/7. Sleep deprivation, no pain Meds worked, excruciating pain in hips, buttock and legs. Countless visits to specialists for umpteen spinal blocks that were useless. Mesh erosion surgery which also discovered part of the mesh kit had dislodged into my groin area. Pre- mesh I was attending gym everyday and cycling 60-80 km a week. Post surgery I was a cripple suffering depression, anxiety and wanting to die to escape the pain. Family and marital issues arose and escalated as result. I have had inflammation issues constantly since mesh. Eventually pudental nerve entrapment. I had to go to Istanbul for pudental nerve release surgery.”

“Erosion into bladder and urethra, excruciating pain like a serrated edge knife in vaginal/bladder area, laser surgery x 2 to remove mesh from inside bladder, constant pain for 9 years and for the rest of my life”

“Constant odourous vaginal discharge and bleeding”

“Mesh erosion, Hardened mesh exposed and cutting vaginal wall, random swelling everywhere(foreign body response, Auto Immune disease, fibromyalgia, teeth falling out, poor eyesight, poor hearing, chronic fatigue, chronic depression, Anxiet, panic attacks, swollen lymph glands, sciatic nerve pain from my back to my knees, groin nerve pain, weight gain,skin rashes, vaginal bleeding, blood in stools, costochondritis, joint pain and swelling, poor hygiene due to energy levels, broken relationship, cant work, no money, very little movement, extreme exhaustion, miissing out on kids and grandkids fun times, bedridden 5 days out of 7, extreme sweating, NO QUALITY OF LIFE...SUICIDAL TENDENCIES etc etc etc”

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Name	Description	No of References
Bowel Problems	Women spoke of the embarrassment of faecal incontinence that was a consequence of the erosion problems, other described extreme pain with bowel actions.	34

Sample Responses

“inability to hold on if I need to poop, many embarrassing moments, having caused me many times to consider quitting my job”

“Loss of bowel control have had nearostimulator fitted post op”

“vaginal & rectal bleeding, uti infections, lower back pain, groin pain, bladder & bowel incontinence, pelvic pain, can't stand or sit for long periods, anxiety, depression etc etc”

“It has not fixed the problem I now have difficulty having a bowel movement due to the stitching being too tight I went through all the pain and discomfort of the procedure for nothing. But now find I have difficulty going to the toilet”

Women were also invited to comment on how their mesh procedure had more generally affected their life:

Name	Description	No of References
Major social and physical impact on my life	Large numbers of women spoke of their life being “ruined” by the mesh implant. They spoke of not being able to undertake routine daily tasks, care for their children, financial hardship and emotional distress. Some women indicated that they had suicidal thoughts and were scared for the future.	160
Affected my ability to work	A number of women indicated that they could not longer work or had to significantly reduce their working hours.	34
Depression/ Anxiety	A number of women spoke of having mental health issues as a result of the physical problems caused by the mesh implants	36

“6 months ago I loved life, was happy healthy and fit. When I went for a routine pap smear I was talked into having a TVT. What should have been a simple procedure left me broken. Traumatized, in pain and dreams

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shattered. Since then my life is hell. I am near suicidal due to pain and bladder dysfunction. My entire family is traumatised. Fear the future”

“This has ruined my life, my relationship, my financial security my physical well being.”

“My life has been ruined. I’m a mum im also only 32 years of age and the meshing procedure that was done on myself has not been done on anyone of my age before i have suffered everyday from the day i came out of surgery. 12 hours after i was back in with my bladder shut down and bowel. took three dys for them to start back up. I know also can walk the pain is phenomenal and i need a walking stick. I wet myself non stop and have no control on my bladder and bowel. I cant pass urine properly and sex well not for me ever as the pain is lik being run over by a steamroller. I cant be a mum this hurts more than any pain as i can no longer hold my two year old daughter. i have seen specialist to be told nothing can be done for me as im so complex due to y Endometriosis now attaching itself to the meshing as im progressive stage 5 endo surgery is now out as my chronic pain is to wide spread. Im 32 my life is over i take 25 tablets plus a day and live in my room. i cant go out i cant leave as the cold at this point has me house bound and i contantly am bed ridden. this is no life and have tried to take mine due to this pain with it falling on deaf ears all the time as womans issues are just so overlooked i know this as i have tried to take it to court to be seen by our government to have it rejected before being seen. This is sadly the truth of our lives nothing but pain.”

“Vaginal bleeding, intercourse pain during and after sex, husbands penis cut, mesh erosion into vagina, crippling pain affecting walking, sitting, driving. Pain even when laying down. Continuous pain 24/7. Sleep deprivation, no pain Meds worked, excruciating pain in hips, buttock and legs. Countless visits to specialists for umpteen spinal blocks that were useless. Mesh erosion surgery which also discovered part of the mesh kit had dislodged into my groin area. Pre- mesh I was attending gym everyday and cycling 60-80 km a week. Post surgery I was a cripple suffering depression, anxiety and wanting to die to escape the pain. Family and marital issues arose and escalated as result. I have had inflammation issues constantly since mesh. Eventually pudental nerve entrapment. I had to go to Istanbul for pudental nerve release surgery.”

“Words can't describes the horror the mesh has done”

“I would not advise any person to have this done ,it recks your life ,so many women have had this done ,it is not some thing that can be fixed easy ,I so wish I never had it done ☹”

“When I have days that I can't function without chronic pain I don't want to live anymore”

“Constant pain depression lack of quality of life”

“I am truly humbled being so incapacitated”

“Worst decision of my life.”

“I have lost my career and my ability to walk, sit or stand. My insurance company does not recognise my disability.”

“Mesh destroyed my life in so many ways.”

“I can't work!”

“3.5 years later I have to lay in bed for 20 hrs a day due to pain. I haven't been able to sit without being in agony since I woke from surgery.”

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6. The Therapeutic Goods Administration's:

- a. role in investigating the suitability of the implants for use in Australia;**
- b. role in ongoing monitoring of the suitability of the implants; and**
- c. knowledge of women suffering with health problems after having transvaginal mesh implants.**

We hold the TGA specifically accountable for a number systemic failures including:

- Failure to conduct clinical trials into the efficacy and safety of the various mesh kits;
- Failure of their adverse events reporting system to effectively capture the extent and severity of adverse outcomes;
- Failure to act on international warnings (including FDA) and Australian based research (dating back to 2003) in a timely or decisive manner;
- Failure to take action to force manufacturers to recall products in disrepute
- Failure to take appropriate action based on precautionary principles by elevating the risk status of mesh implants and to proactively warn the health industry and consumers of the potential for unintended consequences;
- Failure to establish risk profiles for mesh procedures thereby making it impossible for women to make informed elective decisions.

But we question why the Inquiry has limited its terms of reference to only one institution, the TGA.

We submit that this health crisis is indicative of a catastrophic failure of the entire safety and quality regime created precisely to safeguard the public from unintended consequences. This implicates all stakeholders in public health including state and federal health departments, the TGA, the Australian Commission for Safety and Quality in Healthcare (ACSQHC), the various state and federal consumer complaints commissions and offices, the relevant professional Colleges and associations and the many (but certainly not all) clinicians who failed in their duty of care to their patients.

Specifically we question why it has taken until 2016 for the peak national health safety agency, the ACSQHC, to engage with this problem.

We question how the various Complaints Commissions and Offices could have received significant numbers of mesh related complaints without finding cause for alarm and initiating proactive investigation;

We question the tepid and equivocal responses of the relevant professional Colleges in the face of mounting evidence that a significant part of the problem lies with inadequate specialist training in mesh implant procedures;

It is vital that the government immediately establish a register of products and procedures and determines which of these institutions should carry primary responsibility for establishing and maintaining it;

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And it is vital that there be a review of current data collection methodologies which rely on health professional reporting of adverse events.

It is illuminating to note that the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, in its updated statement on “Polypropylene vaginal mesh implants for vaginal prolapse”, defines informed patient consent in terms of awareness of “potential benefits and complications” which includes many of the adverse consequences reported by our survey respondents. We submit, however, that in the absence of statistical risk profiles, the dangers associated with these complications has been consistently downplayed by surgeons meaning that their patients could not make an informed judgement when giving consent.

The calibre of a safety regime is measured, not by how it manages business as usual, but how it galvanises its resources to pre-empt emerging health crisis and respond quickly and decisively to protect the public. By any measure of this fundamental criteria, the system has failed abjectly.

Behind this system failure, however, we add the cultural shortcomings of a health service industry that espouses patient centred care but manifestly continues to operate according to its own assessment of the best interests of consumers.

Sample responses

“Take the mesh off the market, so no other women suffer and make the surgeons who knew it was bad to be accountable”

“Mine and many women’s lives have been completely destroyed because of these pelvic meshes. They need to be banned from use and taken off the market. “

“i would like to see all mesh banned from use. With TGA fully investigated for allowing such devices to be implanted with little or no success and bad complications and that propylene be banned And proper surgeons that can remove the mesh fully in Australia”

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7. Options available to women to have transvaginal mesh removed.

Name	Description	No of References
Mesh removal	<p>Many women indicated they have tried to have the mesh removed. Some had not been able to find a doctor who would agree to remove it, many were told it was not possible to remove it. Most of those that reported having partial removal indicated that it had not resolved their symptoms.</p> <p>A small number of women (n=10) reported that they had gone to USA/UK to have the mesh removed; most of these indicated that symptoms had improved.</p>	51

Sample responses

"I could not get my tvto fully removed in western australia. I travelled to the USA for full removal."

"I subsequently travelled to the USA for a mesh removal as no surgeon in Australia was capable of the removal."

"I had a [REDACTED] implanted in 2006 and had issues right from the get go, multiple surgeries to try and fix problems ended up going to the USA for removal at great cost physical emotional and financial cost, but the was no one in Australia that could successfully remove my mesh . It needs to be banned"

"Two trim revision surgeries within 2 years of implant. First cut through the tape causing SUI to start again. Even removal surgeon (when I finally found someone) was skeptical that removal would assist my pain."

"I had removal in the USA"

"Recently I had an operation to TRY and REMOVE mesh. Some pieces were removed a few stitches. Told it was impossible to remove the mesh (entirely) as my body had "claimed it". Was very uncomfortable. Have had 2 ops..previously..2007/2008 in Canberra..1st mesh was attached to? (I have diverticulitis). 2nd mesh attached to hips. Now waiting on another op..to get a Y shaped MESH to put all back in place, ASAP..Have aching hips, aching knees, aching legs..for "NO" reason?"

"I have had an operation to remove mesh, only part could be removed. The incontinence is worse. It took eight years to find a Doctor willing to operate. I have ongoing infections. The urether was damaged in both operations."

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RECOMMENDATIONS

The nature of this submission requires us to prioritise the interests of its contributors. We therefore recommend:

1. That a medical advisory service be established in each state to provide compassionate, supportive and expert remedial advice and treatment to women suffering chronic adverse outcomes including mental health and socio-economic impacts;
2. That training and certification of surgeons in implant procedures be urgently introduced;
3. That provision be made for the training of an appropriate number of Australian surgeons in clinical best practice for full mesh removals;

At an institutional level we further recommend:

4. An integrated review of the roles and processes of the relevant institutions with a view to ensuring:
 - a. The efficacy and safety of all mesh variants is established through clinical trials prior to their general release;
 - b. A register of mesh products and implants is established to track all future procedures;
 - c. That a patient generated system for recording adverse events is established as an early detection system of emergent unintended public health trends;
 - d. That mesh implants are categorised at an elevated risk level requiring a greater level of disclosure informing consent;
 - e. That until such time as reliable information can be provided on the statistical risks associated with adverse outcomes, surgeons and patients be dissuaded from electing mesh implants as a default option;
5. That manufacturers be required to recall all distributed inventory when their products are withdrawn from market

The majority of our recommendations, however, are represented in the submission on behalf of all state peak consumer health bodies and we reiterate or endorsement of these rather than replicate them here.