



Adverse outcomes from hernia mesh

A report on the consumer experience of mesh implants used for treatment of hernia

used mesh given general sign said cause nothing really information operation
think hernia repairs pain definitely surgery mesh repair mesh
problems told given information risks going hernia possible
surgeon mentioned complications never time post surgery procedure
detail used taken know fix discussed

February 2019



OVERVIEW

In November 2018, the Health Issues Centre (HIC) undertook social research to investigate adverse health experiences among Australian men and women who had undergone a medical device implant. The research was product non-specific in order to identify any devices that demonstrated a pattern of failure.

Foremost in reported products were mesh implants used to treat hernia. On this basis HIC specifically targeted people who had suffered a hernia (irrespective of their treatment intervention or outcome) to better understand the nature and impact of their adverse outcomes.

Over a period of four weeks, 183 respondents reported hernia mesh related injury across a range of brands and across categories of hernia.

The survey results and individual testimonials (see appendices) highlight a number of serious problems with hernia mesh implants which may point to inherent deficiencies with the product but which also highlight a breakdown of safety and quality provisions intended to ensure public safety and to manage unintended outcomes.

This breakdown includes systemic failure to obtain informed consent prior to procedures; failure to validate patient-reported adverse outcomes and failure to access available care and treatment options where an adverse event has occurred. The research shows that:

- The vast majority (87 per cent) of respondents believe they were not given sufficient pre-operative information on risks, impacts and options to enable informed consent to a hernia mesh procedure.
- Most respondents (91%) suffer ongoing post-operative chronic pain as well as other physical and mental health impacts that are frequently debilitating in severity. Adverse outcomes commonly include depression, incontinence, allergic reaction, infections, disfigurement and neurological issues.
- Many respondents reported that the impact of mesh related injury extended beyond medical consequences and included the loss of relationships, social networks and employment prospects as well as general economic hardship.
- Most respondents claimed their self-reported adverse impacts were subject to gross minimalization by their GPs and surgeons. Sometimes clinicians simply refused to acknowledge that there was a problem.
- Patients were frequently made to feel responsible for their outcome by being overweight, difficult/lying or suffering hypochondria.
- 86.7 percent of respondents had either not received treatment to address their implant injuries, or treatment had not been successful. Only 8.7 per cent of respondents said they have had successful treatment to address the problem/adverse outcome.

KEY FINDINGS

Demographics

- More than 70 per cent of survey respondents were men.
- The majority of survey respondents were within the 40-69-year age bracket (81.6 per cent), with the largest cohort of responses (38.7 per cent) derived from people aged 50-59.

- 45 per cent of surgeries took place in public hospitals, 55 percent in private hospitals.
- Only 40 per cent of respondents specified the type of hernia they had been treated for. Of these, 50 per cent nominated inguinal hernia and 14 per cent umbilical hernia.
- Only 20 per cent of participants could identify the product that had been implanted with the most prominent brands being CR Bard, Covidien, Johnson & Johnson and Medtronic.

Absence of informed consent

- 87 per cent of respondents believed that they had not been given sufficient pre-operative information to enable informed consent to mesh procedure.
- Many respondents said that their doctor or surgeon did not provide any information about the procedure, and in many instances the use of mesh was not even discussed.
- Risks and complications were minimized or not mentioned at all.
- Many respondents said that had they been informed of risks and options they would not have proceeded with the mesh surgery.

Adverse outcomes of hernia mesh implant surgery

- 91% of respondents listed chronic pain as an adverse outcome of their surgery. 28% cited a neurological outcome, 16% an allergic reaction and 15% incontinence. 63% cited “other” outcomes including adhesions, sexual dysfunction, chronic fatigue, infections, depression, bowel/gut issues and disfigurement.
- Severity of impact ranged from discomfort and inconvenience through to total physical and mental health debilitation and the loss of relationships, social networks and employment.

Negative response by clinicians to patient-reported outcomes

- More than 70 per cent of survey respondents reported their adverse outcomes to their clinician.
- The majority of respondents reported that their adverse outcomes were trivialised or discounted by the GPs and surgeons. Sometimes clinicians simply refused to acknowledge that there was a problem.
- Patients were made to feel that they were the problem for being overweight, difficult/lying or suffering hypochondria.
- Patients were also made to feel that they were overreacting and needed to lower their expectations or to toughen up.

Remediation

- Only 8.7 per cent of respondents said they have had successful treatment to address the problem/adverse outcome.
- 28 per cent said they had received treatment but that it was unsuccessful.
- 58.7% have not received treatment to address the problem.

METHODOLOGY

In November 2018, the Health Issues Centre (HIC) undertook social research to investigate adverse health experiences among consumers who had undergone a medical device implant. The investigation was prompted by unsolicited, anecdotal reports from affected consumers.

Using social media as its primary investigative tool, HIC used a Facebook conversation in conjunction with a de-identified, long-answer survey to explore the experiences, attitudes and sentiments of consumers in relation to the research question: *Do you have a medical device that's failed?*

The research was product non-specific in order to identify any devices that demonstrated a pattern of failure.

Participants were invited to discuss their experiences or fill out the linked survey. Algorithms were used to define cohorts of consumers who were likely to have required medical devices and posts were promoted ("boosted") to reach them. Over the space of four weeks in excess of 55,000 consumers were reached.

To maximise completion rates, the survey was constrained to seven material questions (depending on the response pathway) and three demographic questions.

The primary target audience was defined as residents of Australia aged 18 and above. Algorithms were used to define cohorts of consumers who were likely to have required medical devices and social media posts were promoted ("boosted") to reach them.

Over a period of a month the campaign received over 340 consumers completed surveys of which 183 related to hernia implants.

While other identified medical devices will be the subject of their own reports it can be said that consistent patterns of systemic failure were identified across all devices and implants. This leads to the conclusion that general reform is required in the way medical devices are approved and their post-market monitoring and the need for strengthened provisions around informed consent and adverse event reporting.

This report is a summary of findings ONLY of those consumers who reported an adverse outcome from hernia mesh repair.

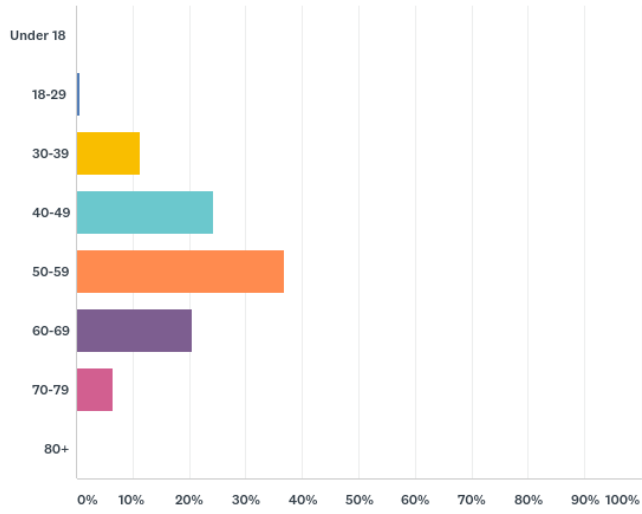
DETAILED FINDINGS

While both men and women were targeted, men represented over 70% of survey respondents.

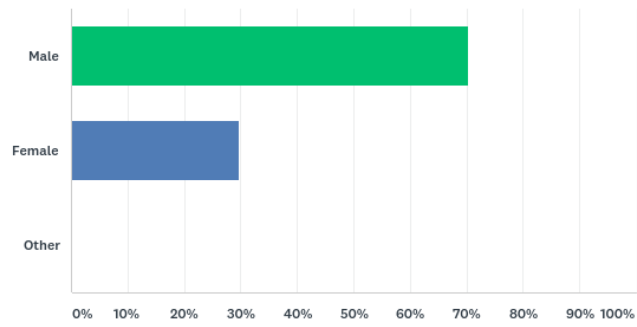
The majority of survey respondents were within the 40-69 year age bracket (81.6%), with the largest cohort of responses (38.7%) derived from people aged 50-59.

45% of surgeries occurred in public hospitals.

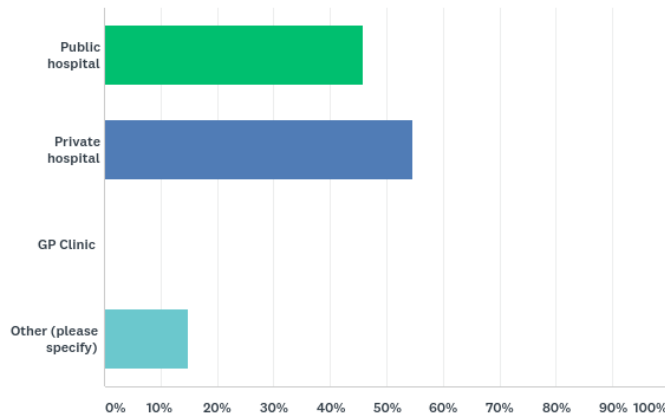
Q8 Your age group?



Q9 Gender



Q7 Where was this procedure carried out?



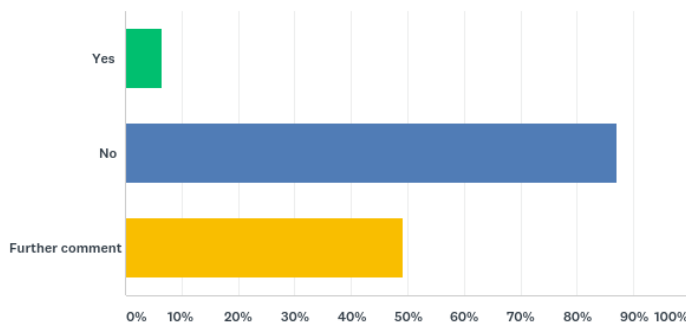
Type of hernia and implant brand

The findings of the research indicate widespread adverse outcomes from hernia mesh implants across all types of hernia. Only 40 per cent of respondents specified the type of hernia they had been treated for. Of these, 50 per cent nominated inguinal hernia and 14 per cent umbilical hernia.

Even fewer participants (20 per cent) could identify the product that had been implanted with the most prominent brands being CR Bard, Covidien, Johnson & Johnson and Medtronic.

Informed consent

Q2 Do you believe you were given enough prior information about the risks and benefits of this product to give informed consent to your procedure?



87% of respondents believed that they had not been given sufficient pre-operative information to enable informed consent. (A full account of the 91 supplementary comments provided by participants is listed in Appendix 1.) Their comments reflected several common themes:

Risk minimalization

They were reassured that the procedure was safe, well proven and that their recovery would be swift:

"No there was no negative information provided I was told that I should be able to play football in about 4x weeks' time"

"surgeon told me very safe"

"I was told there was a slight risk of hernia but nothing about inflammation, seromas etc. Was also not aware it was plastic"

"No warning at all. However a few minutes before the surgery the Surgeon popped into my enclosure and asked me if i was sure i wanted the mesh as he would be happy to do it without. He didnt however mention anything about problems with it and it was my second bilateral inguinal hernia repair".

"I was told it had a high success rate and was less than 1% risk of complications. I was not offered any other methods and was given most information on the theater table."

Complete absence of information

In many instances the use of mesh was not even discussed

"Not told I was having mesh or anything about type"

"The doctor never discussed the procedure at all"

"Was just told I had triple hernia and sign here for the operation. When they did the surgery nothing was said to me"

Risk assessment and options

Many consumers made the point that had they been informed of risks and options they would have made different choices:

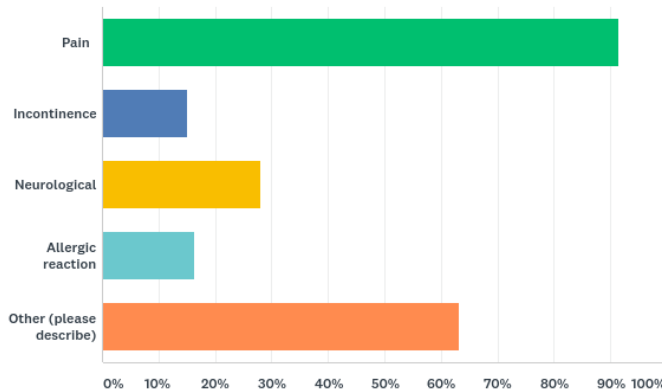
"Definitely was not informed of alternative options ie non mesh repair, sit and wait. Made to think it's routine/common and run of the mill surgery and focus was more on non-recurrence of hernia than other potential complications of mesh repair eg chronic pain was not really discussed. I have since done research and know that prior to my surgery in 2013 and 2014, there was already many papers on chronic pain post inguinal hernia surgery"

"It's ruined my life I would have never done it if I knew there were risks involved"

"Never knew I'd suffer like I do, I would have left the hernia how it was"

Adverse Outcomes

Q3 What has been the unintended outcome (you can select more than one)?



91% of respondents listed pain as the outcome of their surgery. 28% cited a neurological outcome, 16% an allergic reaction and 15% incontinence. However, 63% cited “other” outcomes. These include adhesions, seromas, sexual dysfunction, chronic fatigue, infections, depression, bowel/gut issues and disfigurement in an array of combinations and individual manifestations. A full report of adverse outcomes provided is listed in Appendix 2.

Impact

Impact reports ranged from discomfort and inconvenience through to total physical and mental health debilitation and the loss of family relationships, social networks and employment prospects.

Self-esteem/confidence

“It has had a psychological effect by not being able to perform simple things that I should be able to do. And not be able to wear the clothes that I want.”

“Self doubt when not believed by doctors that it is causing pain. Impaired immune system”

“No confidence to have intimate relationship”

“I use to feel like I was useless, I still do but getting into mindfulness and meditation I have found things easier to cope with, but it doesn't take away the pain”

Debilitation

“I am no longer able to travel freely, am often in a great deal of pain and have to monitor myself constantly to adjust my way of life to accommodate the changes in my body”

"I can no longer drive. Playing with my children and nieces and nephews is out of the question because I have to always feel guarded of where I am sore. Basically my whole life has been turned upside down and trying to tell specialists and doctors that it is the mesh causing my pain. It is like they are just dismissive right away and try placing the blame for the pain on things like me smoking weed is causing my pains"

"Life changing for the worst"

"Can't work Loss of income Chronic pain Relationship strain Mental health" I am very angry and bitter about what has happened to me and how it has impacted on me and my family. I have not been able to work full-time, the pain takes its toll on me both mentally, emotionally and physically. I am not the husband, father, son, brother or friend that I would like to be. I hate seeing my wife being always on the edge worrying when a pain spike will hit me, when I will become enraged due to the pain I feel."

"Loss of sex life Ended relationship as I was to sick apparently to be fun anymore Have not been to cinemas in years due to fibro and tinnitus Can't have CT scans without fibro flares My nervous system is all over the place some days loud noise can trigger seizures. Also I have not worked since January 2015 Had to by an automatic as driving a manual became impractical extent of nerve damage means I can't clutch with left leg anymore, Had to sell my home in Victoria as could no longer afford the mortgage due to not being able to work, been put on new start since 2015 but apparently even with all the damage I'm not yet eligible for pension, Mesh injuries seem to consistently end me up in financial hard ship No matter what I do as the measures I take to manage the symptoms caused by mesh failure are not cheap but they help to some extent,"

Q4 What has been the impact on you of this experience

A word cloud of terms related to the impact of the experience. The most prominent words are 'pain', 'life', 'years', 'work', 'time', 'mesh', 'uncomfortable', 'much', 'depression', 'limited', 'unable', 'days', 'constant', 'quality', 'life', 'daily', 'pain', 'sitting', 'use', 'operation', 'worry', 'due', 'try', 'want', 'remove', 'fear', 'relationship', 'sometimes', 'life', 'turned', 'upside', 'never', 'sex', 'constant', 'one', 'loss', 'able', 'work', 'suffering', 'issues', 'chronic', 'pain', 'sex', 'life', 'live', 'concern', 'make', 'lack', 'problem', 'groin', 'lost', 'leg', 'body', 'second', 'movement', 'will', 'end', 'gone', 'away', 'longer', 'low', 'level', 'pain', 'put', 'return', 'months', 'anxiety', 'bad', 'excruciating', 'pain', 'Unable', 'work', 'job', 't', 'extreme', 'pain', 'able', 'intermittent', 'hernia', 'income', 'doctors', 'lot', 'ongoing', 'loss', 'income', 'side', 'sick', 'family', 'come', 'exercise', 'still', 'causing', 'health', 'depression', 'Limited', 'take', 'debilitating', 'impact', 'experienced', 'surgery', 'uncomfortable', 'much', 'Reduced', 'discomfort', 'days', 'unable', 'causing', 'pain', 'mesh', 'walk', 'time', 'activities', 'work', 'left', 'pain', 'changed', 'life', 'told', 'years', 'severe', 'now', 'Stopped', 'feel', 'always', 'going', 'severe', 'pain', 'quality', 'life', 'daily', 'pain', 'sitting', 'use', 'way', 'operation', 'worry', 'due', 'try', 'want', 'remove', 'fear', 'relationship', 'sometimes', 'life', 'turned', 'upside', 'never', 'sex', 'constant', 'one', 'loss', 'able', 'work', 'suffering', 'issues', 'Chronic', 'pain', 'sex', 'life', 'live', 'concern', 'make', 'lack', 'problem', 'groin', 'lost', 'leg', 'body', 'second', 'movement', 'will'.

Loss of trust

"Another failed surgical procedure with loss of faith in the medical profession"

"Don't trust hospital, self employed made my work much harder, extreme pain during sexual intercourse,"

"I held my life together while six doctors failed to diagnose the problem over 12 months."

"i dont trust dr as much and when come asking if need hip ect later in life i probly wont have it done due to having the issues and askinh ages i go the dr made feel like it was in your head and not the mesh"

Work/social life

On top of the physically limiting nature of injuries, participants were dealing with catastrophic life altering impacts to their relationships, economic independents and mental health.

“Cannot continue doing my job as a freelance filmmaker. Working now at about 20-30% capacity. Serious impact on quality of life, especially due to pain and fatigue.”

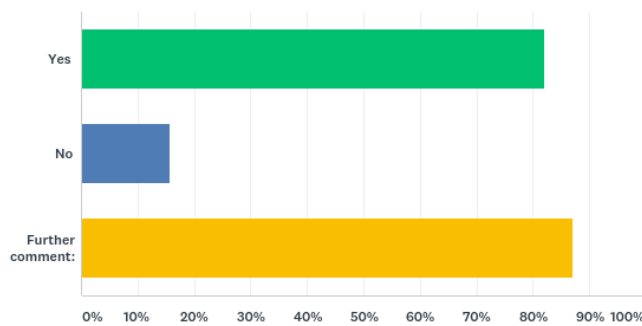
“Stopped work, sometimes cant move outside the house or drive Very limited life”

“Unable to work, disabled unable to walk any distance without a mobility aid. It has affected every aspect of my life”

“Quality of life greatly reduced. No sex no sporting activities. Social interaction greatly reduced”

Response to Complaints

Q5 Did you report your adverse outcome to your clinician and what was their response?



Q5 Did you report your adverse outcome to your clinician and what was their response?

hospital medication now head anything also trying end thought happens doctor since referred
talked nerve cause Dr sent reported weeks problem know issues contact
nothing learn time difficult see discomfort GP deal told live
mesh settle surgeon really pain concerns surgery
post said pain management specialist go kept one different specialist go away
years ultrasound want will later give months hernia repair take body response may
normal denied operation hernia suggested Still found advised

In general, respondents felt that they were subject to the gross-minimalization of the severity of their symptoms. They were either told that their symptoms were “normal”, would recede given time, were something they would have to adjust to or, in extreme instances, were a figment of their imagination.

Normalisation

Patients were told that their experience was not an adverse outcome, but within the realm of normal expectations.

"On numerous occasions, one comment was that it would settle down after a couple of years."

"During consult a few weeks after, said pain was normal and that it should go away"

"Told me could not understand why I would be upset with suffering constant pain and learn to live with it. I could look into permanent nerve blocking procedures"

"I haven't talked to my doctor about it (even though my operation was 12 or so years ago). Although the discomfort is daily, the intense pain is only every now and then which I thought was normal. I only realised today after reading a news story that many others have similar issues after surgery where mesh has been used and I have now realised that there may be an issue with mesh and that it's not meant to be normal."

Invalidate the patient

Patients were made to feel that they were the problem for being overweight, difficult/lying or suffering hypochondria.

"Initially I rang his surgery and spoke to his receptionist who promised me she would get the surgeon to contact me. I rang several times and he did not get back to me. I later discovered that he had sent a letter to my GP suggesting that I was a difficult patient and he would see me if she wanted him to. My GP did not let me know and I only discovered this when I left that surgery and collected the notes to take to the next doctor."

"Was told it was pretty much in my head and the surgery was successful."

"They were not sure why, one dr thought I was making it up to get pain meds another one told me it was all in my mind and then referred me to a physio"

"Went to hospital emergency and essentially told that I was making it up, wasting their time and given 2 panadol"

"Go and lose 37 kilos so we can repair the hernia.he also wrote a nasty letter about me to the referring gp"

Minimise the problem

Patients were made to feel that they were overreacting and needed to lower their expectations or to toughen up.

"I noted my concerns to my GP, 4 weeks post surgery and he referred me back to the specialist. Their response is "just lose weight"

"Said pain was not mesh related. Joked that I wanted the body of a 20 year old."

"O well this some times happens"

"Surgeon told me I was fine and to get back on my bike (literally)"

"Was told it's rare and not much can be done now as it may cause further complications"

“They said that there is nothing more that they can do surgically and that I would have to live with it and that the best management is pain management.”

Denial

Sometimes clinicians simply refused to acknowledge that there was a problem.

“Could not be the hernia patch.”

“There was no admission of wrong practice or errors. Doctors accepted no responsibility for the negative outcomes.”

“My surgeon is in denial that the mesh could be causing my issues and he's not responding to my further communication”

“He was most focused on the fact that his job was done as he couldn't see a recurrence of the hernia. He told me pain will likely resolve itself within 12 months. It hasn't (it's been 4 years). He said he wouldn't contemplate doing any revision surgery and just referred me to pain management clinic and we have not been in touch since.”

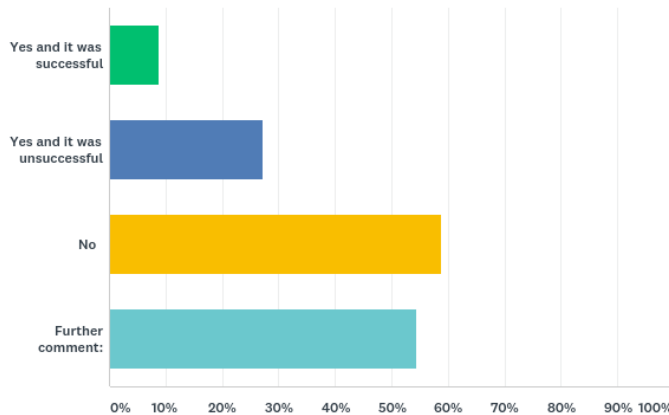
“Difficult to contact the surgeon, when I did he did not want to accept any responsibility.”

“My surgeon is in denial that the mesh could be causing my issues and he's not responding to my further communication”

“Been to 5 different specialists/surgeons Just handball me to the next one”

For a patient suffering pain and other unintended outcomes, there can be nothing more soul-destroying than to have their lived experience invalidated and minimalised. This reflects other social circumstances (rape, domestic violence, sexual abuse) where traumatised victims are made to feel responsible for, or unreliable witnesses to their own experience.

Q6 Have you received treatment to address the problem



Only 8.7% of consumers reported that their condition had been successfully remediated. Alarming, 58.7% have received no treatment to address the problem but this does not mean they hadn't tried.

For many, **multiple tests have drawn a blank:**

"I have been sent for ultrasounds, x-rays, gastroscopy's, colonoscopy's, by specialists. I have been told it might be irritable bowel syndrome or a stomach bug."

"No because nothing was found to be wrong."

Some have been dissuaded from attempting further intervention:

"I have been advised that to have the mesh removed may entail removing some of the bowel and could cause all sorts of other complications,"

"It is hard to find and one surgeon told me there is a risk of death also."

Some are still waiting:

"2.5 years waiting for a colonoscopy. They tried laxatives at one stage but the results were intolerable & it didn't fix it. Apparently I have a large (almost poolball sized) lump where my bowel was pinched off / blocked. (Detected by ultrasound)"

Some believe there is nothing that can be done:

"I assumed there was nothing that could be done about it"

But for most, there only resort has been to attempt pain management:

“Yes, Variety of pain killers! Cortisone injection.”

“Seeing psychologist at pain management clinic only every couple of weeks - advised to not take opiates as addictive, told to pace myself and that’s about it.”

“I’m in a position where pharmaceutical meds make my issues worse so I had to work with my naturopath on practical intervention to help me cope without the dietary intervention and supplements I believe I would not be around today I also believe I would be wheelchair bound as I almost bought a wheelchair in 2015 I realized if I sat down in a wheelchair I was going to die with my multiple issues so I do all I can to stay on my feet, Insomnia from pain issues has also been a major complication, I’m at the point where I can only manage the damage I believe my issues are a life time thing thanks to the implantable mesh device”

“I have been to a Naturopath to try help with the pain in my stomach, it is ongoing, but totally out of my reach financially”

“Amitriptyline With all kinds of side effects”

“Paine killers and anti inflammatory medication with little relief. I get relief at night when i fold a small wheat bag and place at the area of pain and roll onto the pillow to sleep”

“Cortisone injections a few months after surgery. They said nothing else could be done. Just need to live with it. Sometimes I think they didn’t believe I was in so much pain.”

“Drugs and more drugs”

BROADER IMPLICATIONS OF RESEARCH FINDINGS

This report does not set out to determine the quality or safety of the various mesh products used for hernia repair. The limited nature of the research makes it impossible to differentiate between product failure, surgical mishap or the natural variance in post-operative outcomes and foreign body reaction. The reality is likely to be a combination of all the above. Ultimately product safety is the jurisdiction of the Therapeutic Goods Administration (TGA) and we simply advise that the frequency and impact of adverse outcomes from hernia mesh implants warrants closer investigation.

However apart from raising questions about the safety and efficacy of mesh products this research points to multiple failures in health care, not least being the inadequacy with which our health system supports patients experiencing unintended clinical outcomes and the difficulty many clinicians appear to have in acknowledging those outcomes when they occur.

The collective lived experience of patients suffering adverse outcomes following hernia mesh implants points to a perfect storm of systemic failures. This includes a failure by clinicians to ensure patients are provided with adequate pre-operative information to make informed choices; the absence of device registers which in combination with the under-

reporting of adverse events makes it impossible to meaningfully quantify risk; the post-operative minimalization and invalidation of patient reported outcomes; a widespread professional failure to respond empathically to post-operative complaints and the inadequate navigation of care options and remediation when something goes wrong.

At a time when the health system extolls patient centred care as a pillar of good health care delivery it is ironic that the most fundamental aspects of patient centredness are found wanting when put to the test.

The testimonials of participants confirm the high regard and trust most people place in their physicians. This exacerbates the erosion of that trust when subsequent unintended outcomes are dismissed or trivialised. Consumers could be expected to show some forgiveness when something unexpectedly goes wrong but their dismay turns to anger and bitterness when they encounter clinicians who minimise the impact of adverse outcomes, deny responsibility, invalidate the lived experiences of their patients and seek to blame them for their circumstance.

There appears to be an unwillingness or inability by a section of the medical profession to countenance that their own best efforts may sometimes result in life-ruining outcomes. There is clearly a dissonance between their best intentions to “do no harm” and the reality of their patients’ experience. It would seem that physicians, like the rest of the community, have a problem dealing with inconvenient truth.

As social media facilitates the widespread sharing of consumer experiences that once occurred in isolation, the reputation of and confidence in the health system will continue to decline while this disconnect persists.

Acknowledging the problematic consequences of denial by calling for “culture change” is a failure to recognise and eliminate the specific shortcomings of our quality and safety safeguards.

143 cases of adverse outcomes from hernia mesh implants gathered over four weeks should send alarm bells and trigger a further review of the risk profile of mesh products and the circumstances in which they are prescribed.

However, this research also strongly signals that even without product failure, the health system needs better mechanisms to deal with risk and the impact of adverse events, whatever their cause.

Danny Vadasz

CEO, Health Issues Centre

February, 2019