# Auckland Women’s Health Council Newsletter

# December 2022

# Endometrial ablation: another bloody disaster for women’s health

By Sue Claridge

Menstruation has been regarded as a curse, as punishment, as tabooed uncleanliness, and as shameful in un-civilised cultures; while in civilised cultures it has been masked by silence, by euphemism, by mystery and by long dresses. - Fred E. H. Schroeder

For centuries, periods have led to women being shamed, ostracised, believed to be unclean or weak; our “monthly” bleeding masked by silence and often ignorance. Menstrual blood was regarded as anything from unclean to poisonous and outright evil. Pliny wrote that it “that it kills bees by its vapours, makes dogs mad if they taste it, destroys any plant that comes near it,” and Guillaume Mauquest de La Motte wrote, in his 1746 General Treatise of Midwifry, that a menstruating red-haired servant in his house, caused his wine to go sour and pork to spoil.

Even in the 21st century many myths and misunderstandings about women’s periods persist. And, if all the societal myths and misogyny around periods were not burden enough, for many women it seems as if their bodies turn against them, leaving them quite literally, bleeding to death.

Menorrhagia – heavy periods or abnormal uterine bleeding (AUB) – has been recorded for centuries and historically was particularly associated with perimenopause and menopause.

Often, women’s behaviour and lifestyles were blamed for excessive menstrual bleeding, and all manner of “inappropriate” activities were labelled by puritan and/or misogynist doctors as the cause for heavy periods and menorrhagia, including “prurient incitement of passion-stirring pictures, statues, music, novels, and theatres,” “a long visit to cities [and] a diet of exciting food” and, weirdly, singing. Some even claimed that “all sanguineous flow is abnormal, that there should be no show of blood in a perfectly healthy woman.”

For centuries women’s health has been misunderstood, misdiagnosed, ignored or invisible, and “medical” treatment very much the subject of a misguided, misinformed and patriarchal approach. So, it should come as no surprise that the causes of heavy menstrual bleeding were poorly understood and the lack of adequate treatment led to women dying from persistent severe blood loss and fatal anaemia. For the women who survived persistent heavy menstrual bleeding, the only relief was menopause and the final cessation of their periods.

Early modern attempts to control menorrhagia began with bilateral oophorectomy or removal of the ovaries, inducing surgical menopause. Abandoned because of complications, hysterectomy was then favoured as a “cure” for heavy bleeding, but that was not much better.

While hysterectomies were recorded as early as 20 years BC, up until the beginning of the 19th century abdominal hysterectomy resulted in almost certain death and the first “modern” abdominal hysterectomy was performed in 1843 in the UK. Mortality in these early hysterectomies is described by Wilbush3 as appalling – the 1843 surgery resulted in death in the immediate post-operative period – but women suffering constant heavy bleeding were prepare to take the risk to end the impacts of uncontrollable menorrhagia on their health and ability to function. It took seventy years – and presumably many deaths and mutilated women – before hysterectomy started to develop and improve as a surgery.

The progress in hysterectomy surgery would not have been possible “but for the cooperation of women. It would have never happened had not gynaecologists been constantly pressured by ailing women, invalided by constant bleeding, who clamoured for relief: it would have not been accomplished had not women taken chances against all odds, demanding gynaecologists do the same and help them.”

In 1988, Joel Wilbush wrote two papers looking at menorrhagia and menopause from an historical perspective, and suggested that the incidence of menorrhagia had declined as the use of hysterectomy became more common. From the 1920s, with the rise of feminism the popularisation of hysterectomy as a method of birth control saw women having hysterectomies at a younger age, well before perimenopause. He wrote that hysterectomy “has not only made excessive menstrual loss in the late childbearing years uncommon, or easily rectifiable, but has helped to dissociate such episodes from the climacteric.”

However, he acknowledges at the end of his second paper that “reports of excessive climacteric menstrual loss are being heard afresh.”

Perhaps the advent of less invasive methods of birth control, and particularly the contraceptive pill, has led to a return to the days of women suffering heavy bleeding as they reach perimenopause. Research suggests that typically one third of menstruating women suffer from heavy periods, but the results of studies vary from 25% to as high as 52%. A Cochrane review found that heavy bleeding is very common and “can affect 20% to 50% of people who menstruate during their reproductive years.”

## Heavy Bleeding or Menorrhagia

Heavy menstrual bleeding or menorrhagia is defined both quantitatively and qualitatively; that is, excessive menstrual blood loss of more than 80 ml per cycle, that interferes with a woman's physical, emotional, social wellbeing and quality of life.

Because it is difficult for women to assess the actual volume of blood lost during their periods it can be easier to assess in ways other than direct measurement of blood loss. For women with abnormally heavy bleeding they may:

* need to change pads or tampons every one to two hours or fill a menstrual cup every two to three hours;
* experience ‘flooding’ that soaks through bedclothes, pyjamas, clothing or upholstery;
* need to get up in the middle of the night to change their pad or tampon;
* find blood clots the size of a NZ$1 coin on their pad or tampon;
* feel very tired or short of breath.

Research has shown that women experiencing heavy menstrual bleeding have significantly worse health related quality of life in all areas compared with women with normal menstrual bleeding. In one study, “inability to fulfil usual roles at home or in the workplace were central to discussions of periods as a problem”, and that severe pain associated with heavy bleeding exacerbated the impact that their periods had on their quality of life. It is a significant health problem for many women, increasing with age and peaking during perimenopause.

In one study of 15,107 women in Canada, US, Brazil, France and Russia, of whom 6210 women reported heavy menstrual bleeding, 80% reported being worried about bleeding-related accidents; 70% avoided social activities because of their heavy periods; and 40% had experienced embarrassing situations.

In addition to the personal burden experienced by individual women, there are significant costs to both economy and health services.

**Women’s Experiences**

“I would sleep with three or four pads and towels underneath me, and I’d still bleed through everything.”

“I was at a cocktail party for my husband’s work, and I could feel blood running down my legs and dripping onto the floor; it was literally gushing. I was wearing a floor-length dress so at least it wasn’t too obvious as I rushed off to the toilet.”

“I had to use tampons and pads at the same time, couldn’t be more than five minutes away from a toilet and in the end – before my hysterectomy – as well as using a menstrual cup I was going through a packet of maternity pads every day during my period. I was severely anaemic. It took five years of doctor visits before I was finally diagnosed with severe fibroids.”

“My periods were so heavy I had to change my pads every 30 minutes. I would bleed for two weeks or longer, then bleed in between cycles. I also had terrible clotting — the clots were huge, bigger than my fist, and really painful.”

“At a café we sat outside on seats with cushions on. During lunch, I bled through the cushion and almost fainted. We just fled the scene like criminals and ran through the streets with blood dripping down my legs. Traumatic? Yes. Embarrassing? Definitely.”

The causes of heavy menstrual bleeding can be related to physical problems with reproductive system, hormones, illnesses and some medications, including:

* uterine cancer, polyps, fibroids (leiomyoma), adenomyosis or endometriosis;
* ovarian dysfunction or conditions such as PCOS, leading to hormone imbalance;
* chronic medical conditions, such as diabetes, obesity or disorders of the thyroid or adrenal gland, and genetic disorders, such as poor clotting ability;
* non-hormonal birth control IUDs, hormonal medications and anti-inflammatory medication.

The treatment for or management of heavy bleeding “depends on the underlying cause and the woman's preference and her fertility wishes.” The first choice is typically medical, including hormonal treatments such as oral contraceptives, hormone releasing IUDs (e.g. Mirena), and other hormonal medications. Other medical options include antifibrinolytic medicines, such as tranexamic acid, which prevent clots from breaking down and causing excessive bleeding.

Surgical options include dilatation and curettage, operative hysteroscopy, endometrial resection, endometrial ablation, uterine artery embolization, and hysterectomy, the latter of which is commonly used when other options are unsuitable or have failed.

It is endometrial ablation that the rest of this article will focus on.

## What is Endometrial Ablation

Essentially, endometrial ablation is a procedure in which the lining of the uterus or endometrium is destroyed using laser, heat or freezing. The aim is to leave very little of the endometrial tissue and in theory the endometrium will heal leaving scarring, which usually reduces or stops menstrual periods.

The term endometrial ablation covers a “spectrum of procedures performed with or without hysteroscopic direction” and are categorised as first, second or third generation. Bofill Rodriguez et al., in their 2022 Cochrane review of interventions for heavy menstrual bleeding write that there is evidence that endometrial ablation started in the late 19th century, with two types of procedures described; atmocausis, which used steam directly on the endometrium, and zestocausis, which used metal to provide the heat.

Bofill Rodriguez et al., go on to define modern endometrial ablation as either: resectoscopic endometrial ablation using different forms of energy delivered through a hysteroscope, such as electrocoagulation or desiccation, transcervical endometrial resection, or vaporisation; or non-resectoscopic endometrial ablation designed to destroy the endometrium without fluid distention of the uterine cavity. Modern ablation techniques use different types of energy sources from radiofrequency to electric to heated water.

Endometrial ablation is promoted as safe, effective, minimally invasive procedures, performed through the cervix. However, while it is widely regarded in the literature as a successful technique offering safer and less invasive and less risky relief for women suffering from heavy menstrual bleeding, there is significant evidence that this is frequently not such a wonderful solution for menorrhagia. In fact, some women go on to suffer devastating endometrial ablation failures and crippling pain, sometimes within weeks and sometimes as many as eight to ten years after the procedure.

In research for this article, a large number of medical papers were reviewed. Typically satisfaction with endometrial ablation procedures was high, 80 to 95%; however, follow up was typically relatively short, only a matter of a few months up to five years. For women closer to menopause, success of the procedure appeared to be higher, because symptoms of failure are generally related to the menstrual cycle, and once that ceases failure is a moot point.

In early 2020, MedPage Today published two articles investigating endometrial ablation. The first article interviewed women suffering harm from the procedure. The women said that they were “pitched endometrial ablation as a simple, easy procedure with few risks”. However, the article pointed out that “like any surgery it can carry complications, and there are limited data on rates of ablation "failures". such as bleeding heavier than before, severe labour-like cyclic pain, and subsequent hysterectomy.” Additionally – and many women are not told this – scarring from the procedure may obscure uterine cancer, delaying diagnosis and potentially worsening the prognosis.

The MedPage Today article mentions a private [Facebook support group, NovaSure & Other Endometrial Ablation Procedures Info & Support](https://www.facebook.com/groups/264368540364822), that now has more than 13,200 members, all seeking answers about endometrial ablation, and where women “women share stories of crippling pain, haemorrhaging on operating room tables, having bowel surgeries and hysterectomies, and becoming violently ill with sepsis. They also lament economic losses from missed work due to complications, and the damaging impact ablation had on their relationships and their sex lives.”

I joined this group – making clear I was doing so for research for this article; the stories of women from all over the western world, including New Zealand, make painful, terrifying reading.

A [petition to pursue a class action](https://www.thepetitionsite.com/287/347/635/novasure-class-action-lawsuit/) started by one of the members of the group has, as of the 18th of December 2022, 2755 signatures. Many of the signatories have left brief descriptions of the harm they have suffered; again painful reading.

While New Zealand has no systematic collection of reports of harm for endometrial ablation MedPage Today searched the FDA's Manufacturer and User Facility Device Experience (MAUDE) database for the most frequently used endometrial ablation device – Hologic’s NovaSure – and found hundreds of reports documenting serious harm: severe sepsis, bowel surgeries, hysterectomies, burns, perforations, and other events, including fatalities.

Dr Jill Long, a public health researcher who previously worked for the FDA, says it is well known that harm to the MAUDE database is underreported.

In the second of the MedPage Today articles, they focused on physicians evolving attitudes to the procedure. Several physicians said they no longer do endometrial ablation, or they perform it only selectively. Dr Linda Bradley, medical director of the American Association of Gynecologic Laparoscopists, said “I stopped ... over personal concerns about treatment failures.”

Dr Diana Bitner said “When endometrial ablation first came out, we all thought it was the best thing since sliced bread. A month later, patients didn't bleed, they were happy, then six, eight months later, they're failing.”

The doctors spoken to cite severe pain resulting from endometrial regrowth and blood trapped under scar tissue as one of the main problems. Some believe that “that patients aren't always selected appropriately...” and say that “the procedure pays well, and some physicians have taken tens of thousands of dollars from Hologic for NovaSure, the market leader.”19 In the US doctors received about US$1,100 for an outpatient procedure that takes five minutes.

Contraindications for endometrial ablation include endometrial cancer, anatomic conditions such as classical caesarean section or transmural myomectomy, genital or urinary tract infection, IUD implantation, small uterine cavity or unusual uterine anatomy such as a retroverted uterus, active pelvic inflammatory disease, younger age, polyps, fibroids, or painful periods, endometriosis and tubal ligation.

Despite this, these contraindications appeared in only one of the many patient information websites reviewed for this article, and in all but one, most of the potentials harms of the procedure were not mentioned.

McCausland and McCausland discuss the long-term complications of endometrial ablation and write that “The problem is that after this procedure, intrauterine scarring and contracture can occur. The problem is that after this procedure, intrauterine scarring and contracture can occur.” Bleeding from persistent or regenerating endometrium behind the scar may be obstructed and cause central hematometra, cornual hematometra, postablation tubal sterilization syndrome (PATSS), retrograde menstruation, and potential delay in the diagnosis of endometrial cancer.

## Jenni’s Story

**Jenni was 48, perimenopausal and with low iron levels when she was referred for a Mirena a hormone-releasing IUD. The IUD caused serious side-effects and when it was removed she suffered extreme menstrual bleeding. At 50 she had a Novasure endometrial ablation to ‘treat’ the severe bleeding leaving her with debilitating pain, devastating her health and her life.**

I was referred to the Greenlane Women’s Department for low iron at the age 48. My periods were starting to get irregular, and I had low iron levels. I had never had one period pain my whole life. At that time I was going to the gym for a hour, mowing the lawns, travelling, having a normal life with my kids.

Going to Greenlane was the worst mistake of my life; I was coerced into having a Mirena hormone-releasing IUD inserted. I had never been on birth control pills in my life but the IUD was toxic overload and affected me mentally and physically; it made me terribly sick. When I saw the doctor about the side-effects of the IUD and all were ignored or belittled. For me it was hell on earth and I had to beg to get it removed.

Once removed I nearly bled to death, it was like a dripping tap and I haemorrhaged for two months. It was traumatic! The doctors wanted to insert another IUD to stop the bleeding. I said “No way.”

I then went to Auckland Gynaecology Group thinking that private care would be superior; how wrong I was.

I was subjected to a sales pitch for Hologic’s NovaSure endometrial ablation; it was sold to me as a harmless easy procedure, as a dream come true. I was provided with insufficient information to provide informed consent, and they didn’t investigate or test my iron levels for iron deficiency despite knowing that I had been bleeding for two months solid. They also didn’t do and hormone tests (I was only a year away from menopause), pelvic exam or any scan of my uterus. They didn’t know that I had fibroids, cysts, and cuts to my womb from the IUD being torn out.

They did do an endometrial biopsy, but I have never received the results. I was never told of any of the consequences of endometrial ablation, the risks and the possibility of failure of the procedure. I was not told about post ablation syndrome or any of the other risks such as not being able to detect uterine cancer, or that it can cause sudden menopausal symptoms because of the burning of the uterus and the shock.

I had a holiday to Australia booked and they said they could rush me in before I went. I never met the gynaecologist who performed the procedure beforehand. He rang me at 6.30pm in the evening and did a five-to-seven minute consultation that he didn’t even bother to write up in my medical notes. That counted as informed consent!

Afterwards he said just three words to me: IT WENT WELL. But it didn’t!

Straight away something was wrong. That night I woke up with intense night sweats and my hands and feet were tingling. I thought to myself what has that [expletive deleted] done to me. It felt like all the nerves in my body had been electrocuted. Later I had lower abdominal pain that has never gone away.

I was on holiday in Sydney and had no strength in my arms or legs. I went to A&E there and had an ultrasound. I had never had period pain, had two natural births with no pain relief, but the pain I was left in now was ten times worse than childbirth.

When I got back to New Zealand I could not email AGG as they had blocked me. I didn’t even have post-op check-up. When I had my consultation with the gynaecologist I asked him why he didn’t tell me about Post Ablation Syndrome, or uterine cancer issues or organ damage. He looked down at his desk. He stabbed at my painful abdomen and showed no concern and shuffled his papers on his desk without a hint of guilt. I asked for a ultrasound but I never got the results. I was offered free consultation with his colleague, but he was even more chauvinistic and demoralising, and gave me a breast exam even though I was complaining of pelvic pain.

I live in agony or on pain tablets that do nothing. Horrific electric shock-like pain to my whole body, muscles, nerves, organs. I could go to hospital every day with the pain.... but they gaslight me, belittle me and laugh at me.

My nerves have been damaged, I was burnt so badly my ovaries stopped working putting me into sudden menopause. I suffer from chronic inflammation, bowel and bladder urgency; I am literally housebound. I can’t sit without absolute agony, I can’t walk without pain, I can’t sleep. I can’t work because I can’t function now – I used to be an architect earning a six-figure income; I worked hard and was good at my job. I can’t have sex with my husband, my g vagina burns, and I suffer incredible pain in my inner groin and legs.

I was always fit and healthy, but I can no longer move. I’ve gone from a size 12 to size 20. I have aged twenty years in the last four. I am a cripple because this barbaric procedure. It has catastrophically changed my relationships with my husband and my children; no children should have to see such agony inflicted on their mother. I was fit, healthy, bubbly. I had a nice life; travelling, friends and family normal existence. Now I have none of that.

## Sarah’s Story

**Sarah had reached desperation point with long-term chronic painful and heavy menstrual cycles, so in May 2021, she had a NovaSure endometrial ablation, D&C, and tubal ligation with Filshie clips. She was just 26 years old.**

I was experiencing periods that were anywhere from 9 to 18 days long at a time; often I would experience a mini period that would finish for a few days and then the ‘real’ period would start, which included multiple days of very heavy bleeding and crippling pain. I was taking anywhere between 30 and 40 pills each cycle consisting of various types of pain relief and tranexamic acid (to try and lighten the bleeding).

My entire life revolved around my period, and there were very few days in a month where I could comfortably do anything without the fear of bleeding and pain, so that pretty much ruled out holidays, most outdoor activities such as camping and swimming, staying over at friends' houses, or on my worst days I couldn't even be away from the house for more than an hour at a time. I was also unable to be as active as I wanted and my sex life was pretty terrible too, both of which had impacts on my self-esteem. My iron levels were chronically low, eventually requiring an iron infusion at the end of 2020.

There was no cause that could be found for my period issues, and none of the treatment options were effective at that point. So, I asked the doctor if I could have a hysterectomy (in 2016) following the laparoscopy but was declined due to age and not having children. I stated I was childfree by choice but was told I would change my mind and to keep waiting was told her “periods may come right after you have a child, anyway”.

Between 2016 - 2021 I was put on various treatments. Eventually, after moving, I ended up with a great GP who was very proactive and respectful of my choice to not have children. After seeing two gynaecologists, one finally agreed that I had waited long enough and thought about it enough, and he discussed the Novasure ablation option with me, saying that hysterectomy would need approval from the medical director because of my age.

Hysterectomy was my preference, but he thought the ablation was far less invasive and an easier recovery so we should try that option first instead of going for the bigger procedure. I also had serious reservations about the Filshie Clips, ultimately preferring the removal of the tubes, but was not provided with an alternative to this method. He really downplayed any risks of the endometrial ablation and said that I was “overthinking most of my concerns”.

Following discharge after the procedure, no follow-up appointment was scheduled; I was told I didn't need one. This doctor never saw me again.

The potential risks were explained to me and lots of information from the NovaSure supplier was provided, including about how successful the procedure is. I expressed repeated concerns about the types of issues that could occur afterwards but I was told it would be very rare to have any real issues after the fact and the majority of women found everything much more improved after the procedure.

After my procedure, my periods never stopped. They were definitely improved in that they lasted four days, I had one heavy day, and there was finally some level of predictability with it. They were also still painful, but not as bad. During that first 6 months, I considered the ablation reasonably successful, and any niggles were due to still not having fully recovered, at least that’s what I thought.

Issues became increasingly apparent around six months after the procedure and have gotten progressively worse since then. Ovulation has become really painful; I get awful electric shock-like pains that travel down my legs; and it feels like someone has scissors on my fallopian tubes for a few days each month. My lower back has been sore since the operation, and nothing helps or makes it go away. It’s just always sore now. Using my abdominal muscles can cause pain all in my pelvic area, especially around my tubes, also with coughing and sneezing.

Each period I have is slightly worse than the last, and I now fear it will not only go back to how it was but much worse. My cervix can randomly have throbbing pains that take my breath away and pain I get is getting harder to manage each time. I tried to go back to the specialist only to find he had retired six months after I saw him. His replacement was unfamiliar with the procedure and focused on the pain being my clips and performed an ultrasound in which he noted my endometrium was surprisingly active. There was no indication from him that the ablation could be causing the issues; he quite literally shrugged his shoulders and said, "that's weird I don't know, it's pretty rare to have these issues".

After finding the Facebook group, and seeing that thousands of other women are experiencing what I am experiencing, I finally felt like I had some answers about the past year of my life and that, sadly, I am not experiencing something rare or unique at all. The only solution is a hysterectomy, which has left me even more upset knowing I should've just had that in the first place.

I don’t know a single woman who has had the procedure for whom the ablation didn’t eventually fail or cause long-term complications. I don’t understand how this procedure can continue to be performed with the narrative being that 90% of women are happy with the procedure, it’s quick and easy, and yet there is more information coming out that shows this isn’t true.

As it stands, I am waiting to plan a time next year to get a hysterectomy and finally be done with my monthly terror. My major concern now is, am I able to wait that long? What if I end up needing something more urgently?

## Another Bloody Disaster for Women

Endometrial ablation may work for some women; perhaps not all women or perhaps only a relative minority of women suffer failure and suffer with excruciating pain. However, it is yet another example of procedures, devices and drugs being “foisted” on women, often providing a healthy profit for the manufacturers and doctors in private practice, that all to often result in lifelong harm for some women.

For many women the only answer for a failed endometrial ablation is a hysterectomy. In some cases, women sought hysterectomies only to be refused or persuaded that endometrial ablation was safer, quicker and effective at controlling their heavy menstrual bleeding. What they get is often years of pain and disability, impacting not only on them but their families, only to have to have a hysterectomy anyway.

One of the worst aspects of what is happening is that, like with surgical mesh, women are not being told about the risks; they are prevented from making informed decisions. It is also apparent that women for whom endometrial ablation is not suitable, who have a reproductive and medical history that is contraindicated, yet some gynaecologists persist with recommending the procedure.

Astonishingly, in New Zealand there appears to be not only inadequate regulation and oversight of these procedures, but not systematic reporting of harm, no-one collecting reports of harm data. As a result it is impossible to establish just how many women suffer failed ablations and the resultant harm that this causes.

There is little beyond hysterectomy and a genuine, heartfelt apology from all concerned in the health sector to help the women who currently live with the damage done by endometrial ablation. However, the Therapeutic Products Bill, currently open for submissions from the public, is a once in a generation opportunity to ensure that devices and procedures are stringently regulated and that there are significantly better regulations and mechanisms put in place to gather data on treatment injury and harm caused by devices and procedures. Patient safety is paramount and it is long past time that the authorities in this country took the required steps to ensure that women are safe from medical treatment that not only fails to improve their lives but leaves them living with pain, dysfunction and disability.

## The Stats in NZ

It is difficult to know how many endometrial ablation procedures have been undertaken in New Zealand. Several former DHBs (now district providers under Te Whatu Ora) have general information on endometrial ablation on their websites.

AWHC lodged requests for information regarding harm/ treatment from endometrial ablation from Medsafe, ACC and the HDC under the Official Information Act.

Between 1 July 2016 and 30 June 2021, 61 claims for treatment injury as a result of endometrial ablation had been lodged with ACC; 47 claims were accepted and 14 were declined. A total of $1,266,967.65 was paid out over the same period in relation to endometrial ablation treatment injury claims.

ACC noted in their response to our request that “It is important to note that the number of claims lodged with ACC cannot be taken as an accurate indication of the occurrence of injury during treatment or the quality of care. This is because, among other reasons, not all occurrences of injury during treatment are lodged with ACC.”

Therefore, it is highly likely that more treatment injuries have occurred than claims have been lodged.

In the response from the office of the Health and Disability Commissioner (HDC), we were told that the “complaint database does not have a category for ‘endometrial ablation’, therefore these numbers are based on a search of the database for the word ‘ablation’ and may not have captured all complaints about this procedure.”

“Since 1 January 2012 a search of HDC’s complaints database found 9 complaints about endometrial ablation. Four of these complaints related primarily to ‘inadequate treatment/ procedure’ and five related primarily to ‘consent not obtained/ adequate’.”

Of the four relating to ‘inadequate treatment/procedure’, two complaints were investigated and in one of those the health services provider was found to be in breach of the Code of Rights, while the other was closed with no further action but with recommendations made to the provider.

For the ‘consent not obtained/adequate’ complaints, three were investigated, of which one provider was found to be in breach of the Code of Rights, and one was closed with no further action with educational comment made to the provider.

One complaint in each category was closed with no further action with educational comment made to the provider, and one in each category are still under assessment by the HDC.

The Ministry of Health responded to the OIA request to Medsafe, saying: “The Ministry does not hold reports relating to endometrial ablation. Therefore, your request is refused under section 18(g)(i) of the Act, as the information requested is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act.”

It appears that, despite the fact that a device is used in the performance of an endometrial ablation, there is no regulation of the procedure by Medsafe. The only mention of endometrial ablation on the Medsafe website is regarding the use of Zoladex as an endometrial thinning agent in preparation for endometrial ablation. There appears to be no information online about the regulation or licensing of endometrial ablation in New Zealand, nor any information about endometrial ablation on the Manatū Hauora | Ministry of Heath website. There seems to be absolutely no Government/Ministry accountability or official channels through which New Zealand women can get information on the risk of harm.

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# Te Pae Tata | the interim New Zealand Health Plan

By Sue Claridge

On the 28th of October, Minister of Health, Andrew Little, officially released Te Pae Tata | the interim New Zealand Health Plan. The [document](https://www.tewhatuora.govt.nz/assets/Publications/TePaeTata_A4.pdf) sets out the first two years of action for Te Whatu Ora and Te Aka Whai Ora.

However, while the priorities of the interim plan are hard to argue with, there is a significant disconnect between the apparent commitment to people being the heart of the new health system and the importance of the voices of consumers and whānau, and what Te Whatu Ora is doing in reality. In addition, New Zealander’s are losing faith in the health system, as it has all the appearance of being in an irretrievable downward spiral.

## The Content

Te Pae Tata, as an interim, two-year plan, is “focused on ensuring the health system continues to provide care to New Zealanders, while we start to implement the improvements in the way services are delivered and work toward the first full New Zealand Health Plan,” according to the Te Whatu Ora Comms email sent out to coincide with the release of the interim health plan.

The plan, [available online](https://www.tewhatuora.govt.nz/assets/Publications/TePaeTata_A4.pdf), says that the “foundations of our new health system are to improve equitable health outcomes, embed Te Tiriti, implement a population health approach, drive equity of outcomes and access, and to be a sustainable system.”

The plans states that the six priority actions are to:

* place whānau at the heart of the system to improve equity and outcomes;
* embed Te Tiriti o Waitangi across the health sector;
* develop an inclusive health workforce;
* keep people well in their communities;
* develop greater use of digital services to provide more care in homes and communities; and
* establish Te Whatu Ora and Te Aka Whai Ora to support a financially sustainable system.

The interim health plan reflects one of the central planks of the health system reform, which is to “improve health outcomes and achieve health equity for populations with poorer experiences of health outcomes.” Over the next two years Te Whatu Ora and Te Aka Whai Ora will focus on the areas they believe have the greatest opportunity for health gain:

* Pae ora – better health and wellbeing in our communities,
* Kahu Taurima – maternity and the early years,
* Mate pukupuku – people living with cancer,
* Māuiuitanga taumaha – people living with chronic health conditions,
* Oranga hinengaro – people living with mental distress, illness and addictions,
* Improve equity of health outcomes – deliver on improving pae ora for Māori, Pacific people and Tāngata whaikaha | Disabled people.

Within the detail of how these priorities will be acted on, and in the other parts of the plan there is much to agree with, to support. For example:

* joined-up and integrated pathways of care so that patients move seamlessly through the health system;
* ensuring the quality and safety of services;
* an enhanced national public health system that promotes health and wellbeing, prevents disease and prolongs life;
* strengthening primary and community care in order to reduce the risk and burden of disease, reduce demand for more costly care, and achieve better and more equitable health and wellbeing outcomes for all, including addressing barriers to access;
* ensuring hospital and specialist services work cohesively across Aotearoa, making optimal use of capacity to meet demand and improving the consistency of access and outcomes.

However, there have been promises of health sector transformation in the recent past, such as the response to the 2018 [*He Ara Oranga: Report of the Government Inquiry into Mental Health and Addiction*](https://mentalhealth.inquiry.govt.nz/inquiry-report/he-ara-oranga/), in which the government promised to transform the country’s approach to mental health and to rectify disparities caused by decades of underinvestment. That $2 billion commitment to “transformation” has done virtually nothing to address issues in mental health care. In one of the most recent of numerous reports on the state of mental health care and services, Shaun Robinson, chief executive of the Mental Health Foundation, describes a response to mental health that’s failing completely. Subsequently it was been reported that a “half-billion-dollar programme to deliver better community and primary mental health care is still failing to reach tens of thousands of people.”

As I write, the health system is in crisis, with worsening reports every day:

* A GP leaving her job and the country, clearly disillusioned with desperately trying to do her best for her patients in an impossible situation, writes “the New Zealand health system is broken, and it has broken me.”
* Pregnant women have awful birthing experiences because there are staffing shortages at their hospital.
* Some patients are choosing not go to emergency departments when they need to, as long waits and overcrowding continues after several high-profile incidents of people leaving before they're seen and getting sicker, or dying. At the overcrowded ED at Wellington Hospital, overworked nurses are handing out laminated card with the Andrew Little’s public contact details so patients can complain directly to him. The nurses started doing this in response to verbal abuse from patients caused by lack of staffing and long waits.

New Zealanders want to believe an amazing new equitable and responsive health system is almost within our grasp, but there is a level of health sector fatigue that Te Pae Tata will likely not alleviate. Many people can’t see their own GP, or any GP, at short notice; they face six, eight, ten or more hour waits should they be unfortunate enough to need to go to a hospital emergency department; and many with serious and/or complex health conditions wait months to see specialists.

We are all looking forward to ***pae ora*** – a healthy future – but don’t hold your breath.

## Developing Te Pae Tata – No Public Consultation!

In announcing the release of Te Pae Tata | the interim New Zealand Health Plan, Te Whatu Ora | Health New Zealand said in their regular email newsletter, that the release of the health plan “marks a huge milestone for our New Zealand health reform”.

It is a considerable shame that this “huge milestone”, something this important in the much-lauded people/consumer and whānau centred health system, was developed and written without public consultation and released as a “done deal”.

This is a hugely disappointing start for Andrew Little, the Ministry of Health and Te Whatu Ora | Health New Zealand.

Te Pae Tata is the document that will direct our health system and its priorities for the next one and a half to two years before the first comprehensive plan under the Pae Ora (Healthy Futures) Act 2022 is prepared for delivery in early 2024.

Under the Pae Ora (Healthy Futures) legislation, health entities must engage with consumers, whānau and communities in the planning, design, delivery and evaluation of health services. But apparently that doesn’t apply to the New Zealand Health Plan, or at least not the interim plan. The irony is that in the pages of Te Pae Tata, the authors of this document state:

“The reason for reforming the health system – and for Te Pae Tata – is to create a more equitable, accessible, cohesive and people-centred system to improve the health and wellbeing of all New Zealanders. This means people will be far more involved than they are today in determining what good care looks like.”

Throughout the document the apparent commitment to a people-centred health system is there for all to see, but words are cheap and so far Te Whatu Ora is ‘talking the talk’ but not ‘walking the walk’.

We had every expectation that there would be public consultation and an opportunity to provide feedback on the interim health plan. At the first Health Forum Aotearoa\* hui early in 2022, we were told that a high-level draft of the health plan would be available in June for public consultation and feedback. At a subsequent hui the date had been pushed out until July. Then silence!

Auckland Women’s Health Council did not ever receive any notification of public consultation or an invitation to make a submission on Te Pae Tata. Were we just overlooked as long-term stakeholders in the health sector?

We emailed the person in Te Whatu Ora responsible for Te Pae Tata Engagement, and asked for clarification around the issue of public consultation: We wrote:

“If there has been no public consultation can you please explain how this reconciles with Minster of Health, Andrew Little’s stated commitment that Te Whatu Ora | Health New Zealand is to be a people/consumer/whānau centred health system, or with the creation of Health Forum Aotearoa and the HQSC claim that they (as a Government health entity) support consumers being actively involved in decision-making for their health, at all levels.

If there has, in fact, been public consultation in the development of Te Pae Tata, can you please explain why Auckland Women’s Health Council, as members of Health Forum Aotearoa, and more importantly with 34 years standing as stakeholders in the health sector and with an outstanding record of making submissions on a wide range health issues, including very substantial written and oral submissions on the Pae Ora (Healthy Futures) Bill, were not notified of the opportunity to make a submission on Te Pae Tata.”

The response was less than encouraging and there seems to be a deep disconnect between the concept of a people-centred health system in which consumer and whānau engagement is required under the Pae Ora (Healthy Futures) Act and what that actually looks like in the real world. We were told:

“Te Pae Tata was developed following engagement with a range of sector and stakeholder groups. This included submissions on the Health and Disability System Review and on the Pae Ora (Healthy Futures) legislation.

There were many organisations and people who provided their time and expertise to assist in the development of Te Pae Tata. Though there may have been early discussions of consultation, it was decided that it was not feasible to consult on this interim plan as its focus is on the essential first actions.”

So, a Clayton’s consultation; the claim of consultation when you’re really not consulting with health consumers at all!

We fail to see how submissions on the Health and Disability System Review and on the Pae Ora (Healthy Futures) legislation is in any way the same or a valid proxy for consultation on the actual interim New Zealand Health Plan. When we made submissions on the Pae Ora (Healthy Futures) Bill we addressed the specifics in the bill, and the omissions. Our submissions were nothing to do with the health plan and legislation is not a health plan.

Te Pae Tata “establishes a national service coverage and operating policies”… and lays out a foundational set of actions towards our goals.”

Not legislation! Therefore, submissions on the Pae Ora (Healthy Futures) Bill are irrelevant and it is an insult to the intelligence of all those who would have provided feedback on Te Pae Tata to say that their submissions on the legislation were a proxy for consultation on Te Pae Tata.

To rub salt into the wound, the email response we got also says “it sets out priorities and actions for the next two years, including valuing the voices of consumers and whānau.” Clearly they didn’t value the voices of consumers and whānau enough to ask them what they thought of the draft plan.

In our [August AWHC Newsletter](https://www.womenshealthcouncil.org.nz/wp-content/uploads/2022/09/AWHC_Newsletter_August_2022.pdf) (Managing Expectations: “Consumer Representation” in Te Whatu Ora, page 21), we expressed reservations about how well consumer engagement in the new health system was going to work and whether or not a truly consumer/people-centred health system would be achieved. The evidence so far is that for them it doesn’t mean seeking the views of health consumers on vitally important high level health sector documents, let alone co-design with consumers on these documents.

## Te Pae Tata on Consumer Engagement

The header page for Section 1 of Te Pae Tata states that:

“The reason for reforming the health system – and for Te Pae Tata – is to create a more equitable, accessible, cohesive and **people-centred** system to improve the health and wellbeing of all New Zealanders. **This means people will be far more involved than they are today in determining what good care looks like**.” [our emphasis]

On next page Te Whatu Ora says it wants to “build a system that is always thinking about the people and whānau it serves, making sure that the delivery of health services works for them and genuinely improves health outcomes. This requires a high-performing health system where people participate in the design and delivery of care that supports them to live well in their communities. All people – whether they are using, delivering, planning or leading services – are central to this change.”

Followed by:

**In practice**, this means we:
Put people and whānau at the centre, **with people having more influence over how we plan and design services, and shape the care** available to them locally.” [our emphasis]

Subsection 1.1 is headed “Valuing the voices of consumers and whānau” under which they say:

Transformation of health and healthcare requires people to be at the heart of everything that we do, driving the direction of change so that the care we provide enables people to thrive. **We will amplify the voices of consumers and whānau to ensure that when we plan and design health services, we have the mechanisms in place to be held to account for acting on people’s feedback.**

Repeatedly in this section the plan talks about including the voices of consumers “in the design, delivery and performance of the health system.”

Oh, the irony!

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# Inclusivity and Maternity Services

**midwife/ˈmɪdwʌɪf/**

**from Old English mid, "with", and wif, "woman"**

Te Tatau o te Whare Kahu | The Midwifery Council has recently revised the Midwifery Scope of Practice, and the new version is leaving a bad taste for many women.

The Scope of Practice (SoP) for midwives is a requirement under the Health Practitioners Competence Assurance Act 2003; the Act states that “Each authority appointed in respect of a profession must, by notice, describe the contents of the profession in terms of 1 or more scopes of practice.”

The Midwifery Council state on their website that “The Scope of Practice statement provides the broad boundaries of practice across the profession. It is not specific to an individual, however, all care provided by midwives must sit within it.”

The immediately noticeable change between the current 2010 SoP and the new, revised version is the significant inclusion of te reo Māori and reference to Te Tiriti of Waitangi.

Auckland Women’s Health Council support Te Tatau o te Whare Kahu | The Midwifery Council in honouring and empowering Te Tiriti o Waitangi in the revised SoP. We believe that the articles of Te Tiriti should be embedded in our new health system, and in all the documents that guide and regulate it, including midwifery practice.

## Recognising Gender Diversity

We are also very supportive of addressing gendered language in the health sector, and in particular, using language that is inclusive of all New Zealanders, including people who identify as non-binary or transgender.

In our submissions on the Pae Ora (Healthy Futures) Bill in 2021, we specifically address issues faced by the LGBTQI+ community, advocating for an LGBTQI+ health strategy to sit alongside the other health strategies such as those for Māori, Pāsifika and those with disabilities, and the now approved women’s health strategy. We know that, despite advances in the rights and legal status of LGBTQI+ New Zealanders, social prejudice and bias that extends deep into our health system negatively impacts on members of the LGBTQI+ community.

A 2013 report found that “Rainbow communities, especially those of diverse gender identity (transgender) and diverse biological sex (intersex) have a troubled history of interaction with the health system.”

*Counting Ourselves*, a 2019 report on the health and wellbeing of trans and non-binary people in Aotearoa New Zealand found that transgender and non-binary New Zealanders had particularly negative interactions with the health system and suffered significant barriers to adequate and culturally appropriate health care. High numbers of transgender and non-binary New Zealanders want but are unable to access gender-affirming healthcare.

The language that health care service providers use is critically important in the quality of experience that non-binary and transgender people have.

However, in an attempt to be ***inclusive***, it seems that the Te Tatau o te Whare Kahu | The Midwifery Council and the revised SoP has become ***exclusionary*** by removing the words wāhine/woman and māmā/mother and replacing them with the gender neutral and plural “whānau”. The vast majority of pregnant New Zealanders seeking midwifery services identify as cis-gendered women and use wāhine/woman and māmā/mother to describe themselves in their lives and in relation to having a child.

It is entirely possible to recognise the status of all pregnant people without excluding those who do not identify as women and mothers, and without making family/whānau the centre of a midwife’s practices and effectively undermining a pregnant person’s autonomy.

## A Multiplicity of Issues with Replacing Woman and Mother with Whānau

We appreciate that the use of whānau is aligned with te ao Māori and also with the ways in which it would be beneficial for all our health services to see people, parents and children as part of families that shape what is important and possible for them.

However, while use of the term whānau may be “philosophically consistent with mātauranga paradigms of holism in social structures”, and there is no doubt that whānau/family are vitally important in supporting a person during pregnancy, labour and birth, and in the early period of parenthood, it is not as simple as just replacing the singular “woman” and “mother” with the plural “whānau”.

A midwife’s duty is to the pregnant person first and foremost, no matter whether they identify as cis- or trans-gender, or non-binary. While, in an ideal world, whānau/family would be involved in a person’s pregnancy and birth, ultimately it is the pregnant person who is, by law, the one to make informed decisions about their care during pregnancy and birth. Their lead maternity carer is their choice; health care services provided to them while pregnant is their choice; where and how they give birth is their choice, not the choice of family/whānau. In an ideal world, a pregnant person would make those decisions with the help and support of their life partner, and their family/whānau.

However, not all whānau/family are supportive of the decisions a pregnant person makes, and, sadly, in some cases the views and involvement of whānau/family are unwelcome, disruptive and possibly even harmful.

The Code of Health and Disability Services Consumers' Rights (Code of Rights) is very clear that consumer rights in the context of the provision of health care services are applicable to an ***individual***. Use of the word whānau takes away the autonomy of, and control by, the pregnant person and partnership at the centre of a midwife’s practice. Removing the individual nouns “woman” and “mother” is inconsistent with the Code of Rights, which very clearly gives the authority to the individual person, not the wider family/whānau.

Sandra Coney writes, “Every individual is deemed to be competent to make their own decisions about their health care unless there are grounds for thinking the person has diminished competence. Even then the Code gives the person the right to make decisions up to their level of competence.”

Under the Code of Rights, even when “a consumer is not competent to make an informed choice and give informed consent”, the health services provider ***may*** take “into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider”. However, that is only one option, as it also states that “if the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent.”

This is the only clause in the Code of Rights in which whānau/family may have a role in health care decisions and the delivery of health services. Everywhere else the Code refers to the “consumer” as an individual, not as part of family/whānau.

The Federation of Women’s Health Councils raise two further issues in their submission on the revised midwifery SoP.

First, they point out that midwifery care only starts for the midwife when services under Section 88 of the New Zealand Public Health and Disability Act 2000 commence in the first trimester. Therefore, midwives don’t commence care of a pregnant person until the pregnancy is confirmed, which is inconsistent with the revised SoP, clause b, which states that a “midwife is responsible for providing culturally and clinically safe care, in any setting, for whānau who are ***planning a pregnancy***, pregnant, birthing, and postnatal.” [our emphasis]

Additionally, the FWHC write that it is the pregnant person, as the health services consumer/claimant, who will make a claim to ACC should a treatment injury occur in the process of giving birth…. Not the whānau!

Finally, compared with everywhere else in the SoP where the Midwifery Council use the English words alongside te reo Māori, the use of whānau without the English “family” feels “exclusionary” of many recent migrants to this country who may struggle with English and may have no understanding of te reo Māori. Including “family” alongside whānau would help to include this significant minority in our population.

## Gender Diversity and Perinatal Care

International and New Zealand research has found that transgender and non-binary or gender diverse people experience a number of barriers to accessing gender-affirming healthcareincluding reproductive health care and pregnancy/perinatal care.

Perinatal Anxiety & Depression Aotearoa | Te mate Tuatea, me te mate Pōuri o Aotearoa (PADA) say that “it is likely that transgender and non-binary parents make up about 1% of the postpartum population at present.” This number is likely to continue to increase with time as the social stigma associated with being transgender or non-binary decreases and more people feel safe to identify as transgender or non-binary.

PADA succinctly describe the issues that transgender and gender diverse/non-binary people face in becoming parents:

“Because queer, gender-diverse or trans people can be more prone to having mental health issues, resulting from the stress effects of being mistreated, disrespected and invisibilised, the journey into new parenting can exacerbate already existing mental health issues. This can happen regardless of whether someone is hapū or is the birthing partner, because parenthood is an additional significant life change, and it is important everybody receives… inclusive and safe perinatal healthcare.”

PADA have an excellent range of resources, not only for LGBTQI+ people wanting to become parents or struggling with mental health issues around pregnancy, birth and the post-natal period, but also for clinicians providing health services for LGBTQI+ people. In particular, they have a great short video, [*Inclusive practice with non-binary and gender diverse people in the perinatal period*](https://www.youtube.com/watch?v=_pCJMne7c5E&t=1s), and a pdf [*Supporting transgender and non-binary parents*](https://pada.nz/wp-content/uploads/2022/08/Supporting-Transgender-and-non-binary-parents.pdf).

They also [provide information](https://pada.nz/rainbow-families/) on how healthcare providers can help, particularly around the use of pronouns and gendered language and advocating for the person in their care, and a list of organisations who are able to help health care providers.

Additionally, PATHA (Professional Association for Transgender Health Aotearoa) provides information and resources, including [*Guidelines for gender affirming healthcare for gender diverse and transgender children, young people and adults in Aotearoa, New Zealand.*](https://patha.nz/resources/Documents/Guidelines%20for%20Gender%20Affirming%20Health%20low%20res.pdf)

**“All human beings are born equal in dignity and rights.”**

**- Universal Declaration of Human Rights, Article 1, ratified by New Zealand in 1948**

**“The States Parties to the present Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”**

**- International Covenant on Economic, Social and Cultural Rights, Article 12, ratified by New Zealand 28th December, 1978**

**“Everyone has the right to the highest attainable standard of physical and mental health, without discrimination on the basis of sexual orientation or gender identity.”**

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# State ‘Sanctioned’ Mesh Harm

By Sue Claridge

For years our health agencies and regulators have known about the harm that surgical mesh causes. In 2019, the restorative justice process heard from more than six hundred mesh-injured New Zealanders; between 2005 and 2020 more than 1600 claims were lodged with ACC for surgical mesh injury and 1231 were accepted;ACC payments for surgical mesh injuries have increased from $500,000 in 2017 to $5.1 million in 2021.

In the August 2022 AWHC Newsletter we reported that ACC data showed that, in the four years since Government officials ordered hospitals to take action to minimise the harm from surgical mesh procedures, at least another 38 women have been injured severely enough to have claims accepted. ACC said that the total number of women harmed since October 2018 is expected to be higher than 38 because “not all claims included the date of operation and those that didn’t were left out of the dataset” and “many women don’t experience surgical mesh complications until several years after surgery and some don’t know they are entitled to lodge an ACC treatment injury claim.”

Given that women continue to be harmed by surgical mesh procedures, it is hard not to come to the conclusion that the continued harm that surgical mesh causes, is sanctioned by the Ministry of Health.

University of Auckland law student, Tamarra Al-Azzawi, has written a research paper on the surgical mesh crisis for her Medico-Legal studies honours course taught by former Health and Disability Commissioner, Prof Ron Paterson. She was inspired to focus her research paper on surgical mesh after a presentation to her class by Charlotte Korte and Renate Schütte\*. The presentation sparked her interest in how the regulatory systems in place had failed to protect women from harm and she wanted to explore why little progressive action was being made in the medico-legal system, despite knowing the cause of harm.

Ms Al-Azzawi writes:

“in rushing to fulfil [demand for surgical mesh as a treatment for stress urinary incontinence and pelvic organ prolapse]… regulators failed to ensure that the device was safe for patients. Consequently, serious health complications from inserting the foreign body became apparent across thousands of women. Over the past two decades, harmed women have collectively triggered extraordinary media coverage calling for awareness and change in the medical field. It has broken many health consumers’ trust and confidence due to the accountable bodies omitting to take responsibility for their wrongdoings. Many countries, such as the UK, US and Australia, have been gradually implementing positive changes to prevent harm caused by transvaginal mesh. Yet New Zealand is still behind.”

Ms Al-Azzawi’s paper addresses “why regulators, and the legal framework in New Zealand, have failed to act to protect patients from harm in the context of the mesh crisis.”

She says, “it is essential to hold New Zealand regulators accountable to ensure that these devices are, in fact, fit for purpose for their nation.”

Her paper explores how the various responsible regulatory bodies have collectively contributed to patient harm; acknowledges and evaluates the actions taken to restore and prevent further injury; and provides recommendations for reforms necessary to effectively protect women's health related to SUI and POP through the implementation of credentialling and registry systems.

*Surgical Mesh Crisis: Why have NZ regulators failed to act to protect patients from harm?* is available on the AWHC website.

\* Charlotte Korte and Renate Schütte have both suffered surgical mesh injury. Since 2012, Charlotte has been helping mesh injured New Zealanders navigate the health system, and has raised awareness about the continuation of harm. She is still advocating to prevent surgical mesh harm in Aotearoa New Zealand, and her work led to the 2019 restorative justice project where men, women and whānau shared their lived experience of mesh injury. As a result of her experiences with mesh injury and a complaint to the HDC, Renate, with the support of Charlotte, law professor Jo Manning, and AWHC member Sue Claridge, petitioned Parliament requesting that the Health and Disability Commissioner Act 1994 be amended to give complainants, and those that are the subject of complaints, the right to appeal decisions made by the Health and Disability Commissioner.

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# The Therapeutic Products Bill – Progress at Last

The Therapeutic Products Bill was finally introduced to Parliament on the 30th of November for its first reading and MPs debated the content of the bill in the first two weeks of December.

Many readers will remember the consultation document (that preceded the development of this version of the Bill), the *Therapeutic Products Regulatory Scheme*, that was released in December 2018 for public submissions. Among many others, Auckland Women’s Health Council made a [submission](https://womenshealthcouncil.org.nz/wp-content/uploads/2021/08/therapeutic-products-regulatory-scheme-consultation-document_dec18-KPdP-16042019.pdf) on the consultation document.

It has taken almost four years to move from the consultation document – which described the rationale for the Bill and features of the new regulatory scheme, content of the draft Bill, and what the new scheme would mean for different sectors and health practitioner groups – to debating the Bill in Parliament.

The Therapeutic Products Bill replaces the Medicines Act 1981 and Dietary Supplements Regulations 1985.

In announcing the introduction of the Bill to Parliament, Health Minister Andrew Little said the Bill will give New Zealanders peace-of-mind about the safety, quality and efficacy of the medicines, medical devices (and natural health products they are using.”

Minister Little described the Bill as “a flexible regulatory framework for how therapeutic products are manufactured, prescribed, imported, advertised, supplied and exported, and makes the regulation of clinical trials more robust.”

One of the most significant announcements is that there will be a new regulator in the form of a branded business unit within Manatū Hauora (Ministry of Health), led by an independent statutory officer who will work independently of the Director General and the Minister of Health. Importantly the new regulator will cover a broader scope of products and activities, including medical devices.

As is the case internationally, regulation of medical devices in Aotearoa New Zealand has been poor, leading to significant harm being caused to New Zealanders over many years. In 2018, In Europe, an investigation involving involved 250 journalists and eight million device related health records – the Implant Files found that governments have allowed products on the market, with little or no human testing, that went on to cause great harm and that the device industry, and the regulators that oversee it struggle to quickly identify hazardous implants after they are released, leaving patients exposed.

Ongoing issues with surgical mesh in Aotearoa New Zealand and the continuing harm predominantly caused to women, epitomises the problems with medical device regulation in this country. The surgical mesh crisis is more than adequate evidence of the need for a better regulatory system; one that properly ensures the safety, quality, and efficacy of devices across their lifecycle. This new regulatory body must be agile and responsive to reports of harm, and have the mandate – and the teeth and fortitude – to suspend or ban the use of products in order to prevent further injury occurring.

Unfortunately, this new regulatory body will not come into force immediately the Therapeutic Products Bill is passed, as secondary legislation needs to be developed. This work will start in 2023 and will take a number of years to put in place.

Disappointingly, the new Bill will continue to permit direct to consumer advertising of prescription medication (DTCA-PM).

Concomitant with the introduction of the Therapeutic Products Bill to Parliament, the Government also announced a new workstream to consider how rongoā Māori can be appropriately scheduled in legislation so that it is protected, and patient safety is assured.

In a press release, Associate Minister for Health (Māori), Peeni Henare said “We recognise the importance of rongoā, and we have been carefully considering how to recognise and protect it. This has included consulting with Te Kāhui Rongoā, a governance body for rongoā practitioners, Māori clinicians and health providers.”

Although rongoā is not mentioned in the Therapeutic Products Bill, because of the inclusion of natural health products in the Bill, aspects of rongoā are captured. Between February and March next year, Manatū Hauora are planning to engage with Māori partners and stakeholders to ascertain their views.

## Public Consultation on the Therapeutic Products Bill

Making submissions is an important way of ensuring that the consumer voice is heard on all aspects of the health system. While the ideal is co-design (consumers at the table with Manatū Hauora and Te Whatu Ora , policy writers, health sector managers and health practitioners) at the very start of any design or development of legislation, regulation, strategies, plans, etc. and of health care services and delivery, it is vital that consumers take part in the consultation process and provide feedback once documents have been drafted.

The current legislation that regulates medicines in Aotearoa New Zealand is more than forty years old, so the new Therapeutic Products could be around for a similar length of time. It needs to be fit for purpose, and that purpose is to serve health consumers, to promote and improve the health of New Zealanders and critically, to ensure the safety and quality of medicines, medical devices, and other therapeutic products.

On the 15th of December, Manatū Hauora announced that submissions were open on the Bill after it had been sent to the Health Select Committee. Submissions close on the 9th of February (at one minute to midnight), The proposed legislation is 288 pages and can be found [online](https://www.legislation.govt.nz/bill/government/2022/0204/latest/DLM6914502.html); information on making a submission on the Bill can be found on the [Parliamentary](https://www.parliament.nz/en/pb/sc/make-a-submission/document/53SCHE_SCF_BILL_130084/therapeutic-products-bill#RelatedAnchor) website. A considerable list of relevant Cabinet Papers on the Therapeutic Products Bill are available on the [Manatū Hauora (Ministry of Health) website](https://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime).

AWHC has expressed their concern to the Chair of the Health Select Committee, Tangi Utikere, about the inadequate time allowed for submissions. We have pointed out that the proposed legislation is long and complex and that the submission period coincides with Christmas, New Year and the summer holiday period, during which time many New Zealanders will be taking two to three weeks off to spend much needed time with their families, and recouping after what has been a hard year for most on very many levels.

The grossly inadequate period of time allowed to make submissions strongly suggests that the Government is simply paying lip service to public consultation and consumer input into the Bill. Such tokenism is not in keeping with the stated intention of the current Government and Te Whatu Ora \ Health New Zealand to create a people/consumer/whānau centred health system. We have raised these concerns about how genuine the Government is about consumer engagement both in this edition of the Newsletter and previously, and the submission period for the Therapeutic Products Bill has not done anything to heighten confidence in the promises of health consumers being at the heart of the new health system.

This seems to be a box ticking exercise and if the Government is to genuinely, and in good faith, create a people-centred health system, they are going to have to do a lot better and allow a realistic time frame in which consumers can properly consider and respond to consultation documents, especially one as important as this legislation, which has significant ramifications for every New Zealander, and may well be in place for four decades, as the legislation it replaces has been.

We have asked that the time in which New Zealanders can make submissions on the Therapeutic Products Bill be extended by at least for weeks, with submissions to close no earlier than the 9th of March 2023.

Irrespective of whether or not an extension is approved, we encourage individuals and organisations to take the opportunity to have their say on the Therapeutic Products Bill, to the extent that they can in the time allowed. We recommend focusing responses on the issues of greatest importance to rather than attempting to address all aspects of the Bill.

## References

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2. Claridge S, 2019: [Medical Devices and Safety](https://womenshealthcouncil.org.nz/wp-content/uploads/2021/08/AWHC-February-2019-Newsletter.pdf), AWHC Newsletter February 2019.
3. Henare P, 2022: [New rongoā workstream announced alongside Therapeutic Products Bill](https://www.beehive.govt.nz/release/new-rongo%C4%81-workstream-announced-alongside-therapeutic-products-bill), Parliamentary Press Release, 30 November 2022.

# Womens Health Strategy Update

Manatū Hauora | Ministry of Health has commenced consumer engagement public engagement on the health strategies that are required to be prepared under the Pae Ora (Healthy Futures) Act 2022. They have launched a Digital Engagement Platform – [Tātou](https://tatou.health.govt.nz/achieving-pae-ora-healthy-future) – an online discussion space for people to share their ideas and help Manatū Hauora understand what the problems are within the health system. They are asking people to join the kōrero, and together, help make the health system work better for all New Zealanders.

This platform has been set up to allow New Zealanders to contribute their thoughts and concerns and ideas about the various health strategies: Māori, Pāsifika, disability, women and rural.

AWHC, along with many other NGOs strongly advocated for a women’s health strategy in our submissions on the Pae Ora (Healthy Futures) Bill and as a result the Government has committed to including that in the documents that guide the new health system. It has been acknowledged by Associate Minister of health Ayesha Verrall, who is championing the women’s health strategy that there is bias in the health system that negatively impacts on women.

This is the first of hopefully many opportunities to have your say about how the women’s health strategy should look, what it should include.

Please register for Tātou and share your experiences in the health system with Manatū Hauora, especially what makes it hard for you to access health services, what isn’t working for you, what makes it harder for you to stay healthy and maintain your well-being. If you have had bad experiences tell them about those, too, and tell them WHAT YOU WANT!

Register for [Tātou](https://tatou.health.govt.nz/achieving-pae-ora-healthy-future) today and have your say!

# Australia’s Women’s Health Advisory Council

On the 8th of December, Australia’s Assistant Minister for Health and Aged Care, Ged Kearney, announced that the Australian Government is “Government is establishing a National Women’s Health Advisory Council to address stark differences in the health outcomes for women and girls.”

The National Women’s Health Advisory Council will be chaired by Ms Kearney, and she said that it “will provide strategic advice to improve Australia’s health system for women and girls.”

“The Council will look at the healthcare offered to women and girls when it comes to menstruation, reproductive healthcare and menopause, as well as medical consent and pain management.

It will also consider medical research and health outcomes for women across a range of conditions, like heart disease, autism and cancer care.”

Australian women face many of the same barriers, disadvantages and negative or harmful experiences in their health system as women/wāhine in Aotearoa New Zealand do in our health system.

Ms Kearney says in her media release, that “It is completely unacceptable that a young girl suffers ADHD symptoms without diagnosis for potentially years longer than a boy her age. Or a woman has her crippling pelvic pain repeatedly dismissed, only to find severe endometriosis.”

Also, that “In Australia no one should fall through the cracks when it comes to safe, high quality and affordable healthcare. It’s happening too often for women and we need to find effective ways to address the problem.”

It happens all too often here as well, and it simply is not good enough for women in this country to be subject to health system misogyny and bias.

One of the most gratifying aspects of Australia’s new Women’s Health Advisory Council, is the recognition of the importance of health consumers; the Council will “comprise some of the nation’s most eminent women’s health experts along with representatives from a mix of peak stakeholder organisations, consumer groups, and medical and professional bodies – including the voice of women with lived experience.”

Aotearoa New Zealand needs a National Women’s Health Advisory Council, and it is such a body, with a healthy proportion of consumers – those with lived experience of the health system – that should be providing advice on the development, content and action plan for the women’s health strategy.

Once again, we are asking for a seat at the table!

**References**

1. Kearney G, 2022: 'Medical misogyny' across health system to go under microscope in new National Women's Health Advisory Council, Media Release, 9 December 2022, Department of Health and Aged Care, Australian Government.
2. O'Halloran K, 2022: National Women's Health Advisory Council to tackle medical misogyny in medicine and health care, *ABC News*, Australia.

# Consumer Health Forum Aotearoa Hui

By Sue Claridge

In early November, I represented Auckland Women’s Health Council at a consumer Health Forum Aotearoa hui at Te Papa in Te Whanganui-a-Tara | Wellington.

AWHC joined the consumer health forum – a platform for consumers, whānau and communities to share their experiences and talk about what matters to consumers at every level of the health system – in 2021 when it first started.

The November hui focused on the hauora of Māori people, Pacific peoples, disabled people and older people, and on mental health and addictions. The day was spent responding to three key questions:

* 1. How would you like to be involved in the planning, design and delivery of health services?
	2. What improvements are necessary to keep people well in their community?
	3. What do equitable health outcomes mean to you, and how can we work to achieve them?

Although there was a very diverse group of consumers across gender, age, culture, dis-ability, life experience and experience within the health system, the responses from each of the five focus groups were remarkably similar, particularly in their responses to question one.

The desire of consumer s to be involved in co-design, and the importance of health entities engaging with consumers with lived experience of the health system, those who are experts by experience were the most consistent and overwhelming messages from the day.

From the report on the findings of the hui:

“Co-design and partnership is important to consumers. Participants felt strongly that groups engaging with consumers for the purpose of co-design projects must include a range of consumers, including everyday people, consumers with lived experience of a relevant condition and equity groups rather than clinicians. People with specific conditions are experts in their own right because of their experience. Consumers must be included as true partners in the process in a variety of contexts and stages, including advisory, strategy and governance. Consumers suggested that having them map out their user journeys would help in the design of systems and services that fit their needs. Participants were very clear that consumers and whānau should be considered a necessary part of planning and design decisions across the sector and that they should be involved right from the beginning.”

The report on the hui concluded that “The passion in the room was evident, as was the hope and expectation that not only will consumer voices be heard but also that tangible actions will arise from these forums.”

The Health Quality & Safety Commission who hosted the hui and facilitate the health forum say that they will provide the information and outcomes of the hui to the relevant agencies and share any resulting feedback with forum members.

What we need now is for the “relevant agencies” – Te Whatu Ora and associated health entities – to listen to the now strident and resounding voices of health consumers and include us in co-design at all levels of the new health system.

Consumer Health Forum Aotearoa, 2022: [Findings from the consumer health forum Aotearoa hui on 10 November 2022 | Ngā kitenga o te wānanga hauora kiritaki Aotearoa i te 10 o Whiringa-ā-rangi 2022](https://www.hqsc.govt.nz/assets/Consumer-hub/Consumer-resources/Report-consumer-health-forum-Aotearoa_10Nov22_December-2022.pdf), December 2022, Health Quality & Safety Commission