Auckland Women’s Health Council Newsletter

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A Legacy of Pain and Disability

What Essure has Inflicted on New Zealand Women

By Sue Claridge and five brave women willing to tell their stories

Espoused as being safer and easier, the Essure contraceptive device has left a devastating legacy for many New Zealand women.

Essure was marketed as a safe, easy alternative to surgical sterilisation; a permanent form of contraception that required no anaesthesia and left no scars. There was no need for a hospital stay. The four-centimetre-long coils could be inserted into a woman’s fallopian tubes in a gynaecologist’s rooms in a short 45-minute procedure, and the woman could go straight back to her day, straight back to her life.

But Essure did not live up to the manufacturer’s hype; not only did the device fail to prevent pregnancy far more often than the alternative tubal ligation, it caused devastating and life-changing harm to thousands of women.

Essure Hysteroscopic Sterilisation

Essure was a permanent sterilisation device that had been offered as a less invasive alternative to tubal ligation, and which was implanted in the fallopian tubes without an incision or anaesthetic. The device comprised an inner core of polyethylene terephthalate (PET) fibres, held in place by a flexible stainless steel inner coil and a dynamic outer nickel titanium alloy coil. The PET fibres were designed to work by stimulating an inflammatory response causing the growth of benign fibrous tissue that blocked the fallopian tube over a period of three months. Women with Essure had to use alternative contraception for three months afterwards, and have hysterosalpingograms at three months to ascertain that the procedure had worked and that the fallopian tubes had become blocked or occluded. (A further hysterosalpingogram would be done at six months if the first showed that the fallopian tubes remained open). The Essure procedure is non-reversible and if side-effects occur the only method of removal is surgery to remove the fallopian tubes. In Aotearoa New Zealand this is only offered as part of a full hysterectomy, although in the US some surgeons offer a limited surgery that removes only the fallopian tubes.

In 2017, the Essure contraceptive device was removed from the market in all countries except the US, and was finally removed from market in the US a year later. Despite Bayer’s insistence that the decision to pull sales and distribution was “not related to a question of safety or dangerousness of the medical device”, the removal of the device followed the banning of Essure in multiple countries, and the addition of an FDA black box warning in 2016 owing to severe adverse events. In addition, a study published in JAMA in 2018 found that women with Essure experienced sterilisation failure seven times more often than women who had their tubes tied, and the documentary, The Bleeding Edge – see page 24, reported more than 800 pregnancies owing to failure of the Essure devices.

Between October 2013 and October 2023, 62,830 medical device reports about Essure were submitted to the US FDA’s Manufacturer and User Facility Device Experience (MAUDE) database, of which 118 related to the death of a patient, 1032 were for malfunction of the device, and 61,680 were for injury.

The Medical Device Network reported that between November 2002 and December 2018, most of the injury reports described more than one complication, with 26,244 reports listing pain and 13,114 listing heavier or irregular periods. “Patients also reported headache (8,398), fatigue (6,912), weight fluctuations (5,853), depression/anxiety (5,175), hair loss (4,880) and hypersensitivity/rash (4,807). Many of these symptoms are thought to be caused by autoimmune reactions to the metals Essure is made of.”

We have reported on Essure previously in the AWHC Newsletter, most recently in the February-March and April 2018 editions. It has been impossible to obtain any accurate figures on how many women had Essure implanted, although one Auckland gynaecologist, Dr Astrid Budden, wrote in 2014 that she had performed “around 200 procedures” since 2010. When asked in 2018, Bayer would not release how many Essure devices were sold in New Zealand, citing commercial sensitivity. A 2021 Newshub article confirms that it isn’t known how many women in Aotearoa New Zealand received the device.

In our 2018 articles on Essure we wrote that we had been advised that 240 procedures had been done in the Auckland DHB, and 31 in Waitematā. Research by one of the women harmed by Essure in Aotearoa New Zealand suggests that seven DHBs offered the Essure sterilisation. In addition, an unknown number of private practitioners offered the Essure device. Bizarrely, one of those, Omnicare Women’s Health, still lists Essure on their website under permanent birth control despite the fact that it was withdrawn from Aotearoa New Zealand in 2017 and Bayer confirmed in 2018 that “no residual stocks remain in the country”!

Based on the information we do have, it is conceivable that 1000 or more women/wāhine may have had Essure implanted.

Essure has left a very unwelcome legacy; many women who had the device implanted continue to suffer pain and serious health complications as a result. They struggle to be taken seriously by doctors and often experience gaslighting from health professionals when they seek help. The women we have spoken to for this article have been:

* fobbed off by doctors;
* told their symptoms are nothing to do with Essure;
* told that it’s all in their head;
* accused of being drug-seekers;
* denied the treatment they need to address their symptoms and improve their health and quality of life;
* forced to repeat their story over and over to different doctors, many of whom do not know what Essure is or anything about it, including its widely documented adverse impacts and chequered history.

In 2017, when Bayer withdrew the devices from Aotearoa New Zealand, Medsafe issued a recall of Essure on the 8th of September. They stated:

“Unimplanted product is being recalled as the CE† mark has been temporarily suspended. Physicians are being informed of possible adverse events following implantation and being requested to monitor patients.”

There is no evidence that any of the gynaecologists or physicians who implanted the devices have monitored or communicated with affected women at all. There is no mention of Essure on the website of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), an organisation that you would expect would have some information for gynaecologists on adverse events associated with these failed devices and Medsafe’s instruction for patients to be monitored. You would expect that it would be incumbent upon the DHBs who implanted Essure to contact each and every patient and discuss their health and potential side-effects of the now thoroughly discredited device.

As well as providing an update on the harm caused by Essure, the aim of this article was to give a voice to some of the women in Aotearoa New Zealand who continue to suffer from the impacts of Essure. Our health entities and our health professionals must be made aware of the impact that their decisions and/or lack of action has on the lives of women who put their faith and trust in the health system, and who have been left to fight that same health system just to regain some semblance of their former lives.

There are, no doubt, many more women in this country suffering in relative silence because of Essure. On behalf of the women we have spoken to and those who continue to suffer, we demand action. The Ministry of Health | Manatū Hauora must issue a genuine “recall” that makes it compulsory for all health professionals and institutional providers involved with the implantation of Essure to contact all women who have had Essure, to provide a thorough check of their wellbeing and health status to establish if they may have suffered from adverse events associated with the device. Urgent follow-up treatment must be offered where required at no cost to the women affected.

In a 2018 article, published in the *Sunday Star Times,* on the crippling side-effects of Essure, Ministry of Health Medsafe group manager Chris James said that Medsafe expects medical device companies to act responsibly and in patients’ best interests.

“We expect companies to ensure their products are designed using current best practice and that they engage in appropriate post-market surveillance to detect any issues. We also expect them to take action, make changes or issue warnings in good time if they discover problems with their products,” James said.

Such an expectation is tantamount to putting the fox in charge of the hen house. Such mindboggling naivety would be laughable were it not for the devastating and ruinous impact that Essure has had on the lives of many women in this country. To this day, Bayer insists that Essure is safe and effective.

The problems extend beyond the refusal of some device manufacturers to take responsibility for their faulty and injurious products, to the grossly inadequate regulatory processes for medical devices, especially the FDA’s 510(K) process in the US (see *The Bleeding Edge* review and the Auckland Women’s Health Council webpage on the [Regulation of Implantable Medical Devices](https://www.womenshealthcouncil.org.nz/regulation-of-implantable-medical-devices/) for more information), upon which Aotearoa New Zealand regulators very largely rely.

We urge all women whose health may have been adversely affected by Essure to [lodge complaints](https://www.hdc.org.nz/making-a-complaint/) with the Health and Disability Commissioner and if further treatment is necessary lodge a claim with ACC through their GP. Additionally, affected women can [report their adverse events directly with Medsafe](https://www.medsafe.govt.nz/downloads/adverse-event-report-consumers.docx).

(Click here for more information on [Reporting Adverse Events and Harm](http://consumeradvocacyalliance.co.nz/consumer-resources/reporting-adverse-events/))

Reports of Essure Harm in Aotearoa New Zealand

In August 2023, AWHC submitted OIA request for information on reports of harm caused by Essure to Medsafe, the Health and Disability Commissioner and ACC. We sought a range of information:

* How many claim/complaints/reports had been lodged regarding the Essure contraceptive device?
* How many claim/complaints/reports were regarding failure of the device to prevent pregnancy?
* How many claim/complaints/reports were regarding pelvic pain, menstrual issues (e.g. heavy bleeding), uterine infection etc?
* How many claim/complaints/reports were regarding systemic issues such as chronic fatigue, headaches/migraine, autoimmune disorders or symptoms, pain, etc?
* How many claim/complaints/reports were regarding sensitivity or allergy issues such as sensitivity to nickel?
* Were any claim/complaints/reports referred to the need for follow-up procedures, such as removal of the Essure devices, surgical removal of fallopian tubes, hysterectomy, etc. as a result of failure or injury caused by the Essure devices?

In addition, we asked ACC how many claims were accepted or declined and how much had been paid out for claims regarding Essure devices. We also asked the HDC the outcomes of the complaints that were lodged.

**Medsafe**

* Medsafe has received 12 reports of adverse events following implantation of Essure.
* Two reports of pregnancy were received, and in two further cases tubal patency was specified (the devices failed to block the fallopian tubes and pregnancy was possible).
* One of the reports specified heavy menstrual bleeding, and two others referred to pelvic pain. One report referred to chronic fatigue and one to migraine. Three reports referred to pain in addition to the two reports that specified ‘pelvic pain’.
* There were no reports of sensitivity or allergy issues.
* Six of the reports mentioned further surgery including removal.

**Health and Disability Commissioner**

The HDC response noted that the complaints database does not categorise complaints as to whether or not an Essure device was involved in the complaint. They obtained the data they provided by searching for complaints where the word ‘Essure’ was used in the complaint description field and said that this is unlikely to represent all complaints received by HDC about Essure devices.

Two complaints which mentioned ‘Essure’ in the complaint description field were found.

One complaint resulted in no further action being taken following assessment, and one is currently under assessment by HDC.

Of the two complaints identified in HDC’s database, both complaints involved informed consent issues and concerns over continued pain and unexpected outcomes following implantation of the device. Neither complaint involved a failure to prevent pregnancy. Both complaints involved follow-up procedures and concerns around removal of the device.

**ACC**

Between 1 July 2005 and 9 September 2023, ACC made a cover decision for nine treatment injury claims that mention the term ‘Essure’. Four claims were accepted for cover and five claims were declined for cover.

To date, the total cost of the four accepted treatment injury claims is $105,547. This amount includes compensation payments of $2,833, rehabilitation payments of $23,704 and treatment payments of $79,010.

The four accepted claims have different primary injuries; foreign body, implants misplaced, perforation and tissue injury/damage.

ACC also noted that until a claim cover decision has been made, they are unable to determine the cause of the injury, in this case, Essure contraceptive device. Therefore, they are unable to provide data for the number of claims lodged relating to Essure.

Beth

“I had Essure implanted in February 2011 and finally had a hysterectomy to remove them in December 2021. My battle, like that of my fellow e-sisters, has been long, harrowing, and wholly unnecessary. I’ve gone from physically fit and active, walking all of our 16-acre hill side property, to housebound, barely able to cope with a flight of stairs.

While looking for a specialist who might know about Essure and be willing to remove it in late 2020, I learned the device had been recalled. What I discovered horrified me, and completely eroded my trust in gynaecology. It wasn’t much help health-wise, but it certainly explained a lot about my own rapid health decline.

I have experienced a decade of excessive pain, bleeding, loss of bodily and cognitive function, an escalation of existing allergies, new allergies, dental and bone issues, sporadic bloating, dizzy spells, cold sweats, digestive issues, hair loss, memory loss, and many other symptoms I believe were signs of bodily rejection of the implant. I have searched for reasons for strange rashes that appeared overnight; stopped venturing too far outside due to constantly stumbling, tripping and falling; and gave up driving due to medication. I became housebound, felt alone, terrified I was dying, watching my life just fall by the wayside.

I’ve been on medication I never had to rely on before, from blood clotting meds, beta blockers (no-one noticed they were killing me), fluid tablets, to four times my normal antihistamine usage, along with daily use of anti-inflammatories and pain medication, including opioids. Over the last 12 years, I have been told my extreme allergic reactions and asthma attacks were stress, my increasing pain was in my head, the bleeding was “just something that happens when some women get their tubes tied”; that I was overreacting to symptoms and should just de-stress.

I saw multiple different specialists, but I was never referred to the gynaecologist I was begging for.

Denied the scans I needed in the public health system, I paid for my own scans and, later, a private gynaecology clinic visit for biopsies. The scan revealed quite severe adenomyosis, along with a left ovary of questionable health. The recommendation was removal of uterus and left ovary. The biopsy also revealed a VIN 3 lesion on my vulva.

In the weeks following the scan I was in excruciating pain, as I was every time I’d had imaging or walked through a metal detector, since the device was implanted.

Prior to my hysterectomy, I began experiencing uterine prolapse along with severe pain (like giving birth to razor blades) and a few weeks later, passed a black blood clot containing pieces of metal. I took this clot with me to hospital on the day of surgery, but the surgeon just shrugged her shoulders and ignored it.

After surgery, I was told that she “could see the coils in the tubes” but that she just “gave the ovary a squeeze” and decided to leave it because she’d rather leave something half functioning than remove it.

It is now stuck to my bowel, with my intestines around it, causing me pain and additional digestive issues, and is now unable to be removed without another surgery involving multiple specialists.

I had asked for return of my uterus, and when I collected it one of the coils appears to be very broken; the other was visible and appeared to be barely under the outer layer of tissue in the tubes. My uterus also appeared to have shards of metal in it. All these issues have been ignored by my surgeon.

Due to the specialist not giving the device the serious consideration she should have, ACC declined my case for expense reimbursement, and of course, no one is covering my recovery.

Sadly, hysterectomy is not the end of the issues the device can cause, and detox and recovery is slow, expensive, and full recovery is not always possible.

The whole experience has been very traumatic and soul destroying. I am now waiting to have trauma counselling to help me come to terms with the loss of my health, intimacy and physical function, and the loss of employment. Additionally, due to the toll the device has taken on my skeletal system, I am now undergoing what will be lengthy physiotherapy to try to return my body to a more functional state.

This is my life, ruined by Essure.

Devices are allowed to remain on the market because specialists refuse to accept the devices they use can cause harm, do not take them seriously enough, and consequently fail to notify issues to Medsafe, who are then fooled in to thinking that there is no problem.

It is a catastrophic failure of the medical system to protect women in their care.

In Australia, the first of many international trials involving over 1,000 women versus the importers (the same importers in New Zealand) and manufacturers of Essure is coming to a close. In New Zealand women are still struggling to be heard.

How has this been allowed to happen?”

Shay

Shay is not the woman, the mother, the wife, she once was; she is not the person she wishes she could be.

Essure has destroyed her life, stolen a career that she loved and left her with chronic pain and health issues she didn’t have before Essure was implanted. She has been fobbed off and gaslit by doctors, diagnosed with PTSD and, despite the eventual hysterectomy and removal of the devices, her body has never recovered.

After two children from seven pregnancies, five that ended in miscarriage, Shay couldn’t face more of the same. In 2013, she went to her doctor seeking a tubal ligation or hysterectomy. Citing her young age and her weight, the gynaecologist gave her the “hard sell” on the Essure contraceptive device, telling her that no general anaesthetic was required and she’d be “in and out in a day”.

Very soon after the procedure, the Essure coils set off a cascade of medical injury that she couldn’t have imagined.

At her three-month post implantation hysterosalpingogram Shay experienced extreme pain only to find that the fallopian tubes were not yet blocked and she had to have a second hysterosalpingogram at six months. Despite a sedative the second time the procedure was still agonising. On top of that, there was “flow” of the contrast dye through her fallopian tubes; Essure had been an abject failure as a form of contraceptive.

In May 2015, Shay finally had the tubal ligation she’d originally asked for, and also had a Mirena contraceptive device inserted in her uterus to help deal with the heavy bleeding that Essure had caused.

The next seven years was an ongoing battle in the health system to have doctors listen to her and take her chronic pain and other symptoms seriously. She bounced around from GP to hospital to GP, frequently experiencing gaslighting from the medical “professionals” that she saw. She was accused of being a drug-seeker, was told it was all in her head, or that her mental health was to blame.

During this period, Shay repeatedly had to explain to doctors about the Essure devices, as many didn’t have any idea what they were or how they were supposed to work.

On her second referral to the Burwood Pain Clinic in Christchurch a doctor finally began to think she might be right about the Essure being the cause of her health problems. She had a hysterectomy and it was found that one of the Essure devices had perforated her uterus and that neither coil had been properly implanted in her fallopian tubes. Both had been incorrectly positioned in the cornua of the uterus, the “horns” where the fallopian tubes connect to the uterus, but not in the fallopian tubes themselves. Shay’s Essure implantation procedure had been destined to fail from the start.

The long-term impacts of Essure are significant and debilitating. Shay still suffers chronic pain and takes opioid pain medication every day. She suffers with severe issues with her bladder owing to nerve damage in her pelvis. She has no sensation in her bladder and needs a catheter to pee. In addition, the nickel in the coils has set off a hypersensitivity in her body and she is now hyper-reactive with multiple allergies that she didn’t used to have.

Shay was diagnosed with PTSD by a psychologist. However, because it can’t be tied to a specific incident on a specific date, ACC has denied that she has PTSD and has said that she has an adjustment disorder; difficulty adjusting to the medical injury that she has suffered, effectively telling her it is her fault that she hasn’t “adjusted” to the way her life is now.

“Essure absolutely ruined my life,” she says. “I am no longer who I was.”

“There seems to be no justice for us.”

While women in Australia are involved in class action lawsuits against Bayer, in New Zealand, because of ACC, women harmed by these devices get nothing and have no redress.

Shay became quite depressed for a year, but now that she is starting to come out of that she feels like fighting back.

“It’s time I said this isn’t OK.”

Amanda

“I had the Essure contraceptive coils inserted in June 2013. I didn’t want any more children and I asked about tubal ligation, but was advised that there was an extremely long waitlist. However, I was offered a new, nonsurgical, safe, quick and easy procedure. That day at in hospital was the start of my decade long nightmare.

The procedure went well enough, and I had a small amount of bleeding and some abdominal pain for a few days, both of which had been expected. At my three-month hysterosalpingogram it was confirmed that tubal occlusion had occurred; I could stop taking the pill and get on with life. Fabulous!

Little did I know that, within a few years, I would be living in a haze of brain fog and dealing with chronic abdominal and vaginal pain, not to mention horrendously sore breasts. What started as a great sex life, deteriorated to the point where there has been no intimacy for more than two years now. My periods go for weeks and are so heavy and clotty, sometimes I cannot even leave the house for fear it is going to flood everywhere, which has happened.

More recently I have been diagnosed with autoimmune conditions, including POTS (postural orthostatic tachycardia), [Raynaud’s](https://www.hopkinsmedicine.org/health/conditions-and-diseases/raynauds-phenomenon) and [Sjogren’s syndrome](https://www.mayoclinic.org/diseases-conditions/sjogrens-syndrome/symptoms-causes/syc-20353216). Along with the constant pain and severe fatigue, I deal with ongoing corneal erosions and corneal ulcers, hives and rashes. My face itches and burns and I have developed sudden intolerances to food, which make the inside of my mouth swell with painful bumps, and causes stomach cramps and bloating so severe it can be difficult to breathe. My teeth are cracking, my gums swell and bleed, and my hair falls out constantly.

I have been trying to get help for years, particularly recently as my health is deteriorating more and more. None of the doctors know about Essure, let alone the issues it has been causing. After a referral to the gynaecology department of a another hospital in June, I tried desperately to explain what Essure is and finally got an appointment for an ultrasound and a pelvic x-ray. However, the pelvic x-ray was cancelled four months later (apparently because they could see that the Essure was fine in the ultrasound). A referral to a different gynaecologist was cancelled, six different appointments were rescheduled, and I finally saw another gynaecologist, who told me that the coils are in the correct position but they can remove my tubes if that is what I want.

My experience shows that nobody knows what they are dealing with and they haven’t bothered to research the correct way to remove Essure, or even the correct imaging to ensure that fragments of the coils have not broken off and migrated, or that the PET fibres moved through the uterus and caused inflammation everywhere. I have zero trust in the health system that put these things in me and even less when it comes to removing them.

I just want the health system that implanted these substandard devices to give me a hysterectomy to remove the coils. I am angry, frustrated and tired, and wish I had never ever heard of Essure. I really, really want my life back. I feel like we have been tossed in a corner and forgotten.”

Kim

“I have received horrific treatment by my gynaecological specialist here. He pushed for me to have the Essure procedure rather than have a tubal ligation following the birth of my twins in 2007.

At the same time he implanted the Essure devices, he also inserted a Mirena\* without my consent. I was ***not*** told beforehand that he planned to insert a Mirena at the same time, but post-op he explained it was done so the Mirena would ensure that I wouldn’t fall pregnant in the first few months afterwards.

After getting Essure, I experienced daily pain, migraines, and I bled like a ‘stuck pig’ – the heavy and painful bleeding lasted the whole three years that I had the coils in and continued right up until I had my hysterectomy.

This gynaecological specialist dismissed me numerous times when I saw him post-Essure. I told him I was suffering daily. He told me that the Essure coils were absolutely ***not*** the cause of my pain and other symptoms.

For the last appointment I had with him, I went armed with pages and pages of information and research, which validated my fears and concerns with all the symptoms I was experiencing since the Essure procedure. With his prodigious ego, I’m sure you can imagine, that my attempts to advocate for myself offended him, to such an extent that he stated that he absolutely was ***not*** going to remove my Essure coils that ***he*** pushed for me to have. This doctor vehemently denied that, regardless of the proof and research that I presented to him, my pain and symptoms were 100% ***not*** caused by Essure. He diagnosed me with regional pain syndrome instead, essentially said my pain was in my head, and then that was it! This doctor had seen me for a few years by this point.†

My GP then went on to organise a referral to another gynaecologist at North Shore Hospital. In my appointment with her, I showed her all the information I had, and it really didn’t take long for her to tell me that she would put me on the waiting list for a hysterectomy ASAP.

I had my total abdominal hysterectomy (in the public sector a laparoscopic hysterectomy was not an option) at the end of March 2016.

Since then, I have struggled to get help for an inflamed gallbladder and other symptoms because of my diagnosis for regional pain syndrome.

I see a Professor of Gastroenterology who is well regarded, and he has said I do not have regional pain syndrome. However, because the regional pain syndrome diagnosis is on my record, doctors won’t help me or offer surgery that the Professor has recommended. The Professor has said when you open my notes online, the first thing that comes up is my regional pain syndrome diagnosis.

It’s very difficult to be treated fairly.”

Jess

“In late 2009 I sought a tubal ligation. As health care student at the time, I understood the risks versus benefits and while my BMI was high, I was well and had no blood pressure or diabetes risks, and I understood the risks of general anaesthetic (GA).

I was seen by a gynaecologist who suggested that Essure would be better as it would remove the need for a GA. At the time, I felt like there was pressure on me to accept Essure rather than the tubal ligation as it was a fairly new device and procedure, and as a soon to be health practitioner, I could provide feedback. I left the appointment feeling as if I had been railroaded and talked out of having the tubal ligation.

The care at the time of the implantation and hysterosalpingogram was excellent, apart from the verbal disclosure of the discovery of a possible polyp in my rectum. I am disappointed that disclosure was only verbal and no clinical follow up was suggested, apart from a brief discussion where I was told I should “get that checked out”. I admit I didn’t quite understand the gravity of the situation and only remembered that conversation once I had been diagnosed with rectal cancer eight years later.

I expected some discomfort in the bedding in phase after the Essure was placed. However, after allowing a reasonable amount of time, the discomfort was not easing. I had particularly sharp pains when driving and found the constant dull ache distracting and bothersome. I told my gynaecologist about the issues I was having with pain. The pain was dismissed as normal, and I was advised to wait and see how it went.

I requested the Essure be removed more than once and had always been met with a definitive no. Appointments were made with a pain team, though I could not understand why medication would be prescribed for something that had a clear way to resolve it: removal!

I trialled a few medications, but my regret and frustration led me to decide that it would just have to be a discomfort I learnt to deal with, as the medication pathway wasn’t one I wanted to go down. As someone who worked in women’s health and who advocates strongly for a woman’s right to choose her treatment, I felt being told medication was the only route wasn’t correct, fair or in line with the Code of Patient rights.

As the years went on and the research and reports on the adverse events associated with Essure came out, I felt more and more as if my experiences with pain had been dismissed and invalidated. I am also disappointed my right to clear communication wasn’t upheld. At no point have I ever been contacted about the status of Essure. As a now banned device, I believe the DHB should be accountable to the women they placed the device in. If a device is banned, wouldn’t you want to be informed?

My complaints of pain were not taken seriously until I was diagnosed with rectal cancer and I believe my pain levels were elevated during the cancer treatment due to the underlying Essure discomfort.

The inability to have my concerns taken seriously for the last ten years has left me distrustful of the health service and is a contributing factor in my ending my career in health care. How on earth can I believe in my ability to advocate for my patients when I am in constant discomfort and pain from the placement of a now banned device?

I regret having the Essure. I wish it had never happened and wish that I could have my previous self back. I wouldn’t wish this on anyone.

By 2022 I had lodged a claim with ACC in the hope that removal could be expedited. Finally, in early 2023 – 13 years after having the Essure implanted – I had a hysterectomy. When I came out of the general anaesthetic the constant pain I had suffered from the Essure was finally gone.

While it is a relief that the Essure are gone, it has left a painful legacy for me. There has been a lot of focus on my prior PTSD and my “emotional problems”, with that phrase being added to my discharge papers. I was asked if I wanted to see the mental health team as well.

I also keep being told no-one else has come forward or seems to have an issue with the Essure devices.

Everything that has happened, including dealing with the rectal cancer and ongoing pain for more than ten years, has hit me severely financially. I don’t know how on Earth I can go back to working in women’s health after this? I’ve lost my career to these implants. Working with people who I know dismissed my concerns and obvious pain just feels impossible.

For me there are enormous and ongoing consequences to this; it’s gutting.”

The Bleeding Edge

Netflix Documentary, 2018

Review by Sue Claridge

*The Bleeding Edge* is described by Netflix as an “eye-opening look at the fast-growing medical device industry [that] reveals how the rush to innovate can lead to devastating consequences for patients”.

It is a ‘must-see’ documentary for many health practitioners, including surgeons, and GPs who are inevitably the doctors that patients see first when they suffer life-changing harm from medical devices. However, most importantly this documentary should be compulsory viewing for our health and medical regulators, and the heads of our health entities, such as the Ministry of Health | Manatū Hauora, Medsafe, ACC and HDC.

Medical devices are a $400 billion-a-year industry and, make no mistake, their primary purpose is to make money for their investors.

Despite being five years old, this documentary is still as pertinent as the day it was released. While some of the medical devices that feature are no longer on the market, that they were ever licenced and unleashed on unsuspecting and trusting health consumers is an indictment on the regulatory process for implantable medical devices, and an important warning for the future.

In one review, *The Bleeding Edge* is described as “like an all-too-real horror show that is ongoing for thousands of unwitting patients with meagre relief in sight”. I couldn’t agree more; it is a hard watch at times for anyone who possesses an ounce of empathy.

**“Medical devices are a way of life in America. They are a way of life in post-industrial society. They are a reason, in some ways, for post-industrial society. They help us live longer. They give us better quality of life. And they’re just about everywhere.”**

***— Jim Spencer, Journalist, Minneapolis Star Tribune***

Right from the beginning, the documentary is clear that many medical devices save the lives of many people and significantly improve quality of life for many, many more. But these positives must not outweigh the abject misery and harm inflicted upon thousands of people because greedy, profit-driven pharmaceutical companies and device manufacturers have taken advantage of a regulatory system that is criminally inadequate.

*The Bleeding Edge* features the devastating consequences of the use of metal-on-metal chrome cobalt hip replacements, surgical mesh and the Da Vinci surgical robot, particularly when used to perform hysterectomies. However, it is the focus on the Essure contraceptive device that is the most chilling, following patients who had been literally lied to about its benefits and conned into having the devices implanted, on a downward spiral from health to hell on Earth.

The personal stories – not just the Essure stories – are horrific and the impact on people’s lives soul-destroying. The victims of the industry’s callous disregard for health consumers are predominantly women, whose lives have been ruined by implantable medical devices that should never have been licenced.

One of the worst of these stories is that of Ana Fuentes, a full-time marriedaccount executive with four daughters. Ana and her husband decided that four children was enough and her doctor recommended the Essure contraceptive device.

Immediately after the procedure Ana started suffering from pain and heavy bleeding, and almost immediately the gaslighting began, with her doctor telling her that Essure was nothing to do with her symptoms. She went on to need multiple hospital visits for extreme pain and the uncontrollable menstrual bleeding.

She experienced a cascade of loss: loss of her sex life, her marriage, her job because the pain and repeated hospital visits meant so much time off; loss of income, her home, her independence and dignity. Eventually, having moved from place to place, including having to live with her children in cheap motels, Ana is forced to leave her children with a church affiliated foster family while she continued to struggle with ill-health caused by Essure.

Another very revealing story is that of Gaby Avina, a nurse who assisted with the placement of Essure during the clinical trials, who was convinced by that it was “it was everything I was looking for” in a permanent contraceptive.

“The company liked my story because I was a nurse, I’d participated on both ends of the product. So, I was invited to be a spokesperson. I even went so far as I had my own website called Ask Gaby. Patients would write to me, doctors would write to me. I told them all the benefits. I used to tell them that it took longer to get your nails done than it did to get sterilised.”

Only, Gaby discovered that she had been lied to like so many others. After her procedure she was tired all the time. Then she started falling; her legs would give out. The doctor told her it was an immune response to something.

She was contacted on Facebook by many women who asked her if she was the Gabriella Avina that was the spokesperson for Essure. They asked her how her health was, and all of a sudden it all made sense to her.

Gaby says:

“I failed thousands of women for seven years. It’s a long time to tell women that a product is great. So, the guilt that you live with... and the pain... and just crazy feelings of responsibility because of that.”

Medical Device Regulation in the US

How is it that these defective, incredibly harmful medical devices even get beyond the prototype and clinical trial stage? *The Bleeding Edge* clearly sets out one of the major issues in the regulation of medical devices.

Jeanne Lenzer, author of *The Danger Within Us* provides some early history to the regulation of medical devices:

“For many years, devices just came onto the market with the anecdotes of doctors who used them, who would say, “Well, I think it works.” It was only with the Medical Device Amendments of 1976 that devices came under control of FDA.”

“At that point, industry argued, “We don’t want to have to test everything we’re already using, pacemakers and other devices.” And the FDA said, “Okay, you can grandfather in anything that was on the market prior to 1976.”

Dr Michael Carome, Director of the Public Citizen Health Research Group, continued the story:

“Since 1976, the complexity of devices, the number of devices, the types of devices, just rapidly expanded. So, we have the same framework that was imposed, you know, 40 years ago for a device world that is much more complicated today.”

Dr David Kessler, FDA Commissioner from 1990-1997, admitted that “when it comes to medical devices, we built a system that doesn’t work.”

Because the medical device industry complained that the testing that drugs must go through to prove safety and efficacy is too expensive for the “innovation” that happens in developing medical devices, the US Congress established the 510(K) process. It allows a medical device to be approved on the basis of being substantially equivalent to a previous medical device – or predicate – that was approved.

The 510(K) process was “meant as an exception, in essence, a little loophole... That exception became the rule. So, the vast majority of devices today, regrettably, are regulated under this framework,” said Dr Kessler.

Dr Deborah Cohen, Associate Editor of the *BMJ*, explained that this results in “what we call a daisy chain. And then, quite often what you found is that some of these predicate devices, as they call them... have been actually recalled from the market because they’ve been failing.”

“So, even if the device was recalled because it was dangerous, you can still use it as a predicate and get your device cleared because it’s substantially equivalent. So, there’s a lot of problems with that 510(K) system. And that’s how metal-on-metal hips got on the market,” explained Dr Rita Redberg, *Editor of JAMA Internal Medicine*.

All vaginal mesh devices were cleared through the 510(K) pathway. The FDA did not require human studies.

Even the supposedly more stringent PMA or pre-market approval process for the riskiest devices is not very rigorous and is far less rigorous than the process for drugs.

“Most drugs have to have two clinical trials, and they have to have large numbers of patients. With devices, it’s only one study. Those studies are often small. Sometimes it’s 100 people. I’ve seen studies with 50 people. So, the approval process for the riskiest devices is not good,” said Dr Diana Zuckerman, President of the National Center for Health Research.

What the documentary doesn’t say, is how much other countries rely on regulation and approval of medical devices in the US, for example Aotearoa New Zealand. In this country, we substantially accept devices here based on approval by the FDA. Here, Medsafe only carries out the bare minimum of evaluation of medical devices. The only requirement is that the manufacturer or importer list it electronically on [Medsafe’s WAND (Web Assisted Notification of Devices) database](https://www.medsafe.govt.nz/regulatory/DevicesNew/3WAND.asp) within 30 days of it being first supplied. The Medicines Act contains no pre-market requirements for their assessment and approval whatsoever. Medsafe does not review any clinical or other information about a device, such as warnings or adverse event reports.

At the end, the documentary makers had this advice for health consumers:

* Research any device that will be used on or in you. New is not necessarily better.
* Get a second opinion for any risky or expensive procedure.
* Ask your surgeon how many procedures he or she has performed.
* Have a friend or family member be your advocate while you’re in the hospital.

It is impossible to do justice to *The Bleeding Edge* in a review. It is impossible to adequately convey the horror and the trauma that so many people have experienced as a result of grossly inadequately regulated medical devices. It is impossible to convey the sense of incredulity and injustice that you feel watching this and hearing from the enormous cast of commentators, surgeons and other health professionals, academics, patients, patient advocates, regulators and FDA officials, and pharmaceutical and manufacturing staff and CEOs.

For that reason, I strongly recommend watching *The Bleeding Edge* if you have access to Netflix. However, this recommendation comes with a warning: much of the content could be triggering, especially if you have been harmed by any of these devices specifically or harmed within the health system in other ways.

For anyone who can’t access the documentary, we have posted a [transcript on our website](https://www.womenshealthcouncil.org.nz/wp-content/uploads/2023/11/The-Bleeding-Edge-Transcript.pdf). You may also be able to access it by renting or purchasing it on Amazon or iTunes, and at the time of writing it was available for free on [Vimeo](https://vimeo.com/286151015).

Our Health System: A Crisis of Health Reform Mismanagement

By Sue Claridge

“If you don’t have your health, you don’t have anything.”

— Chuck Pagano, US (former American football coach and player)

To be honest, anyone could have come up with that quote. It is attributed to Chuck Pagano, but I know many who have said the very same thing, without knowing it was a “quote”. I’ve said it myself on very many occasions.

It is so true, so real, that ‘If you don’t have your health, you don’t have anything’ has no need of being a quote. It is a universal truth that most of us know and understand, a truth that anyone who has been ill, even temporarily, knows all too well.

That said, you have to ask yourself how on Earth we have ended up with a health system as broken as ours is now.

In April 2021, I wrote an article on the health system overhaul that had been announced that March, by then Minister of Health, Andrew Little.

In that article I wrote:

*We not only need a health system that delivers equity and excellence, but we need a health system that is properly resourced and funded, that is able to address staffing shortages, particularly in nursing and midwifery.*

*We need a health system that is good enough to retain staff at all levels, rather than one that exhausts and burns out staff forcing them to leave. The changes need to extend to how we train and resource the people who staff all levels of the health system, for example training that addresses the acknowledged institutionalised racism seen in some of our DHBs. We need a health system in which delays in diagnoses and treatment are in the past; a health system in which there is a cultural shift in the provision of services so that complaints to the Health and Disability Commissioner drop year on year rather than rise.*

*It is important that this overhaul, in whatever shape and form the Government decides it must take, is completed; that a shiny new, functional, equitable and whole health system emerges. What we must avoid is a partially completed overhaul that is neither fully new and functional, nor old, flawed but familiar, because a half-renovated health system may well be worse than what we already have.*

I went on to say:

*It is critical that there is cross party support and commitment to change and improvement. In all likelihood it will take longer than the current term of government to achieve the health care system they are setting out to build. In the event that there is a change in government at the next election, an incoming government must be committed to continuing to implement the changes to the health system. There is precedent for incoming governments to undo the work of previous governments, to abandon initiatives in health.*

Two and a half years on this is exactly the situation we find ourselves in; we have a broken health system, one that is on its knees.

A ‘new’ health system that is not *functional, equitable or whole.*

A ‘new’ half-renovated health system that ***IS*** worse than what we already had.

A health system, parts of which the National Party has said it will dismantle as well as rescinding some of the legislation that underpins it.

The comments and analysis provided above are not just a matter of opinion.

A progress report by the System Reform Integration Office, released to *Radio New Zealand* under the Official Information Act, and now available publicly on the [Ministry of Health | Manatū Hauora website](https://www.health.govt.nz/about-ministry/information-releases/general-information-releases/proactive-release-reforms-related-documents), was provided to the MoH, in confidence, in September 2023.

The report found that although progress had been made there were key risks and issues that could impact, or are impacting, successful health system reform implementation:

1. ***Insufficient or ineffective engagement with the health workforce on reform.*** Specifically, the report said that the health entities needed to “find ways to unlock the valuable ideas and efforts that health workers have to contribute to the reforms”. It is hardly surprising that the health entities are not listening to their workforce as it has been clear for some years that the concerns of the health workforce (e.g. nurses, midwives and GPs) are largely ignored by the Government and the MoH.
2. ***Insufficient resources for implementing reform changes.*** Such massive changes in the health system were always going to need massive resourcing on multiple levels. We have seen our health sector workforce diminish; it is substantially under-powered for the increase in population and increasing complexity of health care needs. That the Government chose to pursue the most comprehensive health system overhaul this country has ever seen, in the middle of a pandemic – the response to which demanded an incredible amount of funding and placed an enormous strain on the existing health system – was entirely ludicrous. We didn’t need the benefit of hindsight to know that waiting until the pandemic crisis was over, and the country had recovered, before undertaking such an enormously complex and vast overhaul of the health system, was far more likely to promote success. Instead, the Government chose to pursue the overhaul before the country had emerged from most critical health crisis since the Spanish Flu epidemic 100 years earlier.
3. ***Reform planning and integration is hampered by system complexity.*** The report found that “to implement new operating models and models of care required by reform, a wide range of capabilities such as workforce, clinical and administrative processes, contracts, data and systems need to come together. Entities have acknowledged that existing plans are not sufficiently mature or aligned across all the key dimensions.”
4. ***Readiness for implementation of reform changes.*** As discussed in point 2 above, clearly the workforce and broader health system entities were not ready, and delaying the implementation of the health system overhaul would have made more sense. Essentially, the changes were rushed and the health workforce and health consumers are suffering as a result.
5. ***Insufficient financial resources for reform initiatives.*** Again, the issues discussed in point 2 above are pertinent here. A huge amount of the country’s financial resources were dedicated to the response to the Covid-19 pandemic, leaving the piggy bank pretty empty.
6. ***Organisation design does not deliver on reform intent.*** The report found that “roles and responsibilities between entities (and within organisations) to not be sufficiently clearly defined or delineated, and so leading to misalignment, duplication, or gap in reform activity.”
7. ***Low public trust and confidence in reform.*** This is hardly surprising as ,despite the provisions of the Pae Ora (Healthy Futures) Act, the MoH has paid only lip service to the concept of consumer engagement. For example, the failure to undertake a public consultation process in developing Te Pae Tata | Interim New Zealand Health Plan in 2022. Since the implementation of the health system reforms, health consumers have to wait longer than ever before to see their GP, emergency departments are overflowing and wait times are atrocious, there are delays in treatment and cancellations of life-changing (if not life-saving) surgeries, and complaints to the Health and Disability Commissioner are increasing at about 25% per year.
8. ***Te Tiriti o Waitangi is not given full effect.*** This is worrying given the determination of the new coalition Government: to disestablish Te Aka Whai Ora (the Māori Health Authority) before it has been given an adequate period of time to roll back decades of inequities and disparities in Māori health; and to present a Bill to Parliament that would redefine the principles of the Treaty of Waitangi, thus discarding the “interpretation arrived at through decades of examination from court cases, academic study, and the Waitangi Tribunal.”
9. ***Lack of clarity of reform intent.*** Repeatedly in these key risks and issues, communication seems to be a significant factor. The report states, “there is the potential for the intent of reform to be misunderstood or inconsistently defined, resulting in misalignment of roles, responsibilities, and the associated work of reform.” It goes on to state that without appropriate communications there are issues with effective workforce and stakeholder engagement.
10. ***System performance management and monitoring in not in place***. Monitoring and measuring change is critical; how else will the MoH and Government know if the reforms have delivered the improvements that these reforms are all about. The report finds that there is a risk that if adequate and proper performance assessment is not sufficiently in place “it will be difficult to take appropriate action to improve performance and reduce risk.”
11. ***Critical enablers of reform may not be sufficiently established or integrated***. There are key things that need to be in place to ensure that reform is successfully implemented. The report has found that there is a risk that a wide range of functions and capabilities that need to be established at a national level may not be “sufficiently integrated or progressed to deliver new operating models and models of care required for reform.” Interestingly, one of the key enablers of reform is “the voices of consumers, whānau and community”, which “must be embedded across the system including ‘day to day’ operations”. We are yet to see a commitment to the voices of consumers, and the Auckland Women’s Health Council has for some time harboured significant concerns about the authenticity of the health consumer engagement and genuine consultation with health consumers on a number of issues since the passing of the Pae Ora (Healthy Futures) Act.

While the reforms were supposed to address the issue of siloing within our health system, the report stated that “[c]ommunication and change management activity is being carried within each entity and is designed to drive individual organisational culture and improved ways of working.”

They concluded that “[t]here is no integrated change management approach where communication supports behaviour and culture change as part of one system.”

Other failures include that planning is not sufficiently integrated, there is no common, clear articulation of health reform intent and specifically how the government intends ... the health system to deliver, and a lack of leaders skilled in large-scale change.

As was pointed out in the *Radio New Zealand* article that broke the news of the progress report, the basics that New Zealanders might have expected to be in place when Te Whatu Ora was set up – a capability plan, a change management plan, a communications plan – don’t yet exist!

Former director of the Association of Salaried Medical Specialists, Dr Ian Powell, was scathing in his comments to *Radio New Zealand* journalist, Phil Pennington. He criticised the health reforms transition unit that had responsibility for implementation, saying that the findings of the report shows that core work that was supposed to have been done was not actually done.

Dr Powell said the first focus must be “on the actual real issues that are affecting the health system at the moment: severe workforce shortages that we have that are affecting everything in both community care and general practices and in hospitals across the spectrum of health professionals.”

Women’s Health Movement Under Attack… Again!

For the second time this year Aotearoa New Zealand’s women’s health movement has come under attack by authors who seek to rewrite history and ignore the facts.

In our [July Newsletter](https://www.womenshealthcouncil.org.nz/wp-content/uploads/2023/07/AWHC-July-2023-Newsletter.pdf), we discussed the fallout from a book written by former GP, Dr Helen Overton, that featured in the April 2023 *Listener* magazine. In her book, *Demonising a Good Doctor: the medical scandal that wasn’t*, Overton attempted to both rewrite history and lay the blame for all the ills of our health system at the feet of the “feminist agenda”, and those who triggered and led the judicial inquiry into the allegations of unethical treatment of women with cervical cancer at National Women’s Hospital in the 1960s and 70s.

Overton followed in footsteps of Linda Bryder’s 2009 book, a revisionist version of events leading up to, during and following the 1987-88 Cartwright Inquiry. Now, Bryder has published another book, *The Best Country to Give Birth? Midwifery, Homebirth and the Politics of Maternity in Aotearoa New Zealand 1970-2022.* In this she has claimed that the women’s health movement, and the supporters and architects of The Nurses Amendment Act 1990 that gave midwives autonomy, are anti-science:

“This was a 1970s brand of radical feminism which had an aversion to medical technology and science on the grounds that these upheld the patriarchy,” she said in the *Sunday Star Times*, which published an article about the new book.

Is this the ‘latest thing’?

To accuse people of being anti-science if they happen to hold a different opinion or perspective on events, even if one has no facts or proof to support the accusation.

Linda Bryder is in no position to accuse others of being anti-science. The reality is that Bryder is not a scientist; she recently demonstrated a paucity of scientific understanding, claiming in a letter to the Editor of the *Listener* that the declining rates of cervical cancer had nothing to do with the Cartwright Inquiry (which directly led to the establishment of the National Cervical Screening Programme) but with the discovery of the “main cause of cervical cancer, the human papilloma virus, and was aided by the subsequent immunisation programme.”

We thoroughly debunked this bizarre claim in our July Newsletter. In brief, and among other scientific facts regarding HPV and cervical cancer, Bryder completely ignores the dramatic decline in incidence of, and mortality from, cervical cancer in Aotearoa New Zealand since the introduction of the NCSP. Since 1988, incidence has declined from 165 new diagnoses of cervical cancer per year to 65 new diagnoses in 2017 and mortality has declined from 58 deaths per million females to 18; this represents a 60% reduction in incidence and 69% reduction in mortality. Meanwhile, the HPV vaccine was introduced only in 2008, since which time there has been a levelling off in the decline of both incidence and mortality – demonstrating that there has been no reduction in incidence and mortality that could yet be attributed to the HPV vaccine.

In a Letter to the Editor, published on the 12th of November, Sandra Coney wrote:

“Bryder accuses us of being out-of-step with the Western women’s health movement. This is rubbish.

Feminists throughout the world questioned the medicalising of normal aspects of women’s lives such as childbirth and menopause. But they also sought health interventions such as contraception and abortion, but they wanted those to be safe, and they wanted women to be in control of choices in their health care. They wanted a partnership model of care not the authoritarian model. Feminist views were far more nuanced than Bryder’s facile claim of anti-science.”

In addition to casting aspersions on the women who were pivotal in the women’s health movement in the 1980s and 90s, Linda Bryder seeks to tarnish the reputation of the much loved and internationally renowned midwife, and passionate advocate for women and women’s health, Joan Donley (see page 47), implying that somehow Joan (who died in 2005) was in large part responsible for problems with our maternity services in 2023.

Bryder is critical of our current maternity system and places the blame for the current poor state of maternity services squarely on the 1990 changes – changes that were advocated by members of the midwifery profession as well as women's groups – that saw midwives take the ascendency in birth care, enabling autonomous midwifery practice in which midwives are able to provide primary maternity care without medical supervision. This couldn’t be further from the truth.

The poor state of maternity services in Aotearoa New Zealand is ***everything*** to do with successive governments underfunding the maternity sector and, in particular, not paying midwives fairly for what they do, the hours they work and their importance in the safe and healthy delivery of babies. This chronic underfunding has led to stress and burnout among midwives and seen the women leaving the profession in droves, women struggling to find a midwife at all let alone one of their choosing, and women being discharged from maternity wards before they are ready to leave.

We present here a rebuttal to the *Sunday Star Times* article by Phillida Bunkle who, together with Sandra Coney, wrote the 1987 Metro magazine article on the unethical experiments undertaken by Prof. Herbert Green at National Women’s Hospital in the 1960s and 70s. It should be pointed out that their article was triggered, in part, by the peer reviewed paper by Drs Bill McIndoe, Malcolm “Jock” McClean and Ron Jones, and Peter Mullins, published in the journal *Obstetrics and Gynecology* in 1984,which discussed Herbert Green’s work at National Women’s Hospital on women with abnormal cervical cytology. The paper suggested that some patients had been diagnosed with cervical cancer but not treated.

The Women’s Health Movement – Advocates of Evidence Based Medicine

Donna Chisholm’s interview, is strikingly uncritical of Professor Linda Bryder’s claims in her recent book that the reforms of medical practice and of maternity services advocated by the women’s health movement were based on “an aversion to medical technology and science” and that by distorting scientific evidence the Cartwright Collective have with its allies, undermined the medical profession and harmed women.

Chisholm neglects to ask Professor Bryder why, if our years of work to promote safe, effective medicine that is responsive to women’s needs is not supported by sound evidence, it has attracted prominent scientific and medical endorsement.

Why did the New Zealand Medical Council judge that Professor Bonham, New Zealand’s most senior gynaecologist responsible for National Women’s Hospital had ‘engaged in disgraceful conduct’ in relation to mistreatment of women unknowingly enrolled as research subjects in the Unfortunate Experiment? And why did, in 2017 and 2018, both the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and the Auckland District Health Board issue [***official***](https://www.nzherald.co.nz/nz/auckland-district-health-board-apologises-for-deadly-unfortunate-experiment/EQSR55Q4P26OHIOJETKQPDLHMQ/) apologies to the women patients harmed by their profession?

Were these influential medical bodies indifferent to scientific evidence when they acknowledged the harm done to patients in professional medical care?

And why was Dr Ron Jones, whose publication was foundational in establishing the Cartwright Inquiry, honoured with the world’s most prestigious award for Scientific Freedom and Responsibility by the American Association for the Advancement of Science?

Why, if the origins of the Cartwright Inquiry findings were mired in anti-science, were they endorsed by New Zealand’s most distinguished epidemiologist, Professor Sir David Skegg?

Indeed, Auckland University and its Press are the only public bodies in New Zealand that have failed to recognise the validity of the evidence of harm caused to women patients by New Zealand medical professionals contained in the Cartwright Report.

Professor Bryder continues to cite cancer patients who approved of their care at National Women’s Hospital. But this evidence was given ***before*** these patients were made aware of their case histories by the Inquiry investigation. Their medical records documented the truth of inconsistent, incomplete treatment to which women had unknowingly been exposed. This evidence is contained in the verbatim records of the Inquiry of which Professor Bryder appears to be unaware. She sets aside the evidence of real harm by not following up her allegations by interviewing survivors or surviving families.

If Bryder cared to conduct careful comprehensive research into the verbatim recordings of the Cartwright Inquiry itself, she would not only find the full records of the women who were injured, she would also find our consistent record of advocacy for greater safety in medical practice and proper scientifically valid assessments of medical risk.

The women’s health movement was not anti-science. We demanded better science; science in the interests of patients that was scientifically valid and ethically designed.

For decades the Cartwright Collective and the women’s health movement has engaged fully in evidence-based medicine. We have consistently advocated for a system of scientific and ethical oversight where maverick doctors or scientists could not make up a study method or recruit research subjects without appropriate safeguards. These reforms are now accepted as normal by universities, research institutes and professional bodies.

We advocated, too, for the establishment of scientific Ethics Committees to provide this oversight, which are now accepted as normal not only in medical science but in the physical and social sciences, if not yet in history and the humanities

For over half a century the women’s health movement has worked to make medicine safe and participated in evidence-based processes to promote the interests of patients. When can the women affected by the “unfortunate experiment’ expect to receive a public apology from the University of Auckland?

***Phillida Bunkle***

College of Midwives Disappointed in Lack of Balance

The week after publication of the article on Linda Bryder’s book, the *Sunday Star Times* published an opinion piece from **Claire MacDonald, a Midwifery Advisor at the New Zealand College of Midwives.**

**The article refuted many of the claims made by Bryder in her interview with Donna Chisholm.**

**Bryder claims that “**the feminists driving the change wanted to eradicate doctors – even female doctors – from birth care,” and that “most GPs were driven out of birth care.”However, the truth of it is that “inadequate funding of maternity care in 1996 contributed to the exodus of general practitioners from maternity care that had started to occur in the 1980s. This was a worldwide phenomenon as hospitals placed more demands on GPs’ general medical services, which made providing 24-hour care for maternity difficult to sustain.”

Another of her claims was that changes to maternity services that saw greater emphasis on midwives was “very much a white middle-class ideology” not embraced by Māori and Pacific women.24

Ngā Maia Māori Midwives’ chair, Lisa Kelly, categorically disputes this, saying that, in fact, a number of wāhine Māori were powerful voices at the time. Many wāhine Māori wanted a return to the traditional birthing practice, at home with whānau, turning their backs on distressing childbirth experiences within the hospital-based maternity care system where violation and dispossession of their mana took place.

“It was and is about taking back our indigenous birthing knowledge and practices; a purposeful act of reclamation and self-determination, and was part of the wider movement led by Dame Whina Cooper,” Lisa Kelly said.

Ms MacDonald concludes by writing that what will improve maternity care in Aotearoa New Zealand is “better retention and recruitment of midwives to reflect our multi-ethnic population, financial support for student midwives, and resolution of pay equity for community-based lead maternity carer midwives.”

Joan Donley OBE, RM, MHSc (Honorary) 1916-2005

Joan Donley was a fearless champion of women’s rights, an internationally renowned midwife and author, and a much loved and respected Auckland Women’s Health Council member. She was a tireless and tenacious advocate and an inspiration to all who worked alongside her. She was unstintingly generous in sharing her knowledge and insights and was an example to us all. Her sense of humour and irreverence always kept us going when the going got rough. Her legacy lives on in the babies she helped bring into the world, in the organisations she helped found and those she supported, and in her books advocating for normal pregnancy and birth.

Joan was an early member of the Auckland Women’s Health Council. She was actively involved on the Executive Committee until she was no longer able to attend our meetings. Joan was much loved for her sharp wit: she would create wickedly funny nicknames for various MPs. Indeed, these names stuck.

Joan was best known for her passion for birthing issues; she ensured that our submissions on all things maternity were based on quality research. One example of this was in AWHC’s oral submission to the Health Select Committee on maternity issues in which she gave a cost breakdown of a caesarean birth compared to that of a vaginal birth. The Health Select committee members were very taken by this canny economic pitch and there was a good degree of engagement, which is not always the case.

Joan was a staunch feminist, committed to women not being exploited in the interests of others. She viewed having a baby at home as a ‘feminist and a political act’ in which ‘women rebelled against the technological takeover of their bodies’ by male doctors and hospital nurses. She believed in equity and justice, and recognised the impact of poverty and the need for this to be addressed. Related to this was Joan’s holistic view of health and the importance of good nutrition. Related to this was Joan’s holistic of health and the importance of good nutrition. Joan’s “Weed salad” was well known by AWHC members.

Joan aimed for women to become empowered and enabled to choose for themselves. She provided them with broad information. It is these values and beliefs that are part of the legacy that Joan has left AWHC and which still drive our work.

However, Joan leaves a legacy far beyond AWHC. In 1978 she formed the Auckland Home Birth Association, a lobby group for domiciliary midwives, and she was a founding member of the New Zealand Domiciliary Midwives Society, established in 1981. She was integral in bringing about midwifery autonomy and it was because of her ability to bring together women and midwives that midwifery autonomy in 1990 came about with the Nurses Amendment Act. Her oft quoted slogan for this unique partnership was “Women need midwives need women”. Another oft quoted slogan was “Pizzas are delivered. Women give birth”.

Joan was also a founding member of the College of Midwives. In 2001, NZCOM established the Joan Donley Midwifery Research Collaboration (JDMRC) – the evidence arm of the College that provides the framework and secretarial support for the College’s research programme. Set up in honour of Joan and her commitment to an evidence-based midwifery profession, its core purpose is to promote the development of midwifery research, and thereby the provision of evidence for practice, in Aotearoa New Zealand’s unique maternity service context. NZCOM also holds the biennial **Joan Donley Midwifery Research Forum.**

Her book Save the Midwives is still read, and her Compendium for Healthy Pregnancy and a Normal Birth is not only still available, but highly sought after and prized by women wanting to take a holistic approach to their pregnancies and the births of their babies.

Joan Donley was made an OBE in 1990 for services to midwifery, and was awarded both the New Zealand 1990 Commemoration Medal and the New Zealand Suffrage Centennial Medal 1993. In 1997 she was awarded an honorary Master’s degree in midwifery from the Auckland Institute of Technology.