



NEWSLETTER

August/September • 2021

a voice for women's health





**Auckland Women's
Health Council**

PO Box 32-445
Devonport
Auckland 0744

EMAIL:
awhc@womenshealthcouncil.org.nz

WEBSITE:
www.womenshealthcouncil.org.nz

EDITOR:
Sue Claridge

Copyright © 2021
Auckland Women's Health Council

In this Issue...

Watchdogs, Advocates and Lobbyists — the continuing relevance of women's health NGOs 3

ALCL — the latest danger for women with breast implants 6

Making the Newsletter Accessible 14

STOP PRESS

Changes to ACC legislation imminent!

On the 16th of September when the August/September edition of the Newsletter went into design and production, news was published on the Radio New Zealand¹ website advising that there would soon be legislative changes to ACC to cover traumatic birth injuries suffered by women during labour.

"The Government has now considered the issue and will be making an announcement before the end of the month," Minister for ACC, Carmel Sepuloni said.

Radio New Zealand reported:

"Under current ACC policy only birth injuries sustained through a treatment injury would be covered.

But the government had been under pressure to make changes after RNZ revealed the number

of women successfully claiming ACC cover for perineal tears had dropped dramatically following a policy review last year."

This issue was mentioned in the June/July edition of the AWHC Newsletter in an article on discrimination against women, Māori and tagata Pāsifika. We expect to provide updated information in the next edition of the newsletter.

The announcement came as an open letter from the Green Party², supported by many organisations within the health sector including AWHC, called for all birth injuries and traumatic births to be covered by ACC. We encourage all women's/women's health organisations to also consider lending their support to the letter by getting in touch with Green MP Jan Logie by emailing jan.logie@parliament.govt.nz.

1 <https://www.rnz.co.nz/news/national/451568/government-set-to-make-announcement-on-acc-coverage-of-birth-injuries>

2 https://action.greens.org.nz/better_support_for_birth_injuries

Watchdogs, Advocates and Lobbyists

the continuing relevance of women's health NGOs

By Sue Claridge

Every year, August is a time of reflection for the Auckland Women's Health Council. We visit and lay flowers at the *Spirit of Peace* outside the old National Women's Hospital at Greenlane, and also visit the pohutukawa* that remarkably flowers in August and is a source of delight for local tuis, and in turn are a source of delight for us. The pohutukawa towers over the plaque that bears witness to the bravery and dedication of Dr Bill McIndoe, the cytologist and colposcopist at National Women's Hospital from 1963 to 1983, and Dr Malcolm McLean, the pathologist from 1961 to 1988.

Drs McIndoe and McLean opposed and challenged Herbert Green's experiment on women with cervical carcinoma *in situ* (CIS), and in 1984 (together with Dr Ron Jones and Peter Mullins) published a paper — The Invasive Potential of Carcinoma *In Situ* of the Cervix¹ — that exposed the extent of the unethical experiments on women at National Women's Hospital.

Our pilgrimage to the old National Women's Hospital in August is an opportunity for us to reflect on our history, the women who were the backbone of AWHC for many years and who are no longer with us — Judi Strid, Lynda Williams and Jo Fitzpatrick — and the founding members who are still on our committee; to reflect on what we have achieved, the changes that we have been a part of and our role in an ever-changing health landscape.

A few weeks before this edition of the *Newsletter* went to press, we posted a request from a *New Zealand Herald* health journalist on our Facebook page. Emma Russell was seeking women/wāhine who feel ignored by our current healthcare system. She was particularly interested in hearing from those who have battled conditions unique to women, such as endometriosis, postnatal depression, gynaecological cancers, prolapse, surgical mesh, declined hysterectomies, traumatic birth care and hormonal conditions.

We have had a few conversations with Emma over the last couple of years and support her efforts to raise the profile of women's health issues in the

* It is a winter flowering variety different to the traditional New Zealand variety that flowers later in the year from November through to late December or early January.



Remembrance: Members of Auckland Women's Health Council at the *Spirit of Peace* on the 5th of August 2021.

mainstream media. Unfortunately, her articles have often been put on the back burner by the rise of Covid19 and the timing of lockdowns.

One commenter on the Facebook post was angry that we/Emma were seeking "negative" stories. She wrote:

Wouldn't it be best to do positive stories from women who have had successful experiences for a change. Always focusing on the negative when there are huge positive [sic] out there 🙄

Her comment served as the impetus for further consideration of the role of the Auckland Women's Health Council. Are we needed anymore? Do we have a role in women's health in the third decade of the 21st century?

The question reminded me of a conversation I had years ago with an Auckland breast surgeon when I was working for Breast Cancer Network. A great surgeon who made a living from treating women with breast cancer, Trevor Smith said he would be pleased if he was made redundant, if we could prevent breast cancer and there would be no need for his skills. As a surgeon, no doubt he would have found work doing different types of surgery, or perhaps he would have retired and gone sailing, one of his other passions. Sadly, more than ten years later and we are no closer to preventing breast cancer.

For me personally, there are many other things I could be doing with the hours that I spend doing AWHC work. I suspect that all of our committee members have other things they could be doing with the time they volunteer to AWHC.

The reality is, 33 years on from the release of the *Cartwright Report* into the treatment of cervical cancer at National Women's Hospital, we seem to be no closer to being in a situation where AWHC, and other organisations lobbying and advocating for improvements in women's health, have no role, no purpose and no impact.

AWHC was founded in 1988 against a backdrop of serious issues raised in the Cartwright Inquiry. In the 1990s, we took an active role in the formation of the National Cervical Screening Programme and in the development of the Code of Patient Rights. But our work is not yet done.

For those who have had positive experiences in our health system, that is great; but that is far from a universal experience. Many New Zealanders suffer harm in our health system or are inadequately treated, and women, Māori and tagata Pāsifika are disproportionately affected by inequities and disparities in access to and outcomes from health care.

Unfortunately, there is still very much a need for organisations such as ours to lobby and advocate for the rights of patients, particularly those who suffer harm and have their patient rights breached. We believe that:

- Women users of health services have the right to make informed decisions regarding their own health care and treatment.
- Women have the right to the information necessary to enable them to make informed decisions.
- Health care must be accessible, affordable and available as well as culturally appropriate and acceptable to women.
- Consumer participation on all decision-making processes for health care services is essential.

We are far from a situation in which all women in this country have accessible, affordable, available, and culturally appropriate and acceptable healthcare. Beyond this, an unacceptable number of women are harmed in some way — often extremely seriously — by their experiences of health care, and many more have their basic health care rights breached.

This edition of the Newsletter presents something of a case study in these issues; breast implant associated anaplastic large cell lymphoma (BIA-ALCL, see page 6), a potentially serious and occasionally fatal cancer with an incidence that is showing an exponential rise both in New Zealand and internationally.² In many ways this article epitomises what is wrong with the medico-pharmaceutical industry and our health system, including our regulatory bodies.

Unfortunately, BIA-ALCL is just the latest in a long line of issues that women face regarding their health and wellbeing. To remind myself that what we do is important I only need to review the articles I have written for AWHC over the last four and a half years, including articles on:

- health and disability research involving adult participants who are unable to provide informed consent;
- widespread health system dysfunction and inability to cope with demand;
- abortion law reform;
- insufficient action on addressing the social determinants of health;
- lack of informed consent in women's health services in our hospitals;
- racial discrimination in the health system;
- disparities and inequities in the health system;
- dangerous and poorly regulated/under-regulated drugs and medical devices, including surgical mesh, Essure, Primodos, breast implants;
- delays in changes to the National Cervical Screening Programme and the affordability and accessibility of screening;
- period poverty;
- the failures of the HDC to promote and protect patient rights;
- the midwifery and maternity services crisis;
- maternal mental health and suicide.

Since the time of Hippocrates, women's health has been misunderstood, misdiagnosed, ignored or

invisible. All too often symptoms of physical disease or ill-health have been attributed to our gender, sexuality, hormones and reproductive organs, absolving medical practitioners through the ages of any obligation to investigate or understand us, much less treat us appropriately and with intelligence and dignity.³

To gain some appreciation of how women's health has been viewed and treated over the centuries, and of what women face in their interactions with the health system, readers could start with the March 2020 edition of the *AWHC Newsletter*.³ The lead article provides the background, but don't stop there; the rest doesn't make for comfortable reading either.

While we recognise that some women have positive experiences, this is far from the reality for many and we must keep bringing this to the attention of the general public and those who can make a difference.

After all, just because many women live in relationships based on trust, respect, love and equality doesn't mean that Shine and Women's Refuge should stop telling the stories of women who are victims of domestic violence; because most women and girls can afford period products doesn't mean The Period Place should stop telling the stories of girls who can't go to school because of period poverty; because most people have roofs over their heads and food on their tables doesn't mean that the City Mission should stop seeking support for their work and telling the stories of those Aucklanders who can't feed their families.

Likewise, we will continue to speak for the women in New Zealand harmed in some way in the course of seeking health care. Many of them have no voice and no-one else to speak for them. They are our *raison d'être*. We commend Emma Russell and other journalists for also seeking to tell those stories.

A number of the articles I have written for the *AWHC Newsletter*, have come about because women have contacted us and told us of their experiences; this edition's article on BIA-ALCL is one of those. We are the voice for many women unable to get anyone to do the right thing, make changes, improve the system and outcomes for other women, and other New Zealanders who face inequity and disparity in their health care every day.

As well as our *Newsletter*, AWHC makes regular submissions to government and government agencies on a wide variety of health issues that concern us; we write letters and bring important issues to the attention of politicians and policy makers as they come to our attention. We have an important role in keeping women's health issues, in particular issues of consent, equitable access to health care services

and best-practice evidence-based health care, in front of not only women and their families and whānau, but also our DHBs, health practitioners and service providers, health agencies and policy makers.

Based on evidence from subsequent reports and legislative changes, we believe that our submissions make a difference and contribute to change for the better.

Yes, there are positive, heart-warming stories out there. But the distressing stories of harm, breaches of rights, misdiagnosis, mistreatment, and just plain dangerous drugs and devices, are far more important, and we have an important role in helping to reduce the harm that women experience in the health system. We are not going to stop telling those stories.

We are a voice for women, and a voice for change.



"The moment we begin to fear the opinions of others and hesitate to tell the truth that is in us, and from motives of policy are silent when we should speak, the divine floods of light and life no longer flow into our souls. Every truth we see is ours to give the world, not to keep for ourselves alone, for in so doing we cheat humanity out of their rights and check our own development."

Elizabeth Cady Stanton

— From an 1890 speech to the National American Woman Suffrage Association

"Never be afraid to raise your voice for honesty and truth and compassion against injustice and lying and greed. If people all over the world...would do this, it would change the earth."

— William Faulkner

References

- 1 McIndoe WA, et al., 1984: The Invasive Potential of Carcinoma In Situ of the Cervix, *Obstetrics & Gynecology*, October 1984, 64 (4): 451-458.
- 2 Collett DJ, et al., 2019: Current Risk Estimate of Breast Implant-Associated Anaplastic Large Cell Lymphoma in Textured Breast Implants, *Plastic and Reconstructive Surgery*, March 2019; 43(3S): 30S-40S.
- 3 Claridge S, 2020: Women's Health: invisible, ignored, misdiagnosed, AWHC Newsletter, March 2020, accessed at <https://www.womenshealthcouncil.org.nz/site/aklwhc/AWHC%20March%202020%20Newsletter.pdf>

ALCL – The Latest Danger for Women with Breast Implants

By Sue Claridge

filled implants have been implicated, with a median interval from the time of the implant to the lymphoma of about 10 years.”

Srinivasa *et al.* found that, up to September 2015, there was limited information on BIA-ALCL, including incidence and risk, because of a lack of consistent and complete data on worldwide and country-specific total and textured implant sales, and incomplete or inadequate reporting on clinical history, treatment, and oncologic follow-up.⁴

Over the years breast implants have caused anxiety, anger, and a range of health problems for women who have had them for both cosmetic reasons and as part of breast reconstruction after breast cancer.

The most recent issue with breast implants in New Zealand is breast implant associated anaplastic large cell lymphoma (BIA-ALCL — see page 7), a rare type of non-Hodgkin’s lymphoma, a cancer of the lymphatic system.

The first discussion of ALCL in relation to breast implants in the medical literature came with the publication of a letter to the journal *Plastic and Reconstructive Surgery*, in August 1997.¹ The authors described the case of woman who had developed anaplastic T-cell lymphoma in proximity to a saline-filled breast implant.

In 2011, the US FDA[†] became aware of a possible association between breast implants and the development of ALCL.² There were insufficient cases at the time for them to determine what factors increased the risk. In 2016, in their classification of lymphoid cancers, the World Health Organisation listed BIA-ALCL for the first time,³ saying that it “usually presents as an accumulation of seroma fluid between the implant itself and the surrounding fibrous capsule” and that both “saline- and silicone-

Data collection and research is ongoing, and advice from regulatory authorities continues to evolve. As of October 2019, the US FDA advises:²

- All patients who have breast implants or are thinking about getting them should be aware of the risk of BIA-ALCL.
- The risk of BIA-ALCL is higher for textured surface implants compared with smooth surface implants.
- Certain other textured breast products, specifically certain textured tissue expanders, should not be used.

While BIA-ALCL is generally described as rare in the medical literature, a very recent article in *Plastic and Reconstructive Surgery* found that “Recently published risk estimates for breast implant-associated anaplastic large cell lymphoma indicate that the incidence of BIA-ALCL may be much higher than previously understood, with a lifetime risk of one in 559 women with a textured device.”⁵

In 2019, Collet *et al.*, in concluding their discussion of risk, wrote “Most striking is the exponential rise in incidence over the last decade”.⁶ While their research was international, they said specifically that “recent data from Australia and New Zealand have revealed a dramatic rise in the frequency of diagnosis and incidence of BIA-ALCL. Fifty-six cases in total had

continued on page 8

† Food and Drug Administration: responsible for licencing and regulating drugs and medical devices, and ensuring safety and efficacy.

What is BIA-ALCL?

Breast implant associated anaplastic large cell lymphoma is a relatively rare, 'emerging' type of non-Hodgkins lymphoma, a cancer of the immune system. Although it is associated with breast implants, it is *not* breast cancer and can occur both in those who have had breast implants for breast augmentation, or as part of breast reconstruction surgery following breast cancer treatment and mastectomy.

While it has largely been associated with textured breast implants, there is international evidence that it can also occur with smooth implants. The type of filling in the implant — saline or silica gel — does not appear to influence risk.² In 2016, the World Health Organisation provisionally classified BIA-ALCL as a distinct clinical entity, separate from other categories of ALCL.³

The aetiology* of BIA-ALCL is not entirely understood; however, De Jong *et al.* write that current hypotheses for the causes or contributors include "genetic drivers, chronic inflammation resulting either from bacterial contamination, shell shedding of particulates, or shell surface characteristics leading to friction, or by implant associated reactive compounds."⁷

BIA-ALCL is a cancer that grows in the fluid and scar tissue that forms around a breast implant but

may also take the form of a lump in the breast or a lump in the armpit. It has been known to occur as soon as one year after implantation and as late as 37 years after the implantation. The average time to diagnosis is within eight years of the operation. Symptoms of BIA-ALCL are typically swelling in the breast owing to fluid accumulation around the implant, but may also include pain, asymmetry, lump in the breast or armpit, overlying skin rash, hardening of the breast, or a large fluid collection. It is usually "found near the breast implant, contained within the fibrous scar capsule, and not in the breast tissue itself."² In most reported cases, "the ALCL cells were found in the fluid surrounding the implant (seroma) or contained within the fibrous scar capsule."

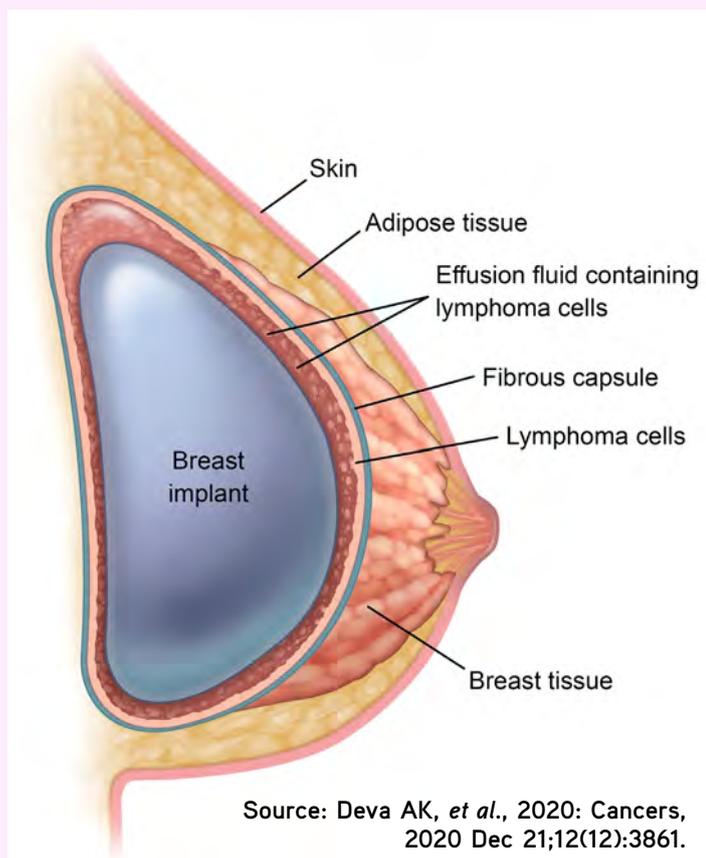
BIA-ALCL is normally diagnosed using ultrasound (mammography is *not* useful for diagnosis of BIA-ALCL), and a fine needle aspiration or biopsy is used to confirm diagnosis.⁸

Treatment typically involves removal of the implant and surrounding capsule and scar tissue, and removal of any mass associated with the implant. It is a more extensive procedure than just removal of the implant.^{2, 8} Some patients may also require chemotherapy and radiotherapy.

The majority of cases are resolved with removal of the implant, capsule and associated fluid and tissue. However, the positive prognosis for the majority of patients shouldn't undermine the fact that this cancer is serious and can lead to death, especially if not treated promptly.²

Collet *et al.* reported that, as of November 2018, 17 deaths had been reported internationally.⁶ The FDA announced 33 deaths globally in July 2019,⁹ and the Australian TGA state on their website that four deaths in Australia had been reported to them as of 26 September 2019.⁸

While the focus in New Zealand and in the US appears to have been on Allergan textured implants, Medsafe posted a notice on their website in March 2020 regarding Johnson & Johnson Mentor Siltex breast implants (including smooth implants), saying that the listed implants carry a risk of BIA-ALCL. The implants were still being supplied but with instructions that will now carry additional warnings and information for patients.¹⁰



* the cause, set of causes, or manner of causation of a disease or condition.

continued from page 6

been confirmed by 2017 with a subsequent 26 new cases of BIA-ALCL diagnosed between January 2017 and April 2018 representing a 47% increase in diagnosis.”

The conclusions of these papers are consistent with statements from Australia’s Therapeutic Goods Administration (TGA). In late 2016 they said that while “health authorities and surgeons had believed the risk was somewhere between one in three million and one in 50,000” the TGA “now estimated the risk ranged between one in 10,000 and one in 1000.”¹¹ At that time the Australian Broadcasting Corporation (ABC) reported that there had been 46 cases diagnosed in Australia and New Zealand.¹¹

BIA-ALCL in New Zealand

BIA-ALCL was first brought to the attention of our readership in an article by Lynda Williams in 2017.¹² At the time, Lynda wrote:

“In December 2016 it was announced on Radio NZ that ten women in New Zealand had been diagnosed with a rare cancer that has been linked to the use of breast implants. Anaplastic large cell lymphoma (ALCL) is a rare type of non-Hodgkin’s lymphoma that has in recent years come to be associated with breast implants. The New Zealand numbers were revealed after Australian health authorities said the cancer was more common than previously thought.”¹²

In contrast with regular reports on BIA-ALCL in Australia by their state broadcaster, since 2016 there has been a dearth of reports in New Zealand’s mainstream media. It would seem that, despite the fact that international health authorities have known since at least 2011 that breast implants can cause potentially fatal ALCL, women in New Zealand continued to receive implants that placed them at risk of ALCL and there has been little publicity or notification to those women that they may be at risk. Since 2016 when Radio NZ broke the story in the New Zealand mainstream media¹³, it appears that concerns about BIA-ALCL have been downplayed by our health authorities.

In response to an Official Information Act (OIA) request from AWHC to the Ministry of Health and Medsafe in May this year, Medsafe advised that they “first published information on the potential for women with breast implants to develop BIA-ALCL in December 2016.” That information said that three cases had been reported to Medsafe.

The most recent Medsafe information was posted in several updates in 2019¹⁴ advising:

- On 11 April 2019 that “Regulatory Agencies around the world are investigating the safety of breast implants on the market following an increasing number of cases of anaplastic large cell lymphoma (ALCL) being reported,” and that Medsafe had received six adverse event reports where breast implant associated anaplastic large cell lymphoma has been diagnosed.
- On 31 July 2019 that Device Technologies, supplier of Allergan textured implants in consultation with Medsafe had issued a recall of unused textured implants. The advice to women was that “Those who do not experience any changes or symptoms need take no action. Those who experience sudden, unexplained changes such as pain, lumps or swelling should see their general practitioner or the surgeon who carried out the breast implant surgery.” Medsafe restated that it had received only six adverse event reports for the implants.
- On 17 November 2019 the Australian regulator, the TGA, “had decided to take regulatory action in relation to all un-implanted breast implants and tissue expanders sold in Australia.” This included removal of some implants from the register and a six-month suspension on supply of other implants pending review of further safety and performance. Suppliers advised Medsafe that those implants that could no longer be supplied in Australia, would also no longer be supplied in New Zealand. Medsafe advised that for available breast implants, newly imposed conditions of supply included a patient information leaflet and updated instructions for use to include the risk of BIA-ALCL, and the requirement for prompt reporting of adverse events to Medsafe.

A number of concerns arise from the Medsafe website information. First, the discrepancy between the officially reported numbers of cases of BIA-ALCL in New Zealand: Medsafe reported only six in April and July 2019, yet in 2016 *RadioNZ* reported ten. Adverse event reporting is a passive, voluntary system, so it would appear that there are cases in New Zealand for whom an adverse event was never formally reported. Wendy Hudson (see story page 10) was told by her surgeon in 2019 that she was the 16th patient who had been diagnosed with BIA-ALCL, three times as many cases as Medsafe is currently officially aware of.

Second, their advice to women with Allergan textured implants was very lacklustre. ALCL is potentially fatal, yet there was no advice to surgeons to advise past recipients of the implants to get them checked or removed or even to keep an eye

on possible symptoms. However, the symptoms are vague and not particularly conclusive — pain, lumps or swelling — many women suffer from pain, lumps and swelling in their breasts for a range of reasons not least of which are associated with their menstrual cycle, and tenderness, enlargement and lumpiness is common premenstrually. Therefore, it would be difficult for women to recognise the signs and symptoms as specifically being caused by BIA-ALCL.

Finally, Medsafe is not the “go to” source for health information for most people. Many New Zealanders would not know of Medsafe’s existence and Medsafe would almost certainly not be the place that people would seek advice or information if they had concerns. Without a directive to GPs and plastic surgeons to actively follow-up with women who had these breast implants, women might go for months or years with vague, non-specific symptoms completely unaware of the potential danger they were in.

In the OIA request, AWHC asked the Ministry of Health “Does the MoH have any information on breast implants and ALCL on its website and if so, why does it not appear in a search of the website? If not, why not, given that the MoH website is an important source of information for consumers?”

Medsafe replied that they were “currently in the process of creating a section in the Medical Devices tab on its website, similar to that for surgical mesh implants, specifically for breast implants,” and that “There is information on the Ministry of Health website on breast implants, and this includes links to the Medsafe website.”

However, on the MoH website¹⁵ there is no mention of BIA-ALCL, there is one link to the Medsafe website at the bottom of the section titled “What are breast implant risks?” The predominant information is on breast implant rupture, and the only mention of cancer (no specific mention of ALCL) states: “There have been concerns that implants may increase the risks of some diseases including cancer and connective tissue diseases; however, the generally accepted view is that these are no more common in women with breast implants than in women without implants.”

The link to the Medsafe website on the MoH website takes you to a page on Silicone Gel Breast Implants.¹⁶ Halfway down the page is a section on cancer which states:

“Another question is whether the silicone in breast implants can increase the risk of cancer. There is no evidence that this is the case, although the possibility cannot be totally ruled out. Studies presently under

way should provide an answer to this question within the next few years.”

There is no mention of ALCL on this page. In fact, if you search for ALCL, BIA-ALCL or anaplastic large cell lymphoma on the MoH website you get no results at all.

It is completely disingenuous of Medsafe to say that those looking for information about BIA-ALCL on the MoH website are directed to that information on the Medsafe website. It is completely untrue and, in fact the information that people are directed to specifically says that there is no evidence of a link between breast implants and cancer. This Medsafe webpage is shockingly out of date and has not been revised since May 2013!

The only way to find information about BIA-ALCL on the Medsafe website is if you know what you are looking for. If you have breast implants and symptoms, unless you are very well read, know someone who knows about BIA-ALCL or have come across one of the very few media articles on BIA-ALCL, you have no idea what to look for.

Should Your Plastic Surgeon Advise You About BIA-ALCL?

The short answer is yes, but it is unclear how many, if any, women have actually been told about the issue.

When Wendy Hudson was diagnosed with BIA-ALCL in 2019, her surgeon told her that they were not advising women with Allergan textured implants about the risk of BIA-ALCL because it was so rare; they didn’t want to be inundated with women wanting their implants removed, and were advising women only if they came in for check-ups.

While their website is out of date, Medsafe has at least recognised that BIA-ALCL is a disease that requires further action. In March 2020 the manufacturer of the breast implants at the centre of this issue — Allergan and Device Technologies — under a directive from Medsafe, sent a letter to all providers (e.g. plastic surgeons) of a range of BRST and Natrelle Allergan breast implants. The letter stated:

continued on page 12

* The letter is posted on the AWHC website (under the Health Topics menu > Breast Implants) as a public service to women who may have had breast implants about which they are concerned, and wish to know if their implants are the ones listed in the letter from Allergan and Device Technologies. Anyone who has concerns about their breast implant/s no matter the brand and type should seek advice from their GP or plastic surgeon.

Anger About ALCL Diagnosis

Wendy Hudson* is angry and she wants other women to know what she now knows.

After her breast cancer diagnosis, she did everything she could to prevent getting cancer again, but despite going to lengths that many would shy away from, she was struck again, with a cancer she had never heard of.



In 2007, at the age of 40, Wendy found a pea-sized lump in her right breast. She had a mammogram and biopsy that confirmed breast cancer, and ten days later she had a double mastectomy. She chose to have her left breast removed at the same time, not wanting to constantly worry about the chance of cancer recurring in either breast.

I'm really, really angry. I'm angry and upset that I wasn't told about the risk. I did everything I could to avoid cancer, but I wasn't informed about this.

"I didn't want to be worried about every change in my breast, every period when they got a bit lumpy, that it might be cancer again," she said.

Wendy just wanted to be rid of the cancer and get back to a normal life. Her cancer was non-invasive when it was found, oestrogen receptor positive†, and confined to the milk duct. Her mastectomy was followed by two types of chemotherapy and then tamoxifen, a drug that is taken to block the action of oestrogen.

At the time of her surgery she had silicon-saline breast implant reconstruction. The implants were flexible silicone shells filled with a small amount of saline. More saline was slowly added via a portacath to increase the size to a size she was happy with.

In 2009, Wendy had a full hysterectomy. She had uterine fibroids and because of her concern about a recurrence of breast cancer, she had her ovaries

removed at the same time. While an oophorectomy causes immediate surgical menopause, it also meant that her body would produce far less oestrogen, the hormone that had fuelled her breast cancer and raised her risk of recurrence. With no ovaries she switched from tamoxifen to arimidex, an aromatase inhibitor that works by blocking the enzyme aromatase, which turns the hormone androgen into small amounts of oestrogen.

With late life breast cancer among her female relatives, Wendy had genetic testing, and to her relief was found not to carry the BRCA gene mutations that significantly raise the risk of, and mortality from, breast cancer. She had regular mammograms and ultrasounds and believed she had done everything possible to protect herself from cancer.

In 2013, one of these regular check-ups revealed that one of her implants was damaged and silicon from the shell had leaked into the saline. She underwent further surgery to replace the original implants with Allergan textured breast implants. She knew nothing about the issues with these implants, and if her surgeon had any idea of the risks, he didn't mention them.

It wasn't until 2019 that Wendy knew anything about BIA-ALCL. Again, her annual ultrasound and mammogram picked up a problem — there was fluid around the implant in her right breast. At that point she had no real symptoms, perhaps some very minor swelling but not enough for her to notice that anything was wrong. Were it not for the check-up she may have gone for some time before symptoms bothered her.

The fluid was biopsied, and ALCL was diagnosed. While she had no symptoms before the biopsy, the procedure "stirred" things up and her breast became swollen and extremely painful, a "really raw feeling", she said.

In yet another surgery, the whole implant capsule, fluid surrounding it, and associated scar tissue were

* her name has been changed to protect her privacy.

† hormone sensitive or hormone receptor-positive means that the hormone oestrogen can attach to the receptors and fuel the growth of the cancer. Some breast cancers are also progesterone receptor positive.

removed, and a different brand of smooth breast implant was implanted. Wendy's surgeon said she couldn't have any other types of reconstruction (for example, using her own tissue in a TRAM flap (abdominal tissue) or *latissimus dorsi* (using tissue from the back) reconstruction) as she had had implants.

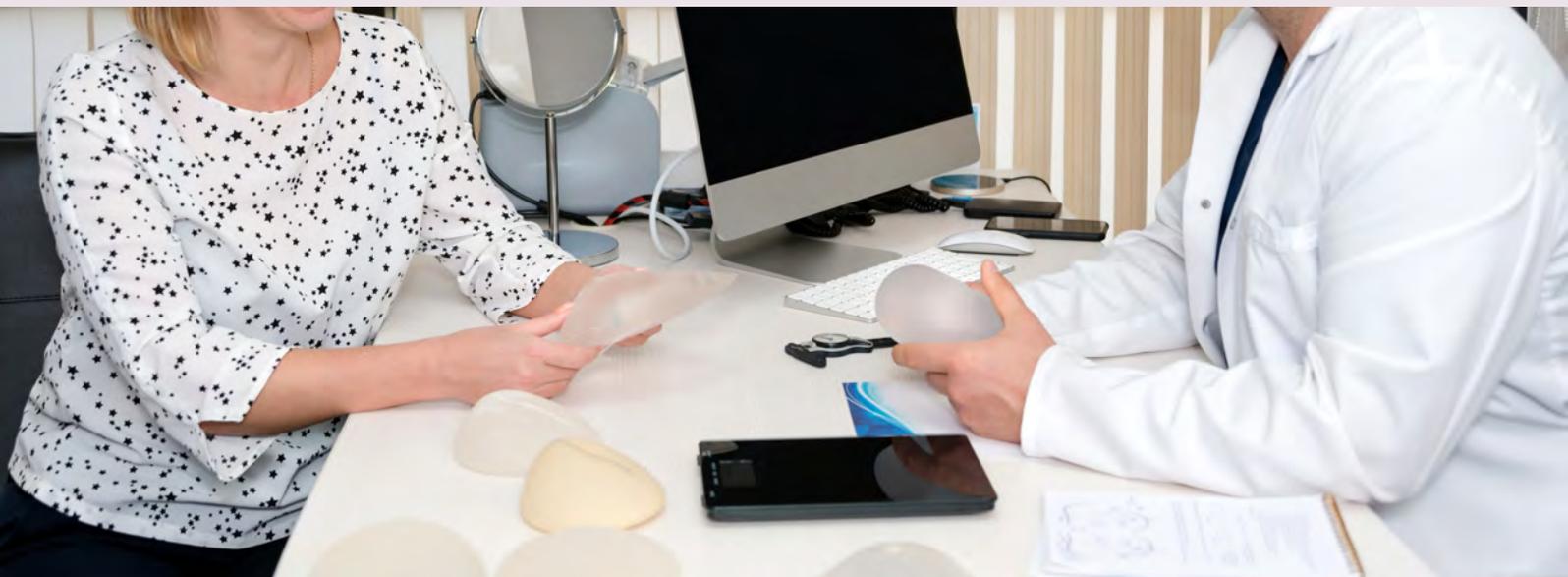
Although concerned about the possibility of further health problems, because the removal of the capsule left the muscle wall very thin, not replacing the implants would have left Wendy with indentations in her chest where previous implants had once been. She couldn't face the prospect of waking every morning with a stark and confronting reminder, as she showered and dressed, of the breast cancer and now her ALCL diagnosis.

Wendy's surgeon and oncologist found that the cancer had been contained and hadn't spread. She had no other treatment and is effectively in remission.

that Medsafe have had alerts and information about BIA-ALCL on their website since 2017, Wendy's surgeon told her they were not routinely advising patients of the possibility that their implants could cause ALCL.

"He told me that they weren't letting women know, because they believe that ALCL is very rare, and didn't want an influx of women demanding to have their implants removed," she told AWHC with obvious annoyance and frustration. The surgeon told her that when women came in for a check-up they would be informed, but Wendy believes that he didn't see there was a problem with the implants because he thought it was particularly rare.

However, Wendy was told that she was patient number 16 to develop ALCL in New Zealand, and there have been more diagnosed since. In a small population, that is quite a few women to have been affected by a potentially fatal disease. There may be



She has check-ups every three months and has just had another scan to check for recurrence or spread. The scan was clear, and she hoped the check-ups might be pushed out to six-monthly. However, Wendy has an appointment with a different surgeon at the end of September to try to decide what to do about the removal of the new implants, after her oncologist said there may be an issue with her having any implants at all.

On the face of it, you'd have to think Wendy has been lucky to have discovered the problem with the Allergan implants, and the fact they had caused ALCL, before the disease progressed. Wendy is just angry.

She is angry about many aspects of what has happened to her, and she is angry because it doesn't appear that plastic surgeons are telling women who have the implants about the risks. Despite the fact

many more women who are unaware of the risk they carry around everyday just under the skin of their reconstructed breasts.

Yes, it is relatively rare, but there is the issue of informed consent. While informed consent is generally considered something you must provide prior to treatment, it seems only fair and just that if information arises after surgery that may seriously impact on your health and well-being, you should be informed and be given the opportunity to make an informed decision about how to proceed from there.

"I'm really, really angry," Wendy said. "I'm angry and upset that I wasn't told about the risk. I did everything I could to avoid cancer, but I wasn't informed about this."

continued from page 11

“Women should have been notified as soon as they [the health authorities and the surgeons] knew about it. Women can die from this!”

In fact, Wendy was told by a surgeon she had for different health issue, that his wife had died from BIA-ALCL. Wendy knows it could have been worse for her, but she has been traumatised by repeat surgeries and constant check-ups.

At the time of her diagnosis, there were 587 known cases worldwide.

“I was told by the surgeon that it was an illness and not under ACC. I contacted lawyers in the US, Canada, England, Ireland and Korea, and finally found a lawyer in Australia who said he would act for me and any other woman in New Zealand with ALCL.”

The lawyer came over here to investigate and found that it because of the no fault accident compensation legislation and the inability of New Zealanders to sue for medical injury, he couldn't act on behalf of New Zealand women with ALCL. This process delayed her application for ACC cover.

“ACC approved my treatment injury claim but said I am only entitled to claim back leave and incidentals, not lump sum payments, because as soon as I had the surgery I no longer had cancer.”

Her health insurance has covered the cost of her

surgeries, and it is up to them to seek reimbursement from ACC for the cost of surgery.

Wendy has also lodged an ACC claim for trauma and mental distress caused by everything that has happened. Despite trying to get back to living a normal life, she is constantly worried and stressed about the possibility the cancer will come back. She has ongoing checks and the scans she must have involve the injection of radioactive dye that she has an allergic reaction to, another issue that must be treated, and that adds considerable stress to an already stressful situation.

Since we first spoke to Wendy, she has had her mental trauma claim for PTSD with ACC approved, but now has to have further checks and assessment to quantify her level of impairment as a result of the PTSD.

When asked what she would like to happen, Wendy says:

“All women with these implants should be notified immediately. The authorities and the surgeons should be treating this like every woman with these implants has the potential to develop ALCL; they should not be downplaying the risks.”

“Once you've got it, it's too late. I trusted my surgeon but feel let down and I no longer trust them. Women who have these implants need to get them checked, and get them removed, and not to take the risk that they may not develop ALCL.”

continued from page 9

“It is required by Medsafe that all providers and patients of this product are notified of the health risks associated with the BRST™ and NATRELLE® Breast Implants. These products carry a risk of Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL). As a provider of this product you will be required to notify these risks to all patients. It is also recommended that the patient be advised to ensure they schedule regular follow-up appointments with their chosen health care provider.”

It also advised surgeons that they were “alerted to this issue and requested to review the relevant literature in the context of their particular patients on a case-by-case basis.”

It was with some concern that a visit to the website of the New Zealand Association of Plastic Surgeons (NZAPS)¹⁷ revealed that the most recent advice or information about BIA-ALCL is dated 19 May 2019 predating the Allergan/Device Technologies letter by almost a year. Under the News and Issues tab on

their website, the most recent item on BIA-ALCL is dated September 2019, again predating the Allergan/Device Technologies letter by six months.

Worse still, their position statement on BIA-ALCL is dated September 2016. The information in the position statement is accurate... for 2016. The problem is that there has been a significant volume of research on BIA-ALCL published in the medical literature since 2016. Of particular importance is that there is now a lot more data of the degree of risk, and as we have already discovered, “risk estimates for breast implant-associated anaplastic large cell lymphoma indicate that the incidence of BIA-ALCL may be much higher than previously understood”.⁵

We have written to the NZAPS and asked if and when they plan to update their website with more current information on BIA-ALCL, and if they are aware if their members have complied with the directive to advise patients with these implants of their risk and what they should do? At the time of going to press we had still not had a response from them.

In Australia there has been a considerable amount of discussion about BIA-ALCL in the mainstream media, particularly in stories from the Australian Broadcasting Authority, which has broadcast or published at least 18 stories on breast implants and ALCL since December 2016. However, in New Zealand there has been very few stories about this in the mainstream media. Therefore, New Zealand women are almost entirely dependent on their surgeons to provide advice on the risk of BIA-ALCL and facilitate them making informed decisions about their health.

What Now for New Zealand Women?

Women with breast implants should seek advice from their health care provider, either their GP or plastic surgeon/surgeon who did their breast implant surgery. This advice will enable them to make an informed decision about how to proceed. It may not be necessary for them to have their implants removed but Medsafe advise that women with breast implants should have regular follow up exams.

Importantly, irrespective of what sort of implants women have, if they experience sudden, unexplained changes such as lumps or swelling in the breast, pain or tenderness, other than what they normally experience during their menstrual cycle (symptoms that are transient and temporary and associated with premenstrual changes), they should see their health care provider.

If a woman is diagnosed with BIA-ALCL, she should ensure that she or her surgeon lodges a report with Medsafe. It is impossible for our regulatory authorities to gain an adequate understanding of the incidence of BIA-ALCL if they are not advised when patients are diagnosed.

In their response to our requests for information, Medsafe said they had only eight reports of BIA-ALCL and several of those were duplicates, suggesting that reports had been lodged for only four women.

BIA-ALCL is effectively a treatment injury, arising as a result of medical treatment, and as such it may be appropriate to lodge a claim with ACC. We requested information from ACC on the number of claims made for BIA-ALCL and were advised:

“There are fewer than four accepted claims for anaplastic large cell lymphoma related to breast implants. There is no indication from the available claim information that any breast implant injuries relate to Allergan specific breast implants. Due to privacy reasons, the associated cost information cannot be provided.”

The Health and Disability Commissioner advised that a search of the detailed description field of complaints, found no complaints received by HDC about a diagnosis of ALCL arising from breast implants or of a diagnosis of ALCL arising from Allergan breast implants between 1 January 2011 and 14 June 2021.

The Ongoing Issue with Medical Devices

Yet again, women are suffering the consequences of medical devices that are inadequately tested and inadequately regulated. In February 2019 we published an article on the safety of medical devices and it made disturbing reading then.¹⁸

Yet, here we are in September 2021, and writing again about another failed medical device.

In that February 2019 *AWHC Newsletter* we reported that one of the *British Medical Journal's* editors, Fiona Godlee, asked ‘Why aren’t medical devices regulated like drugs?’

She asked *BMJ* readers, who are predominantly practicing doctors and physicians, “How much do you know about the safety and effectiveness of the implanted devices your patients are offered? You may assume that pacemakers, neurostimulators, joint prostheses, and breast implants have been tested rigorously before being licensed for widespread use.”¹⁹

“Sadly, and at times catastrophically, that is not the case. Volume 363 of the *BMJ*, published in the last week of November 2018, features four articles on medical devices and the international investigation into their safety.”¹⁸

“The investigation found that when flaws are found in medical devices and safety alerts and recalls are triggered, all too often these warnings fail to reach doctors and patients. Recalls, withdrawals and bans on devices are not uniformly applied from country to country causing confusion and raising risks to patients where insufficient action is taken.”

Almost three years on from the publication of this international investigation, we are publishing another article on the adverse impacts of a medical device on New Zealand women. Three years on from that investigation, published in one of the world’s most highly regarded medical journals, and we are having to ask questions of our regulators, and the professional bodies representing the health providers putting flawed and dangerous devices into women’s bodies:

- Why is this happening?
- What are you doing about it?

- And why are you not ensuring that all women who have these breast implants are adequately informed of the risks you so clearly should know about?

One paragraph in our 2019 article is particularly heartbreaking:

“While the [investigation makes] chilling reading, the key findings of the study are particularly galling, and the final finding confirms what many of us already knew — **that women bear the brunt of the greed of manufacturers and incompetence of regulators and governments.**”

Again, because they still haven't paid enough attention to this:

Policy makers and regulatory agencies in New Zealand it is time you sat up, took notice and protected patients from harm!

References

- 1 Keech JA and Creech JB, 1997: Anaplastic T-cell lymphoma in proximity to a saline-filled breast implant, *Plastic and Reconstructive Surgery*, August 1997, 100 (2): 554.
- 2 FDA, 2019: Questions and Answers about Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL), US Food and Drug Administration, updated on 23 October 2019, accessed at <https://www.fda.gov/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl>
- 3 Swerdlow SH, *et al.*, 2016: The 2016 revision of the World Health Organization classification of lymphoid neoplasms, *Blood*, May 19 2016; 127(20): 2375–2390.
- 4 Srinivasa D, *et al.*, 2017: Global Adverse Event Reports of Breast Implant-Associated ALCL: An International Review of 40 Government Authority Databases, *Plastic and Reconstructive Surgery*, 2017 May; 139(5): 1029-1039.
- 5 Dabic S, *et al.*, 2021: 26 Years of Textured Implants and BIA-ALCL: Continued Vigilance and Counseling Are Warranted, *Plastic and Reconstructive Surgery*, September 2021; 148 (3): 517e-518e.
- 6 Collett DJ, *et al.*, 2019: Current Risk Estimate of Breast Implant-Associated Anaplastic Large Cell Lymphoma in Textured Breast Implants, *Plastic and Reconstructive Surgery*, March 2019; 143 (3S): 30S-40S.
- 7 De Jong WH, *et al.*, 2021: Final opinion on the safety of breast implants in relation to anaplastic large cell lymphoma: Report of the scientific committee on health, emerging and environmental risks (SCHEER), *Regulatory Toxicology and Pharmacology*, 2021 Oct;125:104982.
- 8 TGA, 2020: Breast implant associated cancer (BIA-ALCL): Information for consumers, Australian Therapeutic Goods Administration, accessed at <https://www.tga.gov.au/breast-implant-associated-cancer-or-bia-alcl>
- 9 FDA, 2019: FDA takes action to protect patients from risk of certain textured breast implants; requests Allergan voluntarily recall certain breast implants and tissue expanders from market, US FDA, 24 July 2019, accessed at <https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan>
- 10 <https://www.medsafe.govt.nz/hot/RecallActionNoticesNew/25771.asp>
- 11 Scott S and Armitage R, 2016: Breast implant cancer much more common than previously thought, ABC, 21 December 2016, accessed at <https://www.abc.net.au/news/2016-12-21/breast-implant-cancer-much-more-common-than-previously-thought/8136286>
- 12 Williams L, 2017: Breast Implants Linked to Cancer, *Auckland Women's Health Council Newsletter* February 2017, accessed at <https://www.womenshealthcouncil.org.nz/site/aklwhc/FEBRUARY%202017.pdf>
- 13 RNZ, 2016: NZ women affected by cancer linked to breast implants, *Radio New Zealand*, 23 December 2016, accessed at <https://www.rnz.co.nz/news/national/321096/nz-women-affected-by-cancer-linked-to-breast-implants>
- 14 Medsafe, 2019: Breast Implants and anaplastic large cell lymphoma, Safety Information Monitoring Communication, updated 12 November 2019, accessed at <http://www.medsafe.govt.nz/safety/Alerts/BreastImplants.asp>
- 15 <https://www.health.govt.nz/your-health/conditions-and-treatments/treatments-and-surgery/breast-implants>
- 16 <http://www.medsafe.govt.nz/hot/alerts/silicon.asp>
- 17 <https://plasticsurgery.org.nz/>
- 18 Claridge S, 2019: Medical Devices and Safety, *Auckland Women's Health Council Newsletter*, February 2019, accessed at <https://www.womenshealthcouncil.org.nz/site/aklwhc/AWHC%20February%202019%20Newsletter.pdf>
- 19 Godlee F, 2018: Why aren't medical devices regulated like drugs? *British Medical Journal*, 2018; 363: k5032



Making the AWHC Newsletter Accessible

AWHC want to make the *Newsletter* as accessible as possible for all women and to that end, this newsletter is the first that will be available in a format for people with low vision or who are blind.

The accessible version of the newsletter will be available on request or via a normal newsletter subscription; readers who are blind or who have low vision or anyone who would prefer to receive

the *Newsletter* in an accessible format just needs to let us know and we will send out that version rather than the usual pdf version.

This is new to us, and we will probably make mistakes with our endeavours to make the *Newsletter* suitable for reading with adaptive technologies, so if you receive an accessible version, please let us know where we can make improvements.