# Auckland Women’s Health Council Newsletter

# July 2023

# The Persistence of a Smear Campaign The ongoing besmirchment of the Cartwright Inquiry

By Sue Claridge

The medical establishment, and those doctors who work in it, rarely take criticism well and there are always those who need to be dragged kicking and screaming into a more enlightened era. Many health consumers look back on some historical medical practices with, at best, bemusement and, at worst, horror. When clear individual, collective and systemic failings are brought to light, people and institutions must be held to account and change demanded of our health system and health practitioners.

Unfortunately, some will always hark back to the “good old days” and insist that there was nothing wrong with the way things used to be done. Some will try to canonise the perpetrators of abuses of health consumers and patients; some will try to lay the blame for a multitude of sins at the feet of those who brought such abuses to light.

In the history of Aotearoa New Zealand, the events that led to the [Cartwright Inquiry](https://www.womenshealthcouncil.org.nz/the-cartwright-inquiry/) in 1987 and 1988, and the outcomes and recommendations of the Inquiry, represent probably the greatest, most polarising episode in our medical and health history. In the 35 years since the Cartwright Inquiry wound up, and what has become known as the Cartwright Report and the recommendations of Judge (now Dame) Silvia Cartwright were released, there have been regular attempts to discredit the Inquiry, the report and the changes to our health system that the report engendered.

The latest attempt is 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.

In April 2023, the *New Zealand Listener* published an extract from *Demonising a Good Doctor: the medical scandal that wasn’t*, by former GP Dr Helen Overton. Overton, in a media release describes her book as being “about the undeserved vilification of Professor Herb Green, and examines the process that enabled this travesty of justice, while revealing the origin of the deep-seated issues our health services face.”

I have not read Overton’s book, only the extract published in the *New Zealand Listener,* her media release, andsome of the letters to the editor in response to the *Listener* article. It is clear that Overton is one of the doctors who continue to believe that Professor Herbert Green did no wrong, that he was little short of saintly. Such people seem intent on rewriting history in favour of Green.

The purpose of this current AWHC article is not to rehash and rebut the writings of those who believe that Herbert Green was hard-done by in the Cartwright Inquiry; the reality is that he experimented on women without their consent and without their knowledge; he involved newborn baby girls in his research with invasive vaginal swabbing without their mothers’ knowledge or consent. Irrespective of any and all scientific justification or explanation, what he did was unethical and abhorrent, and no amount of revisionist writing justifies his unconscionable ethical abuses of women.

The striking aspect of Overton’s article in the *New Zealand Listener* is her misguided insistence that all the current problems in our health system can be blamed on the Cartwright Inquiry and a “feminist agenda”. She writes that there was a feminist agenda to “take the power from male doctors” and blames the Cartwright Inquiry for “anger and antipathy” towards doctors. She says that the Cartwright Inquiry disembowelled the medical profession and asks if it made patients in New Zealand any safer.

There is no doubt the health system is broken!

It is in crisis and on its knees. But that is not the fault of the Cartwright Inquiry, or the recommendations made by Judge Silvia Cartwright, or the changes that were implemented as a result. Some of the things that were implemented directly as a result of the Cartwright Report – the National Cervical Screening Programme (NCSP), the Health and Disability Commissioner (HDC) and the Code of Health and Disability Services Consumers' Rights (Code of Rights) – have all directly benefited health consumers in Aotearoa New Zealand.

Neither the NCSP or the HDC work as well as they should or could, and the Code of Rights is inconsistently adhered to by health and disability services providers. But they have all provided significant benefit to New Zealanders and improved outcomes. In many cases we have a very long way to go to properly ensure patient safety in this country and to derive the greatest possible benefit from the NCSP and the HDC. However, New Zealanders would absolutely be the poorer without them. Additionally, the inadequacies of the NCSP and the HDC can be blamed on the same issues that are responsible for our health system crisis.

The Cartwright Inquiry and Overton’s so-called feminist agenda are not responsible for a lack of political will and the failure of successive Labour and National led Governments to properly invest in health and our health system.

## A Feminist Agenda?

Is there really a feminist agenda?

What women want is to have the medical patriarchy treat women with respect and dignity, to treat them as partners in their health and wellness. Women are literally sick to death of being misunderstood, misdiagnosed, ignored or invisible, and treated by doctors as if they are children – to have decisions made for them by the ‘divine’ doctor, to be seen and not heard. The attitude of Herbert Green, and those who support/ed him are entirely symptomatic of much that is wrong with the medical establishment. It is astounding that some of the people who buy into the idea that there was nothing wrong with what he did ***are women***.

For centuries, 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.

Dr Patricia Niland and Professor Antonia Lyons write about “bias in medical textbooks used between 2004 and 2006, with gender-specific information scarce or absent for cardiovascular disease, alcohol abuse and pharmacology, and a general inference that women’s health problems were aberrations of the male norm.”

Despite the Cartwright Inquiry, in the third decade of the 21st century, it is clear that for the women/wāhine of Aotearoa New Zealand little has changed. Our health system is failing half the population. The overwhelming evidence is that it is a health system designed by men for men.

The issues that women are faced with every day in their interaction with the health system run far deeper than just inherent bias and discrimination in Aotearoa New Zealand health policy and service provision. Women have traditionally been left out of medical research altogether. Dr Janine Austin Clayton, associate director for women’s health research at the US National Institutes of Health, says “We literally know less about every aspect of female biology compared to male biology.”

For example, almost everything we know about heart disease is based on studies of men, despite the fact that heart disease and heart attacks present differently in women. Heart disease is the leading cause of death in women, and although we have fewer heart attacks than men, we are more likely to die. A *Lancet* editorial in 2019 said: “The structural gender bias in cardiology stems from a historical failure to ensure gender balance in cardiology research.” Women die because doctors assume that women experience heart attacks the way men do, and “women get consistently worse care… women with heart attack symptoms were less likely to receive aspirin, be resuscitated, or be transported to the hospital in ambulances using lights and sirens than were men.”

In the last twenty years, there has been considerably more focus on the issues around gender inequalities in biomedical research and calls for journals, funding agencies and researchers to give women parity with men, in studies and in the clinic. Yet, recent studies have shown that while “sex equity has progressed… sex bias in clinical trials persists within medical fields, with negative consequences for the health of all individuals.” Despite requirements in some countries that publicly funded medical research include women, studies have found that publicly-funded trials are no better than industry-funded trials at ensuring gender parity.

In Aotearoa New Zealand women suffer under an inadequately resourced and under-regulated health system. For example:

* Women are disproportionately affected by the harms caused by surgical mesh; 76% of ACC claims for mesh injury between 2005/06 and 2017/18 were from women.
* Aotearoa New Zealand has a tragically high rate of maternal suicide, with 30 maternal deaths by suicide reported by the PMMRC between 2006 and 2018. “Wāhine Māori have statistically significant higher rates of maternal mortality than New Zealand European women... [suicide] remains the single largest cause of maternal death in Aotearoa/New Zealand, with suicide accounting for 44 percent of direct causes of maternal death since 2006.”
* Access to contraceptive advice and contraception is “often guided by morality rather than evidence and informed consent.”
* A number of small provincial birthing units have closed forcing women to have to travel long distances — sometimes for two hours or more — to have their babies. According to the Ministry of Health 2017 report on maternity, 11 primary birthing facilities have closed around the country. Since this report was written a further unit, Lumsden, has been downgraded to a “hub” forcing local women to travel to Southland or Dunedin hospitals. Only two weeks before this edition of the newsletter was published the St George's Hospital maternity unit, the only primary birthing unit in Christchurch, after a year of community lobbying to keep it open. Meanwhile, Ngā Hau Māngere Birthing Centre – where more than 800 babies have been born since it opened in 2019, and 300-500 wāhine attend each month for parenting advice and lactation classes – is at risk of closure because Te Whatu Ora don’t plan to pick up the contract.
* In a review of severe maternal morbidity (SMM) in New Zealand in 2018, researchers found that “severe maternal morbidity was 6.2 per 1000 deliveries with higher rates for Pacific, Indian and other Asian racial groups.” The research found that “over a third of cases were potentially preventable, being due to substandard provider care with increased preventability rates for racial/ethnic minority women.” Provider factors such as inappropriate diagnosis, delay or failure to recognise high risk were the most common factors associated with potential preventability of SMM. Pāsifika women had over twice the rate of preventable morbidity.
* Prof Jackie Cumming (Professor of Health Policy and Management, Victoria University of Wellington) has said that there are “alarmingly high rates of unmet need due to cost, particularly for Māori and Pacific women and women in the areas of lower socio-economic status.”
* Inequity of access to quality pelvic floor health care, rehabilitation services and education on prevention (pre and post birth).

Sex bias against female patients is a constant battle for many women. For example, Hoffmann and Tarzian reported in 2001 in the *Journal of Law, Medicine and Ethics*, “that women are more likely to be given sedatives for their pain and men to be given pain medication. Speculation as to why this difference might exist has included the following: Women complain more than men; women are not accurate reporters of their pain; men are more stoic so that when they do complain of pain, “it's real”; and women are better able to tolerate pain or have better coping skills than men.” A recent review of that research has found that while there has been “progress in our understanding of the biological and psychosocial underpinnings of differences in pain experience and reporting between men and women”, and health care providers were more likely to attribute women’s pain to psychosocial causes and are more likely to prescribe psychotropic drugs to women than to men for their pain, or to refer them to mental health counselling.

In a 2018 meta-analysis of 77 studies, researchers found that women with pain are more likely to be perceived as hysterical, emotional, complaining, not wanting to get better, malingerers, and fabricating pain, as if it is all in her head, and that women with chronic pain are assigned psychological rather than physical causes for their pain.Additionally, “women, compared to men, received less and less effective pain relief, less pain medication with opioids, and more antidepressants and got more mental health referrals.”

An Aotearoa New Zealand study found that for female patients with male doctors there was an increased likelihood of the practitioner doubting the diagnosis and believing that the female patient had a hidden agenda that she failed to present in the consultation; male practitioners were also more likely to diminish the perceived seriousness of the condition in female patients. Gross *et al.*, conclude that their findings “suggest a need to raise male physicians’ awareness to possible biases when treating female patients. The findings also suggest the need to empower female patients to take an active partnership role to improve their communication with male physicians.”

So, let’s talk again about that feminist agenda.

## The Reaction to ‘The Unfortunate Consequence’

Unsurprisingly, bringing a polarising subject to public attention, once again, elicits diametrically opposed responses.

One of the most powerful and poignant responses to Overton’s book extract was from Russell Harris, the husband of Maria, a woman who died in fear and pain at the age of 35 as a result of Herbert Green’s failure to ensure she was properly treated for her cervical cancer. Mr Harris described sitting beside her in Ward 10 of National Women’s Hospital “as her life gradually leaked away from the ravages of cervical cancer.”

Addressing Overton’s claim that the Cartwright Inquiry “profoundly changed the way the health system is managed”, he agrees it did, but to such an extent that now, “cervical cancer is almost conquered. No more is there a ward full of women waiting to die.” Russell Harris says that the medical profession was “gutted” by the Inquiry for the better, critiquing and eliminating antiquated ideas and practices.

Unfortunately, Linda Bryder responded with a letter that was riddled with misinformation, claiming that the declining rates of cervical cancer had nothing to do with the Cartwright Inquiry but with the discovery of the “main cause of cervical cancer, the human papilloma virus, and was aided by the subsequent immunisation programme.”

Bryder’s comments are completely without merit and do not withstand scientific scrutiny. While Harald Zur Hausen, from the Institute of Clinical Virology at the University of Erlangen-Nuremberg in Bavaria, Germany, first hypothesised that HPV caused cervical cancer in 1976, and had confirmed his hypothesis by 1987, the first vaccine in the world was not approved until 2006, and the vaccine was not available in Aotearoa New Zealand until 2008. There are three major flaws in Bryder’s assertions:

First, there is a massive medical and temporal gulf between knowing what causes a disease and being able to prevent it. The knowledge that HPV was the major risk factor in the development of cervical cancer took another twenty years to be developed into any sort of medical approach to cervical cancer prevention and the knowledge alone did not have any impact on the incidence of or mortality from cervical cancer.

Secondly, the HPV vaccine was not available in Aotearoa New Zealand until 2008, and although was initially rolled out to all girls and women between 12 and 26, it is now aimed at intermediate-school age girls in order to vaccinate them before they become sexually active. Cervical cancer can take years to develop; prevalence of cervical cancer is greatest after 35 years of age and it takes 15 to 20 years to develop in women with normal immune systems. Therefore, with the roll-out of the HPV vaccine in 2008 we would not expect to see a definitive impact on cervical cancer incidence until this year at the earliest. Data on cervical cancer incidence for 2023 will not be available for another two to three years and it would take five to ten years of data to be able to establish that there has been a downward trend in incidence that exceeds the impact of the cervical screening programme since 1990.

Finally, 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. Since the introduction of the HPV vaccine in 2008, the decline has been 14% and 33% respectively; – in fact there is a levelling off in both incidence and mortality – demonstrating that there has been no reduction in incidence and mortality that could yet be attributed to the HPV vaccine.

It is also worth noting that, while persistent HPV infection is accepted as the major risk for cervical cancer, there are a number of important co-factors in the development of cervical cancer that the vaccine does nothing to address:

“High parity, long-term use of oral contraceptive pills, tobacco consumption, co-infection with other sexually transmitted agents, lifestyle factors such as multiple sexual partners, younger age at first sexual intercourse, immunosuppression, and diet have been identified as the co-factors most likely to influence the risk of acquisition of HPV infection and its further progress to cervical carcinogenesis.”

After a flurry of letters to the Editor, the *New Zealand Listener* closed comments on the issue with a final letter from Sandra Coney who, together with Phillida Bunkle, brought the unethical research at National Women’s Hospital to light in *Metro* magazine in 1987.

Ms Coney says that Overton in her book extract seeks to exonerate Herbert Green, yet points out that “neither Helen Overton, nor Auckland University historian Linda Bryder, who has also joined in Green’s defence, have had access to Dr Green’s patient files, nor to the over 70 interviews conducted with his patients by Dame Silvia Cartwright.”

“The patient interviews show how little the women knew of the peril they were in, and also the periodic efforts made by GPs, nurses and other doctors to try and rescue these women, by suggesting second opinions and the like. They also show how tenaciously Dr Green kept hold of his patients and the level of trust his patients had in him.”

She goes on to state that which is the crux of the matter:

“The key issue that has not got much air time in the current discussion is consent. These women did not give consent to being in Green’s various experiments, they did not give informed consent to the long – sometimes years – delays in their treatment.

Neither did parents give consent to their daughters, newly born (under 5 days) at National Women’s, over 2000 of them, having swabs taken from their vaginas to test Green’s theory that some females were born with abnormal cervical cells. Neither did women give consent – once they had developed cancer – to being randomized into a trial of different treatments.”

Ms Coney also addresses accusations of a feminist agenda, saying “As for Overton’s claim that Phillida Bunkle and I sought to disempower male doctors. Gender does come into it, in that all Green’s patients were women and nearly all the doctors were men, but some acted with complete integrity. Perhaps Overton does not know that in 1993 we installed a plaque at National Women’s thanking Drs Jock McLean and William McIndoe for trying, over many years, to bring Green’s experiments to a halt. Overton is just as mistaken about how feminists think as she is about Green’s tragic legacy.”

# What is Happening with our National Screening Unit?

By Barbara Robson and Sue Claridge

**It appears that Te Whatu Ora, behind closed doors, is planning to disband the National Screening Unit!**

Established in 2001 in the aftermath of the Gisborne Cervical Screening Inquiry, the NSU is responsible for: three cancer related screening programmes – cervical cancer, breast cancer and bowel cancer; the Newborn Metabolic Screening Programme, and Universal Newborn Hearing Screening and Early Intervention Programme; and quality improvements in Antenatal Screening for Down Syndrome and Other Conditions. Between them they affect every New Zealander.

If screening programmes are not evidence-based, best practice and monitored across their respective screening pathways for quality, clinical safety and efficacy, they can potentially do more harm than good, and exacerbate existing disparities and inequities in health outcomes.

## Federation of Women’s Health Councils Meets with NSU

In April 2023, Barbara Robson, co-convenor of the Federation of Women’s Health Councils (FWHC), met with Dr Jane O’Hallahan, Clinical Director, and Stephanie Chapman, Group Manager, of the NSU. The meeting was to discuss several issues regarding the National Cervical Screening Programme (NCSP), in particular the decision to drop ‘Asian’ women from the definition of priority women. This was of concern to FWHC because:

* historically, Asian women along with Māori and Pasifika women, were more likely to be unscreened or under-screened;
* as at February 2023, there were just as many Asian women as Pāsifika women who needed to be screened to achieve equity;
* the loss of priority status would mean Asian women would no longer be eligible for free screening;
* the rationale for NSU’s decision needed to be understood; and
* the decision needed to be made public as soon as possible so any Asian women due for cervical screening could access free screening prior to July.

## Startling Revelation

In the course of the meeting Dr O’Hallahan and Ms Chapman were asked about the possible impacts of ‘Simplify to Unify’ – the ***internal***consultation process that was underway looking to streamline roles and reduce duplication within Te Whatu Ora. FWHC was aware the month-long consultation with the National Public Health Service (NPHS), which includes the NSU, had started on the 30th of March. Barbara Robson was advised that:

* irrespective of the consultation, the roles of Clinical Director NSU and Group Manager of NSU were to be dis-established;
* the NSU was to be disbanded;
* the screening teams were to be merged with Immunisation in the Prevention directorate of the National Public Health Service;
* the managers of the respective screening programmes and teams would stay, but would be working within a different environment;
* the NSU Analytics team was to move to Te Whatu Ora’s Service Improvement and Innovation Business Unit; and
* the decisions on the new arrangements were expected be finalised in early June.

These discussions were consistent with Te Whatu Ora’s Simplify to Unify Change Overview timeline, which shows that final decisions on the National Public Health Service were to be announced on the 2nd of June.

Subsequent to the April meeting, Barbara Holland (also a co-convenor of the FWHC) attended a meeting of West Coast cervical screening personnel in early May. The discussion was primarily about the change from cervical smears to HPV primary screening. However, at that meeting attendees from the NCSP and HPV screening team were quite open about the fact that the NSU was going to be disbanded.

## What is Wrong with This Picture?

There are two glaring problems with the ‘picture’ described above:

The National Screening Unit was established as a result of the recommendations of the Gisborne Cervical Screening Inquiry in 1999 and 2000. The Inquiry made it clear the NCSP was inadequately managed and monitored and that failures within the screening programme had gone unnoticed for years, causing significant harm.

**The Gisborne Inquiry**

One of the legacies of the Cartwright Inquiry and resultant report, was a promise to the women of Aotearoa New Zealand that precancerous cervical lesions would be identified through participation in the National Cervical Screening Programme (NCSP) that started in 1990, and treated in order to prevent many cases of invasive cervical cancer.

While incidence of and mortality from cervical cancer in Aotearoa New Zealand had declined since the implementation of the NCSP, the NCSP had its frailties, not the least of which were human errors and failures.

Ten years after the ‘promise’ delivered by the Cartwright Report and the NCSP, it was discovered that for the women of Tairāwhiti/Gisborne the promise had been broken. Hundreds of women who had been told that their cervical smears were normal, actually had cervical abnormalities. Between 1991 and 1996, Dr Michael Bottrill – pathologist and owner of the Gisborne Medical Laboratory and the person who ‘read’ the smears – misread/failed to detect abnormal cervical smears. His laboratory identified only 0.53% of smear tests as having high-grade abnormalities, compared to the national average of 1%. After Dr Bottrill retired in 1996, the rate of high-grade abnormalities found in smears taken in Tairāwhiti/Gisborne jumped to 1.71%.

In May 1999, the then Health Funding Authority (HFA) began an investigation into the reading of cervical smears by a community laboratory in the Tairāwhiti region. This followed the raising of concerns about the work of Dr Bottrill – as a consequence of an interim decision of the High Court in March 1999 – who practiced in the area until his retirement on the 4th of March 1996. As part of its investigation, the then HFA arranged to have almost 23,000 cervical cytology slides re-read by a Sydney laboratory. Early results from that re-reading indicated that the Sydney laboratory was reporting many more abnormalities than Dr Bottrill’s laboratory had reported.

The then Minister of Health announced an Inquiry into the under-reporting of cervical smear abnormalities immediately after these early re-reading results were announced. The Inquiry, which ran from 1999 to 2000, eventually determined that not only had the health of the women of Tairāwhiti/Gisborne been put at significant risk as a result of the failings of one man, but that systemic failings in the NCSP had implications for the health of all New Zealand women. This ultimately led to the establishment of the NSU and substantial changes to the way in which the NCSP was monitored and evaluated, including legislative changes.

**After the Inquiry**

Dr Ann Richardson wrote in the *New Zealand Medical Journal* in 2001 that “it is unethical to offer screening if the screening programme is not appropriately organised and monitored.”

She went on to say:

“Despite the wealth of information available about the features required for successful cervical screening, the programme established [in 1990] in New Zealand did not meet published criteria.”

“For the programme to be successful, every aspect of the programme, from identification and invitation of eligible women, through taking smears, preparing cytology slides, interpreting the slides, reporting the results, referral for assessment and treatment where required, to recall for re-screening must be performed to the highest standard. The best way to ensure that a screening programme is beneficial and minimise the risks of harm from screening is to ensure that the programme is properly organised and appropriately monitored.”

“Population-based screening programmes must be audited in order to protect those who participate. These programmes should not be undertaken unless there is acceptance of the ethical obligation to monitor them appropriately.”

Dr Richardson set out clearly not only the justification for the establishment of the NSU, but the moral imperative for it.

In a speech in September 2001 to the Gisborne Business and Professional Women’s Association, Dr Julia Peters – first Clinical Director of the NSU – pointed out that the World Health Organisation published managerial guidelines for cervical screening programmes and said that “these remain highly relevant and in the New Zealand context are indicative of the need for:

* a central office and centralised management;
* effective health promotion, recruitment and retention strategies;
* high quality screening, assessment and treatment services;
* a population register and programme information systems;
* well-trained workforces at both a national and provider level;
* nationally consistent quality standards for each step of the screening pathway;
* continuous monitoring, audit and evaluation processes contributing to on-going quality improvement processes;
* effective communication strategies.”

The NSU was established within the public health directorate of the Ministry of Health, employing a dedicated workforce at a national level to provide firm, national leadership for screening programmes. Centralisation of all government funding for NCSP and Breast Screen Aotearoa (BSA) under the NSU enabled it to contract directly for these services, ensuring consistent standards and monitoring were applied. Operational policies and quality standards were developed for the NCSP [and BSA]; the laboratory operational policies and quality standards were implemented in all laboratories providing services for the NCSP, including minimum volume standards for cytology screening.

There is evidence the NCSP, BSA and NSU are not perfect, and improvement is needed. However, there appears to have been no significant clinical failures – such the failures in Tairāwhiti that led to the Gisborne Cervical Screening Inquiry – in these two programmes. Similarly, there appear to have been no significant clinical concerns with the Bowel Screening Programme, which, after a pilot programme began roll out to the entire country across four financial years starting in 2017. It is “early days” for the Bowel screening Programme; as of the time of writing this programme has only been rolled out to the whole of Aotearoa New Zealand for two years, and there appears to have been no public reporting of any of the benefit measures as set out in the Benefits Schedule of the Benefits Realisation Plan.

Between July and November 2012, an issue in the screening pathway in the Universal Newborn hearing Screening and Early Intervention Programme (UNHSEIP) was identified in which approximately 2,000 babies between 2009 and 2012 were not screened correctly for permanent congenital hearing loss.

Between 2009 and 2012, eight newborn hearing screeners across six DHBs – Auckland, Waitemata, Bay of Plenty, Lakes (Taupo), Hutt Valley and Canterbury were found to have been incorrectly screening babies or falsifying screening results.

Although it was described in the review of the incident that the screeners were not screening babies “according to known programme protocols,” potentially leading to missed detection of a hearing loss, the reality is that some of the screeners involved were actually falsifying the screening results and recording that the babies had successfully completed the hearing test. The screeners involved were discovered to have failed to follow protocol by:

* screening the same ear of a baby twice; or
* screening one ear of the baby, and then testing one of the screener’s own ears as if it were the baby’s other ear; or
* testing both of the screener’s own ears, in place of the baby’s ears.

The NSU was notified of the first two screeners in July/August 2012 by a ‘whistleblower’ and had not picked up the deviation from protocol as a result of its own clinical oversight and review. “The remaining screeners were identified as a result of a DHB audit of individual screener data requested by the NSU.”

Approximately 2,000 babies were identified as having been incorrectly screened and all of them were invited for re-screening; one baby was identified, at 10 months old, with a sensorineural hearing loss that should have been detected as a newborn.

The review of the incident found that the failures were not associated with screener competence, but were the result of a number of other significant factors including:

* stressors in the screening role including pressure to complete screens in the immediate post-natal period, environmental conditions and pay scales;
* lack of training and support for the co-ordinator role and for continued development of screeners;
* resource constraints on development of a national, accessible data system.
* low visibility of, and accountability for, newborn hearing screening;
* absence of individual screener monitoring and awareness of monitoring.

The review found that an audit tool for individual screener data analysis and screeners aware of such monitoring would have minimised occurrence of the incident.

This incident epitomises the importance of a dedicated agency, such as the NSU, that oversees regular monitoring and auditing of screening programmes, as well as the critical role of quality improvement reviews.

Despite the UNHSEIP screening incident, the available evidence indicates that, on balance, New Zealanders are better off with the NSU than without it.

An issue as equally important as the decision to disband the NSU, is the lack of transparency around Te Whatu Ora’s consultation process and the exclusion of external stakeholders, including consumer organisations such as FWHC, AWHC and the Cartwright Collective, from that process.

**The lack of transparency and lack of consultation makes a mockery of the promises made when Andrew Little announced the final structure of the reformed health system in March 2021, followed up by the Pae Ora (Healthy Futures) Act 2022 that specifically provides for consumers to be engaged in decision-making at all levels of the health system.**

It is immensely disappointing to the AWHC and FWHC as consumer advocates that, less than a year after the passing of the Pae Ora (Healthy Futures) Act 2022 and establishment of Te Whatu Ora, they have so easily dispensed with any pretence of a consumer-centred health system in which consumers get to have a say about everything from system level changes and policy through to health services delivery.

When FWHC brought this issue to the attention of Phil Pennington at Radio New Zealand (RNZ), Te Whatu Ora initially advised Mr Pennington they were only delaying the announcement of the decision on a mass restructure involving about 1600 hundred jobs” that was due on 2nd June.

Some hours later Te Whatu Ora changed its position and said it was the decisions themselves it was postponing as it had reopened consultation with staff about specific areas. It acknowledged “The change process is taking longer than initially indicated, given the importance of the decision-making, and the need to work through and consider the very thoughtful and extensive feedback our staff have shared…. Te Whatu Ora also continues regular engagement with unions representing our workforce.”

It is clear that Te Whatu Ora still views the consultation as an internal process principally related to employment matters and sees no place for consulting with key stakeholders or engaging more widely with health consumers. This may be appropriate in some circumstances but not in the case of the future of NSU.

Te Whatu Ora has sought to placate the public by stating that “no patient-facing positions will be affected by these changes,” and that the “restructure would not impact on the delivery of the screening service received by the public.”

This ignores the critical role of the NSU in maintaining the safety and efficacy of the NCSP and other screening programmes. While we are pleased there will be no loss of “patient-facing positions” we cannot be confident there will be no detrimental impact on the quality of the screening services that are delivered. This matters to us and is why the (proposed) disbandment of the NSU is more than an internal employment matter. It is a (proposed) system level change that requires consultation with external stakeholders that, under the Pae Ora (Healthy Futures) Act 2022, must include engagement with consumers.

The requirement for consumer engagement is strengthened in the *Quality Improvement Review of Clinical Quality and Safety for Breast Screen Aotearoa New Zealand* (dated November 2022 but not published until May 2023, after the scheduled closure date of the Simplify to Unify consultation). Within Recommendation 1 is a requirement for a review of the form and function of NSU to be undertaken. Notably this review did not contemplate the disbandment of the NSU. The timeframe for action was 12 months; a far cry from Te Whatu Ora’s month long, limited internal consultation.

Furthermore the *2021 Parliamentary Review Committee Report into the National Cervical Screening Programme* (dated December 2022 and published May 2023) didn’t appear to be recommending the disbandment of the NSU either. Instead “The 2022 PRC supports the establishment of co-governance and recommends the NSU continue to build on their current work in this area and strengthen communication, robust relationships, trust and role clarity across the entire suite of screening programmes.”

## The Case for Retaining the National Screening Unit

Te Whatu Ora proposes disestablishing the NSU and merging the screening teams with Immunisation in the Prevention Directorate of the National Public Health Service (NPHS). The concerns below set out the argument for the retention of the NSU, as it appears to the AWHC and FWHC, based on the information available to us. We believe these concerns have not been adequately considered in the decision-making process.

1. **Concern: screening is a clinical pathway; immunisation is episodic**

There are some distinct differences that are not necessarily well understood. Screening programmes are not just about a (screening) test. They require clinical leadership and a critical focus on clinical safety along the continuum of the respective screening programme’s clinical pathway. A failure along any part of that pathway puts people at risk. The whole pathway must be monitored and audited to assure ongoing clinical safety.

1. **Concern: importance of robust and timely monitoring and audit to assure quality and clinical safety**

We acknowledge that robust and timely monitoring and auditing has been problematic with NSU, certainly with respect to timeliness and publication of reports. This was endorsed in the *Quality Improvement Review of Clinical Quality and Safety for Breast Screen Aotearoa New Zealand* and the *2021 Parliamentary Review Committee Report into the National Cervical Screening Programme.* Changes must be made to ensure monitoring and audit regimes are fit for purpose, timely and robust. External advice from experts in their respective screening pathway fields, including consumers, should be sought.

There must be a commitment to making reports public along with any changes to policies and practice in response to monitoring and audit recommendations.

However, there is no clarity around ‘who’ will do the monitoring and audit. We don’t believe it is the role of Service Improvement and Innovation Business Unit. It has been suggested “Ministry of Health and Te Aka Whai Ora are appropriate agencies to undertake independent monitoring of the BSA programme. However, they must ensure they have the necessary systems in place to undertake this function.” Are they sufficiently independent?

1. **Concern: the proposal to disestablish NSU and merge the screening teams with Immunisation and Prevention has been done in haste**

The proposal appears to have been driven solely by financial savings and without careful consideration of all the implications, benefits and risks, other options.

Given that it is a change to the structure, there should have been/should still be consultation with external stakeholders, especially given the obligation to engage with consumers under the Pae Ora (Healthy Futures) Act 2022.

Additionally, timing the restructure when the NCSP is about to implement a major change to screening, moving from cervical smears to primary HPV testing (September) is extremely risky.

1. **Concern: the new structure and reporting lines within NPHS and up to Te Whatu Ora CEO, and the Public Health Agency (within Ministry of Health) is unknown.**

There is a dearth of information about the operational structure of NPHS and how the proposed ‘new order’ would work.

In considering the proposal that the screening teams be merged with Immunisation in the Prevention directorate, it is critical to understand where the key screening team roles, such as the team manager and clinical director, would sit ‘in the pecking order’, who they would report to, and how many hoops would have to be jumped through should there be a clinical concern or an adverse event. This aspect was the subject of much discussion at the Gisborne Cervical Screening Inquiry, reported in 2001. Those lessons need to be heeded.

If the Analytics components of respective screening teams are to be part of the Service Improvement and Innovation Business Unit of Te Whatu Ora, then their access to screening databases and registers, and reporting lines back to NPHS and elsewhere must be clarified. It is important to understand which roles within what Business Unit are likely to be the first to identify issues and adverse events, be they administrative or clinical; and who they are reported to for action.

1. **Concern: Competing interests/priorities between immunisation and screening risks dilution of focus and effort in existing national screening programmes, concern exacerbated by the major change to the NCSP/cervical screening pathway to be rolled out in September.**

The priority for the immunisation programme as per the recommendation of the Immunisation Taskforce is achieving on-time immunisations and catch up for tamariki from birth to five years, particularly Māori and Pāsifika who are most at risk. Major effort will be required given the parlous state of this part of the programme. The potential risk is the screening programmes will play second fiddle to immunisation activities and lack the necessary focus and attention for their ongoing, optimal operation and clinical safety.

1. **Concern: clarity around internal governance, strategic direction and future of external advisory arrangements**

There is a risk that the internal governance and strategic direction of the national screening programmes will become subsumed/swamped by the national immunisation programme if the NSU is disestablished.

Advice from external stakeholders has been an important feature of the national screening programmes and there must be an ongoing commitment to this. The NSU inherited this culture when it was established in 2001, and while advisory groups and mechanisms have evolved over time, they have added value when given the right opportunities. However, there could have been greater transparency around the advice provided and going forward, transparency and public reporting in general, needs to be significantly improved.

## The Bottom Line!

The FWHC and AWHC would like to see:

* the NSU retained as a discrete unit within the NPHS;
* consultation involving external stakeholders, including consumers, if changes are to be made or other options are being considered;
* a commitment to strong clinical and public health leadership of the screening programmes, and clinical safety;
* a strengthened focus on Te Tiriti and achieving equity;
* fit for purpose, robust, timely and transparent monitoring, audit, and evaluation. This is particularly important to enable the imminent changes to the NCSP pathway to be monitored near to real-time. It also applies to the Bowel Screening Programme where there is no visibility of monitoring, if it is being undertaken;
* ongoing involvement with external stakeholders – clinical, public health, Māori, Pāsifika, health consumers, other vulnerable groups.

Screening programmes have proven to be critical in reducing morbidity and mortality across the entire population of Aotearoa New Zealand, particularly permitting early intervention to treat and manage a wide range of conditions. The NSU must not become a victim of expediency. It must not be disbanded in an effort to save a relatively small amount of money; failures in our screening programmes will lead to far greater individual, whānau, community and health system costs from harm, disability and death caused by a lack of adequate clinical oversight and management.

# The ‘Skinny’ on Our Cervical and Breast Cancer Screening Programmes

By Sue Claridge

Over the last few months, several reports reviewing the performance and quality of our breast and cervical cancer screening programmes have been released.

The Parliamentary review of the National Cervical Screening Programme (NCSP) is a statutory requirement under the Health Act 1956 (Part 4A, Section 112O), which states that a review of the NCSP must occur every three years.

There are three related breast screening reports – Te Whatu Ora Health New Zealand Capital, Coast & Hutt Valley BreastScreen Central Review (2DHB Review), Quality Improvement Review of Clinical Quality and Safety for BreastScreen Aotearoa and Epidemiological Aspects of Breast Cancer Screening Relevant to Aotearoa. They weretriggered by the identification of “a large number of people who enrolled with BreastScreen Central (BSC) [who] had not received an offered appointment within 60 working days of enrolment as stipulated in the National Policy and Quality Standards.”

The 2DHB review identified a cohort of 59 people whose appointments were delayed and who subsequently received a diagnosis of breast cancer; of those, ten cases were reviewed where it was “deemed possible the delay could have adversely affected the outcome for that person.” The review team were unable to quantify the impact of the delay at an individual level; however, they acknowledged the possibility that earlier screening for those ten people “may have resulted in the cancer being diagnosed at a less advanced stage or requiring less intensive treatment.”

The 2DHB review and the Epidemiological report informed the *Quality Improvement Review of Clinical Quality and Safety for BreastScreen Aotearoa*. This review makes 38 recommendations, a number of which extend beyond the breast screening programme to include the cervical and bowel screening programmes, and the NSU.

Kua tawhiti kē to haerenga mai kia kore e haere tonu; he nui rawa o mahi kia kore e mahi tonu
 You have come too far not to go further; you have
done too much not to do more.

— Sir James Henare

In light of Te Whatu Ora’s plans to disband the National Screening Unit it is interesting that the long overdue report on the Parliamentary Review of the National Cervical Screening Programme is prefaced with this quote.

Dr Heather Came, Chair of the Parliamentary Review Committee, writes in her foreword to the report: “Women lie at the heart of whānau and are the heart of the cervical screening programme. We hold up half the sky, we nurture, inspire, provoke and make significant contributions to the world. Ensuring the wellbeing of women is essential to the wellbeing of communities.”

AWHC could not agree more, and this statement sets the context for the importance of our cervical screening programme. The evidence is clear – cervical screening reduces morbidity and saves the lives of New Zealand women/wāhine. So it is with concern that the report of the 2022 Parliamentary Review Committee (PRC) into the National Cervical Screening Programme, which was completed in December 2022, was not released until the 16th of May, after the Te Whatu Ora ‘Simplify to Unify’internalconsultation process had been completed.

Likewise, *Quality Improvement Review of Clinical Quality and Safety for BreastScreen Aotearoa New Zealand*(dated November 2022)and *Epidemiological Aspects of Breast Cancer Screening Relevant to Aotearoa* (dated September 2022) were not released until the 10th of May 2023.

The extraordinary lack of transparency and consultation regarding the ‘Simplify to Unify’ internal consultation process, juxtaposed with the release of these reports two weeks after the consultation process for the National Public Health Service closed on the 28th of April, gives the cynical among us reason to think that the six month delay was deliberate.

## Parliamentary Review Committee Report into the NCSP

Throughout the NCSP report, recommendations refer to actions to be undertaken by the NSU. Despite ongoing changes within the structure of our health system, it was clear that the PRC had not considered that the NSU was in danger of being disbanded, that their recommendations could potentially spill into the vacuum created if the screening programmes/teams were merged with Immunisation in the Prevention Directorate in the National Public Health Service; that priorities for the NCSP and other screening programmes could potentially be eclipsed by more pressing priorities of immunisation.

Despite the success of the NCSP in reducing both morbidity and mortality from cervical cancer, the PRC report confirms that efforts to reduce inequities has made slow progress:

“Māori women are 1.5 times more likely to be diagnosed with cervical cancer, and 2.3 times more likely to die from it compared to European and other women. Cervical cancer disproportionately affects young Māori women, being the second leading cause of cancer death in Māori women aged 25-44 years.”

Additionally, a cursory review of cervical cancer dataconfirms the report’s statement that “the last few years have seen results plateau and in some areas even decline.”The Covid-19 pandemic has only worsened trends in screening coverage for Māori and Pāsifika wāhine and the imposition of additional barriers to screening and colposcopy. The PRC are optimistic that the establishment of Te Aka Whai Ora | Māori Health Authority will drive improved outcomes for wāhine.

It is not just Māori and Pāsifika for whom the NCSP is performing poorly. The review found that there are complex barriers for others including “the rainbow community, disabled people and those living with behavioural health conditions and trauma histories” resulting in poor access to screening for these New Zealanders. There are also systemic barriers to accessing colposcopy services for groups that are poorly served by cervical screening.

The recent decision by the NSU to drop Asian women as a priority group for cervical screening is not supported by the evidence provided in the Parliamentary Review Committee Report.

In a May 2023 media release, the Federation of Women’s Health Councils drew public attention to the fact that from July 2023 Asian women would no longer be eligible for free cervical screening because they have been dropped from the NCSP’s definition for priority women.

Barbara Robson said in the statement, “Historically Asian women have been included in the definition, along with Māori and Pacific women, and other women who are unscreened or under-screened. This means they have been able to access free screening. It didn’t make sense to us that Asian women had been dropped off, when at February this year there were just as many Asian women as Pacific women, i.e. 40,000 for each cohort, who needed to be screened to achieve equity.”

In data presented in the PRC report and supplied by the Ministry of Health, the percentage of Asian women screened between 2017 and 2022 is lower in every year than the percentage of Pāsifika wāhine, and lower than the percentage of Māori wāhine in all years except 2022 in which case the difference was slight. On this data it is hard to see how the NSU can justify its decision to de-prioritise Asian women.

## Recommendations

In total, the PRC made 31 recommendations across nine categories:

* Te Tiriti o Waitangi
* Accessibility
* Elimination of Cervical Cancer
* Integration
* Effectiveness of Monitoring and Evaluation
* Co-Governance and Clinical Governance
* Clinical Quality Assurance in Colposcopy Services
* Workforce Capacity and Capability
* Colposcopy Workforce Capacity and HPV Primary Screening

The aim of the recommendations is to “create a more integrated system across the NCSP pathway that improves accessibility, addresses ethnic inequities in healthcare outcomes, and ensures that the health sector meets its responsibilities under Te Tiriti.”

The recommendations of particular importance, given the apparent plans for Te Whatu Ora to disband the NSU, are those regarding: effectiveness of monitoring and evaluation; co-governance and clinical governance; and clinical quality assurance in colposcopy services. These recommendations are predicated on the continued existence of the NSU as the provider of clinical oversight and management of the NCSP, and evaluation, monitoring and clinical quality assurance are critical to both the success and positive impact of cervical screening, and to preventing harm to our women/wāhine. It is hard to see how these recommendations can be effectively implemented in the absence of the NSU and the clinical oversight that it provides.

**“If we want equitable outcomes from the screening programme we need to value women’s lives and provide a free screening and treatment pathway. This remains the overarching message from the 2022 Parliamentary Review Committee.”**

A significant recommendation of the report is that the NCSP be fully-funded by 2024; the NCSP is the only screening programme that is not fully-funded. Cost has long been an issue that imposes barriers to access for many women/wāhine. The AWHC, FWHC and many other women’s organisations and advocates have lobbied for many years for cervical screening to carry no direct cost to health consumers. While the NCSP receives $45 million in annual baseline funding, most women have to make a “co-payment” to their GP or primary healthcare provider ranging from around $40 to $100. In the current cost of living crisis, even for women who previously regularly participated in cervical screening, such an expense may now be all but impossible for them to manage.

**“It seems that women are still at the forefront of government cost-cutting measures despite the talk of a women’s health strategy and achieving equity.”**

**— Barbara Robson, Co-convenor
Federation of Women’s Health Councils**

In accepting the recommendations, Te Whatu Ora said that “our ability to implement some recommendations – particularly to provide a free cervical screening programme – is dependent on securing additional funding.”

AWHC has previously commented on the need for in-home self-testing\* to be standard when cervical screening shifts to primary HPV testing in September this year. Such a move would significantly reduce the cost for the health system as well as for women, not to mention removing cultural barriers to screening for women. It is bizarre that this has not been a central part of the long planned for change in the cervical screening programme given that this is exactly how the bowel screening programme operates. There is no need for the NSU to reinvent the wheel on in-home self-testing and they should be able to adopt the work done in establishing the bowel screening programme and implement it for cervical screening.

## Breast Screening Quality Improvement Review of Clinical Quality and Safety

As mentioned previously, the impetus for this report was the identification in June 2021 that a large number of consumers in the Wellington region had been waiting longer than the 60 working day target from enrolment to offer of an appointment for their first screening mammogram. It was largely due to a failure of monitoring the problem was not identified sooner.

The purpose of the quality improvement review was to assess whether the arrangements for clinical safety and quality for the BSA programme are fit for achieving the objectives of the programme, and the report on epidemiological aspects of breast screening in Aotearoa New Zealand was prepared to inform the quality improvement review.

The last formal review of BreastScreen Aotearoa was in 2011, and the current quality review found that many of the issues identified in the current review covering the years 2017 to 2022, are similar to those identified in 2011.

AWHC finds this enormously disappointing. Significant resources go into such reviews, including the time and effort of many committed and dedicated health professionals and women’s health advocates. It demonstrates the disdain and disrespect with which successive governments, and health entities hold the views of those working incredibly hard to improve women’s health and health outcomes, to not adequately address issues identified in one review only for those same issues to be identified a decade later.

“It is essential that these issues are addressed, and continuous quality improvement and systematic evaluation are embedded in the programme.”

As with so much of the health system, there has been a substantial negative impact on breast screening by the Covid-19 pandemic, with pandemic-induced services disruptions resulting in about 50,000 (9%) fewer women being screened compared to service levels in late 2019/early 2020, which represents approximately 11% of eligible women, when accounting for population growth. The NSU estimated that the Covid-19 backlog would have been cleared by the end of June 2023. However, there appears to be no publicised information on whether or not this has been achieved. Additionally, critical workforce issues being experienced throughout the health system are also presenting challenges to the breast screening programme.

A very telling comment in the context of Te Whatu Ora’s lack of external/stakeholder consultation regarding ‘Simplify to Unify’ process is acknowledgment by the review panel that “the wider health system is grappling with the challenge of giving effect to te Tiriti and achieving ōritetanga (equity), particularly for Māori and Pāsifika, and implementing the Code of expectations for health entities’ engagement with consumers and whānau.”

It was revealed that one of the limitations in the quality review was that it was completed over only 14 weeks, and that overall the number of interviewees was small, albeit the review panel acknowledged the “rich insights from the women and groups that were interviewed.” The review panel said that “the group could have been more diverse to represent the whole screening population. For example, interviews did not include Asian women, the voices of disabled, LGBTQIA+ or women who did not engage in the system.” Additionally, acknowledging the diversity of our Pāsifika population, they would have “valued more time and opportunity to connect with, and understand the perspectives of, a wider range of Pāsifika consumers and clinicians.”

It is great that the review panel – Drs Dale Bramley, Nina Scott, Sally Urry and Christine Walsh – appreciated and valued the consumers/consumer representatives and clinicians that contributed their views and experience, but this is of scant comfort if the report’s findings and recommendations are not acted upon. Engagement and consultation with consumers is increasingly looking like it has been put in the too hard basket by Te Whatu Ora, and the value placed on the process in this review only serves to emphasise the poverty of consumer engagement elsewhere.

## Key Findings

* Breast, cervical and bowel screening have been established as self-contained programmes, and more work is needed to improve coordination and integration across the programmes. The health system reforms provide the opportunity to develop a cohesive, co-ordinated, population-based approach to all cancer screening.
* Currently the BSA programme is not meeting all its obligations under te Tiriti o Waitangi. The programme function and service delivery are not informed by Māori leadership, mātauranga Māori or grounded in te ao Māori.
* Racism and bias exist across the programme and is not meeting the needs of wāhine Māori and Pāsifika women.
* There are multiple barriers to women participating along the screening pathway, including the lack of a national breast screening register with a list of all eligible women and the systematic invitation and recall to screen.
* There is poor understanding of equity in relation to other underserved populations, including a distinct gap in data about women living with disabilities and women who live rurally.
* There is limited understanding of, and attention given to, consumer engagement within the programme, which is a critical aspect of quality improvement, with an urgent need to establish consumer participation within the programme at all levels, including being part of governance and decision-making.
* Engagement and partnership with Māori clinician leaders is critical to the success of a revised NSU and BSA governance structure, as is co-design, shared decision-making and distributive leadership.
* The BSA needs to improve its equity analysis monitoring frameworks and ensure that quality ethnicity data is analysed.
* The programme standards need to be formally revised; there are too many standards, and they need to be simplified, and the planned formal revision needs to be a co-design process from the start.
* The BSA programme does not, but should, have a monitoring framework that includes clearly defined indicators that are prioritised, describes the frequency of reporting and where indicators will be reported, and escalation protocols if an indicator is out of line. Consumers and whānau have not been included in the process of determining which outcome measures are reported, what is most important to them, and how information is presented. Reporting of indicators is not regular or timely and is not transparent. Most monitoring reports produced by NSU are overdue.
* There is no clear structure for ensuring there is an equitable representation of Māori and Pāsifika health expertise within the NSU and within the BSA programme. Among the non-Māori workforce there is no systematic, comprehensive training in anti-racism, cultural safety, and health literacy or te reo me ona tikanga (Māori language and protocols) and te ao Māori (Māori ways of life).
* The BSA programme is not using information systematically to support learning and continuous quality improvement.

## Epidemiological Aspects of Breast Screening

* The overall design of BreastScreen Aotearoa, and participation rates, compare well with public sector programmes in many other developed countries.
* Target participation is 70% based on the number of women screened as a fraction of the census population; from 2012 to early 2020, coverage was over 70% in Pāsifika and non-Māori non-Pasifika, but was around 62 to 65% in wāhine Māori. This underestimates actual participation, as no account is taken of ineligible women, including higher risk women, women being screened in the private sector, and women making an informed decision not to participate.
* Breast cancer mortality in Aotearoa New Zealand has fallen by almost 50% from about 1988 to 2017 (latest available data). This fall began before the screening programme, and this is usually attributed to improvements in treatment; the rate of decline increased after implementation of the programme. The death rate reduced by 17% in the first few years of the programme, and women who participate have a 34% reduction in their risk of breast cancer death.
* There are significant disparities and inequities in breast cancer incidence and mortality. Between 1996 and 2017, the highest mortality rates at ages 45-69 were in Māori (68 per 100,000), and Pāsifika (also 68), while the rate in non-Māori non-Pāsifika women was 42 per 100,000. The incidence rate for ages 45-69 in the same period was highest in Māori, 383 per 100,000, and Pāsifika – 331 per 100,000, compared to 263 per 100,000 in non-Māori non-Pāsifika.
* Survival rates for women with breast cancer are lower in Māori (10 year survival 84%), and Pāsifika (81%), compared to Asian (91%) and other women (87%).
* The Covid-19 pandemic and associated restrictions saw ‘across the board’ decreases in breast screening coverage, with the greatest drop seen in Pāsifika (11.8%), followed by non-Māori non-Pāsifika (8%), with the lowest drop among wāhine Māori (5%). Despite this lower pandemic-associated decrease in coverage for wāhine Māori, in the latest data available (mid-2020) coverage is lowest among Māori.

# Limited Good News, Overall Disappointment

## The Health Select Committee Report on the Therapeutic Products Bill

By Sue Claridge

On the 13th of June, the Health Select Committee (HSC) submitted its report on the Therapeutic Products Bill (TPB) to Parliament. The TPB was released for public consultation just before Christmas last year and health consumers, health professionals and other stakeholders were given until the 5th of March to make submissions on the Bill. The submission period was increased by 24 days after complaints, including from AWHC, about the short amount of time in which to make a considered and intelligent submission on a complex 288-page document that would lead to such an important piece of legislation, especially as four weeks of the initial period allowed included Christmas and the summer holiday period.

The HSC received 16,375 submissions from interested groups and individuals, and heard oral evidence from 235 submitters at in-person hearings in Wellington and by videoconference. The AWHC made a substantial written submission and were invited to make an oral presentation in support of our submission; [our submissions can be found on our website](https://www.womenshealthcouncil.org.nz/our-impact/policy-advocacy-submissions/).

To review 16,375 written submissions and consider them against a 288-page Bill is no small undertaking and must have been a mammoth task for the HSC to complete in only three months, especially as it is not the only issue on which they have received submissions in that period.

However, this is the high-level work that our politicians are paid to undertake, so it is disappointing that so few real and impactful amendments have been made to the proposed legislation. Their report is riddled with deletions and additions of text, but for the most part these amendments are semantic and of little consequence to health consumers.

There are a couple of major changes that are to be welcomed but these are insufficient to turn the Bill into legislation that will protect, promote, and improve the health of all New Zealanders and place the health consumer at the centre; it falls well short of making the health, well-being and safety of New Zealanders of paramount importance.

Interestingly, the HSC state at the beginning of their report that they “were unable to reach agreement on whether to recommend that the bill be passed. We recommend all amendments by majority.”

It is stated in the Report that the National Party does not support the TPB and that they believe the Bill in its current form (including with the amendments recommended by majority) is an overreach and is not fit for purpose. Some of their concerns have been addressed or partially addressed – the removal of online importation of medicines, the regulation of natural health products, the regulation of rongoā. The National Party does not support direct to consumer advertising (DTCA) and are also concerned with issues around software as a medical device. Regarding NHPs, in the report the National Party say:

“We have seen no compelling evidence for substantive and significant or serious harm from natural health products. We are concerned for the cost of compliance on small manufacturers and retailers. Further, the view of thousands of submitters opposing this part of the bill has not been respected with the failure of the Labour majority select committee to wait for a report-back of an official Government working group on the impact of the bill on small business that would have further informed committee deliberations.”

## Welcome Amendments

The Health Select Committee and the Government have recognised the over-reach in the TPB as it was originally written. Health Minister Ayesha Verrall and Associate Health Minister Peeni Henare announced on the 13th of June that many small-scale Natural Health Product (NHP) manufacturers and rongoā practitioners will be exempt from regulation under the legislation. They recognised that regulatory costs may drive small producers of NHPs out of business, and that regulation needs to be proportionate to risk.

“While NHPs aren’t risk-free, I’m comfortable that the evidence available suggests these products don’t pose a significant public health risk, Ayesha Verrall said.

They also announced that an advisory committee of rongoā experts and Māori health leaders will be established to implement the new provisions in the Bill. Members will be appointed by the Minister of Health, Associate Minister of Health (Māori) and Minister for Māori Development, in consultation with other Ministers and health agencies.

In addition, the HSC responded to concerns expressed by “many submitters” (including AWHC) regarding distinguishing between foods and products that are regulated under the legislation, in particular concerns that foods that have medicinal properties might conceivably be regulated under the therapeutic products legislation.

The HSC stated that “certainty is important to enable effective policy and regulatory decisions where multiple regimes interact, as with food and NHPs” and recommended inserting a new clause, 16(2A), which would exclude products that are defined as foods in Section 9 of the Food Act 2014. However, the HSC also ensured a “get out of jail free card” for regulators, saying that “regulations could be made under clause 16(1) to include a product by declaring that it was a therapeutic product.” On the one hand they have placated submitters on this issue while facilitating regulatory creep\* on the other, enabling the possibility that everyday foods (e.g. lemons, honey, garlic) might be regulated if they were used for therapeutic purposes.

The Government has also responded to considerable lobbying on the proposed ban on personal importation of prescription medicines. This is currently permitted under section 29 of the Medicines Act 1981. Seriously unwell New Zealanders, including many with terminal cancer, can import medicines unfunded and/or unavailable in Aotearoa New Zealand from overseas if they are licenced or authorised for use elsewhere. For some people, the ability to import cheaper medicines, or medicines not available here is life changing, giving them an extended survival and time with their families they would not otherwise have if they remained entirely reliant on drugs available here.

Gisborne woman Theresa Zame has stage 4 lung cancer. Diagnosed in June 2022 she was given nine months to live, but thanks to Tagrix - an unfunded medication she imports from Bangladesh, her health has improved. Under the original TPB she would no longer be able to get Tagrix which costs her $1,000 a month, and she would have to pay $10,000 a month for Tagrisso which is available here but is unfunded. Theresa would only qualify for funded Tagrisso if her lung cancer metastasised so significantly that it reached her brain.

On the 7th of June, Theresa Zame, surrounded by about 200 supporters, marched on Parliament to submit a 6500-signature strong petition asking that the TPB be amended to allow importation of medication.

The HSC recommended changes to the TPB to allow personal importation, with appropriate safeguards. The recommended provisions will enable people to order and import prescription medicines for their own use, provided they have a prescription from a New Zealand health practitioner. Quantity limits and other restrictions will continue to apply to manage the risks associated with counterfeit and contaminated medicines.

A minor amendment is to require under Clause 347, the “publication of the name of any advisory committee established under this provision, the committee’s terms of reference, and its membership. If the Regulator was satisfied that publishing any of the names could affect the safe or effective operation of the committee, they could publish a statement to this effect,” but the amendment requires the Regulator to make public the reasons why name/s of advisory committee members were withheld.

## What They Haven’t Done…

There are a number of significant issues that have not been addressed at all in the HSC report and the sections of the TPB have not been amended to reflect any consideration given to submitters’ views.

Despite years of submissions and surveys on direct to consumer advertising (DTCA), the HSC has not recommended that this practice cease. This is extremely disappointing. We remain strongly opposed to DTCA and this new legislation was the ideal opportunity for the Government to take note of the widespread opposition to DTCA and ban the practice.

It is clear that research demonstrating harm from DTCA and opposition from much of the medical fraternity and the majority of New Zealanders, has failed to counter what can only be the lobbying of those with a vested financial interest in seeing the continuation of DTCA, most notably the pharmaceutical industry. It is alarming that policy makers, advisors and/or those writing the Therapeutic Products Bill seem to have been unduly influenced by those vested interests.

The pharmaceutical industry plays a role in the introduction, promotion and use of medicines in New Zealand through the use of DTCA and through the influence it is able to exert on patient groups. DTCA has had a significant impact on the demand for specific drugs. The need for unbiased, credible and reliable information for consumers about therapeutic products remains a priority gap that needs to be filled.

DTCA clearly influences consumer demand; “in New Zealand, expenditure on DTCA has been estimated to be in the tens of millions of dollars annually” and pharmaceutical companies would not be continuing to spend that amount of money if advertising did not achieve their goals of increased profit through increased sales of their drugs.

The failure to recommend banning DTCA epitomises the failure of the TPB to place the interests and safety of health consumers at the centre of this proposed legislation. [Our written submission](https://www.womenshealthcouncil.org.nz/wp-content/uploads/2023/03/Auckland-Womens-Health-Council-submission-on-the-Therapeutic-Products-Bill-Final-5-3-2023.pdf) focussed heavily on patient/health consumer safety. It is disappointing that none of the language and concepts in the original TPB that potentially facilitated harm to health consumers has been in any way amended in the HSC recommendations.

For example, we expressed significant concerns about reliance on the concept that “likely benefits should outweigh the likely risks”. How benefit and risk is balanced is crucial to whether or not the Bill protects consumers. A simple calculation of “benefits outweigh risks” is a low threshold, and risks permitting products that are deemed to be not harmful just 51% of the time. Using such an inadequate measure, results in situations like the surgical mesh issue, where a therapeutic product could cause catastrophic harm for thousands of people, yet still be evaluated as having benefits, even with a lack of data or evidence of this.

None of the unnecessarily vague, in places contradictory, and in many cases untenably permissible language has been amended, enabling the new Therapeutic Products Regulator to make rules on an *ad hoc* basis and as it pleases often to the detriment of consumers. The legislation remains riddled with highly subjective language and with wording that will ultimately lead to unwelcome regulatory creep.

We also expressed significant concerns regarding the under-regulation and safety of implantable medical devices, in particular the transitional provisions in the Bill that ensures that we have another six and a half years to wait before sponsors of implantable medical devices are held accountable for the lack of safety of their products. We demanded stopgap or temporary legislation or regulation that covers those medical devices already identified as causing harm, and provides for an immediate reassessment of their safety, quality and performance, or force them to be withdrawn until such time as they can undergo a full market authorisation under the new Act.

Again, it was extremely disappointing to find not a single amendment that might indicate that these concerns have been taken seriously.

It is clear that there will be a significant amount of secondary legislation, and we are cognisant of the fact that some or many of our concerns and recommendations might be best addressed in that secondary legislation. This especially applies to patient safety, and the critical need for robust regulations and enforcement around surveillance and monitoring of therapeutic products – particularly implantable medical devices – and ensuring that the Regulator has the ability to respond swiftly and decisively on reports of harm.

However, nothing that we have seen so far, either in the TPB or from Te Whatu Ora in the year since the enactment of the Pae Ora (Healthy Futures) Act, gives us any confidence that consumer concerns will be given the priority and consideration that they deserve.

There are significant indications that, despite the stated purpose of the Act being to “to protect, promote, and improve the health of all New Zealanders”, this Bill is focussed on giving pharmaceutical companies, manufacturers and suppliers, and any other profit driven entity, access to consumers. It is clear that the Bill is market-focussed, favouring corporates within the medico-pharmaceutical industrial complex, rather than being truly focussed on benefit to the health consumer.

We were disappointed that compliance with the Code of Expectations for health entities’ engagement with consumers and whānau (Te tikanga mō te mahi tahi a ngā hinonga hauora ki ngā kiritaki me ngā whānau) was not explicitly set out in the TPB. The HSC has not seen fit to make any recommendations to include this in the TPB. Wording in the Bill still states that the Regulator will determine who will be affected by any regulations, rather than assuming that ALL New Zealanders will be affected by any regulations.

Our promised consumer-centred health system is looking less and less consumer-centred as each month passes. It is not consumer-centred to have any Government agency or health entity, including the new Therapeutic Products Regulator, decide who should or should not be consulted. Ideally consumers should have a “seat at the table” throughout, to be involved in developing the secondary legislation, the rules and regulations to ensure that consumer safety is paramount.

If there is a “bright spot” amid what is overall a very disappointing report from the HSC, it is that clearly the lobbying and petitioning of Parliament by New Zealanders regarding personal importation of prescription medicines made a difference and forced an amendment to the TPB. To ensure that consumers have a seat at the table, that consumers have a voice and a say in the development of the secondary legislation that will set out in much more detail how the Therapeutic Products legislation will be given effect, we may just have to march on Parliament!

# Health Select Committee Response Mortifies Advocates for Mesh Injured Women

*Advocate for mesh injured New Zealanders, Sally Walker, delivered a petition to Parliament on the 30th of June 2022, asking for a suspension of mesh procedures for stress urinary incontinence (SUI). The Health Select Committee invited written submissions on her petition from a limited number of stakeholders, including Sally and patient advocate Charlotte Korte, and oral submissions were heard by the HSC in February and May this year. AWHC have reported on surgical mesh regularly over the last six years, and commiserate with the mesh injured community over the almost complete lack of progress in halting the devastating harm that mesh causes many, many women.*

*The HSC’s report on Sally Walker’s petition and the evidence they considered, was submitted to Parliament on the 30th of June 2023. The recommendation of the HSC is effectively to* *‘pass the buck’ to the Ministry of Health, relevant medical colleges and the Medical Council of New Zealand, all of whom have repeatedly failed to take action to protect women from injury from surgical mesh.*

*Sally Walker and Charlotte Korte are both disappointed and disillusioned by this outcome. Mesh injured New Zealanders have again been forsaken by the very agencies that should be protecting them.*

**“It is no longer good enough to use the excuse that because some women seem fine after having this surgery, it is ok to leave others completely disabled with shattered lives, unable to function in everyday life.”**

**— Charlotte Korte, oral submission to the HSC, 15 February 2023**

## Health Advocates Speaking Out After Response from the Health Select Committee

In a press statement issued on the 3rd of July in response to the HSC report on the petition, Sally Walker and Charlotte Korte say they are speaking up because mesh injured New Zealanders will be mortified at the response from the HSC.

“We are extremely disappointed, we do not feel this report reflects that level of harm that is occurring, and we want the voices of mesh harmed to be heard. We want mesh injured to know we will not give up.”

They believe “the surgical mesh harm speaks for itself, the terrible suffering that is happening is avoidable, and it needs to be stopped.”

The petition requested a suspension of surgical mesh procedures for stress urinary incontinence, because of serious patient safety concerns, and the ongoing harm. These same procedures were suspended in the UK and are permanently banned in Scotland.

The HSC has noted that the Ministry of Health were “already investigating whether a suspension **should** **be** implemented”. They recommended to the Government that instead, “the Ministry of Health, the New Zealand Medical Council and relevant medical colleges should investigate **how it could** effect a time limited pause”.

Shocked and disappointed, Sally says “the 68 women I am supporting will be absolutely gutted and it will be heartbreaking for me to have to tell them. I would like to think the Director-General of Health, Dr Diana Sarfati, who will now decide whether the suspension will be implemented, will do what is right, fight for patient safety.”

“So many lives have already been destroyed, the Health Select Committee has failed to take decisive action and it is understandable mesh injured will feel utterly let down, the committee members had the chance to stop the suffering and prevent others from the same fate,” said co-petitioner and patient advocate, Charlotte Korte.

Both Sally and Charlotte feel the report is inexcusable, that “the committee has ‘passed the buck’, fobbed off this responsibility to the same health entities who for years have been unable to stop this trauma and suffering. Where are the specific recommendations that one would expect from the Health Select Committee? Where is the evidence that the committee took this issue seriously, other than to listen to the people who presented and read their submissions. What conclusions did they make?”

The Green Party clearly support a stronger direction; they “believe that the harm being caused is not acceptable, and they are not confident patient safety can be assured.”

Spokesperson Jan Logie says “there is sufficient acknowledgement of serious harm to necessitate a suspension. The Green Party believes the Government needs to follow England and Scotland and step in and prioritise patient safety until there is a nationwide system of rigorous credentialling that has been completed, and high vigilance scrutiny placed on all non-mesh pelvic floor procedures.”

The Green Party are “concerned the recommendation that the Ministry of Health work with the relevant colleges and the Medical Council of New Zealand to investigate how it could effect a pause essentially gets the same body who have procrastinated for so long to make the final decision.”

## Key Points from the HSC Final Report to Parliament

* Nationwide credentialling for surgeons implanting mesh has not started. There was no information provided to the HSC on when it will begin, how long it will take, or when it will be completed.
* Just 12 of New Zealand’s most experienced mesh surgeons have been credentialled, with only six meeting the minimum standards for removal. There is no clarification on what specific procedures these six surgeons have been credentialled for. Additionally, there appears to be nothing to stop non-credentialled surgeons in the private sector from continuing to work.
* With the credentialling process not yet completed, there was still no clarity provided to the HSC specifically on what is being done in the interim to protect patients, to keep people safe from harm.
* The petitioners want assurance that Te Whatu Ora/Ministry of Health will be able to prevent surgeons from operating uncredentialled going forward, and for more information to be provided to show how they will do this.
* Chief Medical Officer (CMO) Joe Bourne confirmed that the Education and Harm Prevention Programme for surgeons had not begun, but talks were happening, and a meeting was organised at the end of May, this meeting “was to agree a way forward”.
* The Ministry of Health and the medical colleges did not provide any evidence to the HSC to show that there was currently the requisite training/upskilling happening in both mesh and non-mesh procedures.
* Surgical mesh is still being used for pelvic organ prolapse in New Zealand; it is placed abdominally and these procedures are not banned.
* The two mesh centres set up in Auckland and Christchurch are currently not taking referrals from mesh injured consumers who only have a rectopexy mesh device implanted. The service will accept patients who have had a mesh rectopexy device if another mesh device has also been implanted for stress urinary incontinence, or pelvic organ prolapse.
* A surgical mesh register was first considered in 2018 and is still being considered by Manatū Hauora/Te Whatu Ora. CMO Joe Bourne confirmed that currently they prefer the Australian Monash (APFPR) surgical mesh register. Te Whatu Ora/Manatū Hauora are looking at how the register will fit the New Zealand context. The APFPR register is not mandatory, surgeons can opt in or out of the register, and it could potentially take years before surgeons and hospitals are able to sign up to it. The number of procedures being added to the register is increasing.
* Alongside the request for a suspension, petitioners Sally Walker and Charlotte Korte asked: for the reporting of surgical mesh adverse events to be made compulsory; for a change in the legislation to ensure a surgical mesh register would be mandated: that there would be no a voluntary opt in opt out decision for surgeons to join the register; and for high vigilance scrutiny of non-mesh procedures to be introduced, to keep people safe.

## International Expert Opinion Provided to the HSC by Dr Wael Agur

“The risk of chronic pain and most other long-term complications are because of the device itself rather than surgical skill. He emphasised the importance of surgical experience but noted that it is not associated with reductions in device-related chronic pain and other long-term conditions. Dr Agur explained that an inadequate surgical technique by people who are not credentialed is mostly associated with intraoperative complications, such as bladder injury. However, he said that this type of injury does not appear to have long-term complications because it can be diagnosed and repaired during surgery.”

“Dr Agur noted that the United Kingdom pause on mesh remains despite it having a robust surgical training programme in urogynaecology and female urology. The United Kingdom has also established that mesh MUS surgery should only be performed by credentialled and experienced surgeons. According to Dr Agur: the pause is partly based on the understanding that improving surgical skills could not adequately mitigate the device-related risks.”

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