AUCKLAND WOMEN'S HEALTH COUNCIL

NEWSLETTER

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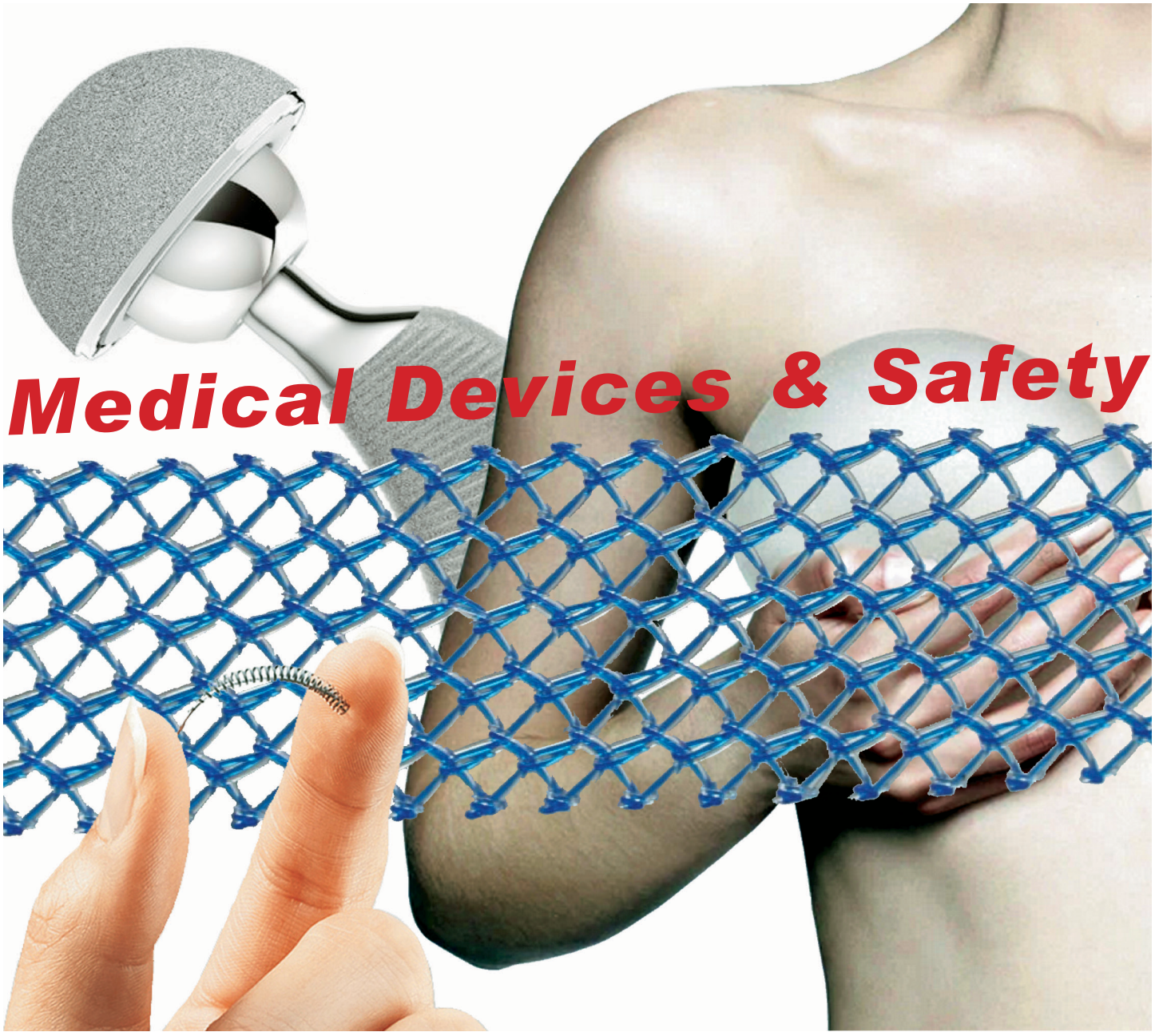
a voice for women's health



Medical Devices & Safety

Also In this Edition

Medical Devices and Safety

Why aren't medical devices regulated like drugs?

One of the *British Medical Journal's* editors, Fiona Godlee, asked this very pertinent question and reported that "a major international investigation, involving 59 organisations and including the *BMJ*, finds device regulation unfit to protect patients from harm."

Surgical mesh has had a lot of publicity of late – both nationally and internationally – and deservedly so, but mesh is only one of many medical devices unleashed upon a largely unsuspecting public only for things to go very badly wrong for many patients.

Ms Godlee asks *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."

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:

- How lobbying blocked European safety checks for dangerous medical implants
- Surgeons call for compulsory registers of all new medical devices
- What happens when the world's biggest medical device maker becomes a "health services provider"?
- FDA recommends "modernizing" review of devices in wake of global investigation.

In Europe, the investigation, which involved 250 journalists and 8 million device related health records, found that "sources of harm to patients include a lung sealant that leaked, breast implants that went rancid, implanted pacemakers that stopped working, and deep brain stimulators that had to be removed."

The website *Implant Files* (www.icij.org/investigations/implant-files/) is devoted to the first-ever global examination of the medical device industry investigation, which has found that health authorities across the globe have failed to protect millions of patients from poorly tested implants.

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.

Surgical mesh is specifically mentioned as an example of how variable the response to problems with devices is, "even when devices have received intense public scrutiny."

"Sales of a controversial variety of pelvic mesh device for organ prolapse repair and incontinence treatment, for instance, were halted over the last year by authorities in New Zealand*, Ireland, Scotland and England — but sales continued in other countries, including Canada and South Africa."

Another device that we have

* Even now, those fighting for action over surgical mesh in New Zealand believe that the action taken here is insufficient to adequately protect patients, as has been discussed on several occasions in the AWHC Newsletter and on our website.

Auckland Women's Health Council

PO Box 32-445
Devonport
Auckland 0744

EMAIL:
awhc@womenshealthcouncil.org.nz

WEBSITE
www.womenshealthcouncil.org.nz

covered in this Newsletter, Essure, is mentioned in the *Implant Files*:

"Despite years of outcry from patient advocates, the controversial Essure birth control device remains on the market in the US until the end of 2018, more than a year after its removal from other markets around the world. Despite being removed from these markets, you won't find much trace of the product in ICIJ's Medical Device Database because its maker, Bayer, maintains that it removed it from countries around the world ***for business reasons, not safety concerns."*** [our emphasis]

Hip implants, pacemakers and defibrillators, breast implants… the list seems to go on and on. Despite New Zealand being one of the countries mentioned with "established national or regional device registries" we don't have registries for all devices. Mesh Down Under have been pushing for a mesh registry for some time and we still don't have one, and when we investigated the use of Essure in New Zealand in early 2018 it was clear that there was no centralised record of who had the device implanted or even how many women there were with the device, let alone any registry of problems or adverse reactions reported.

The *Implant Files* investigation found that the medical devices industry has massive financial resources and broad influence allowing it to spend "hundreds of millions of dollars developing close relationships with doctors and hospitals and on lobbying governments for deregulation, easier approval systems for new devices, and more." In 2017, device manufacturers "made payments to doctors and teaching hospitals for research, travel, royalties, consulting fees and more," and that in the US the average time for a new device to be approved has dropped by more than 200 days in the last 20 years. Faster approval goes hand in hand with minimal testing and a 2016 study in *BMJ* found that devices approved **first in the EU were associated with a higher rate of safety alerts and recalls** than those approved in the US."

While the *Implant Files* make 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**:

- Medical devices improve and save lives, but governments have allowed products on the market with little or no human testing that went on to cause great harm.
- Devices pulled off the market in some countries over safety concerns remain for sale in others.
- The device industry, and the regulators that oversee it struggle to quickly identify hazardous implants after they are released, leaving patients exposed.
- Manufacturers, doctors, and others potentially linked more than 1.7 million injuries and nearly 83,000 deaths to medical devices in reports to US regulators over the last decade.
- Some of the highest-profile controversies in recent years involve products marketed to women, including contraceptive coils, vaginal mesh, and breast implants.

The results of this international investigation should be required reading for our health agencies and policy makers. Policy makers and regulatory agencies in New Zealand it is time you sat up, took notice and protected patients from harm.

AUCKLAND WOMEN'S HEALTH COUNCIL

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AWHC GENERAL MEETINGS

Our last Committee meeting was held on the 21st of February, 2019. Detailed minutes of meetings are available on request. Matters discussed recently include:

- Therapeutic Products Bill consultation
- Funding
- Abortion law reform
- Medical Devices

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Therapeutic Products Bill Consultation

Minister of Health, David Clark, announced in December 2018, that a draft of the Therapeutic Products Bill and a consultation paper have been released on the Ministry of Health's website and submissions from across the sector and consumers are invited. The consultation period is open until the 18th of April, 2019.

The Therapeutic Products Bill will replace the Medicines Act 1981 and establish a new regulatory scheme for therapeutic products, including medicines (including cell and tissue products) and medical devices, while natural health products (including rongoā Māori) will be excluded as far as possible. The Ministry of Health, in its notification of the consultation said that the Government is considering that natural health products could be regulated as a separate process.

In making the announcement, David Clark said: "The Medicines Act is old, hard to use, and doesn't cover products adequately. There is a long history of reform attempts and it is time to finally get a new scheme in place."

"The Bill sets up the main controls on things like clinical trials, product approvals, and prescribing."

An overhaul of a regulatory framework for therapeutic products is long overdue as evidenced by persistent issues with medical devices alone. One only has to consider what has happened with surgical mesh to realise that regulation of devices is totally inadequate. However, mesh is only the latest debacle visited upon trusting New Zealand consumers, with breast implants, hip replacements, pacemakers and the Essure contraceptive device in the recent line-up of medical device disasters.

That regulation of medical devices is grossly inadequate internationally is insufficient excuse for New Zealand's regulatory laxity, and the Therapeutic Products Bill is an opportunity for our Government to not only rectify the problem here but show the rest of the world how it should be done – if they are prepared to hold manufacturers and practitioners to account on the safety and efficacy of devices, rather than bow to industry pressure to pay only lip service to those important issues.

Direct to consumer advertising (DTCA) of prescription medicines is included in the Bill, and the consultation is an opportunity to comment on this controversial practice (only two countries allow DTCA – the US and New Zealand).

The consultation documents, including the draft Therapeutic Products Bill, and information on how to make a submission, can be found on the MoH website at https://www.health.govt.nz/publication/therapeutic-products-regulatory-scheme-consultation.

We urge consumers to review the bill and make a submission on issues of concern to them.

AUCKLAND WOMEN'S HEALTH COUNCIL

Annual General Meeting

The Auckland's Women's Health Council AGM will be held at **5 pm** on **Thursday 28th of March** at the AUT North Campus, 90 Akoranga Drive, Northcote.

Abortion and the Housing Crisis

We have a housing crisis in Auckland. In fact, we've had a housing crisis for while now, and it doesn't seem to be getting any better for our most vulnerable Aucklanders; those living in poverty and in the areas of highest deprivation. While the media reports of people living in their cars have tailed off a bit, there are still occasional articles about people living in grossly substandard situations — converted garages, overcrowded houses and so on.

The rental market is astonishingly stressful — rent is often more expensive than mortgage repayments except for the fact that many families can't save for a deposit that would enable them to get into their own homes. For every rental advertised there seems to be tens if not hundreds of interested tenants. Some landlords have taken to asking for not just references but CVs to winnow out the least desirable potential tenants from those they would be prepared to rent to.

So, is it now so bad in our city that women are choosing abortion over having a baby because they have nowhere to live?

This is the view expressed by Professor Dame Linda Holloway, chair of the abortion supervisory committee in an interview on National Radio* on the 29th of November last year. She pointed out that Auckland was the only region that had had a rise in abortions. Over time with increasing population, a rise in the absolute number of abortions is to be expected. However, Dame Linda said that while Auckland was not the only area that has had a population increase in the last year it was the only one that has had a rise in abortions; and the rise was not consistent across age groups either.

She told Radio NZ that the affected age group – women between 25 and 35 years old – was when women were traditionally starting families and she speculated a lack of housing and increased living costs could be to blame.

Housing Minister Phil Twyford said the association between the housing crisis and the abortion rise in Auckland seemed plausible, but he was keen to get further advice. Similarly, Justice Minister Andrew Little, who in 2018 asked the Law Commission to report on potential changes to the abortion legislation, also agreed that it seemed like a "credible explanation" although he had not seen the figures.

As is so often seen, health and well-being, or the lack of it, is not a simple equation. Before we can adequately address the physical and mental health and wellbeing of New Zealanders, we need to address far more than the inadequacies and under-resourcing of our health sector. We need to address poverty, social issues, education and housing. Only then will we truly start to improve the health and well-being of those currently experiencing inequities and inequalities. That the current housing situation in this country might be impacting on the difficult decisions that some women must make about the future of their pregnancies should be no surprise.

* Jo Moir: Housing shortage in Auckland linked to increase in abortions. Radio New Zealand, accessed at https://www.radionz.co.nz/news/national/377101/housing-shortage-in-auckland-linked-to-increase-in-abortions?

A Win for Women in Science and Medicine

Margaret Brimble made a Dame in New Year's Honours

Women get few awards and little recognition for the contribution they make to science and medicine, so it is great to see one of New Zealand's most eminent biochemists recognised in the New Year's Honours list for her work in both science and medicine.

On New Year's day 2019 it was announced that Distinguished Professor Margaret Anne Brimble was to be made a Dame companion of the New Zealand Order of Merit for services to science.

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Margaret Brimble may not be a household name, but she has made world leading contributions to the synthesis of bioactive natural products and traditional Chinese medicines, including investigating shellfish toxins for the treatment of cardiovascular and neurodegenerative diseases, and as anticancer agents.

Almost two decades ago Margaret Brimble and her team commenced work on a drug to treat traumatic brain injuries; trofinetide is now in phase III human clinical trials for the treatment of Rett Syndrome, a neurological disorder that occurs almost exclusively in baby girls, with symptoms similar to those of autism and cerebral palsy. Trofinetide is also in phase II clinical trials for traumatic brain injury, concussion, and Fragile X Syndrome.

On the announcement of her damehood, Margaret Brimble said about the drug for Rett Syndrome in the *New Zealand Herald*, "What a wonderful disease to have a treatment for. A disease that affects only females and you're a female scientist. It's just a fantastic feeling."

The New Year's honour is the latest in a long line for Dame Margaret. In 2016 she was awarded the Marsden Medal by the New Zealand Association of Scientists; in 2012 the RSNZ Rutherford medal (New Zealand's top science medal), the Hector Medal (Chemical Sciences) and the McDiarmid medal (research for human benefit); and in 2008 the World Class NZ Award for Research, Science and Technology. She was the 2007 L'Oreal-UNESCO Women in Science Laureate for Asia-Pacific in Materials Science and won the RSC Natural Product Chemistry Award (2010), the RACI Adrien Albert Award (2011) and the Novartis Chemistry Award.

Dame Margaret holds the Chair of Organic and Medicinal Chemistry at the University of Auckland, and is also a Principal Investigator in the Maurice Wilkins Centre for Molecular Biodiscovery. She is the Chair of the Royal Society of New Zealand Rutherford Foundation, Vice-President of Organic and Biomolecular Division of the International Union of Pure and Applied Chemistry, Member of the European Research Council PE5 panel for Synthetic Chemistry and Materials Science, Member of International Society of Heterocyclic Chemistry, and Principal Investigator in Brain Research NZ.

Preventing Over Diagnosis Conference

The 7th International Preventing Overdiagnosis Conference will be held in Sydney from the 5th to the 7th of December 2019.

Overdiagnosis is a significant issue in medicine and the provision of health services, and directly contravenes the Hippocratic oath that asserts that doctors will first do no harm. Overdiagnosis occurs when people are given a diagnosis they don't need, leading to unnecessary treatment. Often such people have no symptoms or mild symptoms that do not cause them any harm or discomfort, or they have a disease or condition that is either mild or would never progress to cause them any harm.

Often overdiagnosis occurs through population-based screening. For example, a review of studies published in the *British Medical Journal* found that as many as one in three cancers detected through screening may be overdiagnosed.

Diagnosis can also occur when the definitions or measures of disease are widened to include people who would previously not been diagnosed, or are at very low risk of future ill-health (for example hypertension and ADHD).

The themes for the December conference are:

- Commercial Drivers of Overdiagnosis / Commercial Determinants of Health
- Genomics / Precision Medicine / AI
- Overdiagnosis and the Media
- Addressing Overdiagnosis and Overtreatment in Musculoskeletal Conditions
- Screening and Overdiagnosis in the Asia Pacific Region

A number of keynote speakers have been confirmed including:

- Barry Kramer, a leading global authority on cancer overdiagnosis, NIH National Cancer Institute, USA.
- Fiona Godlee, Editor-in-chief of the *BMJ*.
- Teppo Järvinen, an orthopaedic surgeon who is a leader in the debate about overdiagnosis, unnecessary operations and too much medicine.
- Jin-Ling Tang, Director of the Hong Kong branch of the Chinese Cochrane Centre, with an interest in the consequences of expanding disease definitions.
- Rachelle Buchbinder, a champion of evidence-informed decision-making and the dangers of overdiagnosis and unnecessary care in the world of musculoskeletal conditions, based at Monash University.

More information about the Preventing Overdiagnosis Board and the Sydney conference can be found at http://www.preventingoverdiagnosis.net/ Conference registration for patients and charity groups is £155 (approximately NZ$294)

Period Poverty: *We Need to Follow Australia's Lead*

In October 2018, the Australian Government announced that as of the 1st of January 2019 GST would no longer be applied to sanitary products. Australians have campaigned against GST on sanitary products ever since GST was introduced in that country in 2000. Australia's GST system has always differed from New Zealand's in that some items have always been untaxed – including condoms, lubricants, Viagra and nicotine patches.

Rochelle Courtenay, Founder of Share the Dignity, a charity providing sanitary items for women experiencing homelessness and poverty, said "I don't think it's even about the money. It's about equality."

"Why are condoms, lubricants and nicotine patches all untaxed, yet female items that we don't have a choice in are taxed?" she said.

The announcement is great for Australian women... but what about New Zealanders? Period poverty is a real issue for some women and girls in this country and the Government could make a difference for those who are struggling by removing GST from sanitary products here. Better still, make them available through a PHARMAC subsidy at least for those with a Community Services card.

No woman should have to choose between essentials, like food or paying the power bill, and buying sanitary products. It is long past time those making the rules stopped perpetuating the idea that somehow sanitary products are luxury items, as though any woman would choose to have to spend money on pads, tampons etc, instead of other "luxuries" such as rent and food!

However, Deloitte tax partner Allan Bullot said New Zealand had taken a different approach to Australia with regard to GST, in not allowing any exemptions and he did not expect that to change.

While any exemptions to the tax may make GST an accounting nightmare for businesses, something must be done to provide relief to women and girls who struggle to pay for rent, food, power (especially in winter) and transport to schools and jobs.

A number of charities/non-profits in New Zealand have stepped up to fight period poverty (see sidebar), but what is needed is for the New Zealand government and the Ministry of Health to recognise the significant adverse impact that the cost of sanitary products have on the lives of many of girls and women, and urgently introduce the means to subsidise these products or make them available free to those living in poverty.

Organisations who are working to collect and distribute sanitary supplies to young women in need, either through donation or a Buy One Give One system:

SPINZs (Sanitary Products in New Zealand Schools) – https://spinzs.co.nz/

The Salvation Army Foodbank Project – https://www.foodbank.org.nz/products/womens-bundle

Go With The Flow – https://www.facebook.com/Gowiththeflow.sanitaryequality/

Feel Good Period – https://www.facebook.com/fgperiod

KidsCan – https://www.kidscan.org.nz/our-work/health-for-kids

Shine – http://www.2shine.org.nz/i-want-to-help-others/donating-items

MyCup (Donate a cup) – https://www.mycup.co.nz/donate-a-cup/

Lumii (Donate a cup – Auckland) – https://lumii.co.nz/pages/donate-a-cup

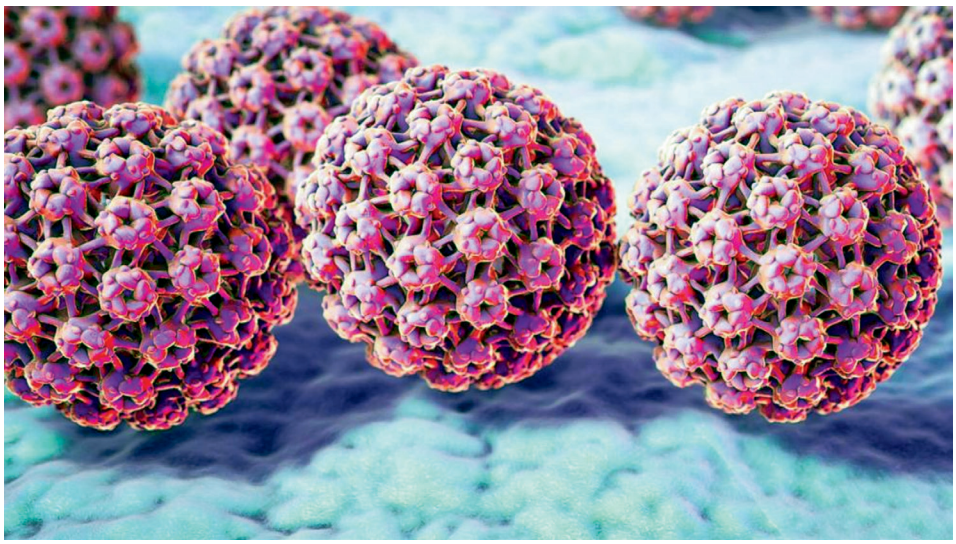
Oi (Buy one give one) – https://oi4me.com/the-story/get-involved

Dignity (Buy one give one for businesses) – https://www.dignitynz.com/

United Sustainable Sisters – http://www.tamakiwrap.org.nz/projects-1

Cervical Cancer Screening and Epigenetics

Advances in cervical cancer testing may address multiple deficiencies in both current and proposed cervical screening practices.



A digitally rendered illustration of the human papilloma virus (HPV) on the surface of skin or mucous membrane (© Katerynakon | Dreamstime.com)

A study published in December 2018 in the *International Journal of Cancer*[1], reported that a new test had a 100% success rate in detecting cervical cancer. The case-controlled research compared a new 'epigenetics-based' cervical cancer test with Pap smear and HPV tests, and investigated how well it predicted the development of cervical cancer up to five years in advance, in a study of 15,744 women aged 25 to 65 in Canada.

Currently two tests are used to screen for cervical cancer – the traditional Pap smear and HPV testing, which tests for the presence of DNA from the human papilloma virus (HPV) believed to be the primary but indirect cause of cervical cancer. Because 95% of women have HPV infection in their lifetime and only a very small percentage of women with HPV infection go on to develop cancer, HPV testing can return a positive result in women who will never go on to develop cervical cancer.[2]

The new test, rather than testing for HPV DNA, "looks at the naturally-occurring chemical markers that appear on top of the DNA, making up its 'epigenetic profile'."

Lead researcher, Prof. Attila Lorincz, said "we are seeing more and more evidence that it is in fact epigenetics, and not DNA mutations, that drives a whole range of early cancers, including cervical, anal, oropharyngeal, colon, and prostate."

The study found that the new test detected 100% of the eight invasive cervical cancers that developed in the 15,744 women during the trial, compared with the 25% detected by Pap smear and 50% detected by the HPV test.

The researchers wrote that the problem with the existing HPV-based cervical screening is that, while it can identify greater than 95% of pre-cancerous cervical lesions (cervical intraepithelial neoplasia [CIN] grade 2 or worse [CIN2+]), it has a relatively low specificity for CIN2+ because "most HPV positive women have transient infections which spontaneously clear, with few progressing to CIN3 and cancer."[1]

Thus, HPV testing returns positive results much more often in women who do not have CIN2 or CIN3 than does the Pap smear testing; this is highly problematic in terms of overdiagnosis and associated harms, and "the medical community has struggled with this fact since the introduction of HPV DNA testing."[3]

The Canadian study used DNA methylation (see side bar on DNA methylation and epigenetics) testing to simplify the triage process for screening HPV positive women for cervical cancer. The researchers wrote that "most pre-cancerous cervical lesions do not progress to cancer, so triage is done to identify those lesions more likely to become cancerous and boost screening specificity."[1] From a subset of 257 HPV-positive women who were representatively selected from the large study, they tested for baseline methylation and found that methylation signatures performed with 93% sensitivity and 18% PPV* for CIN3, comparable to the combination of cytology and HPV genotyping (86% sensitivity and 19% PPV).[1, 2]

The enormous potential benefit of DNA methylation in cervical screening is in reducing overdiagnosis and the harms associated with a positive HPV test result in women who would never go on to develop cervical cancer.

"In order to avoid unnecessary harms associated with excessive colposcopy referral and overtreatment, secondary triage tests are needed to distinguish benign, transient HPV infections

* Positive predictive value

from those that cause cervical precancers."[4]

The Canadian study has shown that using methylation signatures is a feasible way in which to further assess the likelihood of a woman with HPV infection going on to develop invasive cancer. In addition, it would not require the collection of a separate specimen but "can be done as a simple reflex to the original screening specimen,"[3] according to Prof. Lorincz. Research has also shown it is feasible in self-collected specimens[4], making screening more acceptable to women who currently feel that current screening methods are invasive, intimidating and culturally awkward if not inappropriate.

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DNA Methylation and Epigenetics

Epigenetics is a relatively new branch of science that studies the way in which environmental influences control gene expression. Epigenetic "literally means 'in addition to changes in genetic sequence.' The term has evolved to include any process that alters gene activity without changing the DNA sequence."[5]

We all know that the genes we inherit from our biological parents control who we are – the colour of our eyes, our skin colour and the way in which we develop. Those genes can also affect our health, in particular, our susceptibility to certain diseases. A classic example is the BRCA gene mutations, which confer upon their carriers a higher risk of breast, ovarian and prostate cancer.

But the genes you inherited when the sperm met the egg are not the end of the story. Science has discovered that genes can be "switched" on or off. Those "switches" can be influenced by environmental factors such as nutrition, stress and exposure to chemicals, toxins or pathogens, as early as in the womb. Epigenetics is the study of not the genes we inherit but how the function of those genes is regulated by environmental factors. Epigenetic changes are tiny changes in gene expression that are brought about by the things to which we are exposed throughout our life.

Epigenetic changes are important for your long-term health for many reasons. For example, what happens if a protective gene is deactivated, or a dormant gene switched on? Such changes, although they don't involve damage to the DNA, can cause major changes in gene expression, and therefore the processes and functions that go on in your body at a cellular level. Such changes can significantly increase an individual's risk of developing cancer or other diseases.

DNA methylation is one of several known epigenetic processes. It is the "addition or removal of a methyl group (CH3), predominantly where cytosine bases occur consecutively. DNA methylation was first confirmed to occur in human cancer in 1983, and has since been observed in many other illnesses and health conditions."[5]

Scientists believe that exposure to nutrients, heavy metals, diesel exhaust fumes, hormones, bacteria, tobacco smoke, viruses, stress and pesticides, among many others, affect the pattern of gene activity during the lifetime of your cells.

How is this important in cancer development? There are many potential effects that could contribute to cancer development; for example, there are genes that exert a protective effect by suppressing the growth of tumour cells and yet more genes that can promote tumour growth. If the suppressor genes are turned off, or dormant promoter genes switched on, cancer cells can proliferate.

As we understand more about how epigenetic changes – and the environmental factors that cause them – influence our propensity for cancer, we are developing tools and rules for reducing our risk, and for use in cancer screening, such as measuring DNA methylation signatures as screening for HPV infections that are more likely to progress to cervical cancer.

Severe Illness in Pregnant Women:
We must do better!

In the US, preventable medical error* is the third biggest killer behind heart disease and cancer. A 2016 study by Johns Hopkins University calculated that more than 250,000 deaths per year in the US are due to medical error.

In a New Zealand study published in 2006, Auckland University School of Population health lecturers Mary Seddon and Alan Merry found more than 1500 people were killed or permanently disabled annually in this country through preventable medical error. They wrote:

"The evidence is incontrovertible—we are inadvertently harming an unacceptable number of our patients by the very healthcare intended to help them."

An earlier New Zealand study found that "up to 30% of public hospital expenditure goes toward treating an adverse event"[3], and that does not take into account the cost to individuals in both direct and indirect costs, loss of quality of life etc., and to the community in loss of productivity and participation. Brown *et al* found in 2002 that "adverse events are estimated to cost the medical system $NZ870 million, of which $NZ590 million went toward treating **preventable** adverse events." [our emphasis]

While more recent statistics and costs for medical error in New Zealand are difficult to find, there is little reason to be confident that the situation has improved. In 2006 our stats were similar to the US[2], so it is possible that medical error could be making a significant contribution to direct cause of death in this country.

The findings of a recent study by researchers at Victoria University of Wellington, Te Tātai Hauora o Hine Centre for Women's Health Research and the University of Otago, has only contributed to an overall pessimistic picture of the quality of health care in our public health system.

In a paper titled "Preventability review of severe maternal morbidity", Professor Beverley Lawton and colleagues found that "severe maternal morbidity† was 6.2 per 1000 deliveries with higher rates for Pacific, Indian and other Asian racial groups."

"Major blood loss (39.4%), pre-eclampsia-associated conditions (23.3%) and severe sepsis (14.1%) were the most common causes of SMM. Potential preventability was highest with sepsis cases (56%) followed by preeclampsia and major blood loss (34.3% and 30.9%). Of these cases, only 36.4% were managed appropriately as determined by multidisciplinary review. Provider factors such as inappropriate diagnosis, delay or failure to recognise high risk were the most common factors associated with potential preventability of SMM. Pacific Island women had over twice the rate of preventable morbidity."

* Medical error has been defined as an unintended act (either of omission or commission) or one that does not achieve its intended outcome, the failure of a planned action to be completed as intended (an error of execution), the use of a wrong plan to achieve an aim (an error of planning), or a deviation from the process of care that may or may not cause harm to the patient.[1]

† Severe maternal morbidity (SMM) or maternal near-miss are terms used to identify women with life-threatening complications in pregnancy. The World Health Organization defines near-miss morbidity (NMM) at the severe end of the morbidity spectrum as "the near death of a woman who has survived a complication occurring during pregnancy or childbirth or within 42 days of the termination of pregnancy".[4]

Professor Bev Lawton is the founder/director of Te Tātai Hauora o Hine (the Centre for Women's Health Research) at Victoria University of Wellington

Lead author, Prof. Lawton, told the *New Zealand Herald* that "these women did not need to get as sick as they did and called the ethnic disparity in standard of care 'unacceptable'".[5]

The researchers concluded that their analysis showed "that over a third of cases were potentially preventable, being due to sub-standard provider care with increased preventability rates for racial/ethnic minority women."

The study found that of SMM admissions to an ICU or HDU "overall, 34.1% were deemed potentially preventable and 29.5% not preventable but where improvement in care was needed, leaving 36.4% of reviewed cases deemed to be managed appropriately."[4]

Of the three most common clinical reasons for admission, 56% of cases of severe sepsis, 34.3% of preeclampsia-related conditions, and 30.9% of major blood loss were potentially preventable.[4] Among potentially preventable cases, 93.4% were clinician related, with systems factors present in 60.6% and patient factors in 24.7%. Only in 5.3% of cases were patient factors the only preventable factor.

Underlining the ethnic disparities was the finding that among Pasifika women in whom potential preventability was significantly higher, clinician related factors were present in 100% of cases, systems factors in 67.2% of cases and patient factors in only 7.2% of cases.

Clinician factors were predominantly diagnostic – inappropriate, or delay or failure to recognise a "high risk patient – at 70.8%; and treatment – inappropriate, delay or failure to treat – at 88.8%.

In addition to the impact on the health of women, SMM adversely impacts outcomes for unborn or new-born babies, contributing to adverse delivery outcomes at a higher rate than among women without SMM.

"Adverse delivery outcomes such as fetal death, NICU admission, preterm birth, 5-min Apgar score less than 7 and low birth weight occur at a higher frequency among women with SMM."[6] An investigation into outcomes for babies in New Zealand found that "49.4% of women with SMM suffered one or more of these adverse delivery outcomes. Preterm birth is significantly associated with SMM, with between 22 and 41% of women with SMM having a preterm birth."[6]

It simply is not good enough for New Zealand women to be receiving such grossly inadequate care, or for the quality of care to be so clearly tied to their ethnicity. So soon after the report that found a significant racial bias in resuscitation of premature babies in some DHBs (see the December 2018 AWHC Newsletter), this study is a sad indictment on the care provided to pregnant women in this country.

It has been shown that our neonatal mortality rates have not declined over the last ten years in the way that they have declined in many of the countries with which we compare ourselves.[7] If this is to change, we must address the poor record we have with treating severe maternal morbidity and the contribution it makes to adverse outcomes for our babies.

References

1. Makary MA and Daniel M: Medical error - the third leading cause of death in the US. *British Medical Journal*, 2016 May 3; 353: i2139.
2. Merry A and Seddon M: Quality improvement in healthcare in New Zealand. Part 2: are our patients safe--and what are we doing about it? *New Zealand Medical Journal*, 2006 Jul 21; 119(1238): U2086.
3. Brown P *et al*: Cost of medical injury in New Zealand: a retrospective cohort study. *Journal of Health Services Research and Policy*, 2002 Jul; 7 Suppl 1: S29-34.
4. Lawton BA *et al*: Preventability review of severe maternal morbidity. *Acta Obstetrica et Gynecologica Scandinavica*, 2018 Dec 26.
5. 'Urgent action is needed': A third of severe illnesses in pregnant women were potentially preventable, New Zealand Herald, 5 February 2019 accessed at https://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=12200856
6. Geller SE et al: A global view of severe maternal morbidity: moving beyond maternal mortality. Reproductive Health, 2018 Jun 22; 15(Suppl 1): 98.
7. PMMRC: Twelfth Annual Report of the Perinatal and Maternal Mortality Review Committee, Reporting mortality and morbidity 2016; Eighth Report to the Health Quality & Safety Commission New Zealand, June 2018.

UP & COMING EVENTS

Auckland Women's Health Council

Annual General Meeting

The Auckland's Women's Health Council AGM will be held at 5 pm on Thursday 28th of March at the AUT North Campus, 90 Akoranga Drive, Northcote.

If you plan to come please RSVP to Sue on 09 520-5175 or email: awhc@womenshealthcouncil.org.nz. The exact location of the AGM (room number and map) will be provided closer to the time.

DHB meetings for March to May 2019

Waitematā DHB Board 6 March, 17 April and 19 May* at 9:45am; **Hospital Advisory Committee** meetings 27 March and 8 May at 1:30pm; **combined WDHB and ADHB Community & Public Health Advisory Committee** meeting 15 May at 10am. Meetings held in the DHB Boardroom, Level 1, 15 Shea Terrace, Takapuna. (* This board meeting to be held in Waitakere Conference Room, Waitakere Hospital)

Auckland DHB Board 10 April and 22 May at 10am; **Hospital Advisory Committee** meetings 20 March and 1 May at 1:30pm. Meetings are held in the A+ Trust Room, Clinical Education Centre, Level 5, Auckland City Hospital.

Counties Manukau DHB Board meetings 3 April and 15 May at 9:45am in room 101 at Ko Awatea, Middlemore Hospital; **Hospital Advisory Committee** meetings 13 March and 2 May at 1pm in room 101 at Ko Awatea, Middlemore Hospital; **Community & Public Health Advisory Committee** meetings 10 April and 22 May at 9am in the CM Health Board Office, 19 Lambie Drive, Manukau.

www.waitematadhb.govt.nz | www.adhb.govt.nz | www.cmdhb.org.nz

Northern A and B **Ethics Committee Meetings**

(Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland)

Northern A: Tuesday, 19 March | 21 May
all at 1:00pm – open to public at 1:30pm

Northern B: Tuesday, 5 March | 2 April | 7 May
all at 12 noon – open to public at 12:30pm

https://ethics.health.govt.nz

7th Int. Preventing Overdiagnosis Conference

5th to the 7th of December 2019 | Sydney, Australia

More information at http://www.preventingoverdiagnosis.net/

Choosing Wisely Forum

Continuing the Conversation | Friday 10 May 2019

Te Wharewaka, Wellington

More information at https://choosingwisely.org.nz/forum-2019/

WDHB Launching New Consumer Council

The Waitematā DHB is seeking applications from members of the community who wish to be considered for inclusion on a new Consumer Council representing consumers in West Auckland, Rodney and the North Shore. The aim of the Consumer Council is partially fulfil the DHB's wish to be a patient and whanau-centred organisation that works in partnership with its community.

The Council will help the DHB to continue developing effective partnerships in the design, planning and delivery of health care services through its focus on patient experience.

The DHB are looking for people who are passionate about making sure everyone in Waitematā has access to excellent health and disability services. Members of the Consumer Council will be lay people (not health professionals) and should live within, or have strong connections to, the Waitematā area. They will represent a broad cross-section of the community and will include people with strong connections to the local Maori, Pacific, Asian, disability and youth community.

Key strengths required for membership include:

- Experience and some understanding of the health system as a patient and/or whanau member who has used the Waitematā DHB Health Services
- Experienced Waitematā DHB - hospital, outpatient or community services within the last 2-3 years;
- Strong consumer advocacy focus;
- Good communication skills.

Meetings will take place approximately every six weeks and will alternate between Waitakere and North Shore Hospitals. Payment and travel expenses will be provided according to the Waitematā DHB rate for consumer representatives.

More information, including on how to apply, can be found at https://www.wdhbcareers.co.nz/viewjob/1349141/Consumer%20Council%20Expressions%20of%20Interest