AUCKLAND WOMEN'S HEALTH COUNCIL

NEWSLETTER

JUNE 2014

WHAT'S INSIDE:

- **Surgical mesh women petition the Health Select Committee**
- **Opening of Mother & Baby Unit delayed**
- **Update on enrolling unconscious patients in clinical trials**
- **PND Support Network Movie Night Fundraiser – 19 June (see flyer)**

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SURGICAL MESH PETITION

The problems associated with the use of surgical mesh have been the subject of articles in previous issues of the AWHC newsletter. (1) When the AWHC first became aware of the issue we wrote to Medsafe and the Health & Disability Commissioner about the totally inadequate and unsafe processes for approving the use of the surgical mesh and other medical devices in New Zealand. The response from Medsafe was unsatisfactory and not in the least reassuring, and the HDC refused our request that he undertake a thorough investigation into this issue.

The AWHC also wrote to PHARMAC which is in the process of taking over responsibility for the purchase of all medical devices. This resulted in two AWHC members attending a meeting of PHARMAC's consumer advisory group in March last year via teleconference. It was clear that it was going to be some years before PHARMAC is able to do anything about the kinds of medical devices that the Council is concerned about. They have started assuming responsibility for medical devices with the purchase of dressings and other wound care products. PHARMAC's control of surgical mesh devices is a long way down the road.

Two years ago Carmel Berry, one very courageous woman, set up a website and Facebook support group as a way of reaching out to other women who have been seriously harmed by the surgical mesh and were seeking information and support. (2) Injured with surgical mesh in September 2004 Carmel's report about the mesh is the earliest dated adverse event reported to Medsafe, the Ministry of Health agency charged with ensuring that the New Zealand public is protected from unsafe medicines and medical devices.

Medsafe

Medsafe has now received 57 adverse event reports, yet in the three year period ending 31 March 2013 the Accident Compensation Corporation (ACC) received 421 claims and paid out over $2 million in treatment, rehabilitation and compensation for treatment injuries associated with mesh.

In 2008 Medsafe conducted its own investigation into the use of this device and concluded that the problems were due to the lack of adequate training into how to insert the mesh, rather than it being an unsafe product. How convenient.

Over 50,000 law suits have been filed in the USA specifically about pelvic organ mesh products. Some New Zealand women have joined the numbers in what is known as a Multi District Litigation which is similar to a class action.

Despite the horrific amount of damage this device has caused, and the costs involved in terms of human suffering, and ACC and private insurance pay-outs, the New Zealand government agencies have done absolutely nothing to stop the ongoing carnage.

Carmel has determinedly kept the issue in the public eye via her website, two appearances on TV3, and at the end of May she and Charlotte Korte, a fellow advocate, were interviewed on National Radio's *Nine to Noon* programme after they petitioned the Health Select

Committee for an independent inquiry into the use of surgical mesh in New Zealand. (3)

Carmel and Charlotte are not alone in having suffered severe ongoing complications after having the mesh implanted. The two women outlined what had happened to them on the *Nine to Noon* programme. Neither of them was made aware of the risks and side effects of having a mesh implant, and neither was told that it was extremely difficult or impossible to be removed.

When Carmel first complained about her experience with the mesh back in 2004 she was told she was the only one, and was led to believe that no-one else in the world had had the problems she reported. She was referred to a pain clinic, to a psychologist and then a psychiatrist. Her claim for 'medical misadventure' to ACC was declined. It took nearly two years before a different surgeon acknowledged that it was a 'known complication' of mesh. Carmel told the AWHC "I knew the pain was very real, and it started on the day of the implant surgery. I just couldn't prove the link to ACC." She has had several revision surgeries but continues to live with chronic pain.

When Carmel began to read about 'transvaginal mesh' (TVM) lawsuits in the US she made contact with the first woman who had received a jury verdict against a mesh manufacturer. Validated at last Carmel realised that she was amongst thousands of women worldwide that were experiencing the same complications after a mesh implant.

Charlotte had her mesh implanted to treat bowel prolapse in 2010, and suffered extreme pain and could hardly walk. Her experience and investigations led to her discovering that there were many others, men as well as women, who had been severely harmed by surgical mesh.

More recently, another Auckland woman who underwent surgery in October last year to repair a vaginal and rectal floor prolapse was told by her surgeon that he would not be using mesh as it wasn't being used any more. After weeks of unrelenting pain following the surgery, the woman found out that he had in fact used mesh. She then set about laying a complaint with the Health & Disability Commissioner who has now received at least seven complaints in the last two years. (4)

The petition

Having failed to get any government agencies to take action, Carmel and Charlotte have refused to accept defeat and have presented a petition to the Health Select Committee calling for a full independent inquiry into the use of surgical mesh in New Zealand.

It is not just gynaecological mesh causing problems," Carmel told us. "Of the 421 ACC claims, 189 are related to hernia mesh complications. People don't claim for treatment injuries on a whim, these are patients that are at their wits end having waited a reasonable time for normal healing, and being told that their symptoms would "settle with time." Obviously they didn't."

The two women acknowledge that there are a high number of women having complications after pelvic floor repairs, or stress urinary incontinence procedures with mesh. They are not alone as they have been supported by

Dr Hanifa Koya, a gynaecologist at Wellington's Wakefield Hospital.

Dr Koya has removed more than 50 of these surgical implants. She says it is not only the training that is the problem, it is also the competence and supervision of the use of the different types of mesh. "NZ has very poor regulations, and the manufacturers and distributors have discovered there is a very lucrative market for their products here, and New Zealand is a dumping ground for these devices," she said whilst talking on National's *Nine to Noon* programme. Dr Koya was very clear and extremely eloquent about the issues surrounding the use of the various kinds of mesh. She was also very clear about the fact that women are not being adequately informed prior to having a mesh implant.

Dr Koya told *Nine to Noon*: "Medsafe cannot justify anything because Medsafe does not listen. It did not even listen to ACC at the outset. It has never listened to any of us. So doctors usually don't want to write to Medsafe. There is total under reporting. Most doctors are protecting each other and thinking we should not even fill out the surgical accident form, so they are not doing it." (3)

Medsafe, ACC and the HDC all need to work together, and this is what will be presented to the Health Select Committee, she said. The AWHC agrees, but getting them to do this is a Herculean undertaking.

Now it gets murky

Also appearing on the same *Nine to Noon* programme was Associate Professor Malcolm Frazer. He is the urogynaecology spokesperson for the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), and the immediate past vice chair of the Uro-gynaecological Society of Australasia.

He was less forthcoming on radio than he has been in print.

The professor wrote an article on the transvaginal mesh (TVM) for RANZCOG's *O&G magazine* back in 2012. The declaration of interest at the end of the article states:
"Malcolm Frazer holds contracts as a preceptor for Johnson & Johnson Gynecare as well as American Medical Systems mesh products for which he receives a fee. He has received financial support from both organisations to attend scientific con-ferences as an invited lecturer." (5)

The latest issue of *O&G magazine* features another article by Malcolm Frazer which was co-authored by Dr J Oliver Daly. This article outlines some of the events around the use of the transvaginal mesh. It describes the decline in the use as well as the commercial availability of TVM products around the time that the FDA altered the risk classification of TVM from a low-risk device to a high-risk device. (6)

"If this was not enough, the medico-legal industry is in a feeding frenzy … there are said to be hundreds of class actions currently in progress, with several commencing in Australia," the authors state.

"Unsurprisingly, patient advocacy groups have been vocal in their condemnation of mesh products. This has become a deeply emotional and personal issue for some, which is understandable given the reported morbidity caused in particular cases."

Constant pain does tend to make people emotional, especially when nobody told them prior to the surgery that this is a not uncommon outcome of having a mesh implant, and removal is almost impossible.

The lessons learned

The concluding section of the article describes "the need to recognise the lessons offered by the mesh revolution of the last decade:

- Unchecked commercial interest and clinician zeal accelerates the adoption of medical products at a faster rate than the naturally conservative evolution of medical practice would normally allow. This increases the risk of exposing patients to unknown harms that may exceed any perceived benefits.
- Before adopting a new product or technique, ensure level-1 evidence is available for its overall benefit. Failing this, use of such products should only be under the auspices of a well-designed study with long-term monitoring of important outcomes. This recommendation should not be optional and national regulatory bodies need to be more critical and vigilant in this regard."

This was precisely what Professor Quinlivan pointed out during her presentation at the National Women's Health Annual Clinical Report day several years ago. (1)

"If we look back critically and honestly at the introduction of TVM, we can perhaps admit to ourselves that we were too easily persuaded about mesh benefit when the evidence was clearly incomplete and sadly remains so to this day. When the next innovation emerges we can at least ensure we and our patients are better prepared to meet and benefit from it." (6)

If the doctors can't see the wood for the trees – and experience shows us that they usually can't when it comes to the latest lucrative "revolution" in health – then it is up to Medsafe and the Ministry of Health and the Health & Disability Commissioner and ACC to take prompt and protective action.

Under the current system patients are actually being treated as guinea pigs. Drugs and medical devices continue to be unleashed on an unsuspecting public without adequate testing and post-marketing surveillance and monitoring. The transvaginal mesh is just one example of this. The victims of "the mesh revolution of the last decade" deserve far more than a Health Select Committee hearing.

This scandalous saga must be the catalyst for significant and immediate change that includes a far greater level of oversight and regulation of medical devices, more protection for patients, and better compensation.

References

1. http://www.womenshealthcouncil.org.nz/Features/Womens+Health+Issues.html
2. http://meshdownunder.co.nz/
3. http://www.radionz.co.nz/national/programmes/ninetonoon/20140522
4. http://www.3news.co.nz/Surgeon-used-mesh-without-womans-consent/tabid/423/articleID/342298/Default.aspx
5. Malcolm Frazer. "Transvaginal mesh: How should we interpret the evidence available for the use of transvaginal mesh in prolapse surgery?" *O&G Magazine Volume 14 No 2 Winter 2012.*
6. Malcolm Frazer & Dr J Oliver Daly. "Decline and fall: Lessons learned from the troubled history of transvaginal mesh kits." *O&G Magazine Volume 16 No 1 Autumn 2014.*

OPENING OF MOTHER & BABY UNIT DELAYED

The opening of the in-patient mother and baby facility at Starship's Child and Family Unit has been delayed. Work on the refurbishment was scheduled to begin in May 2014, but due to changes in building regulations following the Christchurch earthquakes, the Auckland Council approval process is taking longer than expected.

As part of last year's Budget Health Minister Tony Ryall announced that there was an extra $18.2 million of funding over four years for a specialist in-patient unit in the Auckland region.

The Mother & Baby Unit will have three beds, with a fourth bed based in Whangarei. There is also funding for additional community-based respite facilities, additional staff who will be based in the Maternal Mental Health teams, and increased community support packages.

The Ministry of Health is cracking the whip and insisting on a September deadline for the opening of the Mother & Baby Unit. The In-Patient Service group is working closely with Council to reach a prompt solution. Tony Ryall is no doubt keen for his photo opportunity to take place before the election on 20 September.

Further information is available at:

http://www.networknorth.org.nz/213/home/activities-and-events/projects/northern-region-perinatal-and-infant-mental-health-project-acute-focus

UPDATE ON ENROLLING UNCONSCIOUS PATIENTS IN CLINICAL TRIALS

It is going to take a great deal more than a front page article in the *NZ Herald* (1) and a few radio interviews to change the practice of enrolling unconscious patients in clinical trials.

Despite the fact that the *NZ Herald* followed up the initial story with an interview with a Whanganui mother whose teenage daughter had been asked to give permission for her critically ill mother to be enrolled in two clinical trials, revealing just how widespread the practice is (2), it was business as usual for the Auckland DHB which announced that the antibiotic clinical trials on unconscious patients would go ahead as planned.

75% said no

A poll that ran on the *Herald* website resulted in 75% voting no to the question "Should critically ill people be part of drug trials when they can't consent?" The AWHC received a number of emails and even a carefully handwritten letter from people who were strongly opposed to the concept of being enrolled in any research trial unless the patient has agreed to take part in the study.

During an item on TV3's 6 o'clock News it was stated "that only 5% of unconscious patients complain" when they regain consciousness and are told they have been enrolled in a clinical trial. This is a significant number, and there will also be those who are not happy but feel too vulnerable to complain or even admit to wanting to withdraw from the trial. Then are the patients who are never told and never find out that they have been enrolled in a clinical trial.

Retrospective consent

The concept of being asked to give consent to something that has already occurred is unacceptable and absurd. It just confuses the issue. How can a patient refuse consent for a drug that has already been given to them?

As described in the article in the May newsletter, the clinical trials industry is trying to make it very difficult for patients to withdraw from research trials and their demand that the patient either fill out a form or contact the chief investigator is downright intimidating.

Letter to the HDC

The AWHC wrote a letter to the Health & Disability Commissioner on 15th May asking him to investigate the practice and suggesting that it may be necessary to strengthen the Code of Consumers' Rights, but we have yet to receive a formal acknowledgement of our letter. The AWHC was however contacted by the office of the HDC on 30th May asking if we would give permission for the HDC to admit that they had received our letter as they had received an enquiry from a reporter. The reporter subsequently contacted us and said she was told that the HDC may choose to regard her request as an Official Information Act request which would give the HDC 20 working days to reply!

A copy of our letter to the HDC has now been put on the AWHC website.

References

1. http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11254381
2. http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11255023

AWHC GENERAL MEETING 5 June 2014

Detailed minutes of this meeting are available on request. Matters discussed included:

- Financial reports
- Grant applications
- Bowel cancer screening pilot
- Breast cancer screening
- Clinical trial enrolments
- 2015 Cartwright conference

Further information on some of the topics listed above is contained in this issue of the AWHC newsletter.

AWHC NEWSLETTER SUBSCRIPTION

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UP AND COMING EVENTS

DISTRICT HEALTH BOARD meetings for June/July 2014:

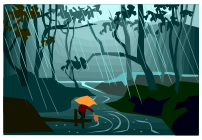
Waitemata DHB (Website address: www.waitematadhb.govt.nz)
The Waitemata Hospital Advisory Committee meeting starts at 11am on Wednesday 2 July 2014 and will be followed by the DHB Full Board meeting which starts at 1.30pm. Both meetings will be held in the DHB Boardroom, Level 1, 15 Shea Terrace, Takapuna.

The **combined Waitemata DHB and Auckland DHB** Community & Public Health Advisory Committee meeting starts at 2pm on Wednesday 11 June 2014.

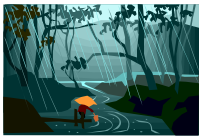
Auckland DHB (Website address: www.adhb.govt.nz)
The Hospital Advisory Committee meeting will be held at 9.30am on Wednesday 25 June 2014 followed by the Full Board meeting at 2pm. Both meetings will be held at the Marion Davis Library, Building 43, Auckland City Hospital.

Counties Manukau DHB (Website address: www.cmdhb.org.nz)
The Hospital Advisory Committee meeting will be held at 9am on Wednesday 11 June 2014 at Ko Awatea and will be followed by the Full Board meeting at 1.30pm.

The Community & Public Health Advisory Committee meeting will be held at 1.30pm on 18 June 2014 at 19 Lambie Drive, Manukau City.



ETHICS COMMITTEE meetings – dates for the four new ethics committees are at:
http://www.ethics.health.govt.nz/about-committees/meeting-dates-venues-minutes



The Perinatal & Maternal Mortality Review Committee is holding its annual conference on Tuesday 17 June 2014 at Te Papa Museum, Wellington.
The topic is "***From Audit to Action.***" This year's programme will include:

- An overview of the latest annual report
- The results of 3 years of neonatal morbidity and mortality review
- Talking to families about post-mortem
- Cooling and the neonate
- Risk assessment in maternity.

To register go to: https://mortalityreviewworkshops2014.lilregie.com