



# AUCKLAND WOMEN'S HEALTH COUNCIL

## NEWSLETTER

DECEMBER 2016



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## **HDC CONSULTATION ON NON-CONSENSUAL RESEARCH**

The AWHC has finally received a response from Health & Disability Commissioner Anthony Hill to the Official Information Act request we lodged seeking information about the consultation process on patients who are enrolled in clinical trials without their consent.

The brief letter makes for very disheartening reading and reveals that very little progress has been made. The HDC is obviously in no hurry to tackle this difficult and contentious issue.

### **Consultation document**

The AWHC wanted to know the date on which the consultation document will be released. The letter advised that “the date for release of the consultation document has not yet been determined.” The excuse given for the ongoing delay is that “the proposed consultation raises several complex and sensitive issues of great public importance” and the HDC is working with the Expert Advisory Group to ensure that the issues are clearly and fairly represented.

The letter goes to explain that “the details of the consultation process continue to be refined and the expected timeframe for the consultation has not yet been finalised.”

This raises serious questions about the apparent reluctance of the HDC to act with the required urgency to protect the rights of a wide range of very vulnerable patients/research participants. The topic has already received extensive media coverage and been the subject of a paper

published in a reputable journal. (1) (2) Meanwhile the research continues, thus normalising the practice of enrolling an increasing range of research participants who for various reasons are unable to give consent.

The HDC goes on to state the obvious – the public will be invited to provide comments on the questions posed in the consultation document, and the consultation process will begin once the document is published.

The Commissioner is also planning to organise focus groups and/or public meetings to facilitate discussion of the issues.

### **Literature Review**

The review of the literature is an ongoing process. The Commissioner says that his office and the Expert Advisory Group “have reviewed numerous publications from New Zealand and overseas during their work on the consultation document” and that “further literature may be consulted if and when new issues arise in the preparation of that document.”

### **The Expert Advisory Group**

The AWHC also wanted to know who the members of the Expert Advisory Group are. The six members were appointed on 11 July 2016. They are:

- Ms Jane Bawden (Chair)
- Dr Colin McArthur
- Professor Alan Merry
- Dr Brigit Mirfin-Veitch
- Dr Jeanne Snelling
- Ms Teresa Wall

Ms Jane Bawden is a lawyer with a background in human rights, medical and health issues. Dr McArthur is an intensive care specialist. Professor Alan Merry practices in anaesthesia and chronic pain management, Dr

Brigit Mirfin-Veitch is a sociologist, Director of the Donald Beasley Institute and has been a member of the Institute's research team since 1994. Dr Jeanne Snelling is an academic lawyer and a Research Fellow at the Bioethics Centre in Dunedin. Ms Teresa Wall, formerly deputy director-general of Maori health in the Ministry of Health, is currently responsible for cross-government relationships and the Trans Pacific Partnership.

"The role of the Expert Advisory Group is to advise and assist me in relation to the consultation," the HDC explains in his letter, and they "were selected primarily to provide expert advice relevant to their particular areas of knowledge and experience, rather than to represent the views of their organisation."

Notably absent from this select group of health professionals and academics is the voice of the consumer. This is an unfortunate although not entirely unexpected omission and casts doubt on the genuineness of the consultation process before it has even begun.

Given that two and a half years after the issue hit the headlines the HDC is still not willing to even commit to a date for the publication of the consultation document, it is difficult to have much faith in what is or is not happening in the office of the HDC.

#### References

1. [http://www.nzherald.co.nz/nz/news/article.cfm?c\\_id=1&objectid=11254381](http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11254381)
2. Professor Joanna Manning. "Non-consensual clinical research in New Zealand: Law reform urgently needed." *Journal of Law and Medicine*. 2016 23 JLM 516.

## **THE AWHC IS SEEKING A NEW CO-ORDINATOR**

The AWHC is seeking a new co-ordinator who can start work early in 2017.

We are looking for someone with an interest in women's health, some experience in advocacy, as well as an interest in the many general health issues that impact on the health system and the health of all New Zealanders.

The work involves responding to requests for information; attending DHB, ethics committee and various other meetings; writing and producing the monthly newsletter, and completing reports for the meetings of the AWHC committee.

This is a part-time position. The current co-ordinator currently works 25 hours per week, but the number of hours worked per week and when those hours are worked is negotiable.

For more information and a copy of the job description please contact the AWHC at (09) 520-5175, or at [awhc@womenshealthcouncil.org.nz](mailto:awhc@womenshealthcouncil.org.nz)

This is a really stimulating job. If you are interested in making a difference, this is the job for you. We look forward to hearing from you. Closing date for applications is Friday 27 January 2017.



## **ESSURE NOW CARRIES AN FDA WARNING**

It is over three years since the AWHC began reporting on the problems associated with the use of Essure, a form of permanent contraception that began causing havoc as soon as it was approved by the USA Food and Drug Administration (FDA) and released on to the market in both the USA and many other countries. (1)

Essure consists of two coils made of a nickel alloy and a polyester-like fibre that are inserted in each fallopian tube through the vagina. The fibres are wound in and around the inner coil and are there for the purpose of creating irritation and inflammation which causes scar tissue to grow over the coils, blocking the tubes.



The FDA approved the use of Essure in 2002 after a fast-track review process that prioritised the device because it was the first sterilisation procedure for women that could be done in a doctor's office, without requiring an incision or a general anaesthetic. It was promoted as being a better option to tubal ligation

but for thousands of women this has not turned out to be the case.

The original clinical trials also did not include control groups for comparison, so it has never been clear whether complications like back pain or heavy bleeding are higher in women who use Essure compared to those who have a tubal ligation.

Fourteen months ago dozens of women injured by Essure testified before the FDA, urging officials to pull the device from the market. FDA officials declined to withdraw the device, saying that Essure was safe and effective for many women although some experienced "very serious and sometimes debilitating problems." (2) However, at the end of November 2016 the agency ordered a black box warning be placed on the device's packaging saying it could cause cramping, nausea and vomiting, dizziness, mild to moderate pain during and immediately after the insertion of the device, and bleeding.

After insertion there are the risks of chronic inflammation, fibrosis, infections, tubal blockage on only one side, perforation of the uterus or fallopian tubes followed by travel into the abdomen and pelvic cavity causing persistent pain and requiring surgical removal. Although the device was not made to be removed hundreds of women have had to undergo a hysterectomy in order to remove pieces of the coils.

Officials at Bayer, the manufacturer of Essure, claim that poor surgical skills are to blame for complications, and insist there is no proof that the device causes chronic pain and autoimmune disorders.

If all this sounds very familiar, it is. The women struggling to get recognition of the suffering caused by surgical mesh have faced similar hurdles and met with the same denials about the damage caused by that particular medical device.

However, in the case of Essure, the FDA has also taken the very unusual step of “guiding Bayer in the development of a new checklist of risks for doctors to review with patients before implanting the device. The three-page checklist is broken into five sections, each followed by a spot for the patient’s initials, and is to be signed by both doctor and patient.

The checklist is not mandatory, and critics say it does not mention many common side effects linked to Essure, like heavy, painful menstrual bleeding.” (2)

### **Removal**

As with the surgical mesh, many doctors who insert the Essure coils do not know how to remove them. It is also not known what the best method of removal is.

As noted previously in the AWHC newsletter, some members of the FDA panel that approved the device in 2002 did raise a number of concerns about the device including the small numbers of women in the phase two and phase three trials, and the lack of long-term data. (1) Despite the fact that Essure was meant to last for life, the FDA approved it after trials lasting only a year or two.

As well as the pain and other serious side effects that emerged in the clinical trials, it was reported that the device could not always be implanted, and it failed to block the

tubes in a significant percentage of patients. According to the new checklist, nearly one in ten women who try Essure cannot rely on it to prevent pregnancy. So much for the claims that it is a better alternative to tubal ligation.

By the end of 2015 the FDA had received nearly 10,000 reports of injuries and pregnancies related to the device, as well as reports of a small number of fatalities. (2)

Bayer has now agreed to begin tracking 1,400 women who have the device implanted over the next five to six years. The study is supposed to report final results in 2023, but it is already behind schedule. There will also be a comparison group of sorts in that 1,400 women who choose the traditional form of sterilisation using laparoscopic surgery will also be followed.

The women in each group will be followed for three years after sterilisation to see how many develop complications such as chronic pain, heavy bleeding and autoimmune diseases, as well as how often each intervention fails, leading to pregnancy. Researchers will also track how many women with Essure develop such severe complications that they have to undergo surgery to remove the implants.

In 2013 the AWHC reported that several DHBs were already implanting Essure. This raises the issue of the information that women are given prior to having these nasty devices inserted.

### **References**

1. <http://www.womenshealthcouncil.org.nz/Features/Womens+Health+Issues/Contraception.html>
2. [www.nytimes.com/2016/11/21/well/bayer-s-essure-contraceptive-implant-now-with-a-warning.html?ref=collection%2Fsectioncollection%2Fhealth&r=3](http://www.nytimes.com/2016/11/21/well/bayer-s-essure-contraceptive-implant-now-with-a-warning.html?ref=collection%2Fsectioncollection%2Fhealth&r=3)

## **PARACETAMOL USE LINKED TO CHILDHOOD ASTHMA**

In February 2016 the *International Journal of Epidemiology* published the results of a study of over 124,000 Norwegian children which found evidence that prenatal and infant paracetamol exposure is associated with the development of asthma. (1)

The article, “Prenatal and infant paracetamol exposure and development of asthma: the Norwegian Mother and Child Cohort Study,” stated that the study is by far the largest study to be undertaken on the link between paracetamol and childhood asthma. As paracetamol is the most commonly used analgesic-antipyretic among pregnant women and infants, uncovering evidence of the adverse effects is of public health importance.

On 26 November Professor Richard Beasley, founder and director of the Medical Research Institute of New Zealand, was interviewed by Kim Hill on Radio NZ. Professor Beasley was recently awarded the Sir Charles Hercus Medal for his contributions to health science research and asthma research in particular. (2) He began by pointing out that New Zealand has one of the highest rates of asthma in the world and that several epidemics of asthma deaths in NZ have been linked to the use of three different drugs. He referred first to the 1970s epidemic which started in 1976 and

last for 10 – 15 years. From 1976 asthma mortality increased three fold over a three-year period. Fenoterol had been introduced and heavily marketed in 1976 despite the fact that it had not been approved for use in asthma patients by the FDA.

The fenoterol scandal took place in New Zealand and Neil Pearce, one of the researchers who discovered the cause of the dreadful epidemic of asthma deaths published a book, “Adverse Reactions: the fenoterol story,” in 2007 which detailed the hostility faced by the researchers involved in the discovery. The book also raised many serious issues about drug safety internationally and the contest between money and science in medical research. (3)

Once the researchers had published their paper – a minor miracle in itself as the Department of Health colluded with the drug’s manufacturer and attempted to block publication – and then Health Minister Helen Clark withdrew fenoterol from the tariff, the use of the drug fell, and asthma deaths dropped by two-thirds over the next 12 months.

Prior to the introduction of fenoterol another drug called isoprenaline had caused similar problems.

Now recently published research has put the spotlight on paracetamol. Professor Beasley described how paracetamol has become such a widely used drug over the past two to three decades, and that it had gone from the medicine cabinet to the larder. It now needed to be taken out of the larder and put back in the medicine cabinet, he said.

He believes primary prevention should now be the focus of future research

on the internationally increasing rates of asthma, that New Zealand has an important part to play in future research, and that there are likely to be multiple factors responsible. As Kim Hill pointed out many of his recently published studies have focused on paracetamol which causes oxidant damage and acts as an inflammatory in the lungs.

While paracetamol is a safe drug for reducing pain, it has no beneficial effect at all on fever which Professor Beasley explained was an important evolutionary defence. The purpose of a fever is to kill the organism that is causing the infection.

The extremely interesting interview with Professor Beasley included discussion of a wide range of health issues – risk factors for obesity, what to do about our obesogenic environment, the study of kanuka honey and its medicinal properties which are likely to be found in all types of honey, oxygen therapy, challenging dogma and going for evidence-based medicine, and ended with a fascinating story of how knowledge about the risk of seated immobility was discovered in London during the blitzes in World War 2 and was then lost for several decades. It is well worth listening to.

#### References

1. <http://ije.oxfordjournals.org/content/early/2016/02/05/ije.dyv366.full.pdf+html>
2. <http://www.radionz.co.nz/national/programmes/saturday/audio/201825421/richard-beasley>
3. <http://www.press.auckland.ac.nz/en/browse-books/all-books/books-2007/Adverse-Reactions-The-Fenoterol-Story.html>



## AWHC GENERAL MEETING December 2016

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

- Financial reports
- Grant applications
- Submissions
- Cartwright Forum follow-up actions
- Ethics committee meetings
- Looking for a new co-ordinator

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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614, Newmarket, Auckland 1149, or  
contact us to obtain bank account details.

## UP AND COMING EVENTS

**DISTRICT HEALTH BOARD** meetings for December 2016 and January 2017:

**Waitemata DHB (Website address: [www.waitematadhb.govt.nz](http://www.waitematadhb.govt.nz))**

The Waitemata DHB Board meeting opens to the general public at 12.45pm on Wednesday 14 December 2016 and will be followed by the Hospital Advisory Committee meeting which starts at 2pm. 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 23 November 2016.

**Auckland DHB (Website address: [www.adhb.govt.nz](http://www.adhb.govt.nz))**

The Auckland DHB Board meeting opens to the general public at 12.45pm on Wednesday 7 December 2016 and will be followed by the Hospital Advisory Committee meeting which starts at 2pm. Both meetings will be held in the A+ Trust Room in the Clinical Education Centre, Level 5, Auckland City Hospital.

**Counties Manukau DHB (Website address: [www.cmdhb.org.nz](http://www.cmdhb.org.nz))**

The Hospital Advisory Committee meeting will be held at 9am on Wednesday 30 November 2016 at Ko Awatea and will be followed by the Board meeting at 1.30pm.

The Community & Public Health Advisory Committee meeting will be held at 1.30pm on 21 December 2016 at 19 Lambie Drive, Manukau.



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



**The NZ Bioethics conference on "Bioethics and Health Law in the Information Age"** will take place on 27 – 28 January 2017 at the University of Otago, Dunedin.

The conference will feature workshops, general sessions, and presentations focusing on the digitalisation of health in the Information Age. The Information Age refers to the collection and storage of (potential) health-related data and metadata, as well as the technologies that provide

the means to manipulate, aggregate, utilise, and disseminate this information. With this shift toward digitalisation come possibilities for future action. This is an area with which bioethics and law need to keep up.

Further information is available at: <http://www.otago.ac.nz/bioethicsconference/index.html>