AUCKLAND WOMEN'S HEALTH COUNCIL

NEWSLETTER

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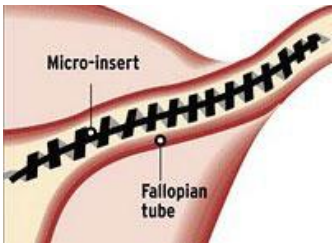
ESSURE: ANOTHER AWFUL MEDICAL DEVICE

Over the past ten years another insidious experiment has been undertaken on women by obstetrician/ gynaecologists keen to be seen to offering women a new form of permanent contraception. Like many other medical devices it was released onto the market by the US Food & Drug Administration (FDA) without any decent sized long-term trials or adequate reporting of all the data. So it was utterly predictable that women began reporting severe problems with the device soon after it came onto the market.

Essure, a form of female sterilisation, was originally developed and manufactured by Conceptus which was then bought out by Bayer Pharmaceuticals. Essure is a thoroughly nasty piece of work. It consists of two micro-coils that are inserted into each fallopian tube. The coils are made up of a stainless steel inner coil, a nickel titanium (nitinol) expanding, super elastic outer coil, and polyethylene fibres or strings. 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 "advantage" of Essure over the other form of female sterilisation – tubal ligation – is that the device does not contain any hormones, and it does not require surgery. It was developed to be inserted in an office setting by health professionals trained in the method of inserting this device. As it takes several months for the scar tissue to completely block off the fallopian tubes, the woman needs to use another form of contraception for the first three months. An x-ray, called a hysterosalpingography, is then done to confirm that the fallopian tubes are blocked. Sometimes an ultrasound scan is used instead.



Side effects of inserting the device
Women report experiencing a number of unpleasant side effects of the "hysteroscopic placement procedure." These include cramping, nausea and vomiting, dizziness or light headedness, mild to moderate pain during and immediately after the procedure, and bleeding.

Adverse events
The ongoing risk of the harms caused by this device are many and include chronic inflammation, fibrosis, severe pelvic pain, perforation of the uterus or fallopian tubes, infections, and tubal blockage occurring on only one side. It is also not a good idea if you are allergic to nickel.

The Mayo Clinic website also states:
"You may not be able to have some electropelvic procedures, such as some types of endometrial ablation, after having the Essure system implanted. This is because Essure inserts are metallic and can conduct electricity, possibly resulting in tissue damage." (1)

Hysterectomy
There are also risks associated with the surgery needed to reverse the

Essure procedure. Like the gynaecological mesh, Essure is not designed to be removed and problems can arise as a result of the surgery undertaken to remove the coils. Hundreds of women have had to have a hysterectomy in order to remove pieces of the device.

As if the side effects listed above weren't enough to cause a woman to think twice about using this form of sterilisation, there is one more thing. The FDA's 2002 briefing document "Essure: Instructions for use" contains the following statement – in bold type: **"There is the potential that unknown risks exist."** (2)

The 304-page transcript of the FDA's meeting at which approval was given to market the contraceptive device also makes for interesting and disturbing reading. It reveals just how closely the FDA works with the pharmaceutical industry during the process of designing and undertaking trials, with the result that meetings such as these are a mere formality as far as the FDA's granting of approval for such a device with no strings attached (no pun intended). (3)

Issues were raised by some members of the FDA panel who expressed concerns about the small numbers of women in the phase two and phase three trials of the device, the age and ethnicity of the women when compared to the data on women who had a tubal ligation, the lack of long-term data for Essure, the use of ultrasound scans instead of x-rays to check if the fallopian tubes are completely blocked, how the device will be marketed and what women will be told. However these concerns were quickly smoothed over and dispensed with.

In 2002 the FDA approved Essure for use as a class 3 medical device which was the first time any contraception had received such a classification. The FDA also made it impossible for women to sue the company for damage.

Erin Brockovich

Women in America have now turned to social media to voice their complaints about Essure. (4) There is now a Facebook group page for women who have experienced problems with the device. It has got so bad that even Erin Brockovich recently got involved. She has established a website for women with the aim of creating "a movement to get this product off the market and find a remedy for those who have been harmed." (5) She has already heard from over 1,000 women.

What really frustrates Erin Brockovich is the fact that when the FDA approved Essure it gave it what is known as pre-emption status, meaning that women who have suffered as a result of Essure can't sue the company that makes it.

"This is a law that will protect the company and if the product's defective, the people who've been harmed by it basically have no recourse. That's not fair," Erin told *NewsChannel 5 Investigates*. (6)

What about New Zealand women?

There is no protection for New Zealanders who find themselves damaged and their lives turned upside down as a result of medical devices, such as metal-on-metal hip joint replacements, gynaecological and other sorts of mesh, and silicone breast implants, to name just a few.

Medsafe

There is Medsafe – the NZ Medicines and Medical Devices Safety Authority. "We are responsible for the regulation of medicines and medical devices in New Zealand. We ensure that medicines and medical devices are acceptably safe," is the proclamation on their website. (7) Unfortunately, Medsafe relies on the FDA and the European Medicines Agency for their information on whether drugs and medical devices are "acceptably safe." Given what we now know about how closely the FDA works with the pharmaceutical industry – to the point of working for the industry rather than for the protection of the general public (8), this leaves the New Zealand public very vulnerable.

In 2011 the FDA allowed Conceptus to remove a contraindication on Essure's official packaging for women with a known hypersensitivity to nickel, as well as a recommendation that women undergo a skin test to see if they have an unknown nickel allergy. Profits before public safety is also the main driver in the FDA.

WAND

Although all medical devices must be notified to Medsafe's Web Assisted Notification of Devices (WAND) database in order to be legally supplied in New Zealand, this is not an approval system. As we saw during the silicone breast implant saga this didn't prevent health professionals importing and implanting cheap medical devices under the radar in the past. The sponsor, the person or organisation that imports a device, is required to notify the device to the WAND database within 30 days of becoming the sponsor of the device. There are no fees involved in a device being on WAND. However only the sponsors have access to this database; there is no public access to this information.

Essure is being used in NZ

The AWHC was recently made aware that women in the Bay of Plenty DHB are having this device implanted. Some doctors seem to think that Essure is superior to a tubal ligation, and at Tauranga hospital are even inserting them under a general anaesthetic. So much for a quick insertion in the doctor's surgery! These same health professionals also have no problems using scarce radiology resources when checking to see if the coils/fibres have done their job and the resulting inflammation has completely blocked the fallopian tubes. Even more important is the information women are getting prior to agreeing to try this method of contraception. Are they tested for an allergy to nickel? Do they really understand how the device works, that the inflammation caused by Essure may cause severe pain, and that removal of the device is problematic and may cause immense damage to their reproductive system?

At some stage the Accident Compensation Corporation (ACC) will become involved when women who have been damaged by Essure begin applying for compensation for the damage to their bodies and lives that this device has caused. It is unlikely that ACC will be very receptive if past experience with medical devices are anything to go by.

Taking a complaint to the Health and Disability Commissioner isn't likely to be successful either as the current Commissioner has already refused requests to investigate other medical

devices such as metal-on-metal hip joint replacements, silicone breast implants, and gynaecological mesh.

While PHARMAC has now been given responsibility for overseeing the purchase of medical devices as well as drugs, it is going to be too late to prevent the damage that this particular contraceptive device will have caused goodness knows how many women in New Zealand.

The message here is that women are much safer having a tubal ligation.

References

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2. http://www.fda.gov/ohrms/dockets/ac/02/briefing/3881b1_03.pdf (page 6).
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Preventing Overdiagnosis 2014

15-17 September 2014

Oxford University, UK

Further information is available at: www.preventingoverdiagnosis.net/?p=315

WAITAKERE WOMEN'S CENTRE

The Women's Centre has a number of courses on offer during Spring:

Knowing Yourself – rebuilding self esteem. A 7-week course on Mondays 10am – noon from 14 October – 2 December 2013.

The Iceberg – Understanding and Managing your anger. An 8-week course on Wednesdays 10am – noon from 16 October – 4 December 2013.

The Journey of the Butterfly: Supporting women to break the cycle of violence. An 8-week course on Fridays 10am – noon from 18 October – 6 December 2013.

A crèche is available on request.

The Women's Centre also offer counselling sessions on Tuesday and Thursday mornings and Friday afternoon. There is a limit of six sessions and a $10 contribution towards the Centre's running costs.

Wellness Recovery Action Planning (WRAP) courses for women wanting help with anxiety and depression.

Relaxing massage by a woman practitioner with a sliding scale of fees from $20 - $40. Monday mornings by appointment only.

There is also a Friendship Group for women wanting to meet others for coffee, conversations, outings and guest speakers.

For more information contact the Women's Centre on phone 838-6381 or email: info@womenscentre.org.nz

OVERDIAGNOSING HYPERTENSION

According to Dr Gilbert Welch the beginning of overdiagnosis began with the diagnosis and treatment of a common condition – hypertension (high blood pressure). (1)

In his book he states that hypertension was the first condition for which regular treatment was started in people without symptoms and no complaints about their health. Such people were suddenly turned into patients by being given a diagnosis and then a prescription for a drug.

While diagnosing hypertension in those who had no symptoms provided the opportunity to prevent symptomatic disease in some people, it did so at the cost of making the diagnosis in many others who would not develop any symptoms or die from hypertension. In other words, at the cost of overdiagnosis.

Like most conditions hypertension exists on a spectrum, from very mild to much more severe forms. Usually, the benefit of treatment rises with the severity of the abnormality. Mild abnormalities are less likely to cause problems than severe abnormalities, and most people are not destined to have anything bad happen to them as result of their mild abnormalities. However, they can be harmed by being overdiagnosed and treated with a drug that has side effects. And all drugs have side effects.

The down side of drugs

The drugs used to treat people for hypertension can cause fatigue, some cause a cough, and others impair sex drive. All of them can make your blood pressure too low, leading to light headedness, fainting and falls. For older people, major falls are often the start of a chain of events that lead to death. (1)

Hypertension Guidelines

One of the presentations at the international Preventing Overdiagnosis conference in Hanover in September described how applying the European hypertension guidelines could destabilise the healthcare system in Norway, one of the world's most long and healthy living nations. Norway also happens to have very good physician coverage. The hypertension guidelines considerably overestimate the risk and/or the amount of resources appropriate for the healthcare system to spend specifically on cardiovascular risk reduction. The presenters concluded that "large-scale, preventive medical enterprises can hardly be regarded as scientifically sound and ethically justifiable, unless issues of practical feasibility, sustainability and the social determinants of health are considered."

Statins

Peter Gotzsche, who co-founded the Cochrane Collaboration in 1993 and established the Nordic Cochrane Centre that same year, says in his latest book that "statins are currently intensively marketed to the healthy population both by the industry and some enthusiastic doctors, but the benefit is very small when statins are used for primary prevention of cardiovascular disease." (2)

A Cochrane Database Systematic Review published in 2011 urged caution in prescribing statins for primary prevention among people at low cardiovascular risk. (3) While

previous reviews of the effects of statins had highlighted their benefits in people with coronary artery disease, the reviewers found there is limited evidence to show that primary prevention with statins is cost effective or that they improve quality of life. They do however turn healthy people into patients.

Totally biased drug trials

The problem with the statin trials is that "there is often no blinding, no concealment of treatment allocation (which means that the randomisation could have been violated), poor follow-up and no intention-to-treat analysis (where the fate of all randomised patients is accounted for, also those who drop out). Funding from the test drug company rather than the comparator drug company was associated with more favourable results (odds ratio 20) and more favourable conclusions (odds ration 35). This is not surprising considering that head-to-head statin trials are not fairly designed, as the compared doses in most of the trials are not equivalent." (2)

Peter Gotzsche also points out in his book which the above quote is taken from, the drug industry's many tricks make the impossible possible, and their duplicity knows no bounds, which is why he compares the industry with organised crime.

This is important information for all those New Zealanders who are being encouraged by the current TV advertising campaign or by their GP to get a heart check. Overdiagnosis is not just a problem in America or in Europe, it is also happening at your local GP practice. So before you agree to go on a statin you need to ask your doctor for the evidence from an independent source that taking statins when you have no symptoms of heart disease will benefit you, or at the very least that it will not harm you.

Prescription drugs are, after all, the third leading cause of death after heart disease and cancer. (2)

References

1. Dr H Gilbert Welch, Dr Lisa Schwartz Dr Steven Woloshin "Overdiagnosed: Making People Sick in the Pursuit of Health." Beacon Press 2011.
2. Peter Gotzsche "*Deadly Medicines and Organised Crime: How big pharma has corrupted healthcare*." Radcliffe Publishing 2013.
3. http://www.ncbi.nlm.nih.gov/pubmed/21249663

AWHC NEWSLETTER SUBSCRIPTION

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UP AND COMING EVENTS

DISTRICT HEALTH BOARD meetings for October/November 2013:

Waitemata DHB (Website address: www.waitematadhb.govt.nz)
Waitemata Hospital Advisory Committee meeting starts at 11am on Wednesday 6 November 2013 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 16 October 2013.

Auckland DHB (Website address: www.adhb.govt.nz)
The Hospital Advisory Committee meeting will be held at 9.30am on Wednesday 30 October 2013 followed by the Full Board meeting at 2pm. Both meetings will be held at the A+ Trust Room in the Clinical Education Centre at Auckland City Hospital.

Counties Manukau DHB (Website address: www.cmdhb.org.nz)
The Counties Manukau DHB Full Board meeting will be held at 1pm on Wednesday 6 November 2013 at 19 Lambie Drive, Manukau City.

The Hospital Advisory Committee meeting will be held at 9am on Tuesday 22 October 2013 and will be followed by the Community & Public Health Advisory Committee meeting at 1pm at 19 Lambie Drive, Manukau.

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

"Managing Perinatal Moods - What tools & resources do I have to empower this mother or father to manage their mental health and wellbeing?"

The Perinatal Mental Health NZ Trust have organised a three-day symposium on 18-20th October 2013 at the Atrium, Albany Campus, Massey University, Auckland.

Details can be found at http://pmhnz.org.nz/resources-events.html