AUCKLAND WOMEN'S HEALTH COUNCIL

NEWSLETTER

NOVEMBER 2013

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Women's health service still controversial

In a recent letter to Southlanders for Life Ombudsman Prof Ron Paterson stated that district health boards should consult on controversial issues before making decisions. This announcement was made in response to a complaint made by the anti-abortion group, Southlanders for Life, in respect of the Southern District Health Board decision to provide a locally based abortion service at Southland Hospital which commenced without public consult-ation in early September 2012.

Previously, abortion services had been provided at Dunedin Hospital and Southland women had to travel a considerable distance to access this. Some women still opt to use the Lyndhurst clinic service in Christchurch.

Paterson said, "In my opinion, where a decision-maker such as a district health board knows that a funding or access decision (such as closing, outsourcing or extending a service) is likely to be controversial and to arouse strong views within the community, it is good administrative practice to consult with the community, to allow community participation in the decision-making process."

However, Paterson explicitly reconfirms the April 2013 opinion of former Ombudsman David McGee that the opening of an abortion clinic at Southland Hospital was an extension of the existing Southern DHB service and did not trigger a lawful obligation to consult.

Requirements of DHBs

The New Zealand Public Health and Disability (Planning) Regulations 2011, S9 require the following:

(1) A DHB that is preparing a DHB annual plan must consult with the public in relation to the plan if the Minister considers that—

(a) the plan proposes changes to services, including to service eligibility, access, or the way services are provided; and

(b) the proposed changes will have a significant impact on recipients of services, their caregivers, or providers.

(2) Before the Minister and a DHB agrees on the DHB's annual plan, the chief executive and the chairperson of the board of the DHB must agree to and sign the plan on behalf of the DHB.

Statement of Intent

The Southern DHB statement of intent for 2011/12-2013/14 certainly indicates within their wider clinical services strategy a goal to adopt a "one service, many sites" approach and that there will be equity of access across the service catchment. Presumably the Minister of Health also believed the addition of another abortion service site didn't meet the threshold for consultation, as per the Regulations, otherwise he would have required Southern DHB to consult.

Paterson further says in his letter that, "in my view it would be good practice to consult on a decision of this nature in the future." There can be little disagreement the principle of "fairness for all" signals consultation is an essential requirement of democracy in practice. But when particular lobby groups are not willing to compromise regardless of the views of other stake-holders who may be the potential

service users, as in this case, when might consultation be deemed adequate to support a DHB decision to proceed?

A 'hyped up saga' by opponents of abortion?

The Contraception, Sterilisation and Abortion Act came into effect on 1 April 1978. Thirty-five years on, women's reproductive self-determination is still a controversial issue for many people.

Whose needs would be served here by further public consultation? Surely it can't be those of the women seeking abortions. Local site service provision certainly improves access to a medical intervention option as women are required to be administered two different drugs on separate days on licensed provider premises. However, a day-surgery procedure remains equally the women's choice. The material impact arising here is undoubtedly a significant improvement in clinical safety for women who no longer have to travel so far or leave home for several days.

There were reportedly 271 medical and surgical abortions performed at Southland Hospital from 1 Sept 2012 – July 2013. Southland women are clearly not shunning this local site service.

Closing the gaps

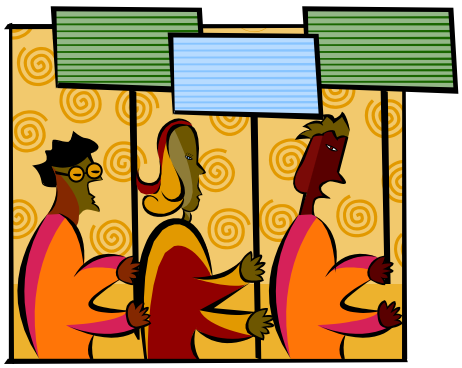
Better, sooner, more convenient health care closer to home is the catch-cry of this government and therefore district health boards nationwide. Removal of barriers to timely, affordable, patient-centred services is generally applauded, but not it seems for all service types that might be provided. That Southland DHB, and subsequently Southern DHB, continued for so long to create inequitable access to publicly-funded, safe, legal, abortion services for women is where this particular controversy should remain - as part of history.

This Ombudsman decision unfortunately now sends mixed messages to the six other DHBs who currently provide limited or no local site abortion services – should they contemplate introducing or extending their current provision of abortion service access options.

The precedent that a DHB may extend current abortion services access without further consultation has been established and confirmed as appropriate. How will this fit alongside the recommendation that there would be an expectation in the future to consult the relevant communities first? Could this now become a requirement? How wide do we leave this door open to keep the abortion services controversy endlessly raging?

I doubt there will be any movement from these particular DHBs any time soon.

Barbara Holland
Co-convenor
Federation of Women's Health Councils



UPDATE ON ESSURE

The AWHC wrote to both Medsafe and the Minister of Health about our concerns over the use of the contraceptive device Essure, after researching and writing the article that appeared in the October issue of the AWHC newsletter. We sent a copy of the newsletter with each letter. In our letter to Medsafe we asked them to place a warning on their website about this device.

No action from Medsafe

Medsafe has responded to our letter, and predictably the letter states that Medsafe does not plan to take any action as "there have been no reports of adverse events or complaints relating to the use of this product." Translation: we need some New Zealand victims to make a complaint before we are willing to do anything. If past experience is anything to go by, even then Medsafe is unlikely to do anything.

Chris James, Acting Group Manager of Medsafe acknowledges that the US Food and Drug Administration (FDA) has recently released safety information relating to Essure on its website, (1) but goes on to say "at the present time there is insufficient evidence to justify further investigation of this issue or the publication of safety information on the Medsafe website." Translation: if the FDA whose by-line is "Promoting and Protecting *Your* Health" doesn't think there is anything to worry about then neither do we.

The FDA claims it has conducted a thorough review of the available information about Essure since they approved it in 2002. The FDA states it has received 943 reports of adverse events related to Essure. The most frequently reported problems were pain (606), haemorrhage (140), headache (130), menstrual irregularities (95), fatigue (88), and weight fluctuations (77). Some of the device problems reported were migration of the device or device component (116), patient device incompatibility, eg allergy to nickel (113), device operating differently than expected (73), malposition of the device (46), and device breakage (37).

While some of these problems "are known through clinical studies" and included in the Essure product information, extreme fatigue, depression and weight gain "were not observed in post-approval studies, or described in the clinical literature."

No action from the FDA

The problem with this is that we have to take the FDA's word that there were post-approval studies, and that the clinical literature wasn't just more bullshit produced by Conceptus, the company that manufactured this device. Conceptus conducted its own 5-year study which simply cannot be relied on to report the truth about its one and only product. It is also extremely convenient that Conceptus was "acquired" by Bayer on 5 June 2013 – shortly before the problems women were experiencing with device began to surface in the media.

"Although there is evidence of complications, as there are with all medical devices, overall results from this study did not demonstrate any new safety problems or an increased incidence of problems already known," the FDA disingenuously maintains (1)

It is well known internationally that the FDA lost its credibility years ago. As noted in last month's newsletter article, 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.

Peter Gotzsche in his book "Deadly Medicines and Organised Crime" describes in depth how corrupt the FDA has become. "The FDA, by spinelessly knuckling under to every whim of the drug companies, has thrown away its high reputation, and in so doing, forfeited our trust," he concludes after describing numerous instances of corruption within the upper echelons of the FDA. (2) That Medsafe is still expecting the New Zealand public to trust the FDA's judgement and advice is therefore extremely worrying.

Over the past month the AWHC has become aware that the Auckland DHB is also involved in providing women in Auckland with this form of contraception and has been using an operating theatre to insert this device, although this is about to change. (3)

The AWHC is concerned about the information women are getting prior to agreeing to this method of contraception. Do they understand how the device works and that it may take more than three months for the scar tissue to completely block the fallopian tubes necessitating the need for several scans before they can be assured that they are completely sterilised? Do they know that removal of the device is problematic and may cause immense damage to their reproductive system?

Meanwhile back in the USA, Mitchell Creinin, Professor & Chair of Obstetrics and Gynecology at the University of California, Davis published a study in 2011 comparing the reliability of sterilisation with Essure compared with tubal ligation at one year. He found that "the efficacy of hysteroscopic sterilisation (Essure) is inferior at a population level." (4)

This is because a successful Essure procedure requires all of these steps:

- Visualisation of both tubal ostia on hysteroscopy
- Successful placement of the microinserts in the correct position
- Hysterosalpingogaphy at least 3 months later with the use of an alternate form of contraception in the interim
- Demonstrated tubal occlusion by the Essure devices

In 2002 Conceptus pulled out all stops to convince the FDA panel that Essure was a superior, more reliable method of permanent contraception than tubal ligation. An independent study has now shown that it is not.

References

1. http://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/ucm371014.htm
2. Peter Gotzsche. "*Deadly Medicines and Organised Crime*." Radcliffe Publishing 2013.
3. Auckland DHB Hospital Advisory Committee meeting 30 October 2013. "Commencement of ESSURE procedures in a procedure room (previously performed in OR)."
4. www.obgmanagement.com/topic-collections/contraception/article/update-on-contraception.html

"Deadly Medicines and Organised Crime: How big pharma has corrupted healthcare"

This latest book by Peter Gotzsche was published in August 2013. Professor Gotzsche is a specialist in internal medicine, who co-founded the Cochrane Collaboration in 1993 and established the Nordic Cochrane Centre the same year. In 2010 he became Professor of Clinical Research Design and Analysis at the University of Copenhagen.

This refreshingly blunt book exposes the pharmaceutical industries and their charade of fraudulent behaviour, both in research and marketing where the morally repugnant disregard for human lives is the norm. Professor Gotzsche convincingly draws close comparisons with both the tobacco industry and the mob, revealing the extraordinary truth behind efforts to confuse and distract the public and their politicians.

This book addresses, in evidence-based detail, an extraordinary system failure caused by widespread crime, corruption, bribery and impotent drug regulations that are in desperate need of radical reforms.

This book is as relevant to New Zealand as to any other country; in fact it begins with a New Zealand story – the story of how fenoterol formerly used in asthma inhalers caused the asthma death rates to go up in the same way as the sales did. For the full story of how the New Zealand Department of Health conspired with the drug company and misinformed doctors against the researchers who tried to blow the whistle, read the book by Neil Pearce "Adverse Reactions: the fenoterol story" which was published in 2007.

The book also ends with a good news New Zealand story – a description of the rock star of our health system, PHARMAC.

In the introduction to his book Peter Gotzsche states:
"The main reason we take so many drugs is that drug companies don't sell drugs, they sell lies about drugs. This is what makes drugs so different from anything else in life … Virtually everything we know about drugs is what the companies have chosen to tell us and our doctors … the reason patients trust their medicine is that they extrapolate the trust they have in their doctors into the medicines they prescribe. The patients don't realise that, although their doctors may know a lot about diseases and human physiology and psychology, they know very, very little about drugs that hasn't been carefully concocted and dressed up by the drug industry … If you don't think the system is out of control, please email me and explain why drugs are the third leading cause of death."

If you only read one book over the next six months, then for the sake of your health and your sanity this is the book you must read. It is immensely readable, terrifyingly funny in parts and just plain terrifying in others.

It is also worth noting that as soon as you start reading the forewords in this book by Richard Smith, former editor-in-chief of the *British Medical Journal*, and Drummond Rennie, deputy editor of the *Journal of the American Medical Association*, you won't be able to put it down.

Fundraising Lunch with Dame Jenny Shipley

12 noon on Wednesday 11 December 2013

Royal NZ Yacht Squadron 101 Curran Street, Westhaven Extension, Herne Bay

The Postnatal Distress Support Network Trust invites you to this fundraising lunch.

With guest speaker Dame Jenny Shipley talking about her life before and after politics.

Seat price is $87 which includes a $30 donation to the PND Network.

RSVP to: pnd.org@xtra.co.nz

If you can't make it but see the great value that PDSN gives to the community you can donate at: www.givealittle.co.nz/org/Postnataldistress

AWHC GENERAL MEETING 24 October 2013

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

- Financial reports
- Grant applications
- PHARMAC consultation
- Ethics committee meetings
- *The Legacy of Cartwright* conference

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

AWHC NEWSLETTER SUBSCRIPTION

The newsletter of the Auckland Women's Health Council is published monthly.

COST: $30 waged/affiliated group
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If you would prefer to have the newsletter emailed to you, email us at awhc@womenshealthcouncil.org.nz

Send your cheque to the Auckland Women's health Council, PO Box 99-614, Newmarket, Auckland 1149.

UP AND COMING EVENTS

DISTRICT HEALTH BOARD meetings for November/December 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 27 November 2013.

Auckland DHB (Website address: www.adhb.govt.nz)
The Hospital Advisory Committee meeting will be held at 9.30am on Wednesday 11 December 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 Hospital Advisory Committee meeting will be held at 9am on Tuesday 26 November 2013 and will be followed by the Community & Public Health Advisory Committee meeting at 1pm at 19 Lambie Drive, Manukau.

The Counties Manukau DHB Full Board meeting will be held at 1pm on Wednesday 4 December 2013 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

Breast Cancer Network NZ is hosting an evening seminar ***"Living Well With Cancer"*** with Dr Nicky Baillie who is both a medical doctor and a medical herbalist.

Date: Wednesday 20th November 7 – 8.30pm
Venue: Domain Lodge, Cancer Society, 1 Boyle Crescent, Grafton, Auckland.
A $10 - $20 donation is appreciated. Supper provided. Booking essential.

For more information see www.bcn.org.nz