AUCKLAND WOMEN'S HEALTH COUNCIL

NEWSLETTER

MARCH 2013

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ETHICS COMMITTEES

It is almost 25 years since the release of the Cartwright Inquiry report which resulted in major changes to the health system, the development of a code of consumers' rights, the establishment of the National Cervical Screening Programme and major reforms to the process of ethical approval for research. New ethics committees were established, and a national standard and guidelines for ethics committees were developed which made the protection of the patient the main purpose of the new system of ethical review.

During the past two decades many changes have been made to the operational standards for ethics committees as well as to the structure and number of committees. Alongside these changes, the focus began to shift away from the patient, who is now referred to as the research participant. The changes that were implemented last year completed the process of ensuring that the focus is now firmly on the research study or clinical trial and was designed to make life easier for the researchers.

Now there are four

In June 2012 the Ministry of Health's seven ethics committees were disestablished and on 1 July four new streamlined, clinical trials focused and thoroughly disempowered ethics committees began work under new *Standard Operating Procedures* (SOPs). (1) The new SOPs drastically reduced the scope of the ethics committee review process and contain a list of studies that no longer require review and approval by these new ethics committees. The studies that require a review by the whole ethics committee are now restricted to those that involve human participants, the use, storage or collection of human tissue, and the use or disclosure of health information.

Studies that do not require ethics committee review include studies on low risk devices, minimal-risk observational studies, audits and related activities, and student led research.

Applications online

Research proposal applications must now be completed online, and during the first few months under the new regime the numbers of research proposals being submitted fell dramatically as researchers struggled with the new online system. Nine months later, flaws with the online application process are still being reported during the ethics committee meetings.

The new system of ethical review is now working to two different clocks. There is a 35-day review clock for the full review pathway, and a 15-day clock for the expedited review pathway. An expedited review does not involve a physical meeting, and is a review involving a subcommittee of the ethics committee.

As already noted, the new committees have now been meeting for nine months. Some of the members of the new committees are new but many have been on the Ministry of Health ethics committees for several years.

Since July last year two members of the Auckland Women's Health Council have attended most of the meetings of the Northern A ethics committee which currently meets in a small conference room at the Novotel Hotel

in Greenlane Road. It is not an easy thing to do as members of the public do not have ready access to an agenda or a summary of information on proposals that are due to be discussed. It is often difficult trying to work out what is going on.

Going "in committee"

One disturbing development is the fact that most meetings of the Northern A ethics committee now include a research proposal that is discussed "in committee" with members of the public having to wait outside the meeting room while the committee discusses the research proposal behind closed doors.

Official Information Act request

The AWHC was so concerned about this development that in December last year we wrote an Official Information Act request asking for the documents on the research proposals that had been dealt with "in committee" by all four of the new ethics committees. The box of documents that subsequently arrived contained most of the documents relating to 14 research proposals, but unfortunately they did not include the key documents – the actual research application and the research protocol.

Merck Sharp and Dohme was the sponsor of eight of the 14 research proposals that were considered behind closed doors. Boehringer Ingelheim, Bayer, Janssen-Cilag, and Amgen were each the sponsors of a study. Living Cell Technologies NZ Ltd was the sponsor of another, and there was no sponsor for the study on S gene mutations and hepatitis B. The population-level Child Maltreatment Research based on Linked Administ-rative Data study was referred to the Ministry of Social Development.

The AWHC is working on a letter to the Ombudsman about the missing documents.

Lack of independence

As reported in a previous issue of the AWHC newsletter, ethics committees were never going to be appropriately managed and safe from being amended to suit professional and commercial interests by being placed within the Ministry of Health. (2) The Minister of Health and the Ministry of Health decide who gets appointed to ethics committees which makes the ethical review process even more unsafe. Consumer groups have argued for more than a decade that responsibility for ethics committees should be placed within the office of the Health & Disability Commissioner.

Lack of accountability

In her 1988 Report of the Cervical Cancer Inquiry Judge Silvia Cartwright referred to the duty of an ethics committee "to safeguard patients and healthy volunteers," and to the "duty to see that unethical practices did not occur" and right of the public "to be satisfied that they did not." (3)

The story that follows reveals just how far the system has strayed from the path of safeguarding patients – these days some patients find they have to opt out of research trials they have automatically been enrolled in.

References

1. http://ethics.health.govt.nz/operating-procedures
2. http://www.womenshealthcouncil.org.nz/Features/Ethics.html
3. Report of the Cervical Cancer Inquiry 1988. Page 148.

OPT OUT CLINICAL TRIALS

The AWHC was sent the following story by a cancer patient who found she had been automatically enrolled in a clinical trial:

“At an early appointment with the oncologist to determine my treatment plan the possibility of being part of a research study was raised. Nurse A who was part of this discussion was asked to find out whether I was able to participate in a double-blind randomised controlled trial (RCT) that was investigating the effectiveness of a pharmaceutical treatment for my particular cancer. As I did not meet the inclusion criteria I was not given any information about the trial.

However some weeks later I received an appointment in the mail to attend a clinic that I had never been to before. When I asked nurse A what this appointment was for she revealed that she made the referral to this clinic for me to be included in the research study as soon as they received the histology results. She explained that this was to avoid any delays affecting the commencement of radiation therapy but she was certain she had cancelled it when she discovered that I was not eligible to take part.

When I remarked that I thought people needed to give their consent before being enrolled in a research study, she replied that they can always say no if they don't want to take part, but most people are happy to be part of the study. I said this sounded like an opt-out approach to the research study and she agreed that it was.

Some time later I received a phone call from the clinic I had never been to and was asked when I would be able to attend. Nurse B said I had been on a waiting list for medical oncology since I cancelled the original appointment. When I asked what the purpose of the appointment was, she said it was to discuss whether or not I should have chemotherapy. She was surprised to hear I was already taking it and demanded to know how and who had prescribed it for me. I told her to contact nurse A.

Nurse B then told me quite sternly that if I cancelled a second time I may miss getting treatment. I thought it was rather odd that there was no mention of any study by the woman I had spoken to on the phone or in any of the information I had seen. It all seemed a bit underhand.

When I subsequently said to nurse A that I would have appreciated a discussion about the study at the histology appointment, she replied that people already have enough to deal with at that appointment, so she just enrols all patients who could be eligible as they can always say no if they don't want to be part of the study!

Several weeks later I received a text message reminder for an appointment at that same clinic. This was the first I had heard about this particular appointment and I rang to ask what it was for, but I got no reply. I left a message but this was never responded to.”

PERINATAL HYSTERECTOMY

Few midwives and even fewer women are aware of the alarming increase in the numbers of emergency hysterectomies, known as perinatal or postpartum hysterectomy, performed during or soon after the birth of the baby in order to save the life of the mother. Such surgery is undertaken when other interventions fail to stop severe haemorrhaging which sometimes accompanies a caesarean section.

The rising numbers of perinatal hysterectomies are a direct result of the rising rate of caesarean sections.

An Official Information Act request about the numbers of hysterectomies performed on women in New Zealand over the past 12 years revealed that several dozen women enter hospital each year to give birth to a baby and leave hospital having had their uterus removed. The numbers of such hysterectomies ranged from 18 in 2001 to 46 in 2008. Over the past seven years the figures have remained between 36 and 46 with one exception – in 2010 there were 24 women who had a hysterectomy during or soon after birth.

Perinatal hysterectomy is often the consequence of a previously performed caesarean section, which in a subsequent birth gives rise to complications such as uterine rupture in the scar from the previous caesarean, and bleeding from the villi of the placenta located on the front wall of the uterus, which have grown into the scar.

Placenta accreta

Placenta accreta, a condition where the placenta implants too deeply into the muscle in the walls of the uterus, is now the most common cause of uncontrolled bleeding during the birth process that leads to the necessity of removing the uterus. Once a rare event that affected 1 in 30,000 pregnant women in the 1950s and 1960s, placenta accreta now affects 1 in 2,500 pregnancies, according to a 2007 report in the *Journal of Obstetrics and Gynecology*. In some hospitals in the USA the number is as high as 1 in 522. (1)

A retrospective study undertaken of data from three obstetric hospitals in Dublin from 1966 – 2005 of 358 women who had had perinatal hysterectomy (out of a total of 872,379 births), revealed that the percentage of perinatal hysterect-omies that occurs after a previous caesarean birth increased from 27% to 57%. During these four decades uterine rupture as an indication for perinatal hysterectomy decreased from 40.5% to 9.3%, while placenta accreta increased from 5.4% to 46.5%. The overall caesarean section rate increased from 6% during the first decade of the study to 19% during the fourth decade. (2)

Previous caesarean sections

In 2007 a total of 36 women in New Zealand had a hysterectomy during or following giving birth. Of these, 16 women had had a previous caesarean section – 11 women had had one previous caesarean section, four women had had two previous caesarean sections, and one woman had had three previous caesarean sections. In 2008, 46 women had a baby which was followed by a hysterectomy. Of these, 22 women

had had a previous caesarean section – 10 women had had one previous caesarean, two women had had two previous caesareans, five women had had three previous caesareans, two women had had four previous caesareans, two had had five previous caesareans and one had had eight previous caesareans.

In 2011, 38 women had a baby which was followed by a caesarean section. Of these, 25 women had had a previous caesarean – seven women had had one previous caesarean, seven women had had two previous caesareans, nine women had had three previous caesareans, one woman had had four previous caesareans, and one had had seven previous caesareans.

The physical and emotional trauma of having gone through a life or death experience while giving birth is immense. When this happens to a mother having her first baby she is also faced with adjusting to the fact that she cannot have any more children. The AWHC knows of one young woman who is currently struggling to come to terms with such a scenario.

The horror that lies behind the above statistics is just one of the unspoken risks associated with the increasing numbers of caesarean sections.

References

1. http://abcnews.go.com/Health/caesarian-rates-placenta-accreta-contributing-rise-maternal-death/story?id=13399308
2. Karen M Flood et al. "Changing trends in peripartum hysterectomy over the last 4 decades." *American Journal of Obstetrics & Gynecology*. June 2009.

AUCKLAND WOMEN'S CENTRE SUMMER COURSES

The Auckland Women's Centre offers a variety of services for women, including information, referral and counselling as well as a number of courses and clinics.

The courses and support groups include:
Amazing assertiveness for women

Power to Change group

Water Element Bellydance class

Women's Bookclub

Hatha Yoga

Yoga/Pilates/Stretch

Budgeting: Intuitive Financial Strategies

The workshops include:
Building a New Life After Separation

SKIP Parenting workshops

Girls' Self Defence

Flourishing Over Forty

Bookings essential for all courses and workshops.

For further information contact the Auckland Women's Centre on phone (09) 378-327, or visit their website: www.awc.org.nz

Australasian Association of Bioethics & Health Law Conference

11-14 July 2013 Sydney Law University School

2013 is an auspicious year. It is:

- 25 years since the Cartwright Inquiry into the treatment of cervical cancer
- 21 years since the decision of Roger vs Whitaker which enshrined the doctrine of informed consent into Australian law
- 21 years since the High Court's decision in Marion's case which transformed the nature of parental consent to medical treatment in Australia
- 18 years since the creation of the NZ Code of Consumers' Rights.

This conference will provide a forum for discussion of several core concerns within bioethics and health care law.

For more information visit the conference website: www.cdesign.com.au/aabhl2013

AWHC GENERAL MEETING 28 February 2013

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

- Financial report
- Grant applications
- Cervical Screening
- Alexion Pharmaceuticals & Soliris
- Medical devices & PHARMAC
- 25th Anniversary of Cartwright Report
- DHB meetings

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

AUCKLAND WOMEN'S HEALTH COUNCIL AGM

In the lead up to marking its 25th anniversary of its first meeting held in July 1988, the Auckland Women's Health Council will be holding its AGM on 11 April.

Date: Thursday 11 April 2013

Time: 6 – 7pm

Venue: AUT Akoranga Campus, Akoranga Drive, Northcote, Auckland

For further information contact the Council on (09) 520-5175 or email: awhc@womenshealthcouncil.org.nz

AWHC NEWSLETTER SUBSCRIPTION

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UP AND COMING EVENTS

DISTRICT HEALTH BOARD meetings for March/April 2013:

Waitemata DHB (Website address: www.waitematadhb.govt.nz)

The **combined Waitemata DHB and Auckland DHB** Community & Public Health Advisory Committee meeting starts at 2pm on Wednesday 20 March 2013.

Waitemata Hospital Advisory Committee meeting starts at 11am on Wednesday 10 April 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.

Auckland DHB (Website address: www.adhb.govt.nz)
The Hospital Advisory Committee meeting will be held at 9.30am on Wednesday 3 April 2013 followed by the Full Board meeting at 2pm. Both meetings will be held in The Marion Davis Library 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 March 2013 and will be followed by the Community & Public Health Advisory Committee meeting at 12.30pm at 19 Lambie Drive, Manukau.

The Counties Manukau DHB Full Board meeting will be held at 1pm on Wednesday 3 April 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

'Working Towards Safer Beginnings'

The Perinatal and Maternal Mortality Review Committee is holding its annual workshop at Te Papa in Wellington on 12 June 2013.

For further information go to http://www.hqsc.govt.nz/our-programmes/mrc/pmmrc/news-and-events/event/804/