AUCKLAND WOMEN'S HEALTH COUNCIL

NEWSLETTER

AUGUST 2014

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THE RIGHT TO SAY NO TO RESEARCH TRIALS

It has become clear over the past few months that patients cannot rely on the Code of Consumers' Rights to protect them from being enrolled in clinical trials or other research studies without their consent having been obtained first. It is proving difficult to find out exactly when patients lost that right, and even more problematic to know how to rectify the current unsatisfactory situation.

What hasn't changed is the fact that many patients/consumers are willing to consider the offer of becoming a research participant – provided they are first given the opportunity to read the patient information sheet about the research trial and to have their questions answered.

Some history

The AWHC was established in 1988 and held its first meeting in July that year, a month before the release of the Cartwright report of the Inquiry into the treatment of cervical cancer at National Women's Hospital. In the wake of the report's publication ethics committees were completely transformed into committees with both lay people and health professionals whose primary role was to protect the rights of patients and ensure that no-one was enrolled in any kind of research without giving their informed consent to be involved.

The office of the Health & Disability Commissioner was set up in late 1994 and consultation on a proposed Code of Consumers' Rights began the following year. On 1 July 1996 a legislated Code of Consumers' Rights came into effect.

Right 6, the right to be fully informed, states that every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including -

1(d) Notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; and

1(e) Any other information required by legal, professional, ethical, and other relevant standards.

Right 7, the right to make an informed choice and the right to give informed consent, states that:

4(c) Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where –

(a) It is in the best interests of the consumer.

For some unknown reason the debate about ethics committees approving research involving participants who lack the capacity to consent to participate has focused almost solely on Right 7(4) of the Code, not Right 6(1) d and e. Even the Health & Disability Commissioner's response to the letter the AWHC wrote about the practice of enrolling people in research trials without their informed consent, focused on Right 7(4). Anthony Hill stated in his letter "as you know there are two passionately held and opposing schools of thought on Right 7(4)."

Actually, the AWHC did <u>not</u> know that. Having been involved in the two consultation processes during the development of the Code of

Consumers' Rights, the Council believed that the mere thought of enrolling people in research trials without their consent was illegal, utterly abhorrent and against the Declaration of Helsinki, and the NZ Code of Rights, being enshrined in legislation, protected patients from such practices. After all, this issue was at the very heart of the Cartwright Inquiry. Once the recommendations in the Cartwright Report were implemented patients would never have to worry about being enrolled in research trials without their consent ever again. Right? Apparently not.

Anthony Hill stated in his letter that "this is not a matter about which HDC has received complaints, nor is it one that prompted many submissions in the recent Act and Code review, soon to be completed."

The AWHC did not include the issue in our submission because we did not know that in New Zealand thousands of unconscious patients in intensive care units around the country are being enrolled in clinical trials without their consent. The Council was also blissfully unaware that there was any debate going on about whether this practice was legal or not.

The Ministry of Health's chief legal advisor, in a letter to the Ministry's ethics committee chairs and members, dated 7 April 2014 but not posted on the ethics committee website until months later stated:
"Research involving participants who do not have the capacity to consent (and where no-one legally authorised to give consent on behalf of the participant does so) is not lawful unless it satisfies Right 7(4) of the Code of Health and Disability Services Consumers' Rights (the Code). Committees do not have the authority to give consent on behalf of participants." (1)

It also says: "Investigators must satisfy the committee that proposed research is lawful before the committee approves an application. Committees are not required or able to give legal advice to investigators; it is the responsibility of the investigator to ensure that the research is lawful."

This is not at all reassuring. There is big money involved in clinical trials and both the investigators and the DHBs have a huge conflict of interest in deciding what research is lawful and what is not.

The letter from the MOH's chief legal advisor has not been enough to stop ethics committees' approving research involving participants who lack the capacity to consent.

The HDC, the consumer watchdog, is sitting on his hands, has refused to undertake an investigation, and is waiting to receive a complaint from someone other than the AWHC, although the Council hasn't given up and has written to him again.

The AWHC has also written to Minister of Health Tony Ryall. As he was the Minister who pushed through the changes that ensured the focus of ethics committees would now be on approving research proposals – not protecting the rights of research participants – it is extremely unlikely that Mr Ryall is going to come to the rescue of the unconscious patients in the country's ICUs any time soon.

References

1. http://ethics.health.govt.nz/

LOW UPTAKE OF HPV VACCINE

The results of a cost-effectiveness study undertaken by the University of Otago Wellington and released in April 2014 has revealed that the vaccine coverage rate for girls and young women was only 47% at the time of the analysis of the available data. While coverage is currently estimated to be around 56% it is still low, especially when compared to vaccination coverage rates in Australia. In marked contrast to other NZ vaccine coverage statistics, coverage rates for Maori and Pacific are higher than for European.

The HPV vaccine Gardasil which protects against two of the HPV (human papilloma viruses) that can cause cervical cancer and two that can result in genital warts, was introduced into NZ in 2008. Despite protests from women's health groups about the lack of sufficient evidence that it would provide protection against the development of cervical cancer, it was introduced as the cervical cancer vaccine.

In May 2008 then Prime Minister Helen Clark announced that the government would provide $177 million in funding over five years for the 3-dose vaccine. From September 2008 the vaccine was offered free to 300,000 teenage girls between 12 – 18 years of age. The government said the cervical cancer vaccine was expected to save around 30 lives each year.

Since 2011 Gardasil has been routinely offered to 12-year-old girls (Year 8) in schools, who also have the option of having the vaccine at their GP a few years later.

University of Otago Wellington researcher Professor Tony Blakely says the reason for the low coverage rates may be that parents are given too many options. In a press release dated 15 April 2014 he said: "Having the option to either have the vaccination at school, or delay a few years and get it from a GP is likely causing a lot of parents to delay. One possible way to achieve higher coverage might therefore be to have only a free school-based programme, as in Australia, with the requirement to pay the full market price in other settings." (1)

Since the very beginning of the roll out of the HPV vaccine programme some parents have been concerned with the idea of their 11- and 12-year-old daughters being given a 3-dose HPV vaccine at such a young age, and many parents have opted to wait a few years.

Six years after the introduction of the HPV vaccination programme clinics around the country (sexual health, family planning and student and youth health clinics) have reported a declining number of first presentations for genital warts, with the steepest reductions occurring in young women aged 15 – 19 years.

The study found that the greatest health gain was from the prevention of genital warts, with smaller gains from reduced rates of cervical cancer. As it takes around 15 years for cervical cancer to develop following infection with one of the cancer-causing HPV types, and over 90% of HPVs are cleared by the immune system within 3 years, it is not clear what the claim about the reduced rates of cervical cancer is based upon.

Reference

www.otago.ac.nz/wellington/otago069004.pdf

MASS TREATMENT

"Mass prescription for modest individual benefit is new. Truly informed choice will require more than good intentions. We will need better data, from bigger trials, and better risk communication than for conventional medical treatment," Ben Goldacre, doctor, author of "*Bad Science*" and "*Bad Pharma*" and a research fellow in epidemiology, says in an editorial in 23 July 2014 issue of the *British Medical Journal*. (1)

"When we offer a preventive drug to large numbers of healthy people, we are a long way from the doctor treating a sick patient. In some respects, we are less like doctors and more like a life insurance sales team: offering occasional, possibly life-changing benefits, many years from now, in exchange for small ongoing inconvenience and cost. This represents a new kind of medicine, and delivering informed choice that reflects differing patient preferences will require wholesale structural improvements in how we gather and communicate research evidence."

While Ben Goldacre is writing about mass treatment with statins his observations are applicable to a wide range of preventative drugs that are now being prescribed to large populations in order to lower the risk of a particular patient experiencing a particular adverse event such as a stroke, a heart attack or a hip fracture.

"This persisting uncertainty about the precise risks and benefits of statins is a serious barrier to informed patient choice: after two decades of widespread statin prescription, it also shows that we have so far failed to implement the core principles of evidence based medicine," he says.

In an era of informed choice and increasingly personalised medicine, one size does not fit all. While some people are prepared to put up with considerable side effects in the hope that it will increase their chances of avoiding a heart attack, others are not willing to put up with even quite mild side effects of drugs that they have to remember to take on a daily basis and which they experience as reducing their quality of life.

Informed choice and informed consent mean that healthy people must be given good evidence before they agree to mass prescription. Ben Goldacre believes that before doctors are able to provide this, an information revolution is necessary. Without bigger and better research trials and new information tools, doctors "can say only that statins are – broadly speaking – likely to do more good than harm. This is not good enough," he concludes.

Reference

1. Ben Goldacre & Liam Smeeth. "Mass treatment with statins." Editorial *British Medical Journal*. 23 July 2014

"THE GOOD DOCTOR"

This is not another review of Ron Paterson's excellent book "*The Good Doctor: What Patients Want*" which was published in 2012. (1) A google search revealed that this is quite a popular title for a book.

A few months ago Dr Barron Lerner, a practicing physician and author of several books including "*The Breast Cancer Wars,*" published his own book entitled "*The Good Doctor: A Father, a Son, and the Evolution of Medical Ethics.*" His book is a heart-warming and very intimate story about his doctor father and the practice of medicine as it has evolved over the past 60 years. The book touches on some of the most profound issues in medicine today – autonomy, medical wisdom, empathy, paternalism, medical ethics, and the evolving roles of doctor and patient.

The book begins with the story of how Dr Barron Lerner's father, an infectious diseases physician, had physically placed his body over a dying patient who had stopped breathing, thus preventing his colleagues from performing cardio-pulmonary resuscitation, even though CPR was the ethically and legally accepted thing to do. Over the next few years, the senior Dr Lerner also tried to speed the deaths of his seriously ill mother and mother-in-law in order to spare them further suffering, and he did so in the firm belief that he was right to do so.

The stories his father told him angered and alarmed the younger Dr Lerner, who as well as being a physician was also a historian of medicine, a long-time member of his hospital's ethics committee, and a bioethicist. He had totally rejected physician-based paternalism in favour of informed consent, patient autonomy and patients' rights.

The senior Dr Lerner, a revered clinician, teacher, and researcher who always put his patients first, had for decades kept journals. Reading these journals showed his son how his father's outdated paternalism had grown out of a fierce devotion to patient-centred medicine which, much to his father's disgust, was rapidly disappearing. His father was a doctor who knew all his patients well, and he had spent his whole life putting their needs first, above those of his own family. He kept in touch with his patients even when on his annual family holiday in France.

As his father slowly died of Parkinson's disease, Dr Barron Lerner began questioning and re-evaluating not just his father's strongly held opinions but his own equally strongly held beliefs. He faced these issues both personally and professionally as he found himself being pulled into his father's medical care, even though he had criticised his father for making medical decisions for his relatives.

As one reviewer of this small gem of a book wrote: "this is a lovely and a loving book; it's a book about medicine and family and ethics and history that embraces complexity and speaks to all those subjects with wide-ranging compassion and great good sense. And it's a father-son doctor saga with much to say about the healing power of story and understanding."

References

1. AWHC Newsletter July 2012.
2. Barron H Lerner. "*The Good Doctor*." Beacon Press 2014.

NATIONAL WOMEN'S ANNUAL CLINICAL REPORT DAY

Time: 8am – 4pm
Date: Friday 15 August 2014
Venue: Clinical Education Centre, 5th Floor, Auckland City Hospital.
Cost: Free registration.

The programme for this year's Annual Clinical Report day includes:

- Critique of the 2013 maternity report by Dr Rose Elder
- Neonatal presentations
- Critique of the 2013 gynaecology report by Dr Peter Can Der Weijer
- Review of the use of vaginal mesh
- The Waitemata/Auckland DHB Women's Health Collaboration
- Review of Colposcopy
- Review of Management of GDM by Dr Rose Elder
- Early Registration with an LMC
- Abnormal Uterine Bleeding
- Neonatal Hypoglycaemia by Dr Deborah Harris
- Helping families understand the process of perinatal autopsy

Registration is essential.

Further information is available at:

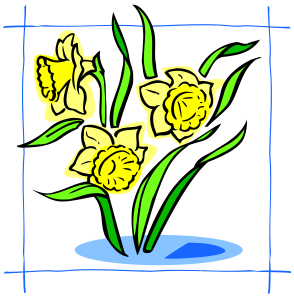
http://nationalwomenshealth.adhb.govt.nz/health-professionals/annual-clinical-report

AWHC GENERAL MEETING 24 July 2014

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

- Financial reports
- Grant applications
- Non consensual clinical trials
- Northern A ethics committee
- 2015 Cartwright conference

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



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UP AND COMING EVENTS

DISTRICT HEALTH BOARD meetings for August/September 2014:

Waitemata DHB (Website address: www.waitematadhb.govt.nz)
The Waitemata Hospital Advisory Committee meeting starts at 11am on Wednesday 13 August 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 3 September 2014.

Auckland DHB (Website address: www.adhb.govt.nz)
The Hospital Advisory Committee meeting will be held at 9.30am on Wednesday 6 August 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 13 August 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 20 August 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 Breast Cancer Network NZ is holding a Seminar on "***Reducing Breast Cancer Risk***" on Saturday 30 August 2014 at Kings School, 258 Remuera Road, Remuera, Auckland.
The day's programme includes:

- Professor Ian Shaw on "Breast Cancer – nature or nurture?"
- Dr Helen Smith on "Dietary and lifestyle risk reduction."
- Dr Peter Tanbridge on "There is more to breast cancer than genes>"
- Liz Hart on "Emotional Freedom Techniques"
- Sue Dykes on "Mindfulness based stress reduction."

To register contact Bonnie on: admin@bcn.org.nz or phone (09) 636-7040.