AUCKLAND WOMEN'S HEALTH COUNCIL

NEWSLETTER

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MAJOR FLAWS IN SOPs for ETHICS COMMITTEES

At the end of December 2011 the AWHC received a copy of the draft Standard Operating Procedures (SOPs) for ethics committees. The changes set out in the document are the latest step in the government's response to the Health Committee's clinical trials inquiry.

The NZ House of Representatives report was released in June 2011 and was entitled "Inquiry into improving New Zealand's environment to support innovation through clinical trials." The government responded with a document containing recommendations for change, followed by the "Draft standard operating procedures (SOPs) for health and disability ethics committees (HDECs)." The changes which are due to be implemented by the middle of the year will effectively spell the end of the purpose, role and function of ethics committees that were set up in the wake of the Cartwright Inquiry.

The New Zealand ethics committees established in the early 1990s were designed to provide extensive safeguards for research participants. The changes about to be introduced will seriously undermine these safeguards, and are "a departure from international standards." (1)

Women's health groups are not the only ones alarmed by this major erosion of protection for research participants. At the beginning of February 2012, following the New Zealand Bioethics conference held at the end of January five professors published an open letter to Minister of Health Tony Ryall regarding the proposed changes. They were the head of Otago University's bioethics centre, Professor Gareth Jones, Professors Donald Evans, John McCall and Charlotte Paul, and Auckland University's Professor Tim Dare. (1)

The letter stated there were major concerns about the processes around the creation and implementation of the new policy and referred to major flaws in the quality of information received by the Select Committee that led to these changes. Even more worrying was the fact that important steps were omitted, including analysis by and consultation with the government's own ethics advisory committee, the National Ethics Advisory Committee.

Other issues raised in their letter to Tony Ryall "are as follows:

- The reduction in number of ethics committees from seven to four, will significantly increase the workload of each committee. To meet that workload, the committees are expected to reduce the level of scrutiny of clinical trials, provide expedited review by the chair, and not review some research. The outcome is that many studies will not receive full ethical review, and some will not be reviewed at all.

- As a result of the above change, research protocols for clinical trials that will be categorised as low risk, will receive only expedited review by a committee chair. While on the surface this sounds an appropriate way of making ethical review more efficient the draft SOP shows that it is likely on occasion to prove hazardous. For example trials of probiotic use in serious illness would be categorised as not requiring full review. Yet one

such trial conducted in the Netherlands and published in the *Lancet* 2008, reported a major excess of deaths in the probiotic group and subsequent investigation showed that the monitoring arrangements for adverse events were insufficient; hence some deaths may have been avoidable.

Student research will also not receive review by HDECs (unless it is an intervention study conducted at PhD level). Hence the research carried out by a doctor into a clinical matter for the purpose of achieving a Masters degree, would not be reviewed by the HDEC (the appropriate committee for research with public hospital patients)

- The reduction in the numbers of members of ethics committees from 12 to 8 will result in both a loss of expertise, and a reduction in lay participation.

- Ethics committees will not assess scientific validity, even though scientific validity is one of the standards required for research to be ethical.

- A central clearing house for allocating protocols will impersonalise the review process and undermine co-operation between researchers and HDECs and the communities they work in."

The letter also echoes the issue raised by the AWHC in previous submissions and newsletter articles in stating that these concerns "raise issues about the independence of ethics committees housed within the Ministry of Health."

References

1. Open letter to Tony Ryall

TISSUE BANKS

The SOPs for ethics committees contains a section on the vexed issue of tissue banks. The SOPs document allows ethics committees to review applications relating to the establishment and management of tissue banks. The AWHC was unaware that tissue banks were being established in New Zealand until the draft SOPs for ethics committees document arrived in the post.

Section 13 of the SOPs document defines a tissue bank as "a collection of human tissue samples stored for potential use in research beyond the life of a specific research project." The SOPs also state that "the establishment and management of a tissue bank is not within the scope of HDEC review. In addition, it is not necessarily the case that all individual research projects using banked tissue will themselves fall within the scope of HDEC review. Nevertheless, organisations responsible for the establishment and management of a research tissue bank *may* apply for HDEC review for this."

In 2004 the Code of Consumers' Rights was amended to allow body substances to be stored, preserved or used "for the purposes of research that has received the approval of an ethics committee" <u>without</u> the need for the informed consent of the consumer. The addition of clause (10)(b) to Right 7, which is the Right to make an informed choice and give informed consent, thus effectively removed the right of a person to control what happens to their body parts and substances such as blood and tissue when used for research.

However, there is no mention of the commercial use of human tissue obtained in the course of a health care procedure in the Code of Rights.

The world has changed dramatically over the past 10–15 years. Today advances in biotechnology such as the study of how genetic variation affects the body's response to drugs, have changed the way tissues can generate medical and fiscal wealth. As the vice president of one large pharmaceutical company observed "access to quality human disease tissue is becoming increasingly important to the drug discovery process." (1)

Pharmaceutical companies, blood and tissue banks, tissue brokers and other companies that profit from research and biotechnology that uses human tissue are now knee-deep in the stream of buying and selling human tissue. Such activities are now occurring in New Zealand.

Sometimes such tissue is stolen. One of the most well known examples of this is the story of Henrietta Lacks whose death from cervical cancer in 1951 changed the history of medicine. (2) (3)

Henrietta's cancer cells (known as HeLa cells) were taken without her knowledge and despite her husband's refusal. They were the first human tissue samples to be successfully grown in culture. Scientists had been trying to keep human cells alive in culture for decades, but they all eventually died. When Henrietta's cancer cells were put in culture, they not only survived, they reproduced an entire generation every 24 hours, and they have never stopped reproducing. During the decades following her death the pharmaceutical and research industries have made millions of dollars from Henrietta's cells.

The case of John Moore is another example of how researchers made millions from his spleen. In 1976 John Moore learned he had hairy-cell leukemia (HCL), a rare and usually fatal cancer of the white blood cells. He was told by his doctor David Golde, a specialist in HCL, that his grossly enlarged spleen had to be removed. In October 1976 Moore dutifully signed the consent form for the splenectomy. The surgery was a success and Moore survived. It was a success for Golde as well, because although he did not tell Moore, the 22-pound spleen was producing an unusual volume of blood proteins that had triggered an extraordinarily effective immune response against his cancer. The spleen and other of Moore's tissues were used to develop a highly lucrative cell line from a key component of Moore's immune system, his T-cell lymphocytes. (1)

For several years, Golde insisted that Moore travel at his own expense from Alaska to Los Angeles for frequent follow-up visits, during which Golde extracted blood, cells, tissues, and semen, always explaining that this was to ensure that the cancer hadn't returned. A belated attempt by the specialist to get Moore to sign a consent form giving Golde absolute rights to Moore's tissue samples led to Moore discovering a patent had been taken out on his cell line. For more than a decade he fought, but ultimately lost, the battle for ownership of his productive and invaluable cells.

Given that organisations responsible for the establishment and manage-

ment of a research tissue bank are not required to apply for an ethics committee review, it is not at all clear who is going to monitor such highly lucrative activities and ensure that consumer rights are not breached.

To many peoples and cultures the human body is sacred. This includes body parts and substances such as blood, tissue, and semen. Storing bodily substances and using them for research without consent is one issue, but the prospect of having them become part of the tissue-market system is even more problematic and unethical.

The protections put in place for patients and research participants following the release of the Cartwright Report have been slowly but surely undermined over the past decade. New Zealand is fast becoming held to ransom by the profit motive that has taken over medical research and colonised human life. Medical ethics have been compromised in the process, and the latest changes to the standard operating procedures for ethics committees in New Zealand will put another nail in the coffin of patients rights over their own tissues.

References

1. Harriet A. Washington. "*Deadly Monopolies*." Published by Doubleday. 2011. Chapter 7 A Traffic in Tissues.
2. Rebecca Skloot. "*The Immortal Life of Henrietta Lacks*." Published by Pan Macmillan. 2010.
3. Auckland Women's Health Council Newsletter. June 2010.

ABORTION SUPERVISORY COMMITTEE REPORT

The Abortion Supervisory Committee's 34th annual report to Parliament for the year ending 30 June 2011 arrived in the mail just after Christmas. This latest report is more of a preliminary report as it contains no statistical information on the numbers of abortions performed during the 2010/2011 year.

Statistics NZ

The Christchurch earthquakes resulted in considerable disruption to the lives of people, and to many businesses and government services and departments. Due to the fact that the building which houses Statistics New Zealand was substantially damaged in the February earthquake, the Abortion Supervisory Committee (ASC) was not able to access all the statistical data it required to complete its report. Approximately 3,000 forms were trapped in a cordoned building, and were not able to be retrieved and processed until December 2011. The report states that the ASC and Statistics NZ are working on this issue and plan to release a supplementary report containing complete statistical figures some time in 2012.

Lyndhurst Hospital was also damaged in the earthquakes and the abortion services previously provided at the hospital could no longer continue being provided. Its licence was revoked and an application for a new abortion licence was submitted for Christchurch Hospital which was granted on 17 June 2011. This allowed for an abortion service to continue to be provided in Christchurch.

Following the establishment of the Southern District Health Board, abortion services for women residing in the Southland area are now being referred to Dunedin, and are no longer being referred to Christchurch.

The ASC was further hampered by the fact that it was operating with only two members for the 10 months from July 2010 to April 2011. This affected the committee's ability to make institutional visits over the period covered by the report. The report notes that the ASC visited Dunedin Hospital and the Auckland Medical Aid Centre during the year covered by the report, as well as officials from various government departments and universities.

Litigation

The litigation by Right to Life Inc continues. On 1 June 2011 the Court of Appeal upheld the ASC's appeal against the 2009 judgment of the High Court on an application for judicial review brought by Right to Life Inc.

The report states: "The High Court had held that the Committee was wrongly interpreting certain of its statutory functions. The Court of Appeal, by a majority of 2:1, accepted the Committee's argument that the Contraception, Sterilisation, and Abortion Act 1977 does not empower the Committee to review or scrutinise the individual decisions of certifying consultants and form its own view about the lawfulness of those decisions. The majority also found that there was no evidential foundation for the High Court Judge's comments that the approval rate for abortions seemed remarkably high and that there was reason to doubt the lawfulness of many abortions, and that the High Court should not have made such findings.

Justice Arnold wrote a dissenting judgment, indicating that he would have dismissed the Committee's appeal as he took a different view of the ambit of the Committee's powers of review in relation to certifying consultants. The Court unanimously rejected Right to Life's cross appeal, which related to the rights of the unborn child and the Committee's performance of tis functions in relation to counselling.

Right to Life applied for leave to appeal to the Supreme Court against the whole of the judgment. The Committee opposed leave. In a judgment dated 26 August 2011, the Supreme Court granted leave to appeal to Right to Life, but only in respect of limited grounds, being the ambit of the Committee's powers of review in relation to certifying consultants, whether there was any evidential foundation for the High Court's finding in relation to the approval rate for abortions and the lawfulness of abortions, and whether the High Court had jurisdiction to consider whether certifying consultants are obeying the abortion law.

No date has yet been allocated for the hearing of the appeal."

Further information on the history of the legal proceedings is available at:

http://www.alranz.org/_baks/RTLvASCcourtcase.htm.0011.8ee5.bak

BREAST IMPLANTS REVISITED

Breast implants are once again at the centre of a major medical disaster story after it was revealed that implants manufactured by a French company contained a substandard, industrial grade silicone.

The history of breast implants is littered with flawed devices since silicone implants gained popularity in the early 1960s as a way of augmenting breast size.

The latest breast implant scandal is centred round Poly Implant Prothese (PIP), a leading international maker of breast implants founded by French entrepreneur Jean-Claude Mas. The implants were among the cheapest in the world, and were recently found to be filled with silicone made for mattresses rather than medical use.

Investigations began last year into the PIP which manufactured 100,000 breast implants a year and was exporting 80% of them. The implants came under suspicion after doctors reported an abnormal number of rips and leaks in the implants.

While regulators in Britain said tests had shown no evidence of a potential for cancer or chemical toxicity of the industrial grade silicone, and there was therefore no reason for their routine removal – now where have we heard that before? – both the French and German governments advised women to have them removed. Closer to home Australia's medical watch dog agency, the Therapeutic Goods Administration (TGA) stated it would continue to investigate the situation over the coming months but did not believe there was enough evidence to warrant the removal of the implants. This despite the fact that round 8900 of the PIP implants had been used in Australian women, some of whom had complained about the devices splitting and leaking.

In New Zealand, the Ministry of Health said it had no record of any of the PIP breast implants being used, but whether they actually keep records of all breast implants used in New Zealand is far from clear.

Meanwhile, women with implants which include those recovering from breast cancer, report fearing that future ruptures could cause pain and inflammation as well as other problems resulting from the leakage of industrial silicone into their bodies.

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

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UP AND COMING EVENTS

DISTRICT HEALTH BOARD meetings for March/April 2012:

Waitemata DHB (Website address: www.waitematadhb.govt.nz)
The Waitemata DHB has moved to a 6-weekly meeting cycle, with the cycle commencing the week beginning 23 January 2012.

The **combined Waitemata DHB and Auckland DHB** Community & Public Health Advisory Committee meeting starts at 2pm on Wednesday 14 March 2012.

Waitemata Hospital Advisory Committee meeting starts at 11am on Wednesday 4 April 2012 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 28 March 2012 followed by the Full Board meeting at 2pm. Both meetings will be held at the Greenlane Clinical Centre in Greenlane Road.

Counties Manukau DHB (Website address: www.cmdhb.org.nz)
The Hospital Advisory Committee meeting will be held at 9am on Tuesday 28 February 2012 and will be followed by the Community & Public Health Advisory Committee meeting at 12.30pm at Middlemore Hospital.

The Counties Manukau DHB Full Board meeting will be held at 1pm on Wednesday 7 March 2012 at 19 Lambie Drive, Manukau City.

MEDICAL LAW CONFERENCE

The 13th Annual Medical Law conference is being held on 26th and 27th March at the Te Papa Museum in Wellington. The keynote address will be given by Anthony Hill, Health and Disability Commissioner and conference proceedings will be chaired by Peter Skegg, Professor of Law at Otago University.

The conference will feature a range of presentations on current developments in the medico-legal field.

Go to: http://www.conferenz.co.nz/conferences/medical-law-conference