AUCKLAND WOMEN'S HEALTH COUNCIL

NEWSLETTER

MAY 2013

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The Breast Cancer Genes

On the 14th of May Angelina Jolie's revelation that she carried the BRCA1 breast cancer gene and had had a preventative double mastectomy made world headlines and the fear of breast cancer went through the roof. Women's support groups, health centres and health agencies were deluged with calls from fearful women who wondered if they might have either of the BRCA1 and BRCA2 genes that are associated with a high risk of breast and ovarian cancer.

In the aftermath of the publication of Angelina Jolie's story in the *New York Times* (1), risk percentages for breast cancer were exaggerated and talked about as though they were death sentences. Her 87% risk of breast cancer became 90% which according to Professor Geoff Lindeman, head of the RMH Familial Cancer Centre, was "the upper end of risk when the gene was first discovered." (2)

Only about 5% of all breast cancers are hereditary, and not all of them will involve the BRCA1 or BRCA2 gene. The risk of cancer for women with the breast cancer gene is somewhere between 40 – 65% with the risks for women with the BRCA1 gene being higher than for those with the BRCA2 gene. In the midst of the panic that was generated by Angelina Jolie's story it is important to keep in mind that having either of these genes does not mean that a woman will develop either breast cancer or ovarian cancer. (2)

The BRCA genes play an important role in repairing the breaks or mutations in the DNA in our cells. But just as the body has a number of pathways that lead to cancer, it also has several pathways to repair DNA. The majority of women who are diagnosed with breast cancer have completely intact BRCA genes so there is obviously more to this than genomics.

It is also worth noting that men who inherit either of these genes may be at increased risk of prostate cancer as well as breast cancer – "breast cancer in men carrying BRCA2 has also been described in the medical literature." (2)

Genetic Testing

The demand for genetic testing is probably also going through the roof as a result of the *New York Times* article. Yet, Professor Lindeman urges caution, and advises against routine genetic testing. "Testing is offered to people who have developed breast or ovarian cancer where there are features that might suggest a mutation is present," he says.

The test is also extremely expensive as Myriad Genetics, a Utah-based company, patented the test and is currently the sole producer of it. In fact Myriad claims to own the rights to <u>any</u> test associated with the BRCA1 and BRCA2 genes and it has ruthlessly enforced that right, even though their test is inferior to one that Yale University was willing to provide at a much lower cost. The US Supreme Court has recently begun deliberations on the latest of a series of legal challenges to the granting of the patent that has been going on for over three years.

Referring to the fact that her wealth meant she has choices that other women do not have, Angelina Jolie observed that, "the cost of testing for BRCA1 and BRCA2, at more than

$3,000 in the United States, remains an obstacle for many women."

Overdiagnosis

Angelina Jolie's situation also differs in other respects from those of the average woman. She is a woman at high risk compared to the vast majority of women who take part in breast screening programmes and after a biopsy receive a diagnosis of breast cancer. It is now known that about a quarter of cancers detected are so small or slow-growing that they will never metastasise or cause any health problems.

Other women are told they have ductal carcinoma in situ (DCIS), a kind of pre-cancer in which abnormal cells are found in the milk-producing ducts. Before screening programmes were introduced, DCIS was rare. Now they account for around 25% of new breast-cancer cases, and preventative double mastectomies among women in this group have risen by 188% since the late 1990s. (3) This despite the fact that between 50 – 80% of DCIS cases will not develop into invasive cancer. In the USA the impact of such diagnoses turns thousands of healthy women into "cancer survivors" every year, and fuels the culture of fear, adding to women's already exaggerated sense of risk of getting breast cancer. (4)

The results of a large study of breast cancer diagnoses over the past 30 years appeared in the *New England Journal of Medicine* at the end of 2012. It found that despite substantial increases in the number of cases of early-stage breast cancer detecting, screening mammography had only marginally reduced the rate at which women present with advanced cancer and that there is substantial overdiagnosis accounting for nearly a third of all newly diagnosed breast cancers. The study suggested that more than one million women may have been unnecessarily diagnosed and treated. (5)

Preventative options

Professor Lindeman suggested that there were a number of preventative options such as "close monitoring which includes MRI scans and mammograms starting at a suitable age," and breast cancer prevention drugs such as Tamoxifen. As for mastectomy followed by breast reconstruction, he estimated that on average about 20% of women in Australia found to be carrying the BRCA1 and BRCA2 genes opt for this option. (2)

Mastectomy

As the breast cancer survivor quoted earlier put it, "having a mastectomy … is a huge ordeal. And reconstruction, while it can look great, will never have sensation. Not ever again. So before removing her breasts, a woman … should understand her personal risk of future disease. She should know that many breast cancers are survivable, and that the disease is not necessarily a death sentence… Knowledge is power: before you remove a breast, be sure you are fully informed" (3)

References

1. http://www.nytimes.com/2013/05/14/opinion/my-medical-choice.html?_r=0
2. http://theconversation.com/angelina-jolie-has-had-a-double-mastectomy-so-what-is-brca1-14227
3. http://6thfloor.blogs.nytimes.com/2013/05/15/reacting-to-angelina-jolies-breast-cancer-news/
4. http://www.nytimes.com/2013/04/28/magazine/our-feel-good-war-on-breast-cancer.html?pagewanted=all&_r=0
5. http://www.nejm.org/doi/full/10.1056/NEJMoa1206809

PHARMAC CONSULTS ON ITS DECISION NOT TO FUND SOLIRIS

PHARMAC is seeking feedback on its proposal to decline a funding application for eculizumab, also known as Soliris. (1) As noted in the February issue of the AWHC newsletter, Soliris which is manufactured by Alexion Pharmaceuticals, is the world's most expensive drug – the cost of treating one PNH patient for a year is over $600,000.

PNH (paroxysmal nocturnal haemoglobinuria) is an extremely rare blood and immune system disorder. It is an acquired disease characterised by the destruction of red blood cells, blood clots, impaired bone marrow function and a risk of developing leukaemia. The median survival after diagnosis is 10 years; however some patients can survive for decades with only minor symptoms. There is currently no known cure for PNH.

Current treatment in New Zealand for PNH aims to relieve symptoms rather than cure the condition, and includes blood transfusion to treat anaemia, immune suppression with steroids to suppress ongoing red blood cell destruction and anticoalgulation with warfarin to prevent or treat blood clots. (1)

Soliris/eculizumab is given via an intravenous infusion administered to patients fortnightly in a hospital setting. It is not a cure but it relieves the symptoms associated with PNH and it needs to be used for the rest of the patient's life.

PHARMAC received an application from Alexion Pharmaceuticals to fund Soliris in November 2011. Clinical advisors considered the application at the Pharmacology and Therapeutics Advisory Committee (PTAC) in February 2012, at the Haemotolgy Subcommittee in August 2012, and at February and March 2013 PTAC meetings. The minutes of these meetings are available on PHARMAC's website.

PHARMAC's consultation document explains that the reason it is proposing to decline funding is because the price requested by the drug company is extreme.

The New Zealand patient group that was established a year ago, and Dr Humphrey Pullon, a consultant haematologist in Hamilton, appeared on *Morning Report* on 22 May arguing that PHARMAC had overestimated the numbers of patients (12–20 patients instead of 8–10 patients) who would be considered for treatment with this drug and that the price that Alexion Pharmaceuticals had offered the drug to PHARMAC was the lowest in the world. (2)

Alexion Pharmaceuticals has funded both the Australian and New Zealand campaigns for drug. An email sent to Dr Humphrey Pullon several months ago asking about his ties to the drug company has not been replied to.

References

1. http://www.pharmac.health.nz/news/item/proposal-to-decline-a-funding-application-for-eculizumab
2. http://www.radionz.co.nz/national/programmes/morningreport/audio/2555923/pharmac-under-fire-by-patients,-doctor,-over-drug-decision.asx

ATTEMPT TO STOP THE SOLD TRIAL

An attempt has recently been made to stop recruitment of New Zealand women with HER2+ breast cancer in to the Synergy or Long Duration (SOLD) clinical trial.

The SOLD trial is a randomised phase 3 study that compares two Herceptin (trastuzumab) regimes for the treatment of women with early HER2+ breast cancer.

Results from large prospective, randomised trials with limited follow-up indicated that giving adjuvant for 12 months reduces the risk of breast cancer recurrence but this was also associated with cardiac problems.

In a smaller Finnish trial (FinHer), women received nine weekly infusions of Herceptin with their chemotherapy. The risk of the cancer returning and the risk of dying were significantly reduced in the all women who were treated with Herceptin.

New Zealand is part of the ongoing quest to determine whether nine weeks of Herceptin is as effective as 12 months. The Auckland School of Medical Sciences' website states that "the best duration of trastuzumab for early breast cancer is currently uncertain." The NZ arm of the trial is recruiting women with five centres participating in the study – Auckland, Palmerston North, Wellington, Christchurch and Dunedin.

The debate around whether nine weeks of weekly infusions of Herceptin works as well as 12 months of Herceptin has raged since 2008.

Last year the AWHC described the unsatisfactory way the media reported the findings of two studies (the HERA and PHARE trials) which explored different treatment durations of Herceptin. (1) What the researchers actually said about the results of their trials were very different to the interpretations trumpeted in media headlines around the world.

Press releases from Roche, the manufacturer of Herceptin, and the Breast Cancer Aotearoa Coalition (BCAC) stated that both cancer trials showed that one year of Herceptin is best, when they did not. For one of the trials the results were inconclusive, for the other the results showed less is just as good as more.

The Breast Cancer Aotearoa Coalition has recently taken the matter further, presenting their interpretation of the results of the PHARE clinical trial at a meeting of the Northern B ethics committee. BCAC claimed that the PHARE trial results are relevant to the SOLD clinical trial and questioned the ethics of continuing to recruit New Zealand women to the SOLD trial. In a letter to the chairperson of the Northern B ethics committee the Breast Cancer Aotearoa Coalition asked the committee to reconsider ethics approval for the SOLD trial. Several members of the BCAC appeared before the ethics committee on 7th May, along with Associate Professor Chris Frampton, a medical biostatistician from the University of Otago. Their areas of concern related to the balance of risks and benefits to patients, and to the issue of free and informed consent.

After they had spoken Professor Vernon Harvey, who was also in attendance, contested their

assertions, arguing that the SOLD trial is currently the most important cancer trial in the world because "we don't know that 12 months of Herceptin is better than nine weeks."

He acknowledged that all these trials are running behind schedule due to the fact that, unlike the 12 month trials, these trials are independent. Because they are not supported by the pharmaceutical industry, recruitment in the six-month and nine-week trials is much more difficult, he said. Professor Harvey told the ethics committee that the SOLD trial is as relevant now as it was when it was first started.

As the AWHC noted in its previous article on this issue (1), the patent for Herceptin is due to expire in 2014. This means that Roche is not keen to see any research results that undermine their fiercely-held position that 12 months of its over-priced drug is superior to either the six months or nine weeks treatment regime.

After both parties had left, the Northern B ethics committee went in committee to consider their options. It remains to be seen what the ethics committee will do or how the committee will respond to such a challenge, especially considering the strong arguments both sides put forward to support their position.

Watch this space!

References

1. www.womenshealthcouncil.org.nz/Features/Hot+Topics/Herceptin.html

Australasian Association of Bioethics & Health Law Conference

11 – 14 July 2013

Sydney University Law School

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.

Speakers include:
Anthony Hill, NZ Health & Disability Commissioner

Professor Ben White from Queensland University

Professor Ron Paterson, NZ Parliamentary Ombudsman

Professor Julian Savulescu from the University of Oxford

Dr Stacy Carter from the University of Sydney

Dr Marie Bismark from the University of Melbourne.

For more information see website:
http://www.conferencedesign.com.au/aabhl2013/index.html

POSTNATAL DISTRESS SUPPORT NETWORK COURSES

The Postnatal Distress Support Network provides free support services to women throughout the Auckland region who are affected by baby blues, antenatal and postnatal distress and depression, anxiety, stress and birth trauma.

The West Auckland-based group is now running a new course for mothers. The Wellness Resilience Action Planning (WRAP) course for PND provides a safe, facilitated space for new mothers to come along and talk about being a new mother, and discuss the joys and challenges that it brings. Topics include self-care, balancing family and other aspects of life, communication skills, assertive-ness and much more.

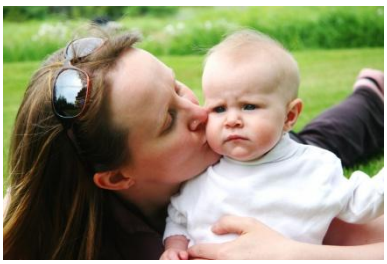
Booking for the 6-week course is essential as spaces are limited on the course and in the creche.

The cost is $60 which includes the crèche fees and a workbook.

For further information or to book, call the Parenting Place on 0800 53 56 59

Further information on the PND Support Network is available at:

http://www.postnataldistress.org.nz/



AWHC GENERAL MEETING 9 May 2013

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

- Financial reports
- Grant applications
- NSU consultation meeting
- ACART submission
- Cartwright anniversary event
- Ethics committee meetings

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 June/July 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 12 June 2013.

Waitemata Hospital Advisory Committee meeting starts at 11am on Wednesday 3 July 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 26 June 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 28 May 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 5 June 2013 at 19 Lambie Drive, Manukau City.

'Australia-New Zealand Roundtouble on Genomics'

Sunday 4th August 2013 12 noon to 4pm in Queenstown

Ethical, Social and Legal Aspects of Next-Generation Methodologies, with particular reference to managing incidental findings and issues relating to prenatal diagnosis will be discussed at the 4th Australia-New Zealand Roundtable on Genomics.

This year, the Roundtable is jointly organised by the International Centre for Society, Governance and Science (SoGoS), led by the Faculty of Law - University of Otago, and the Ethics and Social Issues Committee (ESIC) of the Human Genetics Society of Australasia (HGSA). The sponsors include NZ Genomics Ltd and ESIC.

The Roundtable is open to the public. Registration is required as seating is limited, but there is no charge. Contact Richman Wee at richman.wee@otago.ac.nz or 021 623 622.