



AUCKLAND WOMEN'S HEALTH COUNCIL NEWSLETTER

JUNE 2008



WHAT'S INSIDE:

- Funding for Herceptin
- Free food and drinks from Bayer
- Cartwright 20th Anniversary Conference

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FUNDING FOR HERCEPTIN

For the past two years the AWHC has been closely following the debate surrounding the promotion and funding of various treatment regimes with Herceptin for women with HER2 positive breast cancer. During this time the Council has become increasingly concerned at how the debate has been constructed in the media and has failed to focus on the evidence currently available regarding the benefits and risks of the 9-week and 12-month courses of Herceptin.

The Council continues to advocate for an evidence-based approach to be taken regarding the use of Herceptin while the results from the drug trials are gathered and fully reported upon. The controversy over access to this drug and the best treatment regime being argued for by both the drug's manufacturer and breast cancer groups continue to obscure the facts and has led to a narrow focus on the cost of the drug for patients and the concurrent demand for public funding.

The media

Sophisticated media campaigns continue to use stories of individual breast cancer patients, statements from patient support/lobby groups and selected comments from medical opinion leaders. Media coverage has rarely mentioned doubts about the claimed benefits of the 12-month course of Herceptin, the different outcomes for sequential as opposed to concurrent treatment regimes or the significance of the missing data from the clinical trials. Nor have they

questioned the exorbitant cost of the drug.

A recent study undertaken at the School of Public Health at the University of Sydney examined the media influence on Herceptin subsidisation in Australia and revealed that the "claimed benefits of Herceptin often conflated cancer non-recurrence and survival and favoured quantification rhetoric which emphasised percentage increases in improvement rather than the more modest increases in absolute survival."

As has happened in New Zealand, the Australian government's financial parsimony was framed as responsible for the women's plight, while drug industry pricing was never even mentioned. (1)

As the AWHC reported in its March and April 2007 issues of its newsletter, it is the interests of Roche, the manufacturer of Herceptin, to continue promoting the 12-month treatment regime as "the gold standard." It is also hugely significant that Roche refuses to fund further larger clinical trials that aim to investigate the safety and efficacy of the 9-week concurrent treatment option.

Funding 12 months treatment

The AWHC does not support public funding for a 12-month course of Herceptin for the following reasons:

- There has been no new evidence presented that would indicate that a 12-month course of Herceptin is a great deal more effective than a nine-week treatment period of Herceptin

administered concurrently with taxane.

- There is a reduced risk of cardiac toxicity with the shorter treatment period.
- The evidence published so far has revealed that administering Herceptin concurrently with taxane appears to be more effective than administering Herceptin sequentially after other chemotherapy.
- As Roche has not published the data from a key clinical trial and continues to withhold the results of this trial, the AWHC believes that it is very likely that the data on the missing women are being withheld due to the fact that including them would reduce the claimed effectiveness of administering Herceptin sequentially – Roche's preferred treatment regime.
- The results of a small trial recently presented at the 2008 annual meeting of the American Society of Clinical Oncology showed that the addition of Tykerb to Herceptin improves progression-free survival in pre-treated women (2). This is further evidence to support the proposition that administering Herceptin for HER2 positive breast cancer concurrently is more effective than sequential therapy.
- Despite the small size of the trial, the FinHer study revealed an appreciable effect, where disease-free survival was statistically significant.
- In the context of the New Zealand

health care system and the budget constraints faced by the District Health Boards a cautious approach to the funding of Herceptin is justified, particularly when faced with the withholding of important data from clinical trials and the resulting publication bias. (3)

Dr Susan Love's visit

During her visit to New Zealand in October 2007 as the key note speaker at the conference held in Rotorua for breast cancer survivors, Dr Susan Love commented at the conference and subsequently on public radio, saying "I worry that as with many other treatments the way that we first introduce a drug is not the way that it ends up being the best done.

Chemotherapy for breast cancer was initially done for two years, then we found out that one year was better, then we found out that six months were actually better. So if you are a drug company you're going to introduce a drug for a long period of time because that is how you make your money." (4)

The AWHC notes that Dr Love was supportive of the decision NZ health authorities had made to fund the nine-week course of Herceptin.

As well as supporting an approach that ensures the health and wellbeing of women is the highest priority rather than the vested interests of the drug companies, the Council believes that the research currently being done will result in answers to the questions about the optimum duration and the sequencing of Herceptin treatment.

Until the issues that still need to be resolved regarding the long-term efficacy of the various treatment regimes for Herceptin, the comparative clinical effectiveness of 12 months versus shorter treatment periods, and assessment of toxicity and adverse events, etc, it is entirely appropriate that health authorities resist both public pressure and the private pharmaceutical companies' demands for scarce health dollars to be spent on what is very likely to turn out to be unnecessarily prolonged treatment periods with a vastly overpriced drug that carries an increased risk of adverse effects.

Until further research whose results are not controlled by the drug company reveals whether 12-months is actually more effective than the nine-week course of Herceptin, the AWHC supports the subsidising of treatment with Herceptin for HER2 positive early breast cancer patients when it is administered for nine weeks concurrently with taxane.

References:

1. Ross MacKenzie et al. "Media influence on Herceptin subsidization in Australia: application of the rule of rescue?" *Journal for the Royal Society of Medicine* 101:305-312 2008.
2. J O'Shaughnessy et al. "A randomized study of lapatinib alone or in combination with trastumab in heavily pretreated HER2+ metastatic breast cancer progressing on trastuzumab therapy." Program and abstracts of the 44th American Society of Clinical Oncology Annual Meeting: 30 May – 3 June, 2008; Chicago, Illinois. Abstract 1015.
3. Scott Metcalfe et al. "Trastuzumab: possible publication bias." *The Lancet*. 17 May, 2008.
- (4) Dr Susan Love. Commenting in response to a question posed at the conference for breast cancer survivors and on public radio: October 2007; Rotorua, New Zealand.

Twenty Years After the Cartwright Report: What Have We Learnt?"

This one-day conference hosted by the University of Auckland Faculty of Law will be chaired by Rae Lamb, Deputy Health & Disability Commissioner.

Speakers include:

- Dame Silvia Cartwright
- Sandra Coney
- Professor Charlotte Paul
- Clare Matheson
- Ron Paterson HDC
- Dr Ron Jones
- Dr David Collins QC
- Justice Lowell Goddard
- Professor Alastair Campbell
- Dr Robin Briant
- Dr Kenneth Clark

Date: Friday 29 August 2008

Time: 8.30am – 5.30 pm

Venue: Hyatt Regency Auckland, cnr Waterloo Quadrant and Princess Streets, Auckland.

Cost: \$250

For more information visit Law School website: www.law.auckland.ac.nz

To register email:

k.j.kilgour@paradise.net.nz



WHAT PRICE A FREE DINNER?

On a wild wet windy evening in late June that made crossing the Auckland harbour bridge no mean feat, an event took place in the Spencer on Byron hotel in Takapuna that made even the most hardened cynics amongst us turn ashen-faced.

As the storm raged outside complete with thunder and lightning and a tornado or two waiting in the wings, inside it was all cosy and warm, with immaculately-clad waiters handing out free drinks and delectable nibbles as the guests drifted in and mingled with their colleagues.

The guests were nearly all GPs who at the end of May had received a letter from the drug company Bayer inviting them to a presentation by a senior paediatrician and a drug company representative, after which dinner would be served. The invitation was attractive enough to bring out over 100 GPs on such an inclement night.

The topic of what the letter described as “a dinner presentation” was *Feeding Options for Women Not Fully Breast Feeding*. After half an hour or so of “arrival drinks and canapé” we were ushered into a room and seated at tables set for dinner. Paediatrician Peter Nobbs was introduced and began his presentation on the history and politics of breastfeeding. He began setting the scene for the message he was there to give by focusing on an aspect of the environment that some new mothers

in New Zealand 100 years ago were subjected to. The Plunket Society was put under the spotlight as Peter Nobbs described their staunch support for breastfeeding, their objections to an advertisement for an early version of what was then known as “humanised milk mixture” that appeared in the *Otago Witness* in the first decade of last century, and the two-faced behaviour of Plunket Nurses who, according to a letter that appeared in the *Otago Daily Times* in 1915, were telling mothers to breastfeed while they themselves were bringing up their babies on Glaxo.

We were told Plunket Society’s founder, Sir Truby King’s Melrose property in Wellington is listed as a category 1 Heritage Building, and that it was here that the earliest attempts to make “humanised milk mixture” or infant formula in New Zealand began. Vegetable oil, cod liver oil and dextrose were added to cows milk and this humanised milk mixture was marketed by the Plunket Society under the name of Karilac along with “Plunket cream” known as Kariol.

Following a bit more history Peter Nobbs showed a slide documenting the falling breastfeeding rates in the middle of last century – it was recorded as being 91.5% in 1939, 82.1% in 1945, and 74.4% in 1952.

By now it was clear that the message we were being given was that not fully breastfeeding was normal and natural, that health authorities were often hypocritical about the advice they were required to give to new mothers about breastfeeding and what they

actually said and did, and that the pro-breastfeeding stance was just a lot of politically-correct behaviour. Along with this were some subtle and not so subtle messages about the problems and risks of breastfeeding.

Turning his attention to the politics of breastfeeding Peter Nobbs went on to talk about the WHO Code on the International Marketing of Breast-Milk Substitutes, the advice given to new mothers in hospital, and the argument around whether complementary feeding with a bottle does have any affect on breastfeeding.

He referred to the erroneous perceptions of groups like La Leche League and quoted from one of the group's 2007 newsletters in which the sentence "Formula companies' only aim is to make money" appeared. He assured the audience that formula companies in New Zealand do comply with the WHO Code and therefore see themselves as providing a complementary service.

NZ Breastfeeding Authority

The next organisation to come under attack was the NZ Breastfeeding Authority. He described their website, their current proposals around the Baby Friendly Hospital Initiative, and the accreditation of the hospitals in the Auckland region in critical terms. The NZBA website refers to the benefits of breastfeeding but not the risks, and risks of infant formulas but not the benefits. He cited as an example the fact that the website mentioned bacterial contamination of infant formulas. He was very critical of how ridiculous this was when the incidence is less than one in a million.

Bottles and pacifiers

The issues surrounding the use of pacifiers and bottles featured next with Peter Nobbs referring to some of the evidence about their supposed effects on breastfeeding. Studies on the use of pacifiers show no consistent results, he said. The effects of supplementary bottle-feeding had been studied in two studies from the USA and one from Switzerland. One showed an effect on breastfeeding and one did not. The duration of breastfeeding in both groups was the same.

No RTCs

The lack of randomised controlled trials was something Peter referred to several times during his presentation.

Peter ended his presentation with a list of the five most common conditions that mothers and babies present with at the doctor's office. They included reflux, colic, poor weight gain, allergies, and diarrhoea. As he talked about each condition he showed a slide with the image of the appropriate Bayer Infant Formula (brand name is Novalac) product – Novalac Reflux, Novalac Colic, Novalac Hypoallergenic, Novalac Diarrhoea. There was even a Novalac Sweet Dreams! With the exception of Novalac Diarrhoea, all products are suitable for use from birth onwards and are described as a "nutritionally complete formula suitable for long-term everyday use." Given that each of these special formulas costs around \$30 a tin (almost double that of ordinary infant formula), the statement that the aim of the drug company is to make money does not seem at all unreasonable.

Bayer Consumer Care

The presentation by Ayumi Uyeda, the young female drug company rep was unremarkable in that it was clearly her job to promote the wonders of the Novalac range of specialised infant formulas. She consistently described them as “premium products’, and the higher cost was simply “a price differential.”

Ayumi Uyeda referred to the EDEN study of 3.500 babies, “an observational study of what happens in private practice” that was firstly an epidemiological study on presenting problems, and secondly the effects of Novalac on the problem. However, there was no mention of RTCs!

Her slides showed the “scientifically developed” range of specialised infant formulas and how they differed from each other. The slick marketing of solutions to “problems” such as reflux, colic and constipation, the expansion of the diagnostic criteria used to identify such commonplace events as spilling or spitting up, periods of prolonged crying and distress, and constipation and diarrhoea, along with the supply of free drinks and good food, was both impressive and incredibly dishonest.

Needless to say, I left after the presentations – before dinner was served – because I suddenly found I had completely lost my appetite. I went instead to the bar and bought a spiced tomato juice and sat mulling over what I had just witnessed with a health professional friend.

Lynda Williams (aka Linda Watson)

AWHC GENERAL MEETING 12 June 2008

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

- Financial reports
- Grant application to ASB Trust
- PHARMAC PTAC submission
- New executive committee member
- AWHC website
- Cartwright Event for 2008



AWHC NEWSLETTER SUBSCRIPTION

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

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\$45 supporting subscription

If you would prefer to have the newsletter emailed, email us at awhc@womenshealthcouncil.org.nz

Send your cheque to the AWHC, PO Box 99-614, Newmarket, Auckland.

UP AND COMING EVENTS

DISTRICT HEALTH BOARD meetings for July 2008:

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

The Community & Public Health Advisory Committee meeting starts at 11am on Wednesday 9 July 2008 and will be followed by the Hospital Advisory Committee meeting at 1.30pm.

Waitemata DHB Full Board meeting starts at 1pm on Wednesday 30 July 2008 and meets in the DHB Boardroom, Level 1, 15 Shea Terrace, Takapuna.

Auckland DHB (Website address: www.adhb.govt.nz)

All Auckland DHB meetings are held all on the same day (now on the first Wednesday of the month) in the Marion Davis Library, Auckland City Hospital.

The Community & Public Health Advisory Committee meeting is at 9am on Wednesday 2 July 2008. This will be followed by the Hospital Advisory Committee meeting at 11am and then the Full Board meeting at 1.30pm.

Counties Manukau DHB (Website address: www.cmdhb.org.nz)

The CMDHB Full Board meeting will be held at 1pm on Wednesday 2 July 2008 at 19 Lambie Drive, Manukau City.

The Hospital Advisory Committee meeting will be held at 9am on Tuesday 22 July 2008 and will be followed by the Community & Public Health Advisory Committee meeting at 1pm.



CHOICES, CHALLENGES & DIVERSITY – the NZ College of Midwives' 10th biennial national conference will be held in Auckland at the SKYCITY Auckland Convention Centre, from the **12th – 14th of September 2008**.

The organisers plan to provide attendees with new knowledge, renewed friendships, expanded networking opportunities and a lot of fun.

- Contact Trish or Kim, conference managers at the NZ College of Midwives: conference@nzcom.org.nz

