AUCKLAND WOMEN'S HEALTH COUNCIL

NEWSLETTER

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HERCEPTIN – SHORTER BEATS LONGER

On 18 July 2013 the *Lancet* online published the results of the randomised controlled trial (RCT) comparing one year of treatment with Herceptin (trastuzumab) with two years on the drug for women with HER2+ breast cancer.

The long-awaited results of this important trial, known as the HERA (HERceptin Adjuvant) trial, report on eight years of follow-up for 5102 patients with HER2+ breast cancer who were randomly assigned after surgery and completion of chemo-therapy to either one year or two years of treatment with Herceptin.

Last year the AWHC took the media to task for its premature reporting of the results of this trial, reporting which was heavily based on press releases produced by Roche, the manufacturer of Herceptin. (1)

The publication in the *Lancet* of the results of the HERA trial reveal the truth about the differences between women who had a one-year treatment regime with Herceptin as compared with those who had two years. The editorial comment in the *Lancet* summed it up this way:
"Most patients tolerated trastuzumab well, but 2-year treatment was associated with greater toxicity than was 1-year treatment. Cardiac adverse events were recorded more frequently in the 2-year group (136 patients, 8.2%) than in the 1-year group (83 patients, 4.9%). Only 17 (1%) patients had a cardiac adverse event recorded in the observation group. Overall, 1 year of adjuvant trastuzumab had similar efficacy to 2 years of adjuvant trastuzumab, but was better tolerated. Treatment costs were not assessed, but the economic winner is evident." (2)

No evidence for 12-month standard
The editorial also points out that while the recommended duration of Herceptin treatment is 12 months, there is little evidence to support this time period. The so-called "gold standard" of 12 months of Herceptin became the accepted standard because it was the only duration assessed in the large trials – funded by Roche – that established the safety and efficacy of Herceptin. It must also be remembered that not all of the data from these large trials were released as Roche refused to produce the data from one arm of these trials.

Of course, Roche has a vested interest in ensuring that 12 months remains the recommended duration, especially given that the patent on its "goose-that-lays-golden-eggs" drug is due to expire in a year or so. It has no interest in supporting trials comparing 9 weeks of treatment with 12 months, or those comparing 6 months with 12 months.

The results of this latest study mean that it is perfectly reasonable to suspect that the optimum duration may be much less than 12 months, especially when both the toxicity and the high cost of the drug are taken into account.

Herceptin trials must continue
Thus a strong argument can be made for continuing with the trials that are assessing shorter treatment durations. The winners here are the women being treated with Herceptin, the researchers who remain dedicated in the face of considerable opposition

and a real lack of support to finding the answer to whether even shorter beats longer, and of course the health system.

There is one other confounding factor that needs to be mentioned when discussing the Herceptin trials.

When the HERA trials began Herceptin was given to women after they had completed their chemo-therapy treatment. It is now known that administering Herceptin at the same time as other chemotherapy drugs are being taken, eg drugs such as taxanes, increases the efficacy of Herceptin treatment.

This finding may be an important part of the ongoing trials that are trying to show whether nine weeks (or six months) of Herceptin works just as well as 12 months.

SOLD trial to continue

As reported in the May issue of the AWHC newsletter the Breast Cancer Aotearoa Collection recently sought to persuade the Northern B ethics committee to stop further recruitment of New Zealand women to the SOLD trial. (3) Fortunately, the committee decided at its August meeting that there were insufficient grounds to justify withdrawing ethical approval for the SOLD trial. (4)

References

1. http://www.womenshealthcouncil.org.nz/Features/Hot+Topics/Herceptin.html
2. http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2813%2961448-8/fulltext
3. http://www.womenshealthcouncil.org.nz/Features/Hot+Topics/Herceptin.html
4. http://ethics.health.govt.nz/about-committees/meeting-dates-venues-minutes/northern-b-committee-minutes

The Cartwright Legacy: At 25 years

Friday 27 September 2013

Fickling Centre, Three Kings, Auckland

A Cartwright Collective has formed to organise a one-day event to mark the 25th anniversary of the release of the Cartwright Report in August 1988.

Cartwright Collective members include Sandra Coney, Phillida Bunkle, Betsy Marshall, Ruth Bonita, Jo Fitzpatrick, Lynda Williams, Jo Manning and Clare Matheson.

Confirmed Speakers include: Silvia Cartwright

Charlotte Paul on Screening Programmes.

Martin Tolich on Ethics Committees post 2012.

Lester Levy on DHBs and hospital services

Phillida Bunkle on ethical issues post Cartwright.

Marie Bismark on patient complaints.

The conference will also feature two panel discussions on ethics committees and on patient rights.

For more information contact Lynda Williams at: awhc@womenshealthcouncil.org.nz

2012 ANNUAL REPORT FROM NATIONAL WOMEN'S

National Women's released its Annual Clinical Report for 2012 in August 2013. The report is the 20th in the current series.

The 264-page report contains a wealth of statistical information on the 7664 women who gave birth at NWH in 2012 and the 7832 babies they gave birth to, plus the 31 women who gave birth before they actually got to the delivery unit. In 2012 there were 156 sets of twins (159 in 2011) and 2 sets of triplets (4 sets in 2011).

Normal births decrease

The intervention rates have risen slightly over the past year or so. In 2012 54.2% (4173 out of 7695 birthing mothers) had what the report refers to as a "spontaneous vertex birth," and 0.6% (45 birthing mothers) had a vaginal breech birth.

Only 45.8% of first-time mothers had a spontaneous vertex birth, compared to 46.7% in 2011.

Induction of labour

In 2012 32.3% of mothers had an induction of labour. More than one in three first time mothers – over 37.5% – had an induction of labour. The rate for multiparous mothers was 28.6%.

The report notes that prolonged latent phase of labour, premature rupture of membranes and post-dates were the most frequent reasons for induction of labour in 2012. When post-dates was the primary indication for induction, 15% occurred prior to 41 weeks (up from 10% in 2011) and 16% occurred at or beyond 42 weeks (down from 22% in 2011).

"The advent of the post-dates virtual clinic at the end of 2011 has meant that referrals for post-dates induction of labour prior to 41 weeks will not be accepted in women meeting the criteria for a normal birth pathway." Hopefully this will help reduce the number of inductions which are often the beginning of the cascade of interventions that result in a caesarean section.

33.4% caesarean section rate

In 2012 the caesarean section rate was 33.4%, compared to 32.5% in 2011, and 20.8% in 1995 and 1996. There was little difference between the caesarean section rate for first-time mothers (34.1%, compared to 34.5% in 2011) and for mothers having subsequent births (32.7%, compared to 30.8% in 2011).

The most common reason given for all elective and pre-labour emergency caesareans was "repeat caesarean section." Among multiparous mothers, 61% of all caesarean sections were performed primarily for repeat caesarean. The next most common indication overall was malpresentation at 13%. "In first time mothers, concerningly, 16% of elective or pre-labour emergency caesarean section were for maternal request."

The report notes that "research evidence is clear that repeated caesareans are strongly associated with adverse maternal outcomes, such as abnormal placentation, postpartum haemorrhage and peripartum hysterectomy.

Forceps and Ventouse

In 2011 the rate of forceps and ventouse deliveries (combined under the term "instrumental vaginal birth") dropped below 12% for the first time

since 1997, with a rate of 11.1%. In 2012 it was rose again to 11.8% of all births, 19.7% of first-time mothers, and 4.2% of multiparous mothers.

Some mothers are subjected to more than one instrument – forceps and ventouse, or different types of forceps, and to the birth of a baby by caesarean section after an attempted vaginal instrumental birth. In 2012 34 mothers had a double instrumental birth, and 48 mothers had an attempted vaginal instrumental birth prior to emergency caesarean section. The report notes that these are rare events but are associated with more severe outcomes for both mother and baby.

Epidurals

The epidural rate among labouring women was 60.3% in 2012. For first-time mothers it was 82.6% if labour was induced and 58% if labouring spontaneously. For multipara it was 57.9% if labour was induced and 27.2% if labouring spontaneously.

The use of epidurals is highest in first-time European mothers (73.7%) who are over the age of 30 (72.9%), with a private obstetrician (82.2%).

Breech birth

Of the 356 singleton babies presenting as a breech, 318 were delivered by caesarean section. Among the 55 breech births at 32-36 weeks the percentage of caesarean deliveries was 89%, despite there being no evidence to support such a practice. For the 252 breech births at 37 weeks and over the percentage of caesarean sections was 97%. Caesarean section for breech presentation contributes 12% to the total caesarean section rate.

The report notes that the NWH guideline on Breech Birth was updated in May 2012 to reflect changes in guidelines internationally.

Waterbirth

There were 37 babies born in water in 2012 - five mothers were cared for by NW LMC midwives, and 32 were cared for by independent midwives.

Postpartum Haemorrhage

The postpartum haemorrhage (PPH) rate continues to rise and it remains a cause for considerable concern. It is associated with the increasing caesarean section rate. The overall primary PPH rate (500mls and over) was 33.6%. It was 16.4% following a spontaneous vaginal birth compared to 71.7% following an emergency caesarean section and 54% following an elective caesarean section. It also varied by onset of birth, from 25% in spontaneous onset of labour to 32.8% in induced labour.

Peripartum Hysterectomy

In 2012 11 women had an emergency postpartum hysterectomy compared to twelve in 2011. Hysterectomies following birth are usually associated with caesarean sections.

Maternal Mortality

There were no maternal deaths in 2012.

Breastfeeding

In 2012 80.3% of mothers were discharged from National Women's exclusively breastfeeding their babies.

- A copy of the 2012 Annual Clinical Report is available at: http://nationalwomenshealth.adhb.govt.nz/health-professionals/annual-clinical-report

HIV/AIDS REPORT FOR 2012

The AIDS Epidemiology Group at Otago University's Department of Preventative and Social Medicine recently published its annual report on HIV infection and AIDS diagnosed in New Zealand in 2012.

The report reveals that 124 people were diagnosed with HIV through a Western blot (WB) antibody test (compared to 109 in 2011), and points out that while this was slightly higher than in 2011 it was lower than in every year in the period 2003-2010.

A further 46 people with HIV who had not had a WB antibody test in New Zealand, had a first viral load (VL) test in 2012. Nineteen were first diagnosed in 2012 in New Zealand. This year's report is the first to include both sources of data.

There were 20 people notified with AIDS in 2012 compared to 24 in 2011. Ten were men infected through sex with other men, five people (two men and three women) through heterosexual contact, and for five people the means of infection was unknown.

Of the 124 people diagnosed with HIV through a WB antibody test, 77 were men infected through sex with other men, including two who were possibly infected through injecting drug use, 38 people (23 men and 15 women) through heterosexual contact, and one child through mother-to-child transmission.

Ethnicity
Of the 23 men and 15 women diagnosed with heterosexually acquired infection in 2012, 10 (26%) were European, 8 were African (21%), 13 (34%) were Asian, three (8%) were Maori, three (8%) were Pacific and one was "other." Their ages ranged from 22 to 65 years.

Overseas acquired HIV infection
Of the 38 people diagnosed with heterosexually acquired infection, 17 (45%) people were reported to have been infected in New Zealand, 20 (53%) overseas, and for one the information was not available. The report notes that there has been a marked drop in the number of people diagnosed with heterosexually acquired HIV overseas since it peaked at around 70 in 2006.

Of the 19 diagnosed women, 8 were African, 4 Asian, 3 European, one was Maori, one was listed as "other," and for two the ethnicity is not known.

Antenatal HIV Screening
In 2012 two women were diagnosed with HIV as a result of having an HIV test during pregnancy.

Children with HIV infection
The one child diagnosed with HIV in 2012 was born in New Zealand in 2002. The report notes that the fact this child was aged 10 at the time of diagnosis suggests that there are likely to be other undiagnosed children in New Zealand.

Since 1995 there have been 115 births to women with diagnosed HIV at the time of the birth. None of these children have become infected.

A copy of the full report is available on the AIDS Epidemiology website:
http://dnmeds.otago.ac.nz/departments/psm/research/aids/newsletters.html

Researchers now accessing Guthrie cards

Since June 2011 researchers have been able to obtain approval from ethics committees for research that involves accessing residual blood spots on Guthrie cards without having to obtain consent from parents or the adult individual whose card it is.

It is difficult to know how many parents are aware that the protocols around accessing Guthrie cards have changed, as there is no monitoring of how many new parents are given the National Screening Unit's (NSU) booklet and have read and understood that their baby's Guthrie card will be permanently stored in what is essentially a biobank, and can be used by researchers without their knowledge or consent.

The NSU's 8-page booklet contains one brief mention of the fact that the stored blood spots can be used "for research approved by an ethics committee." (1) There is a little more information on the NSU website: "For blood spot samples collected after June 2011, any applications for population research must first be approved by an ethics committee and then is reviewed by the Newborn Metabolic Screening Programme Governance Team." (2) However, given the vested interests involved there needs to be a completely independent review.

One such research proposal was recently approved by the Northern A ethics committee. Given the type of research involved the ethical thing to do would have been to have sought consent from those involved. Unfortunately, the parents will never know their child's card was used and what the study revealed.

References

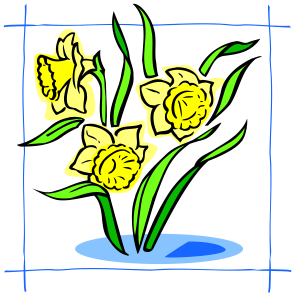
1. http://www.nsu.govt.nz/files/ANNB/Your_newborn_babys_blood_test.pdf
2. http://www.nsu.govt.nz/current-nsu-programmes/2917.aspx

AWHC GENERAL MEETING 15 August 2013

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

- Financial reports
- Grant applications
- Human Genome conference
- Ethics committee meetings
- *The Legacy of Cartwright at 25 years* conference

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



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Send your cheque to the Auckland Women's health Council, PO Box 99-614, Newmarket, Auckland 1149.

UP AND COMING EVENTS

DISTRICT HEALTH BOARD meetings for August/September 2013:

Waitemata DHB (Website address: www.waitematadhb.govt.nz)
Waitemata Hospital Advisory Committee meeting starts at 11am on Wednesday 25 September 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.

The **combined Waitemata DHB and Auckland DHB** Community & Public Health Advisory Committee meeting starts at 2pm on Wednesday 4 September 2013.

Auckland DHB (Website address: www.adhb.govt.nz)
The Hospital Advisory Committee meeting will be held at 9.30am on Wednesday 18 September 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 Counties Manukau DHB Full Board meeting will be held at 1pm on Wednesday 4 September 2013 at 19 Lambie Drive, Manukau City.

The Hospital Advisory Committee meeting will be held at 9am on Tuesday 27 August 2013 and will be followed by the Community & Public Health Advisory Committee meeting at 1pm at 19 Lambie Drive, Manukau.

ETHICS COMMITTEE meetings – dates for the four new ethics committees are at:
http://www.ethics.health.govt.nz/about-committees/meeting-dates-venues-minutes

JOAN DONLEY MIDWIFERY RESEARCH FORUM

The NZ College of Midwives will be holding the sixth biennial Joan Donley Midwifery Research Forum celebrating midwifery research and knowledge in September.

Date: 19th - 20th September 2013
Venue: Rydges Lakeland Resort, Queenstown.

- Further information is available on the NZ College of Midwives website: http://www.midwife.org.nz/research/joan-donley-midwifery-research-collaboration/the-jdmrc-forum/