AUCKLAND WOMEN'S HEALTH COUNCIL

NEWSLETTER

OCTOBER 2012

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REPORT ON REVIEW OF BREAST BIOPSY ERRORS.

At the beginning of September 2012 the review of breast biopsy errors report was released. The review was instigated after a number of women had unnecessary surgery as a result of an error in the laboratory diagnosis of a biopsy specimen.

Four of the errors involved biopsy specimens being mixed up with that of another woman, and they occurred in several different laboratories. The report notes that there is little standardisation of processes and systems between laboratories and "each laboratory seems to need to learn the same lessons for itself." One of the recommendations in the report is that the report should be used to drive improved systems in all of New Zealand's laboratories.

The errors

The errors occurred over a two-year period. Four involved mix ups with the biopsy tissues and one resulted from a misread. Two of the breast biopsy specimens were from patients taking part in the breast cancer screening programme and two were a result of the specimens taken for diagnostic purposes.

The errors occurred in both hospital and community laboratories.

Four women had mastectomies that subsequent examination of the mastectomy specimen showed to be unnecessary as there was no evidence of cancer. The fifth woman underwent a partial removal of her upper jaw bone and the subsequent examination of the surgical specimen showed no evidence of malignancy.

False negatives

Four other women were also involved in these mix ups – these were the women whose biopsy results came back clear when they did in fact have cancer. However in these four false negative cases, further biopsies were done because the original negative result was totally unexpected, and a multi disciplinary meeting decided a second biopsy was needed.

The report notes that while an unexpected negative result prompted clinicians to order a second biopsy, an unexpected positive result did not produce a similar response – the ordering of another biopsy that would have identified the false positive result. Major surgery was carried out despite the mismatch between the laboratory findings and other clinical and imaging data.

The women

The most moving section of the report is the description of the impact of these errors on the women. A member of the review panel and a Ministry of Health representative visited four of the women who had been affected by the errors and who were prepared to meet and reported: "When reflecting on their experience and discussing their ordeal with different professionals and services most women felt there were 'warning bells' of which more notice should have been taken. At the time of assessment there were things that didn't quite match up, yet the treatment continued. In one case none of the scans showed any sign of cancer, "Yet they still went ahead with it," (based on the biopsy results). When two of the women queried aspects of their results they didn't understand (prior to surgery) they were told, 'It was just terminology and

how they write things,' and, 'It was explained.' One woman was told on physical examination that she definitely had breast cancer; then the biopsy came back negative."

Unsurprisingly, the panel found that "as a result of these responses the women have lost faith in the health system summed up in this comment. 'Gone are the days when you believe everything your doctor tells you'" and the report recommended "If the picture doesn't match up, the clinician needs to take a step back in the process and 'consider' a laboratory/pathology error."

Emotional and financial impact

Family members reported that the women who were misdiagnosed with cancer suffered depression, a loss of confidence, withdrawal and different levels of frustration. Some of the women noted that their partners had difficulty coping, getting time away from work to support them and were distressed.

There were also financial problems as a result of time off work. One woman lost her business and another was unable to seek employment. The support from the Accident Compensation Corporation (ACC) was described as "variable."

Compensation

Given the enormity of the impact of these errors on the women, the lack of financial compensation is totally unacceptable and simply adds insult to injury. The women quite rightly believe they are entitled to monetary compensation to make up for the hardship and loss they have suffered. They are not going to get that from ACC which has so far only provided payments for two of the women. ACC is not in the business of making realistic compensation payments to those who as a result of laboratory stuff-ups undergo grossly disfiguring treatment they do not need.

A life sentence

The report acknowledges the life sentence each of the women must now come to terms with:

"The collective narratives paint a picture of emotions ranging from despair and anger to reconciliation and acceptance. The impact of these biopsy errors will remain with these women for the rest of their lives. Their disfigurement will be a constant reminder of their pain and anguish which will surface in their daily interactions with family/whanau, friends and partners as they struggle to come to terms with why this has happened and hope it never happens to anyone else again."

The tragedy is that this has happened before and it will happen again because both the public and private health systems will not be resourced or monitored to ensure that the much needed improvements are implemented and sustained. Nor are clinicians and other health professionals likely to suddenly start listening to the patient.

The report also makes for very disturbing reading when addressing the issue of how errors are managed:

"There are no standardised processes across laboratories for identifying, managing and reporting critical incidents involving loss, transposition or misinterpretation of anatomical pathology specimens. Accordingly there is no way of measuring the prevalence of these events or of establishing whether the current cluster represents an emergent trend."

Noting that private laboratories are not required to report serious sentinel events to the Health Quality and Safety Commission, the panel recommends that all laboratories be required to formally report such events and that nationally consistent processes be developed.

Compliance with standards for internal identification, reporting and monitoring of critical incidents should be audited by IANZ (International Accreditation New Zealand).

Other factors identified by the Panel as contributing to the risk of laboratories losing or mixing up specimens include tight reporting time frames, workforce pressures in the face of increasing demand, and a culture that does not support collaboration between laboratories.

The final section of the report contains a list of recommendations for providers, the Ministry of Health, the Laboratory Roundtable, and for ACC.

The Panel recommended that ACC consider its policies in regard to lump sum compensation for patients affected by biopsy errors, as well as its processes for responding to such claims. They must be dreaming – or living on another planet.

- http://www.health.govt.nz/publication/report-national-panel-review-breast-biopsy-errors

EXTENDING PAID PARENTAL LEAVE

At the end of July Sue Moroney's bill to extend paid parental leave to 26 weeks passed its first reading in Parliament amid loud cheers from the Labour and Green party ranks. The bill was supported by the Maori party, United Future and the Mana party which gave Labour the slender majority required to see the bill reach its next stage.

Labour MP Darien Fenton said the bill would relieve pressure on working parents who are returning to work early because of economic pressures.

The bill then went to a select committee. A coalition of groups – ***26 for babies*** – formed to show there is strong public support for extending paid parental leave. The coalition brings together child and parent advocates, health groups, breastfeeding organisations, and representatives of women and working women in a campaign focused on New Zealand's smallest citizens – newborn babies.

New Zealand is lagging well behind other countries in terms of the amount of paid parental leave available to parents. Research has revealed there are many health, social and economic benefits of providing longer paid parental leave.

Submissions on the bill closed on 5 October.

26 for babies is planning an entertaining and informative meeting on 23 October to garner support for the campaign. See page 8 for details.

- **http://26forbabies.org/**

THE TRUTH ABOUT THE LATEST HERCEPTIN TRIALS

The way the media has reported the latest findings on two studies which explored different treatment durations of Herceptin is a testament to how gullible reporters have become. Admittedly accessing the facts took some time trawling through the press releases from Roche and the Breast Cancer Aotearoa Coalition which were repeated ad nauseam on media websites.

The search for what the researchers actually said about the results of the HERA and PHARE trials finally resulted in finding a very different perspective to that trumpeted in the headlines in mainstream media.

The data from the two different trials were presented at the European Society of Medical Oncology (ESMO) conference in Vienna on 1 October. The subsequent hype around the reporting of the results had both studies being presented as great news for Roche when they are not. The headlines also trumpeted 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 HERA trial

The results from the HERA (HERceptin Adjuvant) study revealed that one year of treatment with Herceptin (trastuzumab) is as good as two years of treatment for women with HER2 positive early breast cancer. Roche was of course hoping that the results would show that two years was better than one, and was preparing to file for regulatory approval for two-year use. With the patent for Herceptin due to expire in 2014, the results have put paid to Roche's ability to squeeze more value out of its over-priced drug. Some reports suggested that the result cost Roche the $1 billion-a-year boost in sales that it was hoping for.

The PHARE trial

In presenting the results of the PHARE (Protocol of Herceptin Adjuvant with Reduced Exposure) study Professor Xavier Pivot said the results were "inconclusive," but showed a "trend in favour of 12 months treatment" rather than six months. He said his team was carrying out deeper analysis of the data and would present more results in December. "The results probably won't give a black and white answer and the researchers will probably need to look at subsets of patients to see who benefits from six months of treatment and who should get a full year," he added.

As Roche faced a loss of up to $1.5 billion in revenue from Herceptin should the six months treatment regime be shown to be just as effective as 12 months, the drug company was quick to issue a press statement saying that the PHARE trial confirmed the one year's trial was the best length of treatment. They went further in claiming that women who got six months of Herceptin were 28% more likely to die or have their breast cancer recur than those who got 12 months of Herceptin.

Not so, said the professor

Professor Xavier Pivot, an oncologist at the University of Franche-Comte who led the PHARE study, responded immediately with a statement saying

that the Roche statement wasn't accurate. While the PHARE trial showed a trend toward a year being better than six months, the data wasn't statistically significant. So while investigators couldn't say that six months are just as good as a year, they also couldn't say that a year is better.

Data still developing

Professor Richard Gelber, the senior biostatistician on Roche's own trial, agreed that the French study was inconclusive. PHARE hasn't been going long enough for the data to be mature, he said. As the data is still developing, he advised doctors to wait at least a year before telling the public six months' treatment is inferior. This is of course not the message that Roche wanted told.

Billions of dollars are at stake as doctors and health systems around the world attempt to come to grips with the data presented in Vienna. If researchers can show that six months of treatment are just as good as or better than a year, public and private health systems as well as women with HER2 positive breast cancer stand to gain. For example, in countries that cannot afford the cost of 12 months of Herceptin, governments would be able to offer women six months of Herceptin.

It is very disturbing to see how the results of these two trials have been presented in the media. The AWHC is also aware that Roche was quick to contact any reporter who didn't spin the story the way they want it spun.

Previous articles on the history behind the promotion of this controversial and very toxic drug can be found on the AWHC's website.

PREVENTING OVERDIAGNOSIS

"Preventing overdiagnosis: challenges and opportunities for the Cochrane Collaboration" was the topic of one of the short symposia held during the Cochrane Colloquium held in Auckland at the beginning of October.

Author and senior research fellow at Bond University in Australia, Ray Moynihan, was one of three speakers. He announced that the Cochrane Collaboration is contributing to the overdiagnosis of disease by confirming the wider definitions of disease, but he also believed that Cochrane was well placed to do something about it.

Ray Moynihan who is undertaking a PhD on Overdiagnosis described overdiagnosis as a modern epidemic that occurs when a person is diagnosed with a disease that would not harm them. It results in the over medicalisation and over treatment of the human condition and is driven by the changing diagnostic technology that discovers a tiny abnormality that is benign. Screening that detects cancers that will not harm or kill is also part of the problem along with the widening of the definition of various diseases, another major contributor to epidemic of overdiagnosis.

He referred to the evidence that showed new diagnoses had raised the rates for five cancers, but the death rates have remained stable. Cancer is just one aspect of the overdiagnosis problem as it also includes asthma, pulmonary embolism, kidney disease, cholesterol, hypertension, ADHD, as well as thyroid, lung, breast and prostate cancers and melanoma.

A study of the panels that widened the definition of many diseases revealed that most of the panelists have strong ties to the pharmaceutical industry – the manufacturers of drugs used to treat these diseases.

Jenny Doust, an Australian GP and professor, supplied a very practical insight into the impact that the epidemic of overdiagnosis is having on many patients who go to see their GP. She described how not all patients with a disease will benefit from health care interventions. No-one wants to pay for treatments that are harming patients, she said. Her challenge to the Cochrane Collaboration was to ensure that CC reviews state explicitly how the results of trials affect the wider population. Most of this information is already in the CC reviews but it is often hard to find.

The final speaker of the session was Anna Noel-Storr who is from the UK and is the Trials Search co-ordinator on the Cochrane Dementia and Cognitive Improvement Group. Her presentation focused on the risk of overdiagnosis in dementia. She is also concerned about the widening definitions of conditions such as mild cognitive impairment and described how the boundaries between normal and dementia fluctuate.

Anna supported Ray Moynihan's call for experts with ties to the pharmaceutical industry to be excluded from being appointed to scientific panels.

The first preventing overdiagnosis conference will be held in the USA in September 2013:

www.preventingoverdiagnosis.net/

AWHC GENERAL MEETING 27 September 2012

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

- Financial reports
- Grant applications
- Ethics committee meeting
- Cervical Screening governance group
- HDC Medico Legal conference
- Cochrane Colloquium

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

AWHC NEWSLETTER SUBSCRIPTION

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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 October 2012:

Waitemata DHB (Website address: www.waitematadhb.govt.nz)
Waitemata Hospital Advisory Committee meeting starts at 11am on Wednesday 31 October 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.

The **combined Waitemata DHB and Auckland DHB** Community & Public Health Advisory Committee meeting starts at 2pm on Wednesday 10 October 2012.

Auckland DHB (Website address: www.adhb.govt.nz)
The Hospital Advisory Committee meeting will be held at 9.30am on Wednesday 24 October 2012 followed by the Full Board meeting at 2pm. Both meetings will be held in the A+ Room, Clinical Education Centre, 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 3 October 2012 at 19 Lambie Drive, Manukau City.

The Hospital Advisory Committee meeting will be held at 9am on Tuesday 23 October 2012 and will be followed by the Community & Public Health Advisory Committee meeting at 12.30pm 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

MORE TIME FOR BABIES

Auckland 26 For Babies is organising a meeting, ***More time for babies*** at 7pm on Tuesday 23 October 2012 at the Fickling Centre, 546 Mt Albert Road, Three Kings, Auckland.

Speakers include comedian Michele A 'Court, TV presenter Jacquie Brown, Labour MP Sue Moroney, Green MP Jan Logie, Marama Davidson from Te Wharepora Hou and economist Professor Tim Hazledine.

For further information or to join the coalition contact Leonie at akcentre@womenz.org.nz