AUCKLAND WOMEN'S HEALTH COUNCIL

NEWSLETTER

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2014 ANNUAL REPORT FROM NATIONAL WOMEN'S

National Women's released its Annual Clinical Report for 2014 in August 2015. The report is the 22nd in the current series.

The 283-page report contains a wealth of statistical information on the 7353 women who gave birth at NWH in 2014 and the 7551 babies they gave birth to, plus the 47 women who gave birth before they actually got to the delivery unit. In 2014 there were 143 sets of twins (147 in 2013) and 4 sets of triplets (4 sets in 2013).

Normal births decrease

The intervention rates have risen slightly over the past year, continuing an ongoing trend. In 2014 53.1% of mothers had a spontaneous vaginal birth, and 0.9% had a vaginal breech birth.

Only 44.5% of first-time mothers had a spontaneous vaginal birth, compared to 43.6% in 2014. The report states that "the spontaneous vaginal birth rate has remained consistently low since 2004," and comments that the way to begin to improve this statistic is by focusing on reducing primary caesarean section in first-time mothers from its current 35.8%. When labour is induced the primary caesarean section rate in these women is 58%.

Induction of labour

In 2014 31% of mothers had an induction of labour, compared to 33.8% in 2013. The report notes that "this may be due to a review of the evidence base for induction and implementation of a regional guideline in late 2014." For the first time there has been a decrease in induction rates for both first-time mothers at term – 40% to 39% – and for multipara from 30% to 26%. In December 2014 a formal booking system was introduced for both elective and acute inductions which may result in further reductions.

Premature rupture of membranes at term, diabetes, post-dates, and suspected small for gestational age were the most frequent reasons for induction of labour in 2014.

When post-dates was the primary indication for induction, 7% occurred prior to 41 weeks (down from 12% in 2013) and 14% occurred at or beyond 42 weeks (up from 12.5% in 2013, but down from 16% in 2012 and 22% in 2011). The report notes that the emergency caesarean section rate is higher following induction than following spontaneous onset of labour for both first-time mothers and mothers expecting subsequent babies who have not had a previous caesarean.

34.6% caesarean section rate

In 2014 the caesarean section rate was 34.6% compared to 34.7% in 2013, 33.4% in 2012, 32.5% in 2011, and 20.8% in 1995 and 1996. This year the difference between the caesarean section rate for first-time mothers was 35.8%, (compared to 36.8% in 2013 and 34.1% in 2012), and for mothers having subsequent births 33.5%, (compared to 32.8% in 2013 and 32.7% in 2012).

The report points out that the caesarean section rate at National Women's is the highest it has ever been, with the most common reason for a caesarean section being a repeat caesarean. This is followed closely by first-time mothers having a caesarean before labour or following induction of labour.

The report states that it is of concern that at NWH in 2014, 129 first-time mothers "had an elective caesarean section for the indication of maternal request; representing 19% of all nulliparous caesarean sections, and up from 16% in 2012."

The report also 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

For the past two years the rate of forceps and ventouse deliveries (combined under the term "instrumental vaginal birth") has remained stable at 11.5%. In 2011 the rate dropped below 12% for the first time since 1997, with a rate of 11.1%. In 2014 the rates were 20.8% for first-time mothers, and 4.2% for 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 2014 there was a significant increase in the numbers of mothers who had a double instrumental birth – 63 mothers compared 41 mothers in 2013, and 32 mothers had an attempted vaginal instrumental birth prior to an emergency caesarean section, down from 48 in 2013.. The report comments that "close attention to this would be prudent in 2015" as this is associated with more severe outcomes for both mother and baby.

Epidurals

Epidurals continue to be the most common form of analgesia for the management of labour pain (67.5% of women in labour), with women having an induced labour being the most frequent users (68.3% compared with spontaneous labour 40%). For first-time mothers it was 80.4% if labour was induced and 67.5% if labouring spontaneously. For multipara it was 51.5% if labour was induced and 33.7% if labouring spontaneously.

The highest use of epidurals is in first-time mothers with a private obstetrician – 83.6%.

Breech birth

Breech births made up 8.1% of all births in 2014 compared to 5.4% in 2013. Of the 294 singleton babies presenting as a breech, 247 (84%) were delivered by caesarean section. Among the 35 breech births at 32-36 weeks the percentage of caesarean deliveries was 91%, despite there being no evidence to support such a practice. For the 201 breech births at 37 weeks and over the percentage of caesarean sections was 96%.

The report notes that the NWH guideline on Breech Birth was updated in May 2012 to reflect changes in guidelines internationally.
"Considerable effort is made in counselling and advising women who wish to attempt vaginal breech birth. Although only a small number of obstetricians will consider conducting vaginal breech births, the desire to accommodate this option is such that these obstetricians make themselves available sometimes out of roster in order to accommodate the wishes of women who make this choice."

Water birth

There were 35 babies born in water in 2014 - two mothers were cared for by NW LMC midwives, and 33 were cared for by independent midwives.

All were live births with one baby being admitted to the NICU.

Postpartum Haemorrhage
The postpartum haemorrhage (PPH) rate remains a cause for concern. It is associated with the increasing caesarean section rate. The overall primary PPH rate (500mls and over) was 35.5% (same as for 2013).

It was 19.2% following a spontaneous vaginal birth compared to 70.9% following an emergency caesarean section and 50.8% following an elective caesarean section. It also varied by onset of birth, from 27.8% in spontaneous onset of labour to 35.9% in induced labour.

Peripartum Hysterectomy
Ten women had an emergency postpartum hysterectomy in 2014, compared to five in 2013. Hysterectomies following birth are associated with caesarean sections.

Maternal Mortality
There were no maternal deaths at National Women's in 2014.

Breastfeeding
In 2014 77.7% of mothers were discharged from National Women's exclusively breastfeeding their babies.

- A copy of the 2014 Annual Clinical Report is available at: http://nationalwomenshealth.adhb.govt.nz/health-professionals/annual-clinical-report/yearly-annual-clinical-reports

NO ACTION ON CLINICAL TRIALS ON UNCONSCIOUS PATIENTS

Despite promising consultation on the practice of enrolling unconscious patients in clinical trials the Health & Disability Commissioner has so far remained remarkably silent on the issue. As noted in the February issue of the AWHC newsletter, at the end of 2014 Commissioner Anthony Hill advised in a letter to the AWHC that the time had come "to commence a more fulsome public information and consultation process" on the vexed issue of "research involving incompetent consumers" and whether Right 7(4) requires amendment.

He stated that he was in the process of finalising details on the consultation process that will be undertaken and expected to release details for this "early in the New Year." He also confirmed he was preparing for a public consultation on the issue at the HDC conference, "*Improving the Consumer Experience"* which was held in Wellington in March this year and that a consultation was planned for this year.

The Council waited and waited, and then followed this announcement up with an email that was sent to the Commissioner at the beginning of July, but as the end of the year is rapidly approaching and the Commissioner has not responded to our email about when we can expect to receive details on the consultation process, we can only assume he is either procrastinating or he has no intention of embarking upon any form of consultation.

Warning: Big pharma may be hazardous to your health

By Barbara Holland

New Zealanders have once again been shown that weak regulatory standards can put consumer health and safety at risk. This time the identified risk is from the lack of truth-telling by the pharmaceutical industry. Recent research has shown that many advertising claims in leading NZ healthcare magazines were unsupported by any reference to rigorous research trials and some claims were not consistent with a trial's findings.[1]

Misleading drug industry claims hurt us all. Patients may derive no benefit at all from a particular new drug when they could have had an older proven drug. Worse, they may be harmed by reliance on advertised claims. There is no obligation to show whether new drugs are worse than old ones, only that they have an effect. The predatory behaviour of big pharma worldwide has repeatedly shown they are willing to put profits before patients by ignoring or trivialising harms, and many have failed to inform authorities about these likely adverse outcomes both pre-and post-marketing.

Doctors don't have time to review the research about all the medicines they prescribe and like their patients they rely on assumptions that the regulatory agencies carefully scrutinise the data before drugs are allowed on the market. We also assume that advertising about therapeutic products will meet the Therapeutic Products Advertising Code standards.

NZ and the USA are the only two countries in the world that allow direct-to-consumer advertising of drugs. The drug industry knows their massive marketing investment in advertising and CME (Continuing Medical Education) pays off by influencing prescribing behaviour as well as patient demand.

Weak regulatory controls in NZ

As Otago University Professor Les Toop commented in regard to the revelations from this NZ study, "the self-governing Advertising Standards Authority in New Zealand, and the self-monitoring codes of practice – designed and policed by industry – are both lax and complaints and sanctions rarely applied. Penalties for breaches, even if identified, are absent or minimal." [2]

There are no fines for illegal drug marketing in NZ even though patients may be harmed, for example, when unproven longer-term use or off-label use creates problems. The public carries the risk and the drug companies collect the profits.

NZ health care policy makers have been seduced into creating closer business relationships with big pharma under the guise of enhancing public-private partnership trading benefits. Peter Gotzsche, in his book *Deadly Medicines and Organised Crime: How big pharma has corrupted healthcare,*[3] refers to this kind of arrangement as "institutionalised cooperation" and wryly observes that "ideologically driven politicians are bad for public health" (p118). Indeed, he contends, "there is a fundamental conflict between the industry's desire for profit and the government responsibility for public health" (p38).

Clinical trials

We also have weak controls on clinical research trials involving NZ participants that allow international drug company research sponsors to exercise full discretion over evaluation of any adverse events occurring while a trial is in progress as well as interpretation and publication of the research outcomes. In the absence of full clinical trial data being publicly available for independent researchers to examine the results or replicate the trials in the interests of good science, doctors and patients are not in a position to have confidence in safety and efficacy claims promoted by drug companies, nor to adequately consider the harms.

AllTrials campaign

The AllTrials.net campaign is making strenuous efforts to achieve this requirement to have every clinical trial logged on a public register along with the full set of data and their conclusions, including past studies that have not been progressed to commercial development. The American based Clinicaltrials.gov also has a register of research trials but the FDA has no corresponding powers to take enforcement action when study reports are not posted, even when these have not been forthcoming years after the study has ended. NZ does not have a public register of its own for posting all NZ-based clinical trials along with full study data and results.

Gotzsche, who co-founded the world-leading Cochrane Collaboration that sets the gold standard for clinical trial reviews, argues that in view of the shocking history of deceit and fraudulent behaviour in research and marketing, which puts patients' lives at risk, responsibility for doing drug trials should be taken away from the drug companies (p166). In the US and Europe, he notes, [licit] drugs are the third leading cause of death after heart disease and cancer (p117).

Many drugs do have a vital place in the range of useful treatment options in our healthcare. Others are often shown to be no better than placebo. But ongoing trust in the system for evaluating the benefits/harms of these products, as well as in the doctors who prescribe them, becomes eroded when the truth is hidden by the drug industry for the sole purpose of maximising their profits. Gotzsche claims that regulatory bodies and government agencies, unwittingly or otherwise, then become "complicit in the exploitation of patients for commercial gains, as the patients are a means to an end and are treated sub-optimally as well" (p140). Our regulatory system has already flexed to become more permissive under industry pressures that clearly don't protect consumer interests.

Whilst our current government hides behind closed doors in the TPPA negotiations about trade for mostly private sector gain the pharmaceutical trade matters to each of us. Under our publicly-funded health system the benefits and harms are spread across the whole population, so openness and transparency about managing drug safety is paramount.

Drug marketing ban needed

We could make a useful contribution to protecting NZ public health and the safety of individual patients by

eliminating marketing ties with big pharma altogether. Government assures us that our drug buying agency, Pharmac, will carry on purchasing the medicines we need (and at the right price). Useful drugs don't need extra marketing. So why do we enable drug company advertising in *NZ Doctor* and *Pharmacy Today* and on our television screens in our homes daily to tell us what our problems are and which drugs we need to fix them?

It is time to ban direct-to-consumer advertising from our NZ shores altogether – right now.

References:

1 Ma A. & Parkin L. *"Randomised controlled trials cited in pharmaceutical advertisements targeting New Zealand health professionals: do they support the advertising claims and what is the risk of bias?"* NZ Medical Journal 4 September 2015. Vol 128 No 1421

2 Toop L. & Mangin D. "*The art and science of marketing medications*." NZ Medical Journal 4 September 2015. Vol 128 No 1421

3 Gotzsche P. 2013. *"Deadly Medicines and Organised Crime: How big pharma has corrupted healthcare".* Radcliffe Publishing Ltd, UK.

AWHC GENERAL MEETING 27 August 2015

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

- Financial reports
- Grant applications
- Ethics committees
- 2015 Cartwright conference
- Symposium for Judi Strid

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 September/October 2015:

Waitemata DHB (Website address: www.waitematadhb.govt.nz)
The Waitemata Hospital Advisory Committee meeting starts at 11am on Wednesday 23 September 2015 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 14 October 2015.

Auckland DHB (Website address: www.adhb.govt.nz)
The Hospital Advisory Committee meeting will be held at 9.30am on Wednesday 16 September 2015 followed by the Full Board meeting at 2pm. Both meetings will be held in the A+ Trust Room in the Clinical Education Centre, Level 5, Auckland City Hospital.

Counties Manukau DHB (Website address: www.cmdhb.org.nz)
The Hospital Advisory Committee meeting will be held at 9am on Wednesday 21 October 2015 at Ko Awatea and will be followed by the Full Board meeting at 1.30pm.

The Community & Public Health Advisory Committee meeting will be held at 1.30pm on 30 September 2015 at 19 Lambie Drive, Manukau.

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

PHARMAC Medical Devices Forums

PHARMAC will be holding a series of forums in DHBs around the country to provide an update on their hospital medical devices activity.

Date: Auckland – 27 October 2015 12 – 1pm
Venue: Clinical Education Centre, Auckland City Hospital.

Date: Counties Manukau – 12 October 2015 12 – 1pm
Venue: Room 106, Ko Awatea Centre, Middlemore Hospital.

For information on dates and times in Hamilton, Palmerston North, Wellington, Christchurch and Dunedin, and to register go to www.pharmac.health.nz/forums