

WOMEN'S health

update

Women's Health Action calls for urgent action on the use of surgical mesh¹

By Dr Sandy Hall

Last year a number of consumer advocacy and women's health organisations, including Women's Health Action (WHA), raised serious concerns about the use of surgical mesh. WHA has since approached Medsafe, ACC and Health and Disability Commission, and the College of Obstetricians and Gynaecologists to find out more about the use of mesh in Aotearoa New Zealand, while continuing to monitor developments overseas.

As a result of these discussions and increasing evidence of risk associated with mesh use from overseas, **Women's Health Action is calling for a register of all New Zealand mesh surgeries to monitor the short and long term outcomes. In addition, we believe a standard informed consent process and a publicly available register of qualified and trained surgeons need to be developed. If these cannot be put in place urgently, we also suggest Medsafe should seriously consider withdrawing mesh products from the market.**

In answer to a 2014 request from WHA for their latest advice on the use of surgical mesh, the FDA responded that their 2011 advice still stands. That advice identified surgical mesh as an area of continuing concern, noting it was not proven to provide better outcomes and that "serious complications including infection, pain, incontinence, perforation of bowel or bladder, are not rare".² Further, mesh erosion and mesh contraction may lead to severe pelvic pain, painful sexual intercourse or an inability to engage in sexual intercourse. Mesh is designed to become incorporated with the body's natural tissue and therefore removal may not always be possible, or may require multiple complex surgeries.

Proving an injury claim to ACC can be problematic as time delays and complications that affect other areas of the body may make it hard to prove a link between the symptoms and the mesh surgery. As of June 2013, ACC

had accepted 297 claims relating to surgical mesh used in various types of surgery. Despite their mandated injury prevention role, ACC said that they "do not routinely inform providers or professional bodies with treatment injury information", do not regularly contact HDC and no records are kept about claims against individual practitioners. We have asked ACC to provide us with regular claim updates but they have so far not responded to this request.

WHA also approached Medsafe again stating our concerns about the lack of monitoring of both the product and the clinicians using it and about whether Medsafe should continue its approval of this product despite increasing research and concerns raised by both clinicians and consumers. Their response has been limited to a warning on their website and they are "continuing to monitor the situation".

WHA is currently working with HDC, particularly on the issues of informed consent and advocating for a specific mesh consent process to be developed. The FDA recommends patients should be informed that implantation of surgical mesh is permanent, that some complications may require additional surgery and that there is potential for serious complications which may affect quality of life. They suggest patients ask questions about why they are being considered for surgical mesh, what the alternatives are, what the effects could be, how often the surgeon has implanted this particular product and with what results, and what would happen if there were complications.³

It is clear from our discussions with these agencies, FDA advice, lawsuits overseas, the research, and the personal stories of women, there are significant problems with both mesh and its use. While we are aware that



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at least one DHB is auditing mesh use and has developed a robust informed consent process, in Aotearoa New Zealand there is no monitoring of these products, which have never been tested for gynaecological or colorectal use. Compounding these problems is the lack of specific informed consent processes where short and long term risks are discussed along with alternatives. Nor are there any registers of qualified practitioners or mandatory training requirements for use of the product which the RCOG says should only be undertaken by surgeons with additional training.

Women's Health Action is now calling for a register to be set up to monitor each use of surgical mesh. There is a precedent for this in the Mirena study and in the hip joint register which monitor the short and long term effects of these medical devices.

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In addition we believe that there is sufficient information to consider suspending the use of mesh products in gynaecological and colorectal surgery until monitoring and

standardised informed consent processes are in place.

1. Surgical mesh is generally used in place of, or in addition to sutures to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material or absorbable biologic material. In Urogynecologic procedures, surgical mesh is permanently

implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence. Surgical mesh is also used for colorectal and hernia repairs

2. FDA 2011 Urogynecologic *Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse*.

3. FDA recommendations for Health Care Providers: As stated in the Oct. 20, 2008 Public Health Notification

Mesh: A consumer perspective

Charlotte Korte is one of the many thousands of people affected by surgical mesh. In 2010 Charlotte had colorectal surgery for a bowel prolapse. She suffered severe pain and had to endure three additional surgeries to eventually remove the mesh. Charlotte's experience has had profound effects on her and her family. Despite this Charlotte, along with other consumer advocates such as Carmel Berry, is using her experience to advocate for change.

The media's reporting about surgical mesh has focused on uro-gynaecological surgery, however, surgical mesh whether used for gynaecological or colorectal surgery or hernia repairs, can cause similar complications.

Many of these complications go unreported as they often occur sometime after the surgery. Doctors are not legally required to report complications and there is no particular agency collecting this information. The onus therefore is on the patient to file their own report with agencies

such as Medsafe and HDC. However many patients may be too unwell, or may not have the necessary skills to file a report, or even know that they can do so.

Lack of cohesion within and between government departments (ACC, Medsafe, HDC and HQSC), no official monitoring of surgical mesh complications and no mandatory reporting process for doctors following it means the data and statistics available are incomplete and unreliable.

To compound the problem, removing surgical mesh is a complex operation. There are limited surgeons in New Zealand who have the necessary advanced surgical skills to achieve a complete explant.

I find it particularly abhorrent that this situation has been allowed to persist despite almost 400 claims being made to ACC, numerous calls on other agencies to investigate further, a large amount of clinical evidence from overseas including warnings by the FDA, and multiple lawsuits internationally.

This is not scaremongering by the media as some surgeons have implied, this is a case of real people and their families being hurt and affected by a real problem. What my family and I have had to endure, is terrible. And there are many thousands of women and men who are going through this same ordeal. No one should have to go through this. I know how hard it has been for me and I do not want this to happen to anyone else.

I believe an official audit of mesh use in New Zealand needs to be implemented involving both DHB and private hospital services. A register of all mesh implants needs to be established, along with a register of qualified doctors who are trained in its use. If Medsafe cannot provide protection for New Zealanders and there is no capacity to regulate and test medical devices that come onto the market, it is also time to reform this system and ensure medical devices such as mesh are properly tested.

The Health Select Committee Report – the Proper Use of Breast-milk Substitutes and Mother Blame

By Isis McKay

In November, the Health Select Committee released its report on the 'Inquiry into improving child health outcomes and preventing child abuse, with a focus on preconception until three years of age'. The inquiry was initiated in 2012 to find what practical health and social interventions can be made to promote children's wellbeing in New Zealand, prevent child abuse, and break cycles of disadvantage, particularly from pre-conception to three years of age.

The two volume report includes an overview and a list of 130 recommendations calling on the government to take a proactive, health-promotion, disease-prevention approach to improve children's outcomes and diminish child abuse.

In response, the government has accepted in full, or in part, 109 of the recommendations. Another 14 recommendations were noted, and seven were rejected. Recommendations not accepted include regulatory and fiscal measures to improve healthy eating such as taxes on fatty foods and sugary drinks; and regulatory or legislative recommendations such as compulsory addition of folic acid to bread, introduction of additional smokefree areas and restrictions on marketing of unhealthy foods and beverages to children.

Although the Health Committee report made comprehensive recommendations, a

large number of initiatives which address the recommendations in full or in part were already in place prior to or had been progressed since the Committee initiated its inquiry. Additional initiatives may be announced in the 2014 budget.

WHA was pleased to see that both the Health Select Committee's recommendations and the government's response recognise the importance of investing in quality maternity care and breastfeeding support. A 2013 report 'The need to invest in babies' provides compelling evidence that supporting new mothers in ways that make exclusive breastfeeding practicable for them, should be a key priority for investment.¹

The Health Select Committee made a number of recommendations to ensure the proper use of breast-milk substitutes, including recommending that if the current self-regulatory, voluntary system for the marketing of breast-milk substitutes is not working effectively regulation should be implemented within the next 18 to 24 months. In its response, the government affirmed that the current voluntary regime is to the highest international standards and makes no mention of introducing regulations should this be found not to be the case.

Following a 2012 consultation Quigley and Watts Ltd² reported that health professional and consumer representatives expressed dissatisfaction with the voluntary INC Code

and the self-regulation model. There was concern from representatives about companies failing to comply with the [voluntary] WHO Code and/or the INC Code. Health professionals and consumers were concerned these companies would market formula inappropriately and compromise breastfeeding rates. Industry representatives were concerned these companies put the whole industry's reputation at risk.

The Committee report also makes recommendations regarding early intervention, pre-conception care, social and economic determinants of health, nutrition, obesity, alcohol and drugs, maternity care, leadership, immunisation, oral health, early childhood education, information sharing, and research on children.

The long-term aim as stated in Health Committee's report is that parents should be as healthy as possible prior to conception, so the next cohort of children is given the best possible start in their first few years. It recommends an ongoing media campaign urging prospective parents to get healthy before conception and to focus on the welfare of their 'future babies'. The report also claims that identification of 'vulnerable mothers', as early as possible during pregnancy, followed by appropriate

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intensive wrap-around services, in line with the government's action plan for children, should prove to diminish later childhood dysfunction and abuse.

With such a strong focus on the pre-conceptual and antenatal period of women's reproductive lives in this report it is important to be attentive to what researchers have identified as a 'serious and pervasive' culture of "mother blame" amongst frontline services and providers that interact with families including health, welfare, education and violence intervention services.³

Davies and Krane argue that child-centred policy and practice inevitably entails the evaluation of women-as-mothers and mothering functions or capacities. These evaluations are often influenced by socially constructed ideas of "good mothers". Research indicates that women who do not fit society's idealised view of motherhood, or who behave in ways not considered appropriate for mothers, carry a burden of societal and professional disapproval and judgement. In a submission to the Health Committee, WHA recommended that policy, legislation and other activities intended to prevent child abuse and improve children's health outcomes must be attentive

to the dynamics of 'mother blame' and its effects.

While it is encouraging to see such a comprehensive list of recommendations from the report and a positive response from the government, it is important any initiatives intended to improve outcomes for children focus on improving the wellbeing of, and support for, their mothers and family whānau through a women and child-centered Whānau Ora approach. All actions to prevent child abuse and improve children's health outcomes should be informed by the government's human rights responsibilities, be evidence-based and coordinated across government.

A full copy of the Health Select Committee Report can be found at <http://www.parliament.nz/resource/0002018580>

For a copy of the Government Response go to: <http://www.parliament.nz/resource/0002200372>

1. 'The need to invest in babies'- *A Global Drive for Financial Investment in Children's Health and Development through Universalising Interventions for Optimal Breastfeeding* BPNi / IBFANAsia 2013

2. Key Stakeholder Consultation to Complete the Evaluation of the Effectiveness of the WHO International Code of Marketing of Breast-Milk Substitutes in New Zealand - Report to the Ministry of Health

3. Davies, L & Krane, J. 1996. 'Shaking the legacy of mother blame: no easy task for child welfare', *Journal of Progressive Human Science*, Vol 7(2) 3 - 22.

Latest abortion statistics in New Zealand: brickbats and bouquets

The Abortion Supervisory Committee (ASC) report for the year ended 30 June 2013 was released in mid December and provides a fascinating insight into the uptake of abortion and the provision of abortion services in Aotearoa New Zealand. George Parker, WHA Senior Policy Analyst, has reviewed the report and highlights both the positive developments and on-going challenges to ensure women in New Zealand can access high quality, women-centered, timely abortion services in their own regions.

There has been a further decline in total abortion numbers, ratios and rates in New Zealand, with 14,745 abortions performed in the 2012 calendar year compared to 18,382 abortions in 2007. This decline has been a continuing trend, with the current total abortions performed the lowest since 1995.

It is not yet clear what is contributing to this decline and it is likely a combination of factors. The ASC speculates that increased education and importance placed on the use of contraception may provide some explanation, and the uptake of Long Acting Reversible Contraceptives (LARCs) is another likely contributing factor. However, research is needed to understand the trend.

Notably, over 50% of women having abortions report using no contraception, and the ASC is now requiring every operating surgeon to report on the type of contraception provided to women at the completion of the procedure. Ensuring contraception is offered and discussed is a positive development, however women's decisions about contraception must ultimately reflect their own informed choice rather than provider preference.

The report also provides an update on the establishment of new abortion providers in Southland, Tairāwhiti, and the Family Planning Clinic in Tauranga. These new providers are helping to ensure women can access abortion services in their own regions without the stress, cost and inconvenience of travelling to main centres. Some anti-choice groups have expressed concern that local access to services will result in an increase in abortion numbers but this is not supported by the data.

Feedback is very positive about the innovative medical abortion service being offered by the Tauranga Family Planning Clinic and this may provide an excellent model for extending abortion services into other areas that currently do not provide abortion services to their local population of women.

The timeliness of abortions remains an on-going issue in New Zealand, with abortions being performed later than necessary increasing the risk of poor outcomes. While there have been improvements in timeliness, especially in smaller centres, this remains a significant challenge for many providers across the country. Uptake of medical abortion as a choice of method remains low, which likely reflects barriers in how medical abortion services are being provided and that a number of abortion providers around the country still are not offering a choice of method.

The full report can be accessed from: http://www.parliament.nz/en-nz/pb/presented/papers/50DBHOH_PAP25739_1/abortion-supervisory-committee-report-for-the-year-ended

Getting behind the Universal Periodic Review?

By Dr Sandy Hall

Every four years, each country in the United Nations has its human rights record reviewed by the UN Human Rights Council, a process known as the Universal Periodic Review (UPR). On January 27th 2014, New Zealand's human rights were assessed, using reports from the government, Human Rights Commission, and NGOs.

WHA participated in the UPR process through its membership to the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW) Coalition of New Zealand NGOs. Made up of tens of organisations, representing thousands of women, the coalition was formed to progress gender equality.

In its report, the CEDAW Coalition of NGOs requested that the UPR urge the New Zealand government to develop an Action Plan for women which "must target violence against women, pay inequality and pay inequity, the status of Māori and Pacific women, and the importance of welfare and employment related reforms on the lives of women and their families. The status of disabled women must also be addressed".

The Coalition's report also highlighted issues around health, including:

- The discrimination suffered by women both as carers and as disabled people
- The lack of health services for Lesbian, Gay, Bisexual, Transgender, Intersex and Queer (LGBTIQ) populations and poor information collection and research
- The serious and ongoing health and other disparities between Māori women and Pacific women and the rest of the population

On January 30th, the UPR working party reported back its responses to the submissions made by government and by the Coalition and other NGOs. It made a number of recommendations to the New Zealand government concerning violence against women, the gender pay gap, the rights of children, the human rights of Māori, the Christchurch rebuild, and the human rights framework in general.

There has been very little media comment and limited public awareness. However, there is still time to attend the post-UPR debrief meeting in Auckland on March 25th, hosted by MFAT, the Ministry of Justice, Te Puni Kokiri and the New Zealand Human Rights Commission to learn more about New Zealand's UPR and provide feedback to delegation members and the Commission. Email alexandra.pierard@mfat.govt.nz to RSVP.

The actions to be taken as a result of the UPR recommendations will be set out in a National Plan of Action for Human Rights to be prepared by the Human Rights Commission.

Consumer engagement: Nothing about us without us

By Maggie Behrend

WHA has had a special interest in consumer perspectives and representation since it came to national prominence in 1987 through its involvement in the Cartwright Inquiry. The ensuing Cartwright Report highlighted a number of issues with health care practice in Aotearoa New Zealand, challenging the provider-centred model of care.

Since the Cartwright Report, WHA has continued to advocate for consumer voices to be considered in policy, and health care planning and implementation, and to promote patient-centred health care, in which patients are supported to make informed decisions about their health.

On February 12th, WHA invited representatives from Auckland, Counties Manukau, and Waitemata DHBs to present their DHBs' strategies at engaging maternity service users to an audience of mainly LMCs, DHB staff, and community provider organisations.

The DHB representatives discussed a shift within health care toward greater recognition of the importance of feedback and designing health care to be responsive to those who utilise the services. This approach is supported by the Ministry of Health, which measures whether DHBs' "maternity services ensure a woman-centred approach"¹ and requires DHBs to collect feedback from their maternity patients and report annually on how feedback has been responded to.

The DHB representatives each described the tools available to enable them to obtain feedback, and how it is used.

Auckland DHB collects feedback from patients and their friends and whanau in person, through paper and electronic feedback forms



and through Reo Ora. Reo Ora is an online community panel made up of thousands of members, who are regularly surveyed. In addition, the DHB holds a monthly maternity services clinical governance group which includes consumer representatives. ADHB is responsive to consumer voices: it replies to individual complaints and works to address the issues raised, and uses feedback from surveys to inform the development of services.

At the recommendation of its Maternity Review, Counties Manukau DHB arranged focus groups of high-needs patients who had recently used their maternity services to gain insight into a number of key areas. It also has two consumer representatives on its Maternity Quality and Safety Governance Group. CMDHB has used consumer feedback to inform the development of new online tools, key messages, and patient surveys.

Similarly, Waitemata encourages a consumer perspective through surveys of patients and friends and family, consumer representatives on clinical governance groups, and through Healthpoint forums. WDHB also holds targeted

focus groups with teen mothers and Pacific Island women. Feedback from each of these avenues informs its service planning and design.

As this forum demonstrated, health care in New Zealand has evolved since the Cartwright Inquiry and increasingly recognises the value of patient-centred care and engaging consumers in authentic ways and in all aspects of care. Health professionals can ensure progress continues by encouraging feedback, explaining how feedback can be made, and ensuring feedback is used to improve services to better meet the diverse needs of consumers.

WHA would like to thank the speakers from each of the DHBs: Pam Hewlett and Sarah Devine, Gwynette Ahmu, and Emma Farmer. Slides from the Engaging Consumers in Maternity Services regional forum are available online: www.womens-health.org.nz/past-events.html. If you would like to be informed about future consumer forums, please email maggie@womens-health.org.nz.

1. Ministry of Health, 2011. New Zealand Maternity Standards: A set of standards to guide the planning, funding and monitoring of maternity services by the Ministry of Health and District Health Boards.

NOTICEBOARD

SAVE THE DATE

CARTWRIGHT ANNIVERSARY SEMINAR - JULY 24TH

BIG LATCH ON - AUGUST 1ST AND 2ND

SUFFRAGE BREAKFAST - SEPTEMBER 19TH

<http://www.womens-health.org.nz/events.html>

HUMAN RIGHTS WORKSHOP

27 MARCH - AUCKLAND

Learn about the Human Rights Act and what to do if you, or someone you know, is treated unfairly because of their race, colour, age, sex or religion or because they have a disability. Email sarahp@hrc.co.nz.

PLAIN PACKS SUBMISSION

CLOSE 28 MARCH

Plain Packs Submission and Media Toolkit can be found online at: <http://www.sfc.org.nz/pubsresources.php>

FERTILITY WEEK

7-13 APRIL

Be Fertility Fit is a campaign to raise awareness of the impact of five key factors on fertility: age, timing of sex, weight, alcohol and smoking. www.fertilityweek.org.nz/

PACIFIC HEALTH PROMOTION AND SOCIAL DETERMINANTS OF HEALTH

10 APRIL - AUCKLAND

This workshop traces the history of 'Pacific health promotion' in Aotearoa New Zealand and discusses how determinants of health can be addressed to produce health equity, wellbeing and success for Pacific peoples. www.hauora.co.nz/

YOUTH WEEK

17 - 25 MAY

Youth Week is about recognising the amazing contributions and achievements of young people in New Zealand. This year's theme is 'Be the Change'. www.arataiohi.org.nz/YouthWeek

YOUTH COLLABORATIVE ANNUAL HUI

9 - 11 JULY - CHRISTCHURCH

In 2014 The Collaborative's annual hui will be bigger and better than ever and will have an expanded format that includes a pre hui 1 day workshop. <http://collaborative.org.nz/>

INTERNATIONAL AIDS CONFERENCE

20 - 25 JULY - MELBOURNE

<http://www.aids2014.org/>

NZ POPULATION HEALTH CONGRESS: CONNECTING COMMUNITIES, POLICY AND SCIENCE

6-8 OCTOBER - AUCKLAND

The NZ Population Health Congress is jointly organised by the Public Health Association, The Public Health Forum of New Zealand and the New Zealand College of Public Health Medicine. The Congress will provide a variety of opportunities to learn, discuss and debate advances in areas of population health thinking and practice. www.pophealthcongress.org.nz/nzphc14



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