AUCKLAND WOMEN'S HEALTH COUNCIL

NEWSLETTER

JULY 2013

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INFORMED CONSENT IN THE AGE OF TARGETS

Over the past 5-10 years the health system has become increasingly focused on meeting targets set by the Minister of Health. As a result District Health Boards (DHBs) and Primary Health Organisations (PHOs) come under considerable pressure to get their populations tested, screened, and vaccinated regardless of the legal requirements to obtain fully informed consent before subjecting anyone to these interventions and other resulting health procedures.

While targets such as shorter waits for cancer treatment, improved access to elective surgery and shorter stays in hospital emergency departments are important goals, there are often complex factors involved that need attending to but are overlooked or ignored when health agencies are put under immense pressure to meet the Health Minister's targets by a certain date.(1)

Two of the health targets – increased immunisation and more heart and diabetes checks – are being achieved by questionable methods that include ignoring the fact that the majority of the people being targeted are well, need to be fully informed about the limitations and risks of these interventions, and permitted to make their own decisions about whether to take part in such health programmes.

Of even more concern are the heart and diabetes checks currently being heavily promoted, as these involve the very real risks of overdiagnosis and of being subjected to unnecessary procedures and/or treatments.

PREDICT

Few patients who visit their GP will be aware that their doctor is now using a web-based cardiovascular disease (CVD) risk assessment programme called PREDICT to undertake a CVD risk assessment. "This PREDICT-CVD programme is integrated into the GP's patient management system to allow systematic cardiovascular risk assessment and provide within-seconds evidence-based patient-tailored decision support according to national guidelines for the management of cardiovascular risk."(2)

"Patient-tailored" it maybe, but it does not represent patient-centred decision making if the patient is completely unaware or does not understand exactly what is going on.

For example, a member of the AWHC recently received a letter from her GP stating that she was due to have a blood test. The letter read:
"Our records show that you are due for a follow up blood test.
Enclosed with this letter is a Laboratory Form. Please take this with you into LABTESTS to have this blood test done.
THIS IS NON-FASTING. You can have it at any time of the day.
We will contact you if there are any concerns with your results."

As she had not had a blood test for over two decades she was puzzled as to exactly what was being followed up. Feeling a little anxious she phoned her GP and asked why she was being asked to have a "follow up blood test."

She was told it was part of the regular check ups for heart disease that doctors were now doing on their older patients. Aware of the TV advertising campaign for diabetes and heart

disease check ups, and having previously declined the offer of a diabetes check, she told her GP that for her the ageing process did not include getting regularly tested for various diseases.

Pointing the bone

Such simplified approaches to health care and the language used when describing programmes such as PREDICT are alarming. One medical newsletter describes the diabetes support system in this way: "This clinical decision support module combines over 1000 rules to create truly patient tailored treatment plans and advice," and refers to their "world leading CVD Risk visualisation tool" under the heading *Your Heart Forecast*. (3)

The weather forecasters may often get it wrong, but if we are to believe such propaganda there are now electronic programmes that offer health forecasts that are much more reliable than weather forecasts. These wonderful "tools" use risk trajectory approaches "to convey CVD Risk to patients," presumably in a manner designed to scare the hell out of us as a way of getting us to change our unacceptable behaviours.

What is also worrying is the fact that the concept of a self-fulfilling prophecy seems to be something that the inventors of this predictor of doom programme are not familiar with.

Overdiagnosis

What is also not being discussed with patients prior to being sent off for their regular WOF check ups is the havoc caused by the rapidly increasing rates of overdiagnosis. If you don't have diabetes then you will almost certainly be told you are pre-diabetic, especially if you are over a certain age or weight. And no matter what your risk factors are for cardiovascular disease, if you are over 40 you will be encouraged to go on a statin, or be told to take them. (4) Why, we should be asking, is the health system attempting to turn us all into pill-popping patients?

Screening Programmes

There is also not much information being provided about the downsides of many screening programmes. The AWHC newsletters have featured a number of articles about the failure of breast cancer screening programmes to significantly reduce the rate of deaths from breast cancer, and the harms done by the overdiagnosis of breast cancers and pre cancers that result in large numbers of women having unnecessary treatment.

DHBs around the country have put a great deal of effort into increasing the uptake of breast screening, especially among targeted groups – Maori, Pacific and Asian populations. Breast screening providers have a real resistance to providing "targeted" women with any information that may put them off having a mammogram every two years.

The Auckland regional DHBs set up a Metropolitan Auckland Cervical Screening Governance Group last year whose task is to ensure that the rate of cervical screening is increased among Maori, Pacific and Asian women. The importance of obtaining informed consent and the acceptance of cultural preferences and behaviours are not issues that feature highly during discussions at the meetings of the governance group. Meeting the cervical screening targets is the main goal.

The woman whose cancer treatment clinical trial story featured in the March issue of the AWHC newsletter told the Council how at one visit to her GP, the GP began hassling her about cervical and breast cancer screening. The GP was totally unfazed when her patient objected, saying "I am already being treated for two types of cancer. Don't you think that's enough?"

Waitemata DHB is currently undertaking a bowel screening pilot which will help the Ministry of Health decide on whether to roll out a national bowel cancer screening programme. None of the information sent to Waitemata DHB residents who are being invited to take part, and none of the information on the BowelScreening Waitemata and MOH websites – including the 88-page document for bowel screening providers – contain any information on the false negatives and false positives of the screening test, or of the follow-up investigations. The latter document contains the vague statement:
"International evidence shows that a bowel screening programme *may* significantly reduce mortality from bowel cancer, and there is *some* evidence that *suggests* it *could* reduce the incidence of bowel cancer through the detection of pre-cancerous lesions." [Italics added] Is it possible to get any less convincing?

The bowel screening pamphlet contains the short sentence: "No screening test is 100% accurate" which presumably is a token gesture towards informed consent and the many unanswered questions which the pamphlet ignores.

One of these questions is where does the over-diagnosis of bowel cancer and pre-cancer fit into this picture? It's a good question that the Ministry of Health does not seem the least bit interested in. And let's not mention the queues of Waitemata DHB residents anxiously waiting for their colonoscopies.

Vaccinations

Finally, no article on health targets would be complete without mentioning the major success of the DHBs to meet the Minister/Ministry of Health's immunisation targets. These targets have been achieved by riding roughshod over the need to gain fully informed consent from parents, and by using bullying tactics in many instances. One mother in West Auckland recently described how she arrived home to find a Plunket bus parked in her driveway. The Plunket Nurse had arrived unannounced and was determined that she was not going to leave until she had vaccinated the baby. This despite the fact that the mother told her she was taking her 7-month-old baby to her GP for her vaccinations. The indignant mother eventually convinced the nurse to leave but it took a great deal of effort.

The methods being used to meet these health targets need to change. Perhaps, the Health & Disability Commissioner could pay a visit to the Minister of Health and remind him of the Code of Consumers' Rights.

References

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2. http://journal.nzma.org.nz/journal/119-1238/2077/content.pdf
3. http://www.enigma.co.nz/?id=5066
4. Dr David B. Agus "The End of Illness." 2011. Simon & Schuster UK.

NZ WOMEN JOIN CLASS ACTION LAWSUIT

In a move reminiscent of the class-action lawsuit taken against the manufacturers of silicone breast implants in the 1990s, some New Zealand women have joined Australian women in a class-action lawsuit filed in the United States. The lawsuit covers hundreds of mesh products made by five manufacturers – Ethicon, Coloplast Corp, Boston, Bard and American Medical Systems – which have caused horrific injuries in thousands of men and women worldwide.

There are currently more than 6000 lawsuits being heard in the USA, but this is the first available for Australian and New Zealand women.

Over the past decade or so the uro-gynaecological mesh, also known as the vaginal mesh, became a common method used by doctors to treat pelvic organ prolapse and stress urinary incontinence. The mesh was first approved by the US Food and Drug Administration (FDA) to treat stress urinary incontinence in 1996. In 2002 the FDA expanded their approval of these devices to address pelvic organ prolapse.

Unfortunately women were not adequately warned of the risks and side effects of having the mesh inserted. Nor were they told how the mesh had been able to come onto the market without adequate testing.

On 2 July 2013 *TV3 News* featured Auckland mother-of-two Carmel Berry who had a hysterectomy in 2004. (1) The surgical mesh was inserted into her pelvic floor during the operation. This common procedure has resulted in hundreds of claims being lodged with ACC as women reported experiencing a range of severe symptoms including infection, intense pain, urinary problems and the inability to have intercourse. However, Carmel Berry's ACC claim was not accepted. Carmel is one of several women who have contacted the AWHC over the past two years with terrible stories of the injuries they have suffered after having the mesh implanted.

Last year Carmel set up a website for New Zealand women dedicated to raising awareness of the complications caused by the mesh – http://meshdownunder.co.nz/

As reported in previous issues of the AWHC's newsletters, the FDA raised serious concerns about the mesh in 2008 and they have now issued two safety advisory warnings. (2)

Meanwhile NZ's regulator Medsafe continues to insist the "Surgical mesh is safe when used in accordance with the manufacturers' instructions by an appropriately trained surgeon." (3)

It clearly isn't.

References

1.www.3news.co.nz/Kiwi-joins-surgery-class-action-lawsuit/tabid/309/articleID/303510/Default.aspx

2.www.womenshealthcouncil.org.nz/Features/Womens+Health+Issues.html

3.www.medsafe.govt.nz/hot/alerts/urogynaecologicasurgicalmeshimplants.asp

TOO MUCH MEDICINE; TOO LITTLE CARE

A recent editorial published in the 2 July issue of the *British Medical Journal* bemoaned the fact that doctors are now so busy managing the increase in "apparent illness" that they lack the time to care properly for those who are seriously ill. (1)

"As the definitions of common conditions such as diabetes and kidney disease have expanded and the categories and boundaries of mental disorders have grown, our time and attention for the most worryingly ill, disturbed, and vulnerable patients has shrunk. Too much medicine is harming both the sick and well," the authors claim.

The developed world is experiencing an epidemic of diagnosis as disease definitions have changed and the dividing line between normal and abnormal has shifted. Many of these "epidemics" have occurred in the context of screening programmes for conditions such as breast cancer and prostate cancer, while the impact of lowering the bar between normal and abnormal is found in a range of conditions such as hypertension, diabetes, osteoporosis, obesity, high cholesterol, and cognitive impairment.

Authors Paul Glasziou, Fiona Godlee, Ray Moynihan and Tessa Richards point to a key component that is behind this sorry state of affairs:

"A key question is how disease definitions are changed and by whom. Currently, there are no agreed standards for the constitution of panels that review or alter the definitions of diseases, including the mix of expertise represented and the methods to manage conflicts of interest. Nor are there clear criteria for when it is reasonable to change disease definitions."

There is also another question that needs an answer – what role does the invisible hand of big pharma play in all this?

The current issue of the *BMJ* includes the first in what will be an intermittent series of Analysis articles looking at the risks and harms of overdiagnosis in a broad range of common conditions. The article focuses on pulmonary embolism and reveals how the introduction of a new diagnostic technology has resulted in an 80% rise in the detection of pulmonary emboli, many of which, the authors argue, don't need to be found.

Future articles will look at chronic kidney disease, dementia, attention deficit hyperactivity disorder, chronic obstructive pulmonary disease, depression, and thyroid cancer.

http://www.bmj.com/content/347/bmj.f4247/rr/652961

The Cartwright Legacy: After 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 and Joanna Manning.

Confirmed Speakers include:
Charlotte Paul, Emeritus Professor, Public Health and Epidemiology, Otago University.

Martin Tolich, Associate Professor Department of Sociology, Otago University.

Marie Bismark, Senior Researcher Melbourne School of Population and Global Health.

The conference will also feature panel discussions on a range of Cartwright issues – screening programmes, ethics committees, complaints procedures, patient rights, information, etc.

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

AWHC GENERAL MEETING 11 July 2013

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

- Financial reports
- Grant applications
- PHARMAC consultations
- The Legacy of Cartwright conference
- Ethics committee meetings

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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UP AND COMING EVENTS

DISTRICT HEALTH BOARD meetings for July/August 2013:

Waitemata DHB (Website address: www.waitematadhb.govt.nz)
Waitemata Hospital Advisory Committee meeting starts at 11am on Wednesday 14 August 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 24 July 2013.

Auckland DHB (Website address: www.adhb.govt.nz)
The Hospital Advisory Committee meeting will be held at 9.30am on Wednesday 7 August 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 7 August 2013 at 19 Lambie Drive, Manukau City.

The Hospital Advisory Committee meeting will be held at 9am on Tuesday 23 July 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

Preventing Overdiagnosis Conference

Winding back the harms of too much medicine

10th – 12th September 2013 in Hanover, New Hampshire, USA

This conference is being hosted by The Dartmouth Institute for Health Policy and Clinical Practice in partnership with one of the world's most respected medical journals, the *British Medical Journal*, the leading New York based consumer organisation Consumer Reports and Bond University.

Further information is available at http://www.preventingoverdiagnosis.net/