AUCKLAND WOMEN'S HEALTH COUNCIL

NEWSLETTER

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PO Box 99-614, Newmarket, Auckland. Ph (09) 520-5175
Email: awhc@womenshealthcouncil.org.nz
Website: www.womenshealthcouncil.org.nz

CASHING IN ON PREGNANCY TEST KITS

It seems there is no end to the lengths some people and industries will go to in order to try and make as much money as possible out of our health system. The latest example to hit the headlines is the EasyCheck pregnancy test kit. (1) (2) (3) The story behind the way in which someone was able to import cheap pregnancy test kits into New Zealand, put in a very low tender with PHARMAC, and become the sole supplier of PHARMAC-funded pregnancy test kits is truly alarming.

Following the publicity generated by the reported failure rate of this particular pregnancy test kit, the AWHC received an email which described how the stage was set for just such a scenario when Medsafe, the Ministry of Health's medical regulatory body, decided to reclassify pregnancy tests as diagnostics. This change removed the expensive and lengthy approval process required to bring a new test to market. Prior to July 2015 pregnancy tests were classed under the Medicines Act as medicines and not diagnostics. This meant there being very few brands available on the market.

Unfortunately, the PHARMAC contract for hCG (human chorionic gonadotropin) pregnancy tests was also under review around the same time and this is where a man by the name of Brad Rodgers and his company Phoenix MedCare enter the picture. Mr Rodgers, who has a background in the courier and logistics industries, saw his opportunity and took it. He tracked down a supply of pregnancy test kits and put in a very low tender with PHARMAC. And of course if you are looking to make or save money by producing an incredibly cheap tender, the current go-to place for low cost products (think steel, railway carriages, pharmaceuticals) seems to be China. At some point these products are subsequently found to be substandard and to pose a threat to the health and safety of the New Zealand public. EasyCheck is no exception.

The price for 100,000 test kits as detailed in an email from Hangzhou Clongene Biotech (4), the "professional manufacturer of the Rapid Test kits," is 6 cents each. The email received by the AWHC points out that Clongene Biotech is a relatively new factory in China and has a very limited certification – "just CE Mark which is extremely easy to obtain." In comparison most hCG pregnancy test manufacturers "will have at the very least ISO 13485, ISO 9001 certification, CE Mark and FDA certification."

A review of the PHARMAC tender showed that the price paid per box of 40 is $17.60. As Mr Rodgers claims he has sold 500,000 units since July, the net profit to him would be an eye-watering $715,000. This is tax-payer funded money for a product whose failure rate is causing concern to both the women who have purchased the pregnancy test kits and to doctors.

Given the sort of profits involved maybe Mr Rodgers should rename his products EasyCheque.

Since the story broke, the AWHC has received several phone calls and emails from women who purchased the EasyCheck pregnancy test kit

over the counter in pharmacies and got a false negative result. In each case switching to another brand resulted in a positive pregnancy test.

The AWHC's experience in dealing with women's health issues over the past 28 years would lead us to believe that this is undoubtedly just the tip of the iceberg.

Following Phoenix MedCare's successful tender the EasyCheck Test Cassette is now the only one funded by PHARMAC and is used by clinics, GPs and hospitals. Phoenix MedCare also sells an EasyCheck Test Strip and EasyCheck Test Midstream over the counter in pharmacies. The pregnancy test is the same in all three models. It is only the packaging that is different. This is why problems have been reported in both the test kit used by health professionals, as well as the test kits purchased over the counter by individual women.

A visit to the Phoenix MedCare website reveals that the company also sells ovulation kits, SwimCount (a sperm quality test), EasyCheck Cholesterol Complete, and Breath-alysers. (5) According to the email the AWHC received, the Advertising Complaints Authority is currently conducting an investigation in relation to misleading advertising about SwimCount which was put out by PEAD PR, a PR firm Mr Rodgers uses to market his products. It claimed that SwimCount was the first sperm test on the market to measure sperm count and motility. The email points out that the FertilitySCORE test has been on the market in over 40 countries including New Zealand for over 10 years.

Another player in this story is Medsafe which should also consider a name change. The history of the registration and use of medical devices in New Zealand is littered with the damaged bodies and ruined lives of thousands of patients. Medsafe is always extremely cautious about taking action once problems surface, and the Ministry of Health people who responded to the problems with breast implants, metal-on-metal hip replacement joints, and mesh products, to name just a few, all seem to belong to the "don't panic/do nothing" brigade.

This continues to result in the New Zealand public being left exposed and unprotected when it comes to medical devices and drugs that Medsafe has allowed to be imported into New Zealand and used in or prescribed for patients. We simply cannot rely on Medsafe to protect us, even when a major problem is drawn to their attention.

Finally, there is the role played by PHARMAC who chose to give the contract for pregnancy test kits to a newcomer on the scene with a very cheap tender. It should be obvious by now that it simply doesn't pay to go with cheap stuff which nearly always turns out to be substandard and not fit for purpose. It's time to learn from past mistakes, especially in health.

References

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3. http://www.newshub.co.nz/nznews/health/concern-pharmac-funded-pregnancy-tests-arent-working-2016060910#axzz4BcIGP900
4. http://www.clongene.com/index-en.html
5. http://phoenixmedcare.co.nz/index.html

"SURGERY: THE ULTIMATE PLACEBO"

Professor Ian Harris is an orthopaedic surgeon with a clinical practice in Sydney. He also directs a research unit that focuses on the outcomes of surgery. Earlier this year he published a book, "*Surgery: The Ultimate Placebo*" which is a must read for anyone contemplating surgery. (1)

Professor Harris begins his book by stating "This book builds a case for a placebo effect of surgery, something that is often underestimated when assessing the effectiveness of surgical procedures." The first three chapters are devoted to exploring the placebo effect, the important but often unacknowledged role it plays in the science of evidence-based medicine, and how to create the perfect placebo.

Chapter four provides some fascinating examples of studies using sham surgery. They include surgery for the following conditions – angina, Parkinson's disease, Meniere's disease, migraine, knee arthroscopy for arthritis and for a torn meniscus (the C-shaped cartilage in the knee), IDET (intradiscal electrothermal therapy) for back pain, tennis elbow, and high blood pressure.

Chapter five lists the operations that have been assigned to the surgical scrap heap due to a lack of effectiveness. However, a brief internet search will reveal that some of them are still being done. The procedures described in this chapter were not tested against a placebo, but were shown to be ineffective or unnecessary in other ways. They include bloodletting (more about this in the July newsletter), radical mastectomy, lobotomy, extracranial and intracranial bypass surgery for strokes, and surgery on the knee for plica syndrome which Professor Harris describes as one of a number of "made-up conditions" which surgeons then devised an operation to treat. He writes: "But without ever validating the diagnosis or doing any comparative trials of treatment, we have no idea whether this is a real condition or not, let alone whether the treatment really does anything. But there is no incentive to do such a trial, as long as the public keeps trusting surgeons to "diagnose" it, and pays them to treat it; and as long as some of them say they feel better afterwards, there is no need to rock the boat."

Chapter six describes current but questionable surgical procedures that are today's placebo surgeries. They include back fusion surgery, surgery for multiple sclerosis, hysterectomy, caesarean section, knee arthroscopy, appendicitis, coronary stenting, shoulder surgery for impingement, surgery for floating kidney, tendon ruptures, laparoscopy for bowel adhesions, and fracture surgery.

Stents

The section in this chapter on coronary stenting was particularly interesting given the large numbers of people who have stents. Professor Harris refers to the debate between the cardiothoracic surgeons who prefer coronary artery bypass grafts in which blood vessels from other parts of the body are used to bypass obstructed arteries in the heart, and the interventional cardiologists who prefer angioplasty/stenting in which tubes are placed inside the blocked heart arteries to re-open them.

"Everyone wants to know which one is best," he writes. "But I am more interested in whether either of them is better than *not* doing them."

"The best evidence tells us that there is no difference between these two methods when it comes to the chance of dying, and not much difference for anything else, except that you are more likely to need another 'revascularisation' with stenting."

Chapter seven examines the reasons behind the persistence of surgery that is not effective, and chapter eight presents the case against using the placebo effect to justify doing the surgery.

Chapter nine outlines what "we" can do about all this unnecessary surgery, "we" being patients, doctors, researchers, funders and society.

Professor Harris states that patients can get good advice from their treating doctor by asking the right questions, and that the best question is to ask about the difference between the results of any proposed surgery compared to the best non-operative alternative. If patients cannot get good advice from their treating doctor he recommends seeing another doctor, or another two doctors. "Surgeons know that second opinions can be helpful for them and for the patient," he writes.

The 30 April issue of the *Listener* featured a major article by Donna Chisholm on Professor Harris' book (2). She writes that "the book is being welcomed here, and although several influential surgical leaders disagree with some of Harris' "don't do" list of operations, they support its basic arguments." Auckland anaesthetist Professor Alan Merry, Chair of the Health Quality and Safety Commission, is quoted as saying that he "accepts some operations are being done "just for the sake of doing something" for patients with ongoing problems.

"There is a widespread expectation that the fact a patient is in pain or otherwise suffering is a reason to do something. That's not logical. The reason to do something is because there is an expectation that what you are going to do will help," he says.

Professor Merry also points out that "there is a debate that says medicine is unaffordable because of progress. Everything becomes more expensive and you can't keep up … the newer stuff comes out with a hiss and a roar and everyone wants it and five years later you find it doesn't really work and you've done bad things. There are lots of examples of that. If we give people only what we have good reason to believe works, and what really aligns with what they need and want, medicine is affordable." (2)

Asking the right questions

Professor of surgery, Ian Civil, Chair of the commission's Safe Surgery NZ, also agrees with Professor Harris' emphasis on the importance of patients asking the right questions. 'If I have this operation, will I be more likely to be better in five years than if I didn't have it,' and 'What are the chances I'll be worse," are great questions," he says. (2)

References

1. Ian Harris. "Surgery, the Ultimate Placebo." Pub. NewSouth Publishing. 2016
2. Donna Chisholm. "Cutting Through the Evidence." *Listener* 30 April 2016.

UPDATE ON THE MESH

The Health Committee recently released its report on the petition of Carmel Berry and Charlotte Korte requesting an inquiry into the use of surgical mesh in New Zealand. (1) It makes for sobering reading as among other things it details Medsafe's response to the issues raised by the petitioners and their call for an inquiry. The incredible damage the mesh has caused to the bodies and lives of hundreds of New Zealanders, the millions of dollars paid out in ACC claims (new figures show that ACC has paid out $10 million in treatment injury claims from botched surgical mesh implants), and the lack of informed consent reported by mesh implant sufferers were not enough to persuade the Health Select Committee that an inquiry was warranted.

However, the Health Committee did make seven recommendations to the government. They are:

- That it work with relevant medical colleges to investigate options for establishing and maintaining a surgical mesh registry
- That a registry be informed by the International Urogynaecological Association classification for recording mesh surgery complications
- That it suggest that the Colleges take note of the petitioners' and others' experiences and review best practice around informed consent for mesh procedures
- That it encourage health providers to ensure that coding for mesh surgery is consistent. This should include a system to allow patients with mesh complications to be identified and monitored
- That it encourage utilisation of the adverse events reporting system as applicable to medical devices
- That it endorse the provision of ongoing education for surgeons on the use of surgical mesh and mesh removal surgery
- That it consider expanding Medsafe's role over time to assess the quality and safety of a medical device before it can be used in New Zealand.

The Committee's report records that Medsafe did not support a New Zealand registry of surgical mesh as they did not believe it would improve patient safety.

The petitioners asked for mesh devices to be reclassified as a class III (high risk) device. Medsafe did not support a change to the classification of mesh as it would require a change to the regulations, and a change would not necessarily prevent a device from being made available in New Zealand.

Medsafe also did not support the petitioners' recommendation that the reporting of all device-related adverse events should be mandatory for surgeons and GPs.

Medsafe's response to the horrendous complications associated with the use of urogynaecological mesh is completely unacceptable.

On 20 June Kathryn Ryan interviewed Patricia Sullivan, another eloquent and informed mesh victim. (2)

References

1. http://www.parliament.nz/resource/en-nz/51DBSCH_SCR69220_1/2ebf5e03f6fae9f78e731ff8ebfce8ded2df857f
2. http://www.radionz.co.nz/national/programmes/ninetonoon/20160620

The Australasian Association of Bioethics and Health Law (AABHL)

is holding its conference at Rydges on Swanston in Melbourne from the 24-26 November 2016. There will also be satellite workshops which will be held on 23rd and 27th November.

The intersections of health, bioethics and law raise challenging questions. Advances in medical science and technology, increasingly sophisticated diagnostic and therapeutic interventions and changing social circumstances reveal new ethical dilemmas. How do we go about making sound decisions in the face of these challenges?

How do patients decide on their treatment or on participation in research? How do substitute decision-makers make decisions? How do clinicians decide on the treatment to offer? How do governments make decisions on health policy and funding priorities? Who makes decisions about the allocation of scarce resources? How do we protect the rights of the vulnerable? How do courts exercise their power to protect people in health care settings?

Early registrations close on 28 September 2016.

Further information is available at: http://www.aabhlconference.com/

AWHC GENERAL MEETING 23 June 2016

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

- Financial reports
- Grant applications
- Submissions due
- Ethics committee meeting
- Cartwright Collective conference
- Succession planning

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 June/July 2016:

Waitemata DHB (Website address: www.waitematadhb.govt.nz)
The Waitemata DHB Board meeting opens to the general public at 12.45pm on Wednesday 29 June 2016 and will be followed by the Hospital Advisory Committee meeting which starts at 2pm. 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 20 July 2016.

Auckland DHB (Website address: www.adhb.govt.nz)
The Auckland DHB Board meeting opens to the general public at 12.45pm on Wednesday 3 August 2016 and will be followed by the Hospital Advisory Committee meeting which starts 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 Community & Public Health Advisory Committee meeting will be held at 1.30pm on 6 July 2016 at 19 Lambie Drive, Manukau.

The Hospital Advisory Committee meeting will be held at 9am on Wednesday 27 July 2016 at Ko Awatea and will be followed by the Full Board meeting at 1.30pm.

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

The Cartwright Collective in association with Women's Health Action and the Auckland Women's Health Council is holding a one-day forum on the control of cervical cancer and the future of cervical screening in New Zealand.

9.30am – 4.30pm Friday 5 August 2016 at 164 Balmoral Road, Balmoral, Auckland.

Further information is available at http://www.womens-health.org.nz/the-control-of-cervical-cancer-in-new-zealand-one-day-forum-5-august/