AUCKLAND WOMEN'S HEALTH COUNCIL

NEWSLETTER

DECEMBER 2014

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INDUSTRY INFLUENCE IN HEALTHCARE & RESEARCH: DOES IT MATTER?

On 24th November 2014 a ground-breaking Cochrane symposium took place at the Faculty of Medical and Health Sciences at the University of Auckland. The symposium was free and was open to the public. The topic was the influence of industry on research agendas' methods and healthcare.

Seven speakers, including Professor Lisa Bero, a world renowned expert on pharmaceutical industry inter-action and influence in medical research, described the impact of the pharmaceutical industry in their various fields.

Professor Bero is a pharmacologist who studies how science is translated into clinical practice and health policy, including the study of how a variety of biases influence the integrity of the research. She described how wide-spread the problems associated with the conflicts of interest in research have become due to industry funding for research and education as well as the growing number of researchers who also have personal financial ties to their sponsors.

Numerous studies over the past decade have provided empirical evidence of bias in research, the effect this has on the subsequent development of guidelines and recommendations, and on purchasing and prescribing decisions. (1) (2) This is compounded by the multiple effects in the research literature.

There are many different ways to bias a clinical trial and the pharmaceutical industry has used and continues to use all of them. They include the research question itself, the population enrolled in the research, the research methods used, how the research is conducted and how it is published. Selective reporting of the studies' results is rife, and negative results are usually buried.

There is however growing interest and investment in changing the system. A Drug Industry Document Archive (DIDA) has been established. (3) It contains internal corporate documents from large pharmaceutical companies including Merck, Parke-Davis, Wyeth, and Pfizer. These documents reveal questionable drug industry practices concerning clinical trials, publication of study results, pricing, marketing, relations with doctors and involvement in continuing medical education.

Industry-independent experts

Two journalists, Shannon Brownlee and Jeanne Lenzer, are also doing their bit for the campaign to restore ethical practices to the research industry. They have compiled a list of more than a hundred independent health care experts to whom reporters can turn. Those on the list state that they do not have financial ties to drug or medical device manufacturers. (4)

Professor Bero ended her presentat-ion with a discussion on the various ways of attempting to manage conflicts of interest – ban them, manage them or disclose them – and provided examples of how effective or ineffective they are. It is obvious that disclosing conflicts of interest is not working that well, and that there is a need to seriously manage them at the very least. As other presenters repeatedly pointed out New Zealand is lagging behind in acknowledging

that we have a problem, and putting in place a robust system of dealing with what has become an increasing large can of worms.

Peter Griffin & *ProPublica*

The next speaker was Peter Griffin, founding manager of the *Science Media Centre* and the founder and editor of Sciblogs.co.nz. He also writes about technology for the *NZ Listener.* He talked about *ProPublica*, an independent non-profit newsroom based in New York City that produces investigative journalism in the public interest, and described aspects of the Physician Payment Sunshine Act.

Peter Griffin began by pointing out that in last five years pharmaceutical companies have agreed to pay over $US13 billion in fines to resolve US Department of Justice allegations of fraudulent marketing practices, including the promotion of medicines for uses that were not approved by the FDA. They include:

- Pfizer – $US2.3 billion
- Merck – $US950 million
- GlaxoSmithKline – $US3 billion
- Sanofi-Aventis – $US109 million
- Johnson & Johnson $US2.2 billion
- Eli Lilly – $US1.42 billion
- AstraZeneca – $US520 million
- Abbott – $US1.5 billion
- Boehringer Ingelheim – $US95 million
- Amgen – $US762 million
- Endo – $US192.7 million. (5)

Obamacare

He then outlined the situation in the USA where one of the provisions of the Patient Protection and Affordable Care Act, known as Obamacare, is a mandatory open disclosure system. The Open Payments database by the Centers for Medicare & Medicaid Services (CMS) is a federal public database that was launched on 30 September 2014 with the intention of bringing transparency to financial relationships between doctors and the pharmaceutical industry. It requires all manufacturers of drugs, devices, and biological and medical supplies covered by federal health care programmes to collect and track all financial relationships with doctors and teaching hospitals. The database includes payments for research, gifts, meals, travel, or speaker fees.

The Physician Payment Sunshine Act was first introduced in 2007. It was initially introduced independently and failed, but it then became part of the Patient Protection and Affordable Care Act and was enacted along with that Act. Although there have been some initial technical glitches, and the predictable expressions of outrage from doctors and researchers, the database is now up and running. (6)

Dollars for Docs

ProPublica has also launched another initiative called “Dollars for Docs” in which patients can log in their doctor’s name and get information on the money she or he has received from drug companies. (7) Peter Griffin pointed out the top 300 doctors getting the most industry money were all men.

Then there is PharmaShine, which claims to be the largest data source of its type with information on over six million individual payment trans-actions to more than 700,000 health care professionals. (8)

Why NZ needs a Sunshine Act

Professor Cindy Farquhar, co-chair of the Cochrane Steering Group, began her presentation with an insightful

account of her own history of how she became “pharma-free.” She started a trend as subsequent speakers then revealed where they were on the spectrum of being on the take from drug companies, and the reaction from some of their colleagues when they decided to come clean and refuse industry money.

PharmFree Scorecard

Professor Farquhar described how the American Medical Student Association (AMSA) became concerned about how medical students and trainees become indoctrinated into thinking that industry funding, gifts and handouts are the norm. In 2007 AMSA launched the first PharmFree Scorecard for students which evaluated conflict of interest policies and curricula at Academic Medical Centers in the USA and Puerto Rico.

The Scorecard is an evolving tool that “offers a comprehensive look at the changing landscape of conflict of interest policies across US medical education, as well as in-depth assessments of individual policies that govern industry interaction between students, faculty, and the pharmaceutical and medical device industries.” (9)

AMSA’s PharmFree Campaign is now called *Just Medicine* – “no kick backs, no speakers bureaus, no free samples, Just Medicine.” The AMSA website states: “Our vision for the practice of medicine is that it is simply based on evidence, not marketing, personal gain, or any interest other than that of the patient. (10)

Professor Farquhar then drew attention to just how far behind New Zealand is in addressing these issues. Many NZ doctors and others are on the receiving end of gifts, fees, travel and sponsorship, and New Zealand has only what she described as “soft options” for dealing with conflicts of interest. This country is desperately in need of its own Sunshine Act. When senior doctors are already getting around $17,000 to attend conferences and other important continuing education events there is really no excuse for them to be accepting drug company money.

Tamiflu – a nice little earner

Dr Vanessa Jordan is a NZ Cochrane Fellow and a methodologist who specialises in systematic reviews. Her presentation described how Roche’s blockbuster antiviral drug, oseltamivir, (Tamiflu) became one of the most widely recognised medicines in the world as concern grew about a new flu pandemic – H1N1 or swine flu.

After over five years of struggling to access the drug trial data which was previously unpublished and hidden from view a Cochrane review was finally able to reveal the unpalatable truth about Tamiflu. (11)

Tamiflu is actually no more effective than an aspirin. It does not reduce flu symptoms to any significant degree and nor does it reduce complications of the flu or reduce hospital admissions. Its adverse effects – nausea, vomiting, diarrhoea as well as headaches, psychiatric disturbances and renal events – far outweigh any of its overhyped and very minor benefits. Yet nearly 100 countries stockpiled supplies of Tamiflu, spending $US18 billion worldwide. New Zealand bought 300,000 doses.

As Ben Goldacre wrote in *The Guardian* back in April 2014, Tamiflu has become the poster child for the missing-data story.

"And it is a great poster child. The battle over Tamiflu perfectly illustrates the need for full transparency around clinical trials, the importance of access to obscure documentation, and the failure of the regulatory system. Crucially, it is also an illustration of how science, at its best, is built on transparency and openness to criticism, because the saga of the Cochrane Tamiflu review began with a simple online comment." (12)

Dr Jordan also emphasised the need for all clinical trials results to be published to ensure that doctors have full information about the medicines they prescribe to their patients. She referred to the AllTrials campaign which is dedicated to making it mandatory to publish the results of all trials. Currently the results of half of all clinical trials are hidden. Even the FDA doesn't get all the data from the clinical trials of all the drugs and devices they approve for use. (13)

There were also excellent presentations from Professor Chris Bullen on clinical trials and industry, and Dr Sarah Hetrick on the 2014 Cochrane antidepressant review, "*Selective serotinon reuptake inhibitors (SSRIs) for depressive disorders in children and adolescents*" that she was the lead author of. (14)

Professor Shaun Hendy's presentation, "Can we trust our scientists?" focused on the role of scientists in today's world. He used two events that received worldwide media attention – the Fukushima Dai-ichi disaster in Japan and the Fonterra botulism scare in New Zealand – to illustrate the role of science in both disasters. Industry funding undermines the trust that the general public has in scientists and limits their ability to talk to the public. There is a real need for independently-funded scientists who do not have conflict of interests to front the media when disasters occur.

The afternoon symposium finished with a panel of five blokes who were interviewed by the *Dominion Post's* Nikki Macdonald. Among them was the Ministry of Health's Dr Stewart Jessamine, who unfortunately never fails to sound like an apologist for the pharmaceutical industry.

The AWHC wishes to acknowledge that this informative and challenging symposium would not have eventuated without the determination and commitment of Professor Cindy Farquhar. Thank you Cindy!

Most of the presenters' slides from the symposium are now available at: http://nz.cochrane.org/symposium

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PROSTATE SCREENING

A recent opinion piece in the *New York Times* by Richard Ablin, the man who discovered the prostate-specific antigen, or PSA, is surprisingly entitled "The Problem with Prostate Screening." (1)

The PSA test is now the most widely used tool in prostate screening and Professor Ablin is concerned at how it is being used. "There has been a growing concern about whether the use of the PSA test has led to over-diagnosis and overtreatment, with millions of unnecessary surgeries, complications and deaths," he writes.

His concerns are centred around the recent publication of the results of two studies which reported large reductions in prostate cancer deaths. One is the European Randomized Study of Screening for Prostate Cancer, and the other is the Swedish Goteborg study, the results of which provided a basis for the European Randomized Study.

Unfortunately there are big problems with both of these studies. Major concerns about the methodology and results of the studies were first raised earlier this year in the *Journal of the National Cancer Institute* by two Australian researchers. In March the Goteborg study's authors announced in the *British Medical Journal* that their data "are not available to outside investigators."

"That the researchers would block access to government- and charity-supported research is bad enough. Even worse, it calls into question why, if the data was strong, the researchers wouldn't open it up to independent scrutiny," Professor Ablin says. The public must be able to trust that scientific data from clinical trials is accurate and unbiased, and he is worried "that this trust, particularly when it comes to American men and their physicians and screening programs for prostate cancer, is now at risk."

The issues that prompted his opinion piece are unfortunately very familiar as the preceding report on the Cochrane symposium demonstrates. At their core is the impact of conflicts of interest on research and how it is reported, and these studies provide a fascinating case study.

The European Randomized Study reported results from seven countries, while Goteborg was a single-site study in Sweden. In both, men were divided into two groups: one group underwent regular PSA tests, while the other group was not screened. The results were published in *The New England Journal of Medicine* and the *Lancet Oncology Journal* respectively.

The Australian researchers noticed that there was something strange about the data sets – a large amount of the data in the European Randomized Study came from a separately reported Finnish study which showed no significant lifesaving benefits of PSA screening.

There were also issues around biased patient treatment. Many of the men who developed prostate cancer received excessive amounts of a treatment called hormonal mono-therapy which has been found to accelerate cancer.

"Further bias was highlighted by Otis Brawley, the chief medical and

scientific officer of the American Cancer Society, and Paul Goldberg, the editor of the Cancer Letter. (2) They pointed out that the non-screened Swedish men who contributed to the two studies *were not even informed that they were in a clinical trial.*" [italics added]

Last but not least is the conflicts of interest issue. Several senior authors of the European trials as well as their American supporters, have conflicts of interest that relate to payments from companies involved in marketing PSA tests, or in holding patents in PSA and prostate cancer diagnostic space.

Professor Ablin concluded his opinion piece by stating "As a result, those physicians who have not examined the data in depth are now treating patients on the basis of deeply flawed data. How flawed? That's the real issue: because the authors won't release their data, we don't know."

It is imperative, he states, that "our regulatory bodies must insist that clinical trials, and especially taxpayer-funded ones, be open to scrutiny by independent investigators who have no ties to industry. Hoarding data, especially flawed data, is unacceptable when lives are at stake."

References

1. http://www.nytimes.com/2014/11/26/opinion/the-problem-with-prostate-screening.html?_r=0
2. Otis Brawley & Paul Goldberg are the co-authors of "How We Do Harm." Chapter 20 has a graphic and disturbing account of what happened after Ralph DeAngelo went for a prostate cancer screening test.

AWHC GENERAL MEETING 20 November 2014

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

- Financial reports
- Grant applications
- Non-consensual clinical trials
- Northern A ethics committee
- Cochrane symposium
- Cartwright Screening conference on 7 August 2015

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 December 2014:

Waitemata DHB (Website address: www.waitematadhb.govt.nz)
The Waitemata Hospital Advisory Committee meeting starts at 11am on Wednesday 17 December 2014 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 4 February 2015.

Auckland DHB (Website address: www.adhb.govt.nz)
The Hospital Advisory Committee meeting will be held at 9.30am on Wednesday 10 December 2014 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 3 December 2014 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 17 December 2014 at 19 Lambie Drive, Manukau City.

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

Peter Gotzsche leader of the Nordic Cochrane Centre and author of "*Mammography Screening: Truth, Lies and Controversy*" and "*Deadly Medicines and Organised Crime: How big pharma has corrupted healthcare*" will be in Australia from 9 - 18 February 2015 on a speaking tour. He will be visiting Adelaide, Melbourne, Sydney and Brisbane giving both public and professional lectures on psychiatry (including the use of SSRIs) and on deadly medicines and organised crime.

For further information on the times, dates and venues of Peter Gotzsche's speaking tour, go to http://mentalaz.wordpress.com/home/