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MEDICO-LEGAL SOCIETY OF NSW INC.

SCIENTIFIC MEETING

WEDNESDAY, 21 SEPTEMBER 2016 AT 6.15 P.M.

THE TOPIC:
THE CASE FOR SHAM SURGERY

SPEAKERS: PROF IAN HARRIS
MICHAEL FORDHAM SC

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QUESTION TIME

MS KEELY GRAHAM: That was a very interesting presentation. I am sure there are lots of questions.

DR ANTHONY LOWY: Full time medico-legal work. Prof Harris, an excellent book, paper, and presentation. Talking of rationality, is it not rational to think that our fee for service system is not only wrong, but is intrinsically evil? More to the point, with all the negativity that you have demonstrated, what keeps you personally motivated to keep on operating on people?

PROF HARRIS: There are two questions there. What keeps me going? I guess what started me was the idea of being able to operate on people and see them get better. I still do that and I still get that satisfaction from it. I just do it a lot less often. I do not do a lot of the operations that I used to do because I found out that they were not effective. What keeps me going is the effective operations. I think I glossed over that and I fear the take home message from my talk is seen as surgery is a waste of time. It is not. There are many operations that are fantastic but I just do not mention them.

The fee for service system is a completely flawed system. The incentives or the disincentives in medicine are crazy. The economics of medicine are crazy. It is not supply and demand. The more doctors you put out there and the more surgeons you put out there, the more operations you have. That is how they earn their money and to be paid to operate does lead to more operations. This is why in the USA, the chance of you getting through your life without having your spine fused is about 10 or 20 times lower than getting through your life in the UK without having your spine fused. That is because in the UK they get paid the same whether they fuse your spine or not. In the USA they only get paid when they fuse your spine.

What we see in New South Wales and in Australia is the two-tier system. Spinal fusions are largely done in the private sector and not in the public sector. The difference is about 20 to 1. This is because when a patient comes to you with back pain you can give them this story. You say there is this operation we do where we fuse the spine. We are not sure if it works or not. However the only way we are going to know is if we try it and anyway it is the only chance you have. That is what you get if you are a private patient. It sounds reasonable. It sounds rational. It is a different

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story when the public patient comes in. Then you say, well we do not really know if surgery helps or not, so you are better off not having it.

MR MICHAEL FORDHAM: May I add something to that? That is also the reason why the statistics show spinal fusions in workers' compensation injuries are at a much higher rate than in the general public population.

There is a legal equivalent to this. If you go to a surgeon, you are going to someone whose natural inclination is to operate. If you go to a lawyer, their natural inclination is to litigate. However we settle a lot more cases than we used to because we have worked out that often the better result is not to run them through to trial with all the costs and the expense associated with it, but come to a negotiated outcome. It is the same logic in a different sphere.

DR ARTHUR RICHARDSON: I am a practising surgeon and I enjoyed both your talks very much. However we should just get a little bit of balance into this. The United Nations did produce a study recently that showed that the greatest problem in the world in terms of loss of life, that is in preventing death, was the lack of access to surgical care in the third world. This has now surpassed the lack of clean water, infectious diseases and all those sorts of things. There are obviously a lot of operations that do work and we must never forget that.

I can tell you I spend a lot of time in my office basically not operating on people. That is probably why I am so unsuccessful and still working.

MR MICHAEL FORDHAM: But you sleep well.

DR ARTHUR RICHARDSON: My own bias is that one of the answers to all this is going to be peer review, which is only really in its infancy. It certainly is in cancer care, which I mostly deal with. The other thing I am involved in is collecting great clinical data in the public sector. I would like both of your opinions about that because personally I think that is going to be the way forward, rather than thinking that all doctors should be on a salary and perhaps we should put all lawyers on a salary as well.

MR MICHAEL FORDHAM: I will start. We are not suggesting we all move to Cuba.

DR ARTHUR RICHARDSON: Where they have very good medical care.

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MR MICHAEL FORDHAM: Correct. Can I say that I initially started out with the idea of opposing this topic but the more I thought about it, the more I thought there was a middle ground. You are quite correct. You look at people who go and do glaucoma surgery in third world countries. It is all fabulous.

I think the only premise we are all talking about, and I will let the Professor speak for himself, is the actual efficacy of a lot of the procedures that are being performed that do not necessarily have to be. That is the balance. As a lawyer looking at that; it is a no brainer. You wrap your car around a tree and there are bits hanging out of you. Someone has to operate on you. I accept that. They are either going to get there or they are will not. They will either have done the job properly or they will not. However where someone walks in and says I have pain and I would like you to operate, to me as a lawyer that says you have to start thinking. What am I about to do? Why am I going to do it?

You are quite correct. The answer to these things is data and big data, but properly obtained data. That is the real trick to it.

PROF HARRIS: Thank you Arthur. I agree with everything you said. Yes, there is an imbalance. Just as we have six bedroom houses and in the third world they do not have shelter. It is the same problem. It is over the top here and it is under done elsewhere. I completely agree with that. Yes, some of the most effective interventions in medicine are surgical interventions such as cataract surgery and hip replacement. The latter is arguably the most effective operation that is done in terms of improved quality of life. Yes, I agree too that we need to be getting data. We are operating and we do not even know what the results of those operations are.

I am doing a study on the results of surgery in workers' compensation conditions, which is why I am going to talk to Michael later about his figures. This is because workers' compensation and Motor Accidents Authority, or SIRA as they are now called, are paying billions of dollars for operations and they have no idea whether they are working or not because nobody is measuring the outcomes.

MR MICHAEL FORDHAM: The number of cases I have handled involving work injuries where the person elects to have the first spinal fusion and later has three more, is frightening. Then later on down the track, you will get someone saying this should not have happened. However it is too late then.

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DR DESMOND REA: Plastic hand surgeon but also legally qualified. This is one of the best meetings I have been to for information. I mean that sincerely. It is different for a doctor. As you know, if you were treating a newborn baby and the baby did not survive after being given air, you would say to me, why did you not give it oxygen? Therefore I am going to give it oxygen, whatever happens because to say air is just as good does not work in the legal setting.

PROF HARRIS: There is this default position we have where we have to intervene. However that is not scientific but rather is a human response. The more I look into this, the more I find that humans are naturally not scientific. We often do not think scientifically. However, if we are to get to the truth of these matters and if we are to practise medicine better, we have to be more scientific.

MR MICHAEL FORDHAM: Some advice for the lawyers in the room. Do not ever forget that the best skill of an advocate is knowing when not to ask the question. Many people can and do get up and make noise. However it is all about knowing when to be silent and to think about what your next question is going to be, and if you are going to ask it at all. It is the same theory. We want to do things as we are humans.

QUESTION: Ian, recently there has been some interesting articles in the newspapers about the different outcomes of similar scientific studies, depending on whether or not they were funded by the supplier of the device or drug or whatever. Is that a form of reverse placebo effect or is it more evil than that?

PROF HARRIS: Yes, it is called industry bias or sponsorship bias. I was not aware there had been something recently, but it has been studied for a long time. There is very good evidence that studies sponsored by a company with an interest in the positive outcome, are more likely to have a positive outcome.

The best example, and a great one as well, involves antidepressants which I just touched on earlier. The most commonly prescribed class of antidepressants are the serotonin reuptake inhibitors (SRIs). When you look at all of the studies on SRIs that have been published and summarise them, you find they are very effective working in 90 per cent of the cases. What a great researcher named Irving Kirsch did was to review all the studies that had been done. This included those studies that were done is a different

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population to all of the studies that had been published. To gain access to all the studies that had been done involved him in a long legal battle with freedom of information through the FDA in America. He then summarised all the studies and found that most of the time SRI antidepressants were no better than a placebo. In other words all the studies that showed SRIs did not work had been withheld from publication.

QUESTION: Are the researchers implicit in that or is it subconscious?

PROF HARRIS: I think a lot of it is subconscious. I am criticising surgeons for doing operations that do not work. I do not think for one minute that the surgeon knows it does not work. In fact the surgeon believes it does work. We say it is all about the money and surgeons are greedy. Some of them are but they are not knowingly doing an operation that does not work just for the fee. My argument here is because there are plenty of other operations that they can do that do work for just as big a fee, they must believe their operation works. I do not know whether or not that makes them complicit.

MR MICHAEL FORDHAM: The other issue is the quality of the research. One of things covered in the book is that just about anyone can get anything published these days. Now people are even paying to have things published, as opposed to the old days when they paid you. In passing I did notice Bill Madden in his blog a couple of days ago put out that a drug has been approved by the FDA based on a study involving 12 patients. That has to be controversial.

PROF HARRIS: The science is bad. There is a famous paper postulating most published research findings are false. The problem is that people take that kind of view and therefore we cannot trust science. We just have to rely on our own observations. No, science is still the best way of findings things out, we just need to do it better.

MS LOUISE HAZELTON: Legal. How would this topic interplay with such procedures as sex change operations? Putting aside emotional psychiatric components, arguably, physically, you have a body that is in working order and you are operating to change it, just for a physical perspective.

MR MICHAEL FORDHAM: I think the first proposition is you cannot separate the psychiatric component of someone who has a gender identity crisis and wants that sex change. So it

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is not as simple as taking a working thing and removing it or adding to it. You are dealing with a whole person.

I did a couple of cases about this, years and years ago, where the real fault happened because people then did gender reassignment surgery without a proper psychiatric profile. It is not answering your question but you cannot split it. I think it is a different mode as opposed to a simpler example such as a piece of orthopaedic surgery.

PROF HARRIS: It is a different benchmark from effectiveness. Here we are not talking about effectiveness, that is, does it relieve pain or restore function? When you are talking about a sex change, is it achieving what the patient wants, which is a different anatomy?

I have done, and this is going to sound really shocking, particularly for someone who does not operate until he has to, amputations on patients who had nothing wrong with their legs. This is because there is a condition whereby the patient wants an amputation so badly that they reach the stage where they will, in some cases, put their leg on a railway track and try and kill themselves in order to get rid of the leg. That is the ultimate ineffective surgery in one way, taking off a perfectly good leg. However in another way it is achieving the goal that has the least harm. It does become very tricky when you start talking about things like that.

MS ANNE UNG: Occupational therapist. My question, prior to what you said just then, was knowing that the placebo effect happens and you have a patient you have matched to benefit from the operation …?

PROF HARRIS: Why not use the placebo effect?

MS ANNE UNG: Yes, to your advantage and help the patient to go in the direction of wellness.

PROF HARRIS: That is the question that comes up every time I give a talk. I have had dinner with orthopaedic surgeon colleagues where I argue with them about these arthroscopy trials that show that it does not work. They say, I love those trials. I do so many arthroscopies now because of those trials. I say, why? They say, because two thirds of the patients are better after the sham. I say, but two thirds of the patients are better after surgery or no surgery? And they say, yes, so two thirds of my patients are better. It is fantastic.

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Why do we not just use the placebo effect? I have got a couple of problems with that, which I do spell out in the book. For example, they are not better because of what you did. The placebo effect is vastly overrated. You are treating patients with fluctuating conditions. It is just one reason why you think they are better. A fluctuating condition, such as osteoarthritis of the knee, is sore one week, may be bad for a month or even sore for just one day. It is all over the place. If you see a patient at a time when they are particularly sore in the knee, and you do anything to them, then at any time after that, they are not going to be as sore as when you "treated" them. The surgery has not done anything. However it is not the placebo effect either. It is just the natural history of the condition and you are playing on it.

It is unscientific and it exposes patients to risk. I do not want to pay for it and yet I am paying for it, and it is unscientific. As soon as we embrace the placebo effect, we have removed the only barrier between mainstream medicine and alternative medicine or witchcraft. Homeopaths live on this placebo effect.

QUESTION: I come to the defence of the placebo effect. In analgesic trials there is about a 30 per cent placebo response. Moreover, for whatever reason we simply do not know, that response is increasing over the last 10 years. Accordingly, to prove that an analgesic works, you have to show that it is better than a placebo. The assumption was that where the analgesic worked in the brain was where the placebo worked. With the recent functional imaging of the brain, we now know that the placebo effect is actually in a different part of the brain to that where the analgesic active substance works. It has also been shown that that response by the brain is sustained over a long period of time and can be repeated. The problem with this is that it now begs the question of what is the value of placebo trials, because you are not comparing apples and oranges anymore. The placebo response is real, it works in the brain and is sustained. However it is not a good comparator anymore.

I think we now have a difficulty with the traditional way of testing many drugs by comparing their efficacy with that of placebo. We are not now comparing the same thing.

PROF HARRIS: Yes you are. You are comparing their effectiveness. What you are arguing is that they have a different mechanism by which they achieve that effect. However you are still comparing effectiveness. This is why

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I stick to surgery, because with surgery it is higher stakes than with Panadol.

QUESTION: I am saying we have to be careful using the word.

PROF HARRIS: Yes we do and that is a big topic.

MS KEELY GRAHAM: Which we will continue at the Queens Club for anyone interested. Thank you very much.

MEETING CONCLUDED

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