Inquiry into The Regulatory Standards for the Approval of Medical Devices

Written Submission as an individual – with thanks for this inquiry

Background

I have been working on a voluntary basis as a health consumer representative since the year 2000, which is when I left the formal workforce because I was not managing well a year after a total knee revision. The revision was required because of a design fault in the primary knee replacement.

I received the first knee replacement in 1993, aged 48 years. I had severe, debilitating post-traumatic osteoarthritis in the knee following a netball injury at the age of 15 years. This injury was before Medicare and my family could not afford the care and follow up required. The shortcomings in management, limited access to appropriate care and lack of proper advice continued over the years and in more than one country (England and Australia).

At the time of the first replacement I was in severe pain and had limited mobility, in range of movement and the ability to get around. The knee replacement addressed the pain, for which I am very grateful (I could not have kept going with four young daughters) but the soft tissue damage was such that range of movement continued to be limited and my rehabilitation, which included a manipulation under general anaesthetic, was slow (well over a year).

It had been an extremely painful operation but I had told myself that it was worth it and even though I had been informed it would be good for around 12 years I was convinced that I could make it last longer.

Life took its normal twists and turns so in 1999 when I had the revision I was newly separated and was a single parent of four school-age daughters on a limited income. I struggled along for some months thinking that the increasing pain and difficulties with my knee were simply a small continuing physical problem with a large psychological component, But no, metal was rubbing against metal where polyethylene had been before. Eventually I had to recognise that I had a real functional problem with my knee. I went to my GP who referred me back to my orthopaedic surgeon. The surgeon knew straight away what the problem was likely to be. The design fault was apparent during an arthroscopy, the prosthesis was irretrievably damaged and I required a total knee revision, with all the difficulties that went along with that (for me, the surgeon, anaesthetist and nursing staff who had to cope with reactive blistering complications).

People now suspect that high levels of chrome cobalt (the composition of the articulating surface of all joint replacements) can have physiological effects, including depression, which in hindsight may have been a confounding factor for me.

Present position

As a consumer representative

I have had ongoing discussion (for well over a year) with the Therapeutic Goods Administration (TGA) representative on the committee about the need to alert those people who receive a prosthesis (later) identified to have a design problem causing increased revision rates. As has been now bandied around quite a bit now, that is what happens when a model of a car has issues with any of its parts that potentially cause safety issues.

The immediate response to my proposal was that this could not be done because it would increase the anxiety levels of those with the prostheses (and increase the number of appointments with clinicians). We did make inroads, however, with increased information for orthopaedic surgeons (through the Australian Orthopaedic Association). The new TGA website is also heading in the right direction of making information more accessible – but cannot solve the present issue as it goes much deeper than that.

I am an evidence-based consumer who prefers to weigh up the levels of evidence and work within deliberative processes, rather than be driven by a cause and legal action, though my experiences do give me a passion and attention to detail that may not otherwise be there. What I had wanted, right from my first knee replacement, was truly informed consent; as well as to be notified when there was a potential problem. Because of my research background I became involved as a consumer with

I wanted to help with assimilating the evidence for healthcare interventions in a way that would help consumers.

Again, when my first knee replacement had not given me 'all I desired' in the way of mobility I had talked with my surgeon about the need to be tracking replacements and the outcomes. It was not surprising therefore that when the National Joint Replacement Registry (NJRR) was set up I applied (stimulated by fellow consumer representatives) to be on the Advisory Committee. I am now on the

as there is much work still to be done, which I can contribute to.

As the consumer member of the

I have been able to track the important place of the data and evidence from the NJRR. The Registry now has nearly 10 years of data on some prostheses, with survival curves over this time that compare how small changes in the inherent design of a prosthesis can alter the survival curve. These reports that are generated for those requesting data from the registry are powerful.

My proposal

The primary obligation of the TGA in the area of safety appears to be the sponsors. Regulation is self funding. The process of identifying potential problems of a medical device is legally in the hands of the sponsors. Alerts and changing the status on the Australian Register of Therapeutic Goods (ARTG) therefore has to follow due process (between the sponsor and the TGA). It is this process that appears to be letting the public of Australia down. It is getting in the way of duty of care – by clinicians for their patients.

I would like to see more information from the NJRR in the public domain; and the NJRR having its own independent role in monitoring the use of joint replacements in Australia. It has shown itself to be responsible, working hard to obtain a near 100% reporting from operating theatres, and identifying training needs as well as providing comparative data for surgeons.

Its position with the relevant professional bodies (which could be strengthened with accreditation and other requirements?), and its ability to respond to consumer queries, puts it in an excellent position to improve care for Australians.

I do not see that adding another overarching layer at the 'top' of our health system can achieve the same goals unless it itself is 'answerable to the Registry. This has already been the issue with the NJRR having to raise its concerns about safety with the TGA, adding years and many additional patients who continue to receive the doubtful prosthesis. This is NOT a cost effective way of managing the health of our Australian citizens.

Safety and comparative effectiveness are very difficult to separate with medical devices, especially high risk devices such as hip and knee replacements. While the TGA does a good job with assessing high risk medical devices (within the present limitations) in order to go on the Australian Register of Therapeutic Goods (ARTG), safety needs to go much closer to the patient/consumer/public-clinician interface.

TGA regulation processes are and need to be under review, for example reusable devices – to differentiate between market drive, necessity because of infection and other safety concerns, funder concerns and other issues; when a device is a device or an instrument (for example catheter tip electrodes/stimulators) that is reusable under well-defined guidelines. This actually has an impact on what is available to consumers and we may not always be receiving the best treatment because of funding issues between interventionalists or surgeons and hospitals/clinics.

Technology is rapidly changing and becoming cleverer (as with insulin pumps). We cannot afford to sit within rigid systems and definitions – which includes 'what a prosthesis is'. Consumers and their healthcare providers

want innovation, and even the 'breakthrough' but this is likely to be only through small steps by industry. Vigilance is really important.

The system of providing a single benchmark price for prostheses in the Private Health System (as a result of the HTA Review) is something that has to be monitored carefully in terms of the end result for consumers – both in terms of best practice and (hidden or unforseen) costs. I am very uncertain that it offers any reassurance to consumers about affordability of such devices – with surgeons and private hospitals.

Review of Health Technology Assessment in Australia (HTA Review) Recommendation 2 (February 2010) Recommendation 2: that the rigorous consideration of evidence be consistently applied across all Australian Government HTA processes – to ensure sustainability of the Australian Government's health financing arrangements (www.health.gov.au/htareview)