Consultation : Regulation of autologous stem cell therapies: Discussion paper for consultation

PATIENT SUBMISSION

I have been a stem cell therapy patient under the current 2011 TGA regulation of medical practitioners caring for patients for a single indication in a single course of treatment, in my case osteoarthritis of the left knee, my most affected but not only affected joint.

I used internet searches for human medical treatment with stem cells over the past three years

(1) to identify research and treatment being carried out in Sydney of autologous stem cell implants for osteoarthritis
(2) To identify researchers seeking volunteers for autologous stem cell implants for osteoarthritis
(3) To seek reports of uses and risks of autologous stem cells by practitioners

I kept my G.P .informed of what I was doing and she was aware that I was reluctant to undergo knee replacement surgery because of a family history of allergy and a parent's rejection of a hip implant device in the 1970s which left him permanently confined to bed.

I have participated in two trials under different conditions. In both cases I felt as protected by the Australian Health Practitioner Regulations as I do with any medical consultations I undertake. The first used conventional double blind trials of a very small, statistically insignificant sample, the second used the same treatment protocols but reported anecdotally. Different processes and machinery were used to produce implant cells in the two trials. I participated in the second because I experienced no benefits from the first trial.

My internet searches showed that most informative sites published in English arose from countries other than Australia and came from Switzerland, India, Thailand and the United States, except for practitioners treating with stem cells in Sydney who advertised their clinics.

RESPONSE TO QUESTIONS

What are the public health risks of autologous stem cells?

As a patient assessing whether to volunteer for treatment, the public health risks of autologous stem cell therapy appeared no greater than for many other surgical procedures and medicines approved by the TGA, and seemed less risky for a hyper allergic patient. Some surgical patients suffer serious infection after hospitalisation and one day approved procedures, and allergic reactions occur to approved medication and to some TGA approved implants, eg hip implants over the last five years. Most TGA approvals rely upon manufacturers' information and do not provide an impartial assessment that is openly available to consumers of medical products. The protocols under which I was treated with stem cells were of the highest standard. I suffered no ill effects from participating in both trials although the second trial was conducted under more pleasant conditions and ensured patient comfort rather than only seeking research publishable results. At no time did I feel I was at any health risk but accepted that the treatment was comparatively novel for humans and did not have a widely reported proven success rate.

Replacing more stem cells than the body can produce is not dangerous but the way in which the autologous stem cells are produced has not yet been evaluated and the efficacy of alternative methods was not well established when I entered the trials. The manufacturers of machinery to produce stem cells are not subject to evaluation or regulation and are able to charge what the market will bear, thereby affecting costs to patients. As more manufacturers enter the market, prices will fall and costs to patients will fall. Ussers' review will become available when anecdotal results of a large number of patients are collected and each processor evaluated. Any public health risk or cost is more likely to occur in the processing of stem cells than in treatment in the surgery.

At present there is little publication of public health risks from autologous stem cell treatment. An association of medical practitioners in Australia and overseas treating with stem cells for a wide range of illnesses has been established, The Adult Stem Cell Foundation, and has invited practitioners to report successes and failures to the Australasian Stem Cell Foundation to be made publicly available. I have been unable to find similar sites for other forms of medical treatments suggesting there is more openness than in some other branches of medicine.

What is the evidence of these risks?

I found no information about risks from internet searches, except that the treatment was not recommended during pregnancy or for patients with an infection, cancer or an unstable illness. I am aware from media discussions that there are some medical practitioners opposed to autologous stem cell treatment but I did not find their arguments or demeanour convincing. I am not qualified to comment further on the evidence.

What identified risks should have the highest priority for resolving?

I am not qualified to comment because I experienced no risk or adverse reactions under the 2011 TGA guidelines.

Are there public health benefits, such as patient access to new and novel treatments?

There are public health benefits and cost benefits of autologous stem cell therapies. The surgical procedure to remove fat is less complex than for mechanical metal implants. They are day procedures of short duration. If anecdotal reports of a statistically significant number of patients under the present regulations establish efficacy, and if stem cell treatments were government funded as an alternative to mechanical implants for suitable patients, they have the potential to greatly reduce public health costs. At present a success rate of 75% is being reported by one stem cell practitioner which offers potential financial savings in public health costs. No expensive implant is required, more procedures can be carried out daily in theatres, less equipment and staff is required in theatres, less anaesthesia is needed, patients are mobile immediately after the procedure and do not require hospital nursing, they return home, they resume normal life within days and need less medication for pain.

There are many advantages of stem cell therapy for osteoarthritis patients. The condition occurs throughout the body and anecdotal reports indicate that sites, other than the treated site, experience improvement. I experienced improvement in many joints other than the prime site for treatment. Any changes over time can be measured with regular completion of a WOMAD scale. Overall improvement does not occur with mechanical implants and many patients go on to require treatment on other parts of their bodies. Stem cell patients do not require post-operative nursing or physiotherapy to walk after treatment, although they benefit from appropriate hydro therapy which can be done at low cost in public pools without continuing paramedical supervision. Patients can continue with their lives immediately after treatment.

It is not appropriate for me to comment on each of the options offered for discussion. It is important that whichever option is selected, no extra costs should be involved for the medical practitioner to be passed on to patients. The same consideration exists if stem cell treatment is recognized and supported by Medicare. The option chosen should not add to costs.