

Therapeutic Goods Administration

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Regulation of autologous stem cell therapies

- Are there public health benefits, such as patient access to new and novel treatments, to consider?
- What do you see as the likely risks, benefits and costs of each option to you? If possible, please attempt to quantify these costs and benefits.

I wish to make a submission on the above matter. I have personal experience of the procedure and have assisted many others to take advantage of it. I used to be a registered nurse, so I understand the clinical procedures and impacts of the procedures on the anatomy and physiology of people in chronic pain, many of whom are old and frail.

My experience with surgery

I have had a Total Knee replacement (TKR) to my left knee. This was done 2006, so nearly 9 years ago. At that time I was on morphine patches for the debilitating pain in the knee and unable to walk without a walking stick. Various Xrays showed the right knee to also be badly affected, however the pain was nowhere near as bad.

I had the replacement even though I was only 48 years old. The surgery was horrifically painful and I was off work for 9 weeks to have the surgery and rehabilitation. The cost was around \$27,000 at the time. Medicare paid around \$6000; I paid around \$7000 and the health fund the balance. I had to use all my annual and long service leave, as coping with the pain had already reduced my sick leave balances. However, given that opportunity cost you could add to that cost the 9 weeks forgone pay.

The surgery was successful in that I was mobile without a stick, could manage the pain on Panadeine forte and had much improved range of movement. However, even in the left knee I still had residual pain and over the 9 years this has got worse. It still limits my activities and causes me periods of intense pain.

My experience with stem cells

Given the above, I was desperate when my right knee started to fail me. I did not want to lose that amount of time nor incur that amount of pain. I looked around for an alternative. I was prepared to balance innovation against the known trauma and costs of the TKR, which I had been told I would need.

In December 2010 I had my first stem cell treatment. I had the procedure before planned leave for Xmas, and needed no additional time off work. In fact a week to 2 weeks leave is all that would be needed. The procedure was not painful, the recovery was not painful. Within 2 days the pain in the right and left knee was relieved. Within 2 weeks I was pain free in both knees – with the swelling and redness gone. Various other points of arthritic change and pain also were resolved. A year later I repeated the procedure as the pain was slowly increasing again, however, I had not been as careful in protecting my knees and had aggravated them by physical

activity that was not recommended. The cost was around \$9000 and worth every cent. It also dropped me off Panadeine Forte onto Panadol Oesteo, a further health gain.

In summary, less invasive, less time off work, no general anaesthetic, excellent pain relief and less expensive over all. The repeat xrays showed a marked improvement in the health of the joint.

I will keep finding the money to repeat this procedure as necessary since it gives me benefits above and beyond the relief of symptoms on both knees. I wish I could be as lucky as some who don't need repeat applications, however, repeat treatments of stem cells are much more acceptable to me than the risks of the TKR.

Wider application in 2015.

The health funds currently seem to quote the cost of a TKR as around \$26000. However, I am unsure if that includes all the co-payments for all the pre-operative checks and the rehabilitation. It will not include the costs of pharmacy or sick leave.

There is no waiting list for stem cells, so you do not lose productivity in having medicated people coping with chronic pain trying to work or live their lives. The results are quick, allowing people to get on with their lives.

I am the CEO of an aged care organisation. As such, I understand the demographics of our ageing population, and in particular the ageing workforce. Arthritis is a debilitating disorder that will reduce our workforce and impair their ability to work at full capacity. The stem cell option is a very cost efficient way to address that. I also understand the major government push to re-enable older people, to keep them as active and as healthy as possible for as long as possible. This treatment avoids all the complications of a general anaesthetic and extremely painful surgery. It is much more acceptable to an older person, being kinder to their bodies and enabling them to quickly get on with their lives. It reduces the dependence on pain killers that have harmful effects on their co-morbidities.

This procedure could massively reduce the health bill even if it only delayed the joint replacements for a few years. The improved mobility gives people a chance to reduce their weight and to get or keep active.

The risks if performed in an approved surgical manner are less than those associated with a TKR or hip replacement and the pain is considerably less.

As our population ages it is essential that such treatments be encouraged and with appropriate management become mainstream.

Yours sincerely

Illana Halliday