

Xenotourism

Will your next trip overseas be for a new kidney?

Peter De Luca

Sick patients travelling overseas for revolutionary new medical treatments in countries such as Russia, China and Mexico. This isn't the plot line of the latest Michael Crichton science fiction thriller. Instead, it is the stark reality for a growing number of Australians who have realised that their only option for a potential life-saving medical cure lies halfway across the world.

Xenotourism is where someone travels to another country for a xenotransplant, the transplantation of animal tissue or organs. Anecdotal evidence indicates that more people are choosing this option to treat conditions such as diabetes and then returning to live in countries where the procedures are not yet approved, rather than waiting for governments to legislate in favour of new treatments.

The use of animal cells in medical treatments is not new (see sidebar). In fact, pig insulin has helped treat diabetics for almost half a century. The genetic makeup of pigs is remarkably similar to humans and, as such, provides a valuable alternative source of insulin.

So why all the controversy? Xenotransplantation has had some bad press in the past and, therefore, regulators are keen to proceed with caution.

In 2004, the Australian National

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Health and Medical Research Council (NHMRC) recommended the banning of whole animal organ transplants for five years, although it said it was 'undecided' about whether to allow animal cell and tissue transplants into humans. The NHMRC did acknowledge the 'lower potential risk of infection and higher expected benefit to humans' of animal cell transplants.

In March 2005, however, the NHMRC released a report suggesting that xeno cell treatments would not go ahead until more evidence was produced which allayed their safety concerns. In the past decade, extensive research has been conducted, including an international study in 1999 which reported no transfer of pig viruses (porcine endogenous viruses) in 160 human patients treated with living pig tissue.

And so, in 2006, the moratorium in Australia remains, while New Zealand is making progress on the xenotransplantation issue.

Australia and New Zealand are working towards a joint trans-Tasman

regulatory policy on therapeutic products. The joint Australia New Zealand Therapeutics Products Authority will replace Australia's Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (MedSafe). It will regulate prescription and over-the-counter medicines, complementary medicines, medical devices and blood products in both countries. There will be three phases of public consultation on the proposed regulatory scheme—began in late May 2006, and continued in September 2006 and March 2007. It will be intriguing to see the joint policy outcomes on key biotech issues where the two countries differ greatly.

After extensive community consultation, the NZ BioEthics Committee released a detailed report in late 2005 which recommended xenotransplantation proceed on a case-by-case basis. NZ Government ministers have indicated that the legislation will be reviewed before the end of 2006.

What is cell therapy?

Cell therapy is the transplantation of cells (of human or animal origins) to replace or repair damaged tissue and/or cells. The goal is for the healthy cells to become integrated into the body and begin to function like the patient's own cells.

How are cell therapies being used today?

- Bone marrow transplants
- To graft new skin cells to treat serious burn victims
- To grow new corneas for the sight-impaired
- Pancreatic cells implanted into diabetics to produce insulin
- To rebuild damaged cartilage in joints, repair spinal cord injuries and treat neurological disorders

What is xenotransplantation?

Xenotransplantation is the transplantation of living cells, tissues and organs from one species to another.

News of cell therapy developments has emerged in the media recently. The Australian Federal Government recently announced funding of \$30 million over four years towards the development of an Islet Transplantation Program. In 2006, approximately 50 patients will be transplanted with human islets under the Program. However, there are 130,000 type 1 diabetes patients in Australia alone and, in 2005, only 204 Australians donated their organs. Two to three donors are needed for each transplant. The equation just doesn't add up.

While type 1 diabetes patients are sometimes able to manage their lives through a complex regime of multiple daily insulin injections, the sufferers of debilitating incurable diseases such as Huntington's Disease are not so fortunate. With no available treatment, their impatience with the policymakers is understandable when a possible clinical trial in their home country is unlikely to take place solely because it uses animal cells.

With the introduction of genetic screening, people now know their predisposition to certain diseases. Who can blame someone with the incurable curse of Huntington's Disease hanging over them for exploring every available avenue of treatment, here and overseas? Embryonic stem cell treatments are still years from becoming a readily available medical reality and xenotransplantation looms large as a potential solution to the critical cell supply problem.

Even though local research groups would prefer to conduct patient trials of xenotransplantation in the southern hemisphere, they, like their potential patients, are beginning to look offshore, conducting early-stage trials in China and the United States.

The US Food and Drug Administration (FDA) has already demonstrated a willingness to support xenotransplantation, allowing animal tissue treatments, such as one for Parkinson's Disease, to proceed. Similarly, more than eight clinical trials using

xenotransplantation are currently under way in Europe.

When it comes to cell therapy, Australia risks being left behind.

First-mover advantages in biotech are significant, particularly when Europe and the United States assume leadership. Australia and New Zealand are in a unique position. Some of the companies within their boundaries are considered among the world's leaders in research and are rapidly approaching the human clinical trial phase after years of research.

Australia's research capability is respected the world over, but doubts have always arisen about the nation's ability to commercialise its research and drive its innovations to the next phase of development. It seems that the process is set to repeat itself.

Waiting for other countries to give the all-clear and establish regulatory frameworks, rather than becoming an active partner in developing the appropriate checks and balances on xenotransplantation, will only see the relocation of investment dollars overseas. The cures for diabetes and neurodegenerative diseases are extremely lucrative, but companies and researchers located in Australia will miss the opportunity if they are not supported by policy makers. Their only option is to relocate if they want to advance their research into the human trial phase.

Let's hope the cautious attitude of domestic policy makers doesn't stall the commercialisation of new technologies such as xenotransplantation at a time when the biotechnology industry receives record levels of public funding. The industry is expected to deliver the benefits of this funding to the economy, investors and patients alike—will policy makers now make it possible?

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A Short History of Cell Therapy

1536 Phillippus Aureolus Paracelsus—German-Swiss physician and alchemist who believed that the best way to treat an illness was to use living tissue.

1667 Jean-Baptiste Denis—Attempted to transfuse blood from a calf into a mentally ill patient.

1912 German physicians tried to treat patients suffering underactive thyroids with thyroid cells.

1930s Blood transfusion established as medical procedure to replace lost blood.

1931 Dr Paul Niehans became known as the 'father of cell therapy' when he used parathyroid gland cells from a calf in a saline solution to treat a dying human patient. The patient lived for another 30 years.

1969 First human bone marrow transplant as treatment for leukemia by ED Thomas.

1978 Human insulin is synthesized in the laboratory as a treatment for diabetes. Until this breakthrough, people with diabetes relied on animal insulin, primarily from cattle and pigs.

1986 First human clinical trials of islet cell transplants in diabetic patients.

1991 Isolation of human stem cells by Weissmann's group at Systemix Inc

1998 First intra-cerebral cell transplant to reverse brain damage caused by stroke.

2006 There are currently at least half a dozen clinical trials underway in Europe and China using xenotransplantation as well as a FDA approved clinical trial of an animal tissue treatment for Parkinson's Disease in the US.