Australasian Science

Volume 37 | Number 6
JULY/AUGUST 2016 | $9.95

SPECIAL ISSUE

Genomics

Do Genome Tests Live up to the Hype?

Are We Prepared for Our Test Results?

Should Genomes Be Screened at Birth?

Should You Share Your Genetic Data Online?

Will a Genome Test Lead to Healthy Behaviours?

Indigenous Questions about Genomic Research

Global Biobanks: A New Frontier for Big Data?

The Changing Landscape of Gene Patent Law

The Stem Cell "Sell"

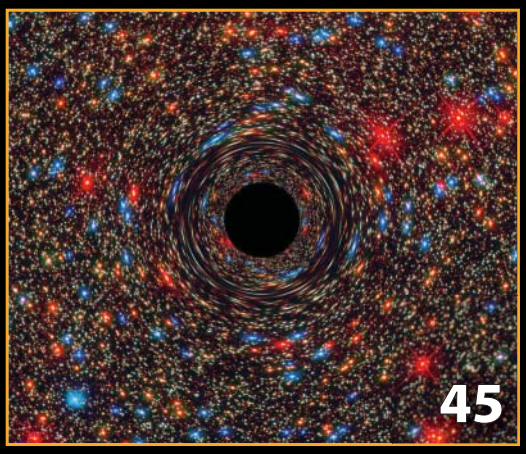
Toxic Legacy of Firefighting Foam • Mindless Scientology • Linguistic Diagnosis of Disease

ISSN 1442-679X 06

9 771442 679017

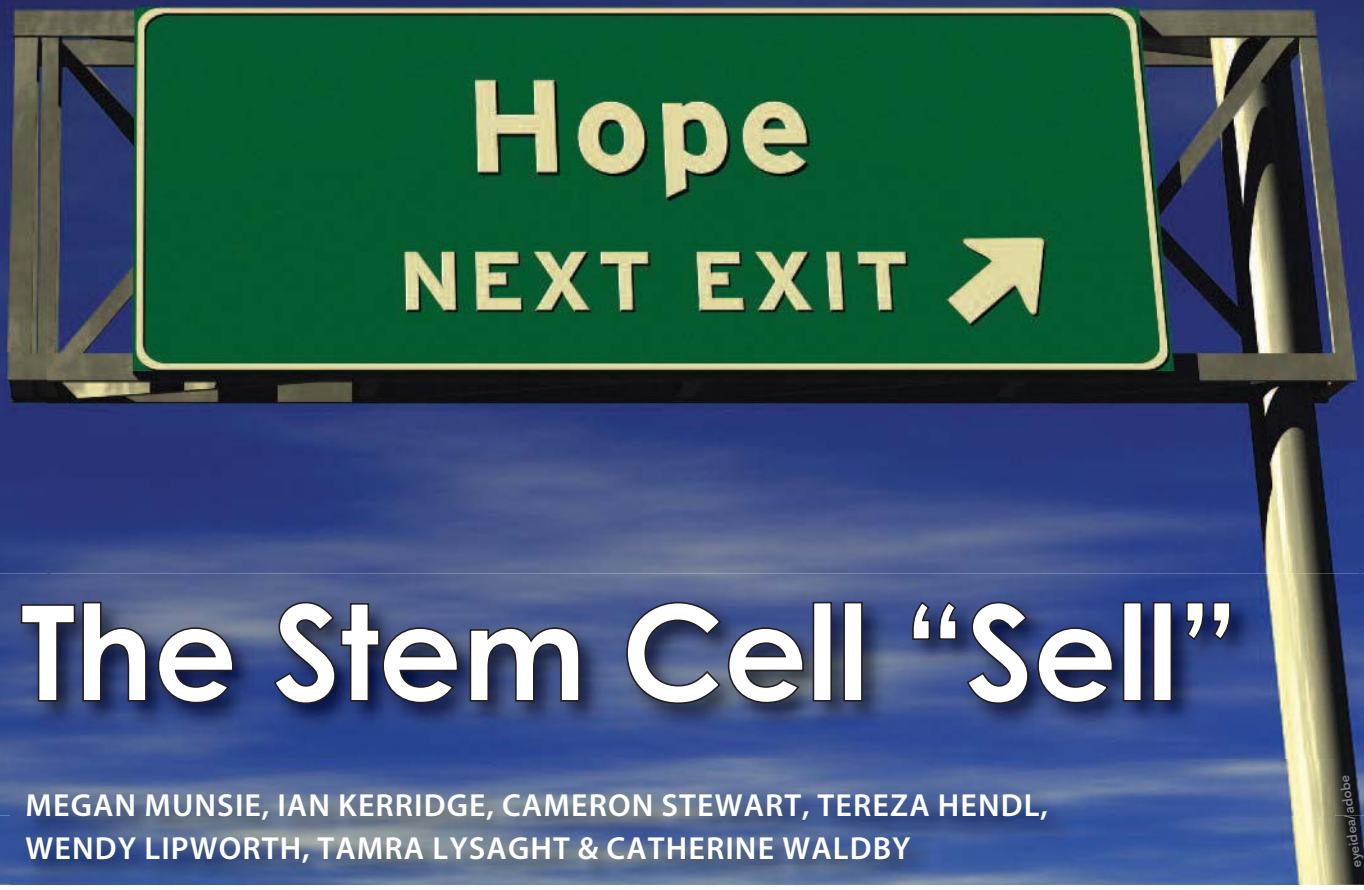
FEATURES

conSCIENCE



NEWS

COLUMNS



The Stem Cell "Sell"

MEGAN MUNSIE, IAN KERRIDGE, CAMERON STEWART, TEREZA HENDL, WENDY LIPWORTH, TAMRA LYSAGHT & CATHERINE WALDBY

The unfettered commercial environment that has allowed stem cell tourism to flourish must be challenged, and the professionals who enable it should be held to account.

In recent years, a growing number of clinics in Australia and overseas have begun to offer therapies that claim to restore health by using stem cells to replace or repair the patient's faulty or missing cells. For those who have been told that conventional medicine has nothing more to offer, a visit to a stem cell clinic may appear to be worth the time, effort and expense that this entails.

The reality, sadly, is very different. Most people are unlikely to benefit, losing precious time, money, hope and trust in the course of pursuing this new form of medical tourism.

What's on Offer?

Stem cell tourism is a phrase used to encompass travel – usually overseas – for a wide range of therapies involving stem cells. These therapies may involve the use of the patient's own (autologous) stem cells from fat or their bone marrow, or donated stem cells from cord blood, embryos and foetal tissue.

Therapy might be administered by having the patient inhale the cells, or by injecting the cells under the skin, into a vein or joint, directly into the fluid around the spinal cord or into the patient's brain. Such therapies have been touted as effective treatments for many conditions and illnesses including arthritis, spinal cord injury, motor neurone disease, multiple sclerosis, cerebral palsy, neurodegenerative conditions and autism. Often the same treatment is offered for conditions with vastly different underlying pathology.

Unlike other forms of medical tourism – such as travel for IVF, cosmetic surgery, joint replacement or dentistry, which are based on access to well-established conventional therapies that are available more quickly and at a more affordable price than in the patient's home country – stem cell tourism provides patients with access to "treatments" that are yet to be proven. These treatments are not based upon rigorous scientific evidence, have not been clearly demonstrated to offer any benefit, and are not recognised or reimbursed by local health systems.

Although it may one day be possible to manufacture replacement cells to restore function to diseased or damaged organs, to date there remain few recognised stem cell therapies beyond the use of blood and bone marrow stem cell transplantation for the treatment of leukaemia, lymphoma and other diseases of the blood and immune system. While new stem cell-based treatments are being evaluated in clinical trials across the globe, the "therapies" offered by stem cell clinics are well outside this framework.

Not only are the benefits yet to be established, but the therapies offered also come with possible health risks. The cells are usually prepared "in-house" rather than in an accredited labo-

ratory with independent verification of exactly what cells, if any, are present in the solution administered to the patient. Some clinics also grow the cells in their laboratories, increasing the risk of infection and/or fundamentally changing the properties of the cells.

While complications are fortunately rare, they have been reported. For example, a Beverly Hills patient who had received a "stem cell" face-lift developed shards of bone around one of her eyes when the doctor mixed dermal filler, a commonly used reagent in cosmetic surgery, with the stem cells – turning them from fat to bone.

Deaths have also been reported overseas. In one case a young man who was left paralysed following a motorbike accident died when his stem cell treatment caused a range of complications, including increased pressure in his skull and brain.

Even if they don't cause direct physical harms, these unproven stem cell treatments are expensive and may pose a significant financial burden for many patients and their families – particularly at a time when many people are not working and are already experiencing the financial strain of chronic or life-threatening illness.

Patients pursuing stem cell treatments may also be diverted from existing and established healthcare, thereby compromising their long-term prognosis and ultimately limiting the options that may be available to them and to their family.

Stem Cell Tourism in Australia

Until recently, the key destinations for stem cell tourism were countries with little infrastructure and oversight of medical practices, such as China, Mexico, Ukraine, the Bahamas, Thailand and India. More recently, however, countries with high levels of healthcare and stringent rules and regulations governing medical practice, such as Australia and the USA, have become attractive destinations for stem cell tourism.

While the bulk of the doctors at Australian stem cell clinics restrict their services to treating osteoarthritis and other joint problems – extracting the patient's own cells and injecting them back into the affected joint, often on the same day – others "treat" a wide range of medical conditions from migraine to Parkinson's disease, multiple sclerosis and even dementia. Generally, these unproven autologous treatments are given intravenously, but in at least one Australian clinic, stem cells are injected directly into the fluid surrounding the patient's spinal cord and brain.

In most cases, the stem cell treatment does not involve a single injection, but rather a "course" of treatments – particularly when a benefit is not apparent after the first treatment.

Clinics also offer other services to prospective clients including accommodation, concierge services, massage, relaxation therapies and proximity to airports, making them readily accessible to interstate and international "tourists". All of this comes at a cost. Because these treatments receive no Medicare rebate or private health insurance refund, the out-of-pocket costs can be around $10,000 for each treatment. On any reading, this is a substantial amount of money to pay for a treatment that has not been shown to be effective and isn't offered as part of standard healthcare or within the context of a clinical trial.

... a Beverly Hills patient who had received a "stem cell" face-lift developed shards of bone around one of her eyes when the doctor mixed dermal filler, a commonly used reagent in cosmetic surgery, with the stem cells – turning them from fat to bone.

Misleading Rhetoric

It could be argued that those pursuing stem cell therapies are chasing an illusion – the false promise of therapeutic benefit. This does not mean, however, that they are foolish or misguided; rather, their choices can be understood as a result of the situation that their illness has placed them in, together with intensive advertising on the part of stem cell clinics and misleading media coverage of stem cell "science".

The websites and other advertising material used by stem cell clinics, both locally and overseas, are steeped in rhetoric of hope and claims of benefit – highlighting testimonials of grateful patients and favourable media stories. They also emphasise the innovative or "cutting-edge" nature of the treatments on offer, and imply that the doctors and scientists working in the clinics are medical pioneers or leading experts in their field.

What is made much less clear is the lack of evidence for these treatments, the potential risks involved and the high costs of care. To the patient, who fears the inevitable pace of illness or the prospect of death, stem cell clinics may therefore appear to offer the only chance to restore their health and well-being.

Another reason that stem cell therapies have become so popular is that stem cell "breakthroughs" feature prominently in both mainstream and social media, fuelling the perception that stem cells are synonymous with a "cure". Indeed, it has never been easier for patients to find out what medical science may promise, what treatment options are open to them and what they can purchase to improve their health. Type "stem cells treatments" into your favourite search engine and you will be presented with a long list of stem cell clinics that are prepared to treat you.

Ambiguous Regulatory Processes

Irrespective of whether stem cell clinics are based in China or Australia, all of them operate by exploiting a "grey zone" of medical practice. By positioning unproven stem cell treatments as "innovative" medical care, those who want to offer these treatments argue that this is reasonable because it may provide patients with a benefit and because patients have a "right" to pursue novel "treatments".

As well as confusing innovation with research, such positioning conveniently ignores the inherent conflict of interest for the doctor who may appear to be helping the patient make an informed choice about their options, but is also likely to financially gain if the patient elects to pursue stem cell treatment.

... in Australia there is no requirement for stem cell clinics to meet manufacturing standards that would usually be expected in the production of a cell-based product.

Such practices are also in stark contrast to the safeguards in place for clinical trials, where those seeking to test an experimental therapy would have to justify the scientific basis of the proposed research, seek independent review of the research protocol and the strategies in place to recruit, select, inform and care for the research participants, and ensure that patient-participants are neither financially penalised for participation or coerced by the prospect of payment.

Ambiguity also surrounds the governance and regulation of stem cell clinics. On the one hand, it would be expected that health professionals performing the treatments would be regulated by the medical and nursing boards responsible for the conduct of health professionals. In addition, because stem cell treatments can be regarded as a medical product, one might also expect that they would be subject to the laws governing therapeutic goods.

However, at present, providers of unproven stem cell treatments, especially those utilising the patient's own cells, appear to operate in a gap between these two modes of regulation. For example, in Australia there is no requirement for stem cell clinics to meet manufacturing standards that would usually be expected in the production of a cell-based product. All that is needed is for the treatment to be performed by a doctor registered in Australia and for the doctor to use the patient's own cells.

In response to concerns raised about these practices, the Australian Therapeutic Goods Administration (TGA) conducted a public consultation in early 2015 to explore ways to better regulate autologous cell-based therapies. The TGA is yet to announce the outcome of the consultation.

Groups such as the International Society for Stem Cell Research and the International Society for Cell Therapy have also been critical of both local clinics and of stem cell tourism, and have called for the adoption of tighter regulations and professional standards. Despite this, the number of stem cell clinics continues to increase, both in Australia and overseas.

The Illusion of Choice

Access to stem cell treatments is often promoted as a right, particularly for those who appear to have no other option for treatment of their disease. While the language of "rights" has strong rhetorical force, it is difficult for patients to make an informed choice about stem cell treatments when both the benefits and risks of treatment are uncertain and/or unproven, and when many clinics make anecdotal and unsubstantiated claims that patients "improve" with treatment. While this may be good for business, it is poor science and does nothing to facilitate genuine informed choice.

While patient choice must remain paramount in this and other forms of medical practice, the current unfettered commercial environment that has allowed stem cell tourism to flourish must be challenged, and the professionals who enable it should be held to account. Healthcare, irrespective of our desire to support innovation and scientific advances, must continue to be underpinned by evidence and ethical practice, and not simply by profit.

The authors are members of an Australian Research Council-funded research project to develop an ethical and regulatory framework for stem cell treatments in Australia. Megan Munsie is an Associate Professor at The University of Melbourne, where she leads the policy and outreach activities for Stem Cells Australia. Ian Kerridge is Professor of Bioethics and Medicine at The University of Sydney, and a Bone Marrow Transplant Physician at Royal North Shore Hospital in Sydney. Cameron Stewart is a Professor at Sydney Law School, The University of Sydney. Tereza Hendl is a Postdoctoral Research Fellow at the Centre for Values, Ethics and the Law in Medicine at The University of Sydney, where Wendy Lipworth is a Senior Research Fellow in bioethics. Tamra Lysaght is Assistant Professor and Director of the Phase III Health Ethics, Law and Professionalism Programme at The National University of Singapore's Centre for Biomedical Ethics. Catherine Waldby is Director of the Research School of Social Sciences at the Australian National University.

