Stem Cell Research (2014) 13, 647–653

Available online at www.sciencedirect.com

ScienceDirect

www.elsevier.com/locate/scr

REVIEW

# A question of ethics: Selling autologous stem cell therapies flaunts professional standards

Megan Munsie [a,*], Insoo Hyun [b]

[a] Stem Cells Australia, Department of Anatomy and Neuroscience, The University of Melbourne, Parkville 3010, Australia
[b] Department of Bioethics, School of Medicine, Case Western Reserve University, Cleveland, OH 44106-4976, USA

Received 23 January 2014; received in revised form 15 April 2014; accepted 22 April 2014
Available online 29 April 2014

**Abstract** The idea that the body's own stem cells could act as a repair kit for many conditions, including cardiac repair, underpins regenerative medicine. While progress is being made, with hundreds of clinical trials underway to evaluate possible autologous cell-based therapies, some patients and physicians are not prepared to wait and are pursuing treatments without evidence that the proposed treatments are effective, or even safe. This article explores the inherent tension between patients, practitioners and the need to regulate the development and commercialization of new cellular therapies — even when the cells come from the patient.


**Contents**



## Introduction

The possibility that stem cells could act as a repair kit to restore function following disease or injury has long been heralded as the next revolution in medicine. Although there remain few established stem cell-based treatments beyond

* Corresponding author at: Level 2, Melbourne Brain Centre, 30 Royal Parade, The University of Melbourne, Parkville, Victoria 3010, Australia.
*E-mail address:* megan.munsie@unimelb.edu.au (M. Munsie).

http://dx.doi.org/10.1016/j.scr.2014.04.014

the use of hematopoietic stem cell (HSC) transplants for leukemia and certain other diseases of the blood and immune system (Daley, 2012), extensive media coverage has fuelled community expectation as it depicts stem cell research much closer to clinical application than in reality it is. For example, while most clinical trials over the last decade were early phase studies using stem cells for cancer and graft-versus-host disease, the majority of newspaper articles during the same period focused on the potential use of stem cells for neurological conditions, cardiovascular disease and diabetes (Bubela et al, 2012). Heightened community expectation is also reflected in survey data where perceptions of the benefits of stem cell research are far greater than perceptions of risk (DIISR, 2010; Downey and Geransar, 2008).

For many who look to stem cells as a means to alleviate their suffering, or that of their loved one, such high expectations are unlikely to be met in the near future. Although the number of clinical trials for novel applications of stem cells has risen rapidly since 2004 (Li et al, 2013), the majority of the trials are focused on establishing safety with enrollment duly limited. Frustrated by the lack of access to clinical trials, many have turned to those offering stem cell treatment outside clinical trials (Kiatpongsan and Sipp, 2009; Lau et al, 2008; Petersen et al, 2013).

In the information age, finding a 'stem cell' therapy is not difficult. A simple on-line search will reveal numerous websites that rely extensively on compelling patient testimonials to promote their treatment and leave the viewer with the impression that a cure is "but a simple injection away" (Ogbogu et al, 2013; Petersen and Seear, 2011). Some providers offer to use the patient's own stem cells – so called autologous treatments – while others claim to use donated sources of stem cells including fetal tissue, cord blood and human embryos. However, what is exactly being delivered to the patient – and indeed if it even contains stem cells – is often difficult to ascertain as few providers have independent verification of the products they administer. The mode of delivery of the cells also varies, with some providers using intramuscular or intravenous injections, while others use intrathecal or intracranial delivery of the cells (Lau et al, 2008; Petersen et al, 2013). Claiming to be able to treat conditions as diverse as spinal cord injury, heart disease, cerebral palsy, multiple sclerosis, asthma, arthritis and chronic fatigue syndrome, the websites offer little in the way of scientific evidence to justify these "optimistic portrayals of stem cell treatments"(Petersen and Seear, 2011).

Although not as frequently promoted as orthopedic and neurological applications, 'stem cell' treatments to improve cardiac function are offered. For example, an Australian patient sought treatment in Thailand for his heart disease and diabetes using ex vivo expanded bone-marrow cells stating that there was a marked improvement in his heart's ejection fraction—"rising from below 20% to over 50%" following the treatment (Stem Cell China News, 2009). Such treatments are expensive with many relying on community fundraising to enable their treatment (Petersen et al, 2013), as can be seen from the following extract taken from a wife's plea for help for her husband:

> "Our family and friends have done a lot of research… stem cells are harvested from his blood and then put back into his heart…. After speaking to several couples that have gone through exactly the same as us, our belief is that this is the better road…. Although this is what we so desperately want, we have exhausted all of our funds."
>
> [GoFundMe (2012)]

While concern about patients traveling abroad to seek out stem cell treatments not available at home has been well documented, with the term 'stem cell tourism' used to describe this phenomenon (Kiatpongsan and Sipp, 2009; Master and Resnik, 2011; Ryan et al, 2010), it is what is happening in our 'own backyard' in relation to autologous treatments that requires closer examination and is the focus of this paper.

## Rise of autologous 'stem cell' therapies

The idea that you can use your own stem cells is highly appealing for many patients. Simple messages – such as the cells won't be rejected; that the risk of a disease is avoided, and that using your own cells is more 'ethical' – resonate in the community and are reinforced in direct-to-consumer marketing strategies employed by providers. Indeed those opposing the use of human embryos in research have long promoted adult stem cell treatments as a more ethically acceptable alternative, despite criticisms that such portrayals fail to acknowledge that the cited treatments await clinical validation (Smith et al, 2006) — a warning that can still be leveled at many promoting autologous cell treatments today.

To a large extent the growth in unproven autologous stem cell treatments has been enabled by the use of liposuction techniques. Despite calls by the American Society of Plastic Surgeons and the American Society of Aesthetic Plastic Surgery warning that 'stem cell' face-lifts and breast augmentation are "not adequately supported by clinical evidence" (Eaves et al, 2012), cosmetic surgeons have started to offer these services to their clientele. In Australia, cosmetic surgeons and others are going well beyond localized administration of cells derived from liposuction for esthetic surgery. For less than $10,000 Australian patients are being offered intra-articular injections of adipose-derived cell extracts for osteoarthritis and cartilage repair, as well as intravenous delivery of crude cellular extract for stroke, multiple sclerosis, retinal neuropathy, spinal cord injury, Amyotrophic Lateral Sclerosis and even autism. All of these treatments are being offered as a medical procedure outside clinical trials.

The underlying justification for such adipose-derived procedures is the assumption that the cellular extract contains mesenchymal stem cells (MSCs) — a type of stromal cell isolated from a wide variety of sources including bone marrow, fat, dental pulp and placental tissue and one of the most common sources of stem cells in new clinical trials over the last decade (Li et al, 2013). For the providers they are an attractive source as they are relatively easy to isolate from the patient, are reputed to be able to form cartilage, bone and muscle, and also exert immunomodulatory properties enabling them to act as an "injury drugstore" (Caplan and Correa, 2011). However, what are exactly MSCs and their use in regenerative medicine – and even whether they should be