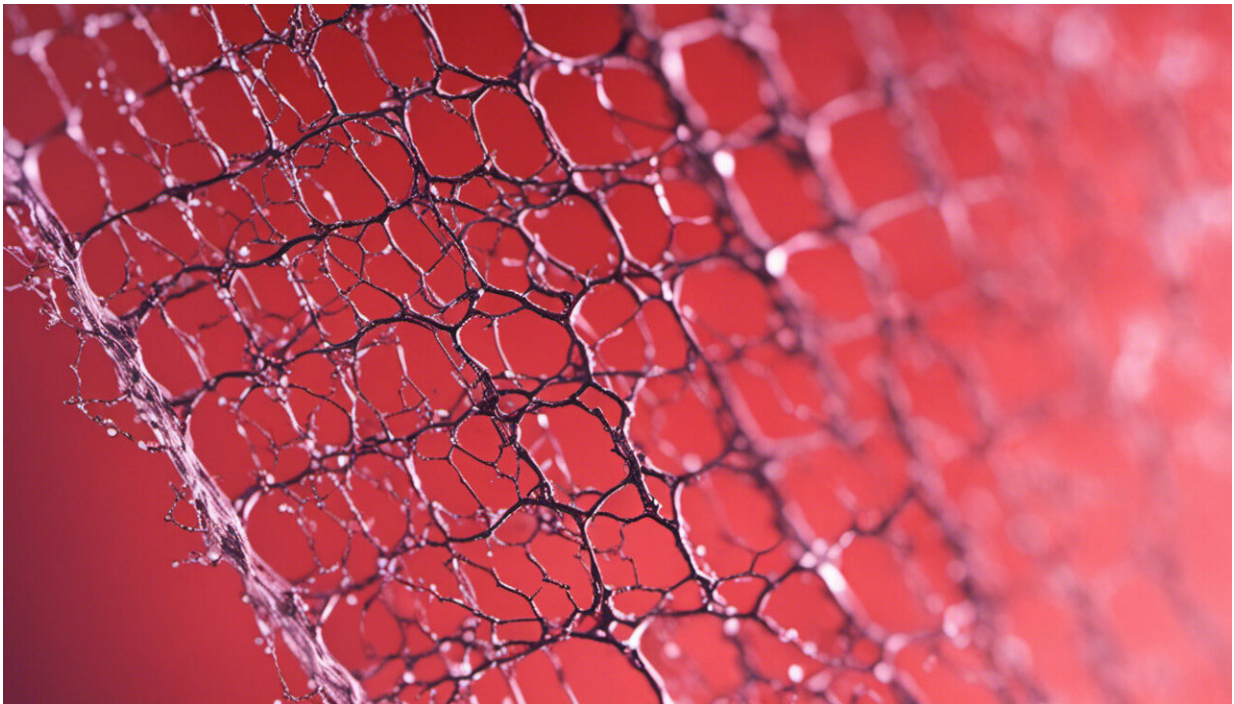


Private clinics' peddling of unproven stem cell treatments is unsafe and unethical

July 7 2017, by Megan Munsie And John Rasko



Credit: AI-generated image ([disclaimer](#))

Stem cell science is an area of medical research that continues to offer great promise. But as this week's paper in [Science Translational Medicine](#) highlights, a growing number of clinics around the globe, including in Australia, are exploiting regulatory gaps to sell so-called stem cell treatments without evidence that what they offer is effective – or even

safe.

Such unregulated direct-to-consumer advertising – typically of cells obtained using liposuction-like methods – not only places the health of individuals at risk, but could also undermine the legitimate development of stem cell-based therapies.

Many academic societies and professional medical organisations have [raised concerns](#) about these futile and often expensive cell therapies. Despite this, national regulators have typically been slow or ineffective in curtailing them.

As well as tighter regulations here, international regulators such as the World Health Organisation and the International Council on Harmonisation need to move on ensuring [patients](#) desperate for cures aren't sold treatments with limited efficacy and unknown safety.

So what's on offer?

[Hundreds of stem cell clinics](#) post online claims that they have been able to treat patients suffering from a wide range of conditions. These include osteoarthritis, pain, spinal cord injury, multiple sclerosis, diabetes and infertility. The websites are high on rhetoric of science – often using various accreditation, awards and other tokens to imply legitimacy – but low on proof that they work.

Rather than producing independently verified results, these clinics rely on patient testimonials or unsubstantiated claims of "improvement". In so doing these shonky clinics understate the risks to patient health associated with these unproven stem cell-based interventions.

Properly administered informed consent is often overlooked or ignored, so patients can be misled about the likelihood of success. In addition to

heavy financial burdens imposed on patients and their families, there is often an "opportunity cost" because the time wasted in receiving futile stem cells diverts patients away from proven medicines.

The many recent reports of adverse outcomes demonstrate the risks of receiving unproven cell therapies are not trivial. In the USA [three women were blinded](#) following experimental "stem cell" treatment for macular degeneration (a degenerative eye disease that can cause blindness). One [man was rendered a quadriplegic](#) following a stem cell intervention for stroke. And a woman whose family sought treatment for her dementia [died in Australia](#).

Other notorious cases involving the deaths of patients include the German government shutting down the [X-Cell Centre](#) and the [Italian government closing the Stamina Foundation](#) it had previously supported.

What's approved?

At present, the only recognised stem cell treatments are those utilising [blood stem cells](#) isolated from bone marrow, peripheral blood (the cellular components of blood such as red and white blood cells and platelets) or umbilical cord blood.

Hundreds of thousand of [lives have been saved](#) over the last half-century in patients with cancers such as leukaemia, lymphoma and multiple myeloma, as well as rare inherited immune and metabolic disorders.

A few types of cancer and autoimmune diseases may also benefit from blood stem [cells](#) in the context of chemotherapy. Different [stem cells](#) are also successfully used for [corneal](#) and [skin grafting](#).

All other applications remain in the preclinical research phase or are just starting to be evaluated in [clinical trials](#).

Often dismissed by for-profit clinics as "red tape" hampering progress, the rigour of clinical trials allows for the collection of impartial evidence. Such information is usually required before a new drug or medical device is released into the marketplace. Unfortunately, in the case of for-profit stem cell clinics, their marketing has gazumped the scientific evidence.

So what can be done?

Action is required on many fronts. Regulators at both an international and national level need to tackle regulatory loopholes and challenge unfounded marketing claims of businesses selling unproven stem cell interventions.

Researchers need to more clearly communicate their findings and the necessary next steps to responsibly take their science from the laboratory to the clinic. And they should acknowledge that this will take time.

Patients and their loved ones must be encouraged to seek advice from a trained reputable health care professional, someone who knows their medical history. They should think twice if someone is offering a treatment outside standards of practice.

The stakes are too high not to have these difficult conversations. If a stem cell [treatment](#) sounds too good to be true, it probably is.

For more information on recognised stem cell treatments visit the [National Stem Cell Foundation of Australia](#) and [Stem Cells Australia](#), [Choice Australia](#), [EuroStemCell](#), [International Society for Stem Cell Research](#), and [International Society for Cellular Therapy](#).

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