

## Japan and Australia's online market for unproven stem cell treatments

### Original publication:

Open for Business: A Comparative Study of Websites Selling Autologous Stem Cells in Australia and Japan

### Author:

Megan Munsie, Tamra Lysaght, Tereza Hendl, Hui-Yin Lynn Tan, Ian Kerridge, Cameron Stewart

A growing number of clinics in Australia and Japan are taking advantage of the permissive stance of regulatory bodies with respect to the use of the patient's own cells, so called autologous therapies, to offer unproven treatments to patients. Examining the websites of these clinics reveals common trends and differences between the claimed stem cell treatments, methods and uses in Japan and Australia, as well as the marketing approaches being used to attract customers.



### What questions & challenges are raised?

Many marketed stem cell therapies have little to no evidence that they work or are even safe, yet the number of clinics offering these treatments continues to grow around the world. Ambiguity around regulation and inaction by regulators particularly for autologous stem SC treatments - treatments that isolate and use a patient's own cells - has fostered this growing industry. In their recent paper Dr Megan Munsie from the University of Melbourne and her colleagues from University of Sydney and National University of Singapore specifically explore how clinics take advantage of current Japanese and Australian regulations. Their research gives insight to the current number of clinics in both countries marketing unproven treatments, explores the range of treatments they offer, their marketing strategies and how the clinics portray their services to appear credible.

marketed for cosmetic purposes, followed by anti-aging, hair loss and heart conditions. In Australia treatments are primarily marketed for treating joint, tendon and ligament problems (orthopaedic purposes), followed by cosmetic, anti-aging and nervous system applications. The authors note that 83% of the clinics in Japan in contrast to 37% of the clinics in Australia offer strictly cosmetic therapies. The most common cosmetic uses are for breast enhancement in Japan and skin 'rejuvenation' in Australia. Most clinics in both Japan (73%) and Australia (80%) claim SCs are prepared from patient fat tissue. Blood and bone marrow are less common sources of SCs, but are sometimes used in combination with fat-derived SCs. Treatments are predominately administered by injection, but many websites don't say where. For both countries where more detail was provided, about ~40% describe injections as being into the blood stream and in Australia, about one quarter discuss injections directly into a patient's joint.

### What insight & direction does this give for research policies?

Dr Munsie and her colleagues point out that they found a greater number of clinics offering unproven autologous SC treatments compared to earlier reports, supporting the general trend that the number of clinics is growing in both Japan and Australia. Their data also helps to understand several of the common themes between the markets in these two countries, as well as their differences. For example, clinics in both countries are primarily using SCs from fat tissue, but generally for different purposes - orthopaedic therapies in Australia and cosmetic treatments in Japan. This information can greatly help to understand how businesses are taking advantage of current regulations, what types of therapies are in demand, the direction of the market and what types of education might help consumers make informed decisions. The authors' study also reveals how the industry of unproven SCs attempts to veil unproven treatments as credible medical procedures by using misleading marketing, portraying treatments as scientific via association with legitimate research institutions. The authors emphasise these issues must be addressed to protect vulnerable patients and avoid eroding public trust in science and medicine.

Dr Munsie and her colleagues also detail how clinics' therapies are promoted on websites, specifically noting how clinics legitimise their services and discuss the effectiveness and safety of treatments. All businesses attempt to build credibility by emphasising the 'scientific' basis of their therapies. Often this is done by relating therapies to external studies or by making broad statements about the promising advancements of SC research. However, very few clinics from either country display examples of publications in peer-reviewed journals that they were directly part of. Proclamations that clinics' treatments are safe and effective are another common trend, however a small number of clinics do have disclaimers stating that results cannot be guaranteed. Many clinics highlight the experience and credentials of their doctors, but Australian clinics appear to take this further by describing doctors as specialised stem cell practitioners. Listing doctors' memberships to professional associations is also a common trend used to build credibility. Notably, many of these associations support reducing regulatory oversight and oppose approving treatments through clinical trials. Testimonials by grateful patients and endorsements by celebrities appear on several websites despite codes of conduct and/or regulations that ban the use of testimonials in medical marketing. Finally, the vast majority of clinics substantiate their work by referring to various kinds of certifications. For example, some clinics associate themselves with laboratories that are 'accredited' by a government agency or comment that they use equipment that is certified in some way. Particularly of interest is that several clinics (3 in Japan and 2 in Australia) are currently registered to conduct clinical trials and list their registration numbers on their website, but they provide little information on what the trial is and how the clinic is involved. These clinics appear to sell the treatments in clinical trials to patients regardless of if they are eligible for the trial or wish to participate in it.

### What background and point are discussed?

Dr Munsie and colleagues searched the Internet to compile a list of 88 locations in Japan and 70 locations in Australia offering unproven autologous SC treatments from hospitals and private clinics. The authors' analysis of these websites shows that SC treatments in Japan are primarily