



Stem Cell Therapy

INTRODUCTION

The Royal Australasian College of Surgeons (RACS) supports an evidence-based approach to medicine and surgery. Stem cell therapy is a rapidly advancing area and is currently approved for bone marrow transplantation for the treatment of some blood, metabolic and autoimmune diseases and cancersⁱ.

Stem cells are cells harvested from body tissues which can be manipulated, expanded and stored outside the body and injected back into the patient as a treatmentⁱⁱ. Stem cell therapies are being explored in immunology, repair, wound healing, ageing, infection, organ replacement and rejuvenation of tissues, in areas such as cancer, degenerative diseases, transplantation, arthritis, trauma and limb replacement. Many of the proposed stem cell therapies are experimental being not yet proven. As such, the RACS recommends that stem cell therapy be part of ethically approved registered clinical trials to establish and ensure the science, safety and effectiveness is valid before treatment is (commercially) used in Australia and New Zealandⁱⁱⁱ.

RACS POSITION (inc. RECOMMENDATIONS)

Due to the possible risks associated with stem cell therapy, RACS does not support surgeons administering stem cell therapy outside of an ethically approved registered clinical trial. Whilst there may be scope for innovative treatment in the future, currently, the clinical effectiveness and safety of stem cell therapies remain scientifically unproven.

Unproven stem cell therapies outside of clinical trials expose patients to a potential risk of harm, and may interfere with proven treatments recommended by treating medical practitioners. RACS advises patients considering non-approved stem cell therapies to discuss this with their treating doctor(s) and to consent to this only as part of a registered clinical trial. This will provide higher patient safety and more ethically sound guidelines have been put into place so that the effectiveness of stem cell therapies can be better evaluated for patients.

KEY ISSUES

RACS is concerned about the existing regulatory frameworks in both Australian and New Zealand regarding stem cell therapy, which are influenced by the complexity of both the cells and the manner in which they are manipulated and used. In Australia, the Therapeutic Goods Administration (TGA) is responsible for the regulation of biologicals (including human cells and tissues); however, it does not regulate medical practice. If autologous treatment is provided while under the supervision of a registered medical practitioner there is limited scope for TGA regulation (through the Therapeutic Goods (Excluded Goods) Order No. 1 of 2011)^{iv}. While New Zealand Medicines and Medical Devices Safety Authority (MedSafe) has approved limited stem cell products, clinics providing autologous stem cell therapy have claimed that stem cell therapy procedures fall under the category of a physician's practice of medicine, under which the physician and patient are free to consider their chosen course of treatment. **For Patients**

The RACS considers that ensuring optimal patient outcomes and safety is paramount. Unregulated stem cell therapy particularly exposes vulnerable patients suffering from severe diseases to costs associated

Approved by: Professional Development and Standards Board	Version: 1	Approval date: June 2018
Document owner: Manager, Professional Standards	Review date: June 2021	Reference number: FES-PST-063



with unproven and/or expensive treatments. Patients who have received unapproved stem cell therapy that was not part of a registered clinical trial may also be ineligible to participate in a formal clinical trial subsequently^v.

RACS advises patients seeking stem cell treatment to do so only as part of an approved clinical trial, registered locally through the Australian New Zealand Clinical Trials Registry (ANZCTR) or internationally with the relevant national clinical trial register and to obtain advice from their treating doctor(s). A second or third opinion may be advisable in some cases where the patient remains uncertain.

An increasing number of clinics offering stem cell therapy are advertising their services using patient testimonials to support the benefits of the treatment, but where no robust scientific evidence is provided to support safety or efficacy^{vi}. This practice breaches the Australian Health Practitioner Regulation Agency (AHPRA) Code of Conduct^{vii} and patients should be cautious of accepting any medical (or non-medical) treatment solely on the basis of testimonials.

For Surgeons

Before considering stem cell therapy for a surgical indication, review the quality and strength of the available evidence. Stem cell therapies provided within private clinics in Australia and New Zealand do not yet have current proven evidence of effectiveness. Therefore, surgeons should not feel pressured to undertake such therapies. The RACS acknowledges the advancing nature of the field in evolution, and that stem cell therapies would eventually have a place in surgical and medical practice, recognising that some surgeons do assume a pivotal role in research and may influence clinical practice into the future (e.g. immunological stem cellular therapies). Stem cell storage for patients is an area under active investigation and could be considered before chemotherapy in some cases, similarly to sperm or ovum preservation.

RACS discourages surgeons from performing stem cell therapy on patients outside of an approved clinical trial while unequivocal evidence remains regarding safety or efficacy of these treatments, and while a concerning lack of knowledge regarding stem cells and their function remains^{viii}. Moreover, by providing unproven stem cell therapies, surgeons risk bringing harm to their patients and their standing.

KEY WORDS

Stem cell therapy, research, patient safety

ⁱ <https://www.tga.gov.au/community-qa/stem-cell-treatments-and-regulation-quick-guide-consumers>

ⁱⁱ Royal Australasian College of Surgeons, Surgical News vol. 18, no., 1 February 2016 <
<http://www.surgeons.org/flipbook3d/Digital/SurgicalNewsJanFeb2017/index.html>>.

ⁱⁱⁱ <https://www.tga.gov.au/community-qa/stem-cell-treatments-and-regulation-quick-guide-consumers>

^{iv} <https://www.tga.gov.au/sites/default/files/legislation-excluded-goods-order-1101-guidance-4opqr-1303.pdf>

^v https://theconversation.com/the-future-of-stem-cells-tackling-hype-versus-hope-72052?utm_medium=email&utm_campaign=Latest%20from%20The%20Conversation%20for%20January%2030%202017%20-%206635&utm_content=Latest%20from%20The%20Conversation%20for%20January%2030%202017%20-%206635+CID_c6b4ec2213061d1efeb2dcc89b2066ee&utm_source=campaign_monitor&utm_term=The%20future%20of%20stem%20cells%20tackling%20hype%20versus%20hope

^{vi} Maddern, G 2017, 'Chaos, impotence and market pressures: the stem cell story', Surgical News, Royal Australasian College of Surgeons, <<http://www.surgeons.org/flipbook3d/Digital/SurgicalNewsJanFeb2017/index.html>>.

^{vii} <http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx>

^{viii} Surgical News, Royal Australasian College of Surgeons, vol. 18, no., 1 February 2016 <
<http://www.surgeons.org/flipbook3d/Digital/SurgicalNewsJanFeb2017/index.html>>.

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