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# Précis Paper

## The regulation of autologous stem cell therapies

**A discussion on the regulation of unproven autologous stem cell therapies in Australia, the need for an improved regulatory framework and the movement towards providing greater protection for patients in Australia.**

**Discussion Includes**

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- **Regulatory measures and failures**
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## The regulation of autologous stem cell therapies

1. **In this edition of BenchTV, Patrick Foong (Lecturer, School of Law, Western Sydney University - Parramatta) and Cameron Stewart (Acting Head of School and Dean, Sydney Law School, University of Sydney - Sydney) discuss the regulation of unproven autologous stem cell therapies in Australia, the need for an improved regulatory framework and the movement towards providing greater protection for patients in Australia.**

### Background

2. **There are for-profit private clinics all over the world including Australia which offer untested stem cell treatments to patients.**
3. **The accounts of unsubstantiated claims of cures, charlatans and even adverse medical events is disturbing.**
4. **Some of these treatments are available in developing countries where the laws were very relaxed, for example in Thailand and Mexico. Travelling to these countries for treatment is known as stem cell tourism, which is a form of medical tourism.**
5. **Even in Australia, there are some private clinics that offer this type of business. The number of clinics which offers autologous stem cell treatments has grown to more than 70.**
6. **Autologous stem cell treatments are stem cells which are derived from the patient's own body and are not donated cells.**
7. **Australia has amongst the world's largest concentration of stem cell clinics which advertise for a variety of illnesses and conditions such as osteoarthritis, spinal injuries, strokes as well as anti-aging techniques.**
8. **There is a regulatory failure in Australia to protect vulnerable patients.**
9. **Recently, the Therapeutic Goods Authority (TGA) has announced some proposed amendments to the law such as regulatory requirements which has the effect of making the laws around autologous stem cell therapies more stringent.**

### The basic science of stem cells

10. **Currently, autologous stem cell therapies are at an investigative treatment stage.**
11. **Stem cells are master cells which have the remarkable quality of self-renewal and are able to differentiate into different types of cells.**
12. **Stem cell research is usually regarded as the Holy Grail of medical treatment for numerous diseases and conditions.**

13. However much work is necessary to translate research into safe and effective treatments.
14. In fact, many medical breakthroughs are the result of years of rigorous work of scientists and are usually ran by universities, research institutes and private companies.
15. This requires a very long laborious process proceeding from basic research to clinical research and then to clinical trials.
16. At the moment the range of conditions for which there are established, safe medical treatments involving stem cells is still very limited.
17. The only proven safe and effective stem cell treatment is the HCST which is the Hematopoietic Stem Cell Transplantation in which doctors are able to extract stem cells from bone marrow to treat certain blood disorders such as leukemia.
18. However all other stem cell therapies are still experimental and have not been proven or even tested in phase three clinical trials.
19. Despite the limited evidence for the safety and efficacy, many of the for-profit private clinics bypass the critical process and advertise these stem cell procedures on the internet.
20. Stem cell research holds much promise for the treatment of a range of illness, however at this stage a lot of work needs to be done to translate the research into safe and effective remedies.
21. It is absolutely crucial for patients and caregivers to know what to look for and what to consider before making a decision on whether to opt for a stem cell therapy.
22. These clinics will often cite studies to support what they are doing but whether what the stem cell clinic is doing actually equates to the clinical trials they are suggesting, is questionable.
23. There is often a disconnect and a borrowing of the legitimacy of clinical trials.
24. We do not know what types of services the clinics are providing, what types of stem cells they are using, whether these stem cells are minimally manipulated (that is that scientists take a cell out, separate it and then reintroduce it very quickly without actually doing anything to the cell) or whether they are doing detailed forms of manipulation.
25. The studies that do suggest positive outcomes for some of these treatments, for example in ligament repair, tend to be ones where there is quite a lot of manipulation in a very heavy concentration of stem cells.
26. It is probably not possible for that type of work to be done at the level of a local, suburban clinic.
27. It usually requires a lot of infrastructure and teams of scientists to be able to produce those types of stem cells. Nevertheless, these are often the ones that the clinics cite on their websites.

## Advertising

28. Advertising appears on clinic websites, YouTube and blogs whereby patients confirm that they went for the treatments and cite how they felt much better subsequent to the treatment.
29. Studies have shown that these clinics tend to underestimate the possible harm and hype the success of the treatments that they offered.
30. Clinics still provide misleading information on their advertisements for example, stating that they are a 'center for excellence.'
31. This is a specific term which applies to Australian Government recognised consolidations of research.
32. It is very difficult to obtain a center for excellence qualification.
33. These clinics have nothing to do with any funding from the Australian Government and call themselves 'centers of excellence' anyway.
34. They will also often refer to themselves as stem cell specialists however there is no specialty in stem cell research or stem cell science as properly understood as a specialty.
35. They will also provide links to particular studies which often suggests that these cells are completely harmless, that they are coming from a patient's own body and going back into your body and lead to some unqualifiable benefit.
36. This is the core of the misleading advertising.

## Risks and harms of unproven treatments

37. There is not much evidence of direct harm however this may be due to the fact that there is no registry which details the harm.
38. However, some reports have found that people using stem cells for beauty or regenerative therapies have found that they have had terrible outcomes. For example, having bone grow in eyelids where they have attempted to get rid of wrinkles.
39. In Australia, one of the worst examples is the example of Sheila Drysdale who was a patient who had a form of dementia.
40. There is no evidence that stem cells can do anything for anyone with dementia.
41. When taking out the stem cells, the most commonly used technique is adipose tissue (fat) which is effectively a liposuction to extract stem cells from the fat.
42. When this procedure was carried out on Mrs. Drysdale, it was not picked up that she was on blood thinning agent and she ended up bleeding to death.
43. Whilst her death has nothing to do with stem cell science, she would not have been having the procedure if it was not for the attraction of using the stem cells to aid her treatment.

44. There is also often financial harm as some of these treatments can cost tens of thousands of dollars and may involve multiple treatments.
45. There is also the harm done to the doctor and the patient.
46. Many people feel disappointed in themselves that they have fallen for the advertising/false promises and many of them think that because it is being advertised in Australia the treatments have been proven.
47. In the Sheila Drysdale matter, the coroner concluded that autologous stem cell intervention is unproven and unjustified and called for more stringent regulatory measures surrounding autologous intervention.

Regulatory measures and failures

48. The *Therapeutic Goods Act 1989* (Cth) and traditional laws including the law of contract, the law of torts and consumer law as well as various guidelines, collectively speaking have not been effective in regulating autologous stem cell therapies and can be regarded as a regulatory failure
49. In 2011, the TGA introduced an exemption for certain types of biologicals, including autologous therapies.
50. Since in autologous stem cell therapies, the stem cells are derived from the patient's own body, the risk is said to be negligible.
51. There is said to be a lower chance of rejection of the stem cells by the patient's own immune system.
52. Item 4Q of the *Therapeutic Goods (Excluded Goods) Order No. 1 of 2011* provided that autologous stem cells are not therapeutic goods and can be supplied without TGA's approval provided some conditions are met.
53. These conditions include
    a. that these cells are collected from a patient who is in the clinical care and treatment of a registered medical practitioner;
    b. the cells are being manufactured by the practitioner or someone under the medical practitioner's supervision
    c. that the cells are for therapeutic application or treatment in and a single course of treatment by the same practitioner or someone under the practitioner's supervision
54. The justification for this exemption was basically to prevent undue interference with this kind of treatment which is said to be relatively safe.
55. The TGA wishes to exclude the more-straight forward kind of practice from having too much regulatory interference.
56. This exemption has created a regulatory gap by enabling the private clinics in Australia to open up practices that offer unproven stem cell therapies.

57. Serious concern has been raised subsequent to 2011 due to the complexity of some of these treatments being offered, about the high levels of manipulation of the stem cells and the increased risks of the patient's response.
58. This higher manipulation of stem cells presents higher risk and calls for more stringent regulation.

Soft law, guidelines and codes of practice

59. Part of the problem with using the traditional law's approach to these problems is that they are very much reactive.
60. For example, normally in both contract and tort there is only responses when there is monetary way of calculating the harm.
61. The role of the TGA is to protect the public and provide for safety for the public.
62. AHPRA is the Australian Health Practitioner Regulation Agency and is also there to protect the public.
63. The ACCC is also there to protect consumers against misleading and deceptive conduct.
64. All these regulators are powerful however none have touched on this area as of yet.
65. Conventional laws are said to be costly, post hoc and there are evidentiary burdens for example contract and torts the burden of proof lays with the plaintiff.
66. AHPRA and the MBA which is the Medical Board of Australia have come up with a number of guidelines however these guidelines are not enforceable .
67. Under the NSW Health Care Complaints Commission anyone can put a complaint in, it is not necessary to have money to do so.
68. It does not need to be done by a patient being treated and it can even be done by a peer professional.
69. Peer professionals are required to report substantial departures from practice that carry a risk of harm to the public. This is mandatory notification under the national law.
70. If this takes place, there is a process of investigation and review and if there is a finding of professional misconduct or unsatisfactory professional conduct these are almost as damaging for doctors as findings in contract or tort.
71. Guidelines may be able to be built into the structure so that they are also a legal requirement under the national law. It would be professional misconduct if doctors did not abide by the guidelines.

The role of TGA

72. The TGA is the national drugs regulatory body in Australia and is responsible for regulating the safety and efficacy of medicines and medical devices and the manufacturing and advertising of therapeutic goods.
73. Their role is to protect the health of Australian society through the effective regulation of therapeutic products and they perform their responsibilities through the application of the *Therapeutic Goods Act 1989* (Cth).
74. TGA has a role in actively monitoring the quality, safety, efficacy and performance of these therapeutic goods and ensuring that there is regulatory compliance with the various requirements.
75. The TGA can also take appropriate enforcement action when they identify non-compliance.
76. The TGA can carry out a number of roles. From providing encouragement and guidance, to issuing warnings, cancellation, suspension and finally prosecution.
77. Some autologous cells are subject to TGA's regulation and will require TGA's approval before being supplied.
78. TGA has the power to deny access to applicants who cannot show that they comply with the regulation.
79. Patients are also able to lodge complaints to TGA about any misleading and deceptive conduct and to ensure transparency, TGA will be able to publish the information about regulatory compliance decisions on the TGA website.

<u>TGA's proposed regulatory framework</u>

80. The TGA has conducted two consultations; one in 2015 and the other in 2016 with various stakeholders to obtain their views and obtain written submissions as to what they consider to be the most appropriate forms of regulatory framework.
81. In November, 2017 TGA made the announcement that there would be some proposed revisions to the biological regulatory framework which would be implemented in 2018.
82. This brings Australia into close alignment with other jurisdictions such as the European Union and the United States
83. The new regulation would entail that a substantial proportion of the autologous stem cell products would be subject to the TGA regulation.
84. An exemption would only apply for those cell products that are manufactured and used in an accredited hospital by a medical practitioner for a patient in the care of the same doctor.
85. However, with all the other cell products especially autologous products which are more than minimally manipulated and for non-homologous use that are manufactured and used outside an accredited hospital will be fully regulated under the biologicals regulatory framework.

86. **With this new regulation, they will prohibit direct advertising to consumers which is similar to the prohibition of advertising of prescription medication.**
87. **With this new regulation, they cannot use colloquial terms such as stem cells, abbreviations for the term or acronyms .**
88. **The prohibitions will apply for every type of media.**
89. **In regard to patient testimonials published online, they will also be regarded as advertising.**
90. **These advertising requirements will apply to doctors, media outlets, businesses and professional organisations.**
91. **When the TGA has a complaint in regard to non-compliance advertising, the advertiser will be contacted and educated on how they can better comply with the advertising requirements.**
92. **If this fails, this is when TGA will escalate to imposing fines up to $840,000 for individuals and $4.2 million.**

**Takeaways**

93. **Patients should empower themselves with information but be careful where they are getting this information from.**
94. **Stem cell therapies have remarkable promise, however they are currently largely unproven and untested.**
95. **If you are suffering from a condition there may be a clinical trial being run by reputable people and this can be checked on the Australian Clinical Trials Registry.**
96. **The TGA has a website in plain English language which will tell patients all about stem cells and regulation and how they work. There are also very good organisations that can provide information about specific conditions such as Arthritis Australia, Motor-neuron Disease Australia and MS Australia.**
97. **These organisations have information about what stem cells have been proven, and not proven to do**

**BIOGRAPHY**

**Dr Patrick Foong**

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**Dr Patrick Foong has taught law for many years in different countries and in the last ten years, in the Australasian region. He teaches undergraduate and postgraduate courses, including the LLB programme. He is the Impact and Engagement (Research) Officer in the School of Law and is a member of the School's Research and Higher Degree Committee in his capacity as the School of Law's Impact and Engagement (Research) Officer. He has written many publications for peer-reviewed journals (national and international) and is pursuing collaborative research. In his PhD thesis, he conducted analysis and made comparisons between the Australian regulatory regime on human embryonic stem cell research and the Malaysian regime against the backdrop of the regulatory theories of Professor Roger Brownsword (Kings College London, UK) and Professor John Braithwaite (Australian National University).**

**Prof. Cameron Stewart**

**Acting Head of School and Dean, Sydney Law School, University of Sydney, Sydney**

**Professor Cameron Stewart is a member of Sydney Health Law and associate of the Centre for Values, Ethics and the Law in Medicine, Sydney Medical School. He has degrees in economics, law and jurisprudence. He has worked in the Supreme Court of New South Wales and has practiced commercial law at Phillips Fox Lawyers. His previous appointment was at**

**Macquarie Law School, where he spent 10 years, the last of which as Dean. He was the Director of CHGLE for 4 years (2009-2012), was the Acting president of the Australian and New Zealand Institute of Health Law and Ethics in 2008-2010 and was the Vice-President of the Australasian Association of Bioethics and Health Law from 2010-2013. Cameron is also the co-editor for the Ethics and Health Law news service and the Clinical Ethics Resource. He also runs a website on Discovering Australian Guardianship Law.**

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### Legislation

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***Therapeutic Goods (Excluded Goods) Order No. 1*** **(2011)**