

SELF REGULATION OF AUTOLOGOUS CELL THERAPIES: A MODEL



Bernard E Tuch¹, Heather Main¹ & Dominic Wall²

¹New South Wales Stem Cell Network, Sydney & ²Australia and New Zealand Region,
International Society for Cellular Therapy, Melbourne, Australia



Introduction

Autologous cell therapies are being practised by an increasing number of clinicians internationally - for the treatment of a variety of disorders. This includes rheumatological conditions where the sources of cells are the vascular stromal fraction obtained from lipoaspirates during liposuction, and platelet rich plasma obtained from peripheral blood.

In Australia, oversight of these procedures by the regulatory body, the Therapeutic Goods Administration (TGA), is not required. This is because the current regulations contain a broad exemption permitting clinicians to treat their patients with autologous cells without restrictions on the extent of manipulation or whether the cells are used in a homologous manner.

Despite this lack of oversight, a number of companies carrying out autologous cell therapies, and other entities have become concerned about the lack of checks and balances. In many cases the clinicians are not specialists in the diseases being treated and the efficacy of treatments has yet to be established. End users also have their welfare to be considered.

Aim

To improve the regulation of autologous cell therapies in Australia.

Methods

1. Conduct a Workshop on the issues of regulation, efficacy, and consent for autologous cell therapies.
2. Establish a steering committee to follow up on outcomes from the Workshop.

Outcomes

1. Implementation of a Workshop

The NSW Stem Cell Network held a Workshop entitled *Cellular Therapies for Repair of Musculoskeletal Injuries* in Sydney during October 2012.

Four key companies practising autologous therapies for rheumatological conditions presented their data, as did Mesoblast, which is conducting clinical trials using allogeneic cells.

A representative of the TGA spoke about the regulatory requirements, and appropriate cell manufacturing requirements were addressed by a representative of the International Society for Cellular Therapy (ISCT).



17th Stem Cell Network Workshop
Cellular Therapies for Repair of Musculoskeletal Injuries
Wednesday, October 31st, 2012
Trades Hall Inn, Goulburn St, Sydney.

8.00am	Registration opens
8.20am	Opening Address – Professor Jim Patrick, Cochlear Limited The Commercialisation of the Cochlear Implant Introduction by Professor Bernie Tuch, NSW Stem Cell Network
Session 1 Chair	Autologous Therapies For Musculoskeletal Injuries Professor Jill Cook, Monash University
8.30am	Dr. Ralph Bright, Macquarie Stem Cells Setting the Scene with Autologous Therapies
8.55am	Dr. Dan Bates, Lakeside Sports Medicine Centre Adipose derived stromal vascular fraction for the treatment of degenerative joint disease
9.20am	Professor Richard Boyd, Magellan Stem Cells Frontiers and Challenges in Stem Cell Therapies
9.45am	Dr Luke Inman, South Sydney Sports Medicine Centre Autologous Platelet Rich Plasma injections to aid in the regeneration of knee particular cartilage lesions. Case studies
10.15am	Morning Tea
Session 2 Chair	Regulation of Cellular Therapies and Managing Community Expectation A/Professor Megan Munsie, Stem Cells Australia
10.40am	Professor Peter Ghosh, Mesoblast Allogeneic Progenitor Cell in Preclinical and Clinical Studies
11.05am	A/Professor Dominic Wall, International Society for Cellular Therapy Ethical, Commercial and Professional Perspectives on Unproven Therapies
11.30am	Dr Mary Boyd Turner, Therapeutic Goods Administration Regulating human cell- and tissue-based therapies in Australia
11.45am	Discussion with Panel: A/Professor Dominic Wall, Dr Ralph Bright, Dr Dan Bates & Professor Peter Ghosh Should the Regulations for Autologous Cell Therapies in Australia be Changed?
12:40pm	Finish

Contact: Sarah Mustafa | 02 9552 9981 | s.mustafa@stemcellnetwork.org.au | www.stemcellnetwork.org.au 22.10.12

www.stemcellnetwork.org.au/past_events/workshops/17thWorkshopBookfinal.pdf

Out of the workshop came a desire for the establishment of a Steering Committee to discuss self regulation by the companies practising autologous therapies.

2. Establishment of a Steering Committee

This was chaired by the Director of the NSW Stem Cell Network and involved the ISCT local representative. It included representatives from the following 9 entities practising autologous cell therapies in Australia:

- Cell Innovations
- Hunter Regenerative Medicine
- Lakeside Sports Centre
- Macquarie Stem Cells
- Magellan Stem Cells
- New Zealand Stem Cell Clinic
- Regeneus
- South Sydney Sports Medicine Centre
- Stem Cell Solutions

Five teleconferences were conducted between November 2012 and May 2013.

Issues raised and agreed to have been:

- (a) the need for the development of evidence based medicine;
- (b) ensuring fully informed consent is obtained;
- (c) manufacturing the autologous product to be injected into the patient using internationally accepted standards, such as those produced by the Foundation for the Accreditation of Cellular Therapy; and
- (d) following the advertising standards set by the Australian Health Practitioner Regulation Agency (AHPRA).

3. Creation of a Written Code of Conduct

To cement these agreed-to standards into practice, it was decided by the members of the Steering Committee to create a written Code of Conduct.

Advice was sought from Ms Deborah Monk, Director of Innovation and Industry Policy, Medicines Australia, who is responsible for ensuring that organization maintains its Code of Conduct. Medicines Australia is now using its 17th edition of the Code for the self regulation of pharmaceutical companies in Australia. The first edition was created 50 years ago.

The template being used to create this Code of Conduct is that produced by the Australian Competition and Consumer Commission (ACCC).



Guidelines for developing effective
voluntary industry codes of conduct



<http://transition.accc.gov.au/content/index.phtml/itemId/658186>

Further information www.stemcellnetwork.org.au

Professor Bernie Tuch b.tuch@stemcellnetwork.org.au

It has been agreed that the Code of Conduct will include the mechanisms of implementing the necessary checks and balances to provide guidance to its users, as well as independently monitoring the practices being followed.

Once a draft of the Code has been created, it has been agreed that the input of stakeholders also will be sought. Before the document is finalized. These include:

- All Autologous Cell users, loosely termed the Australian Autologous Cell Therapy Consortium (AACT);
- Stem Cell entities, such as the NSW Stem Cell Network, Stem Cells Australia and ISCT;
- Regulatory authorities, such as the TGA and AHPRA;
- Medical insurance industry;
- Consumer representatives.

Recognizing that the creation of a written Code of Conduct requires considerable effort, the autologous users have agreed to **employ a part time person** to achieve this outcome. The cost of this is being born by the users, with initial agreement of funds being for 9 months duration.

In April 2013, the **job description for this position was advertised**. At the last and final meeting of the Steering Committee, on 10 May, 2013, a short list of candidates was advised, with the finalization of the outcome expected in the following week.

The role of the Steering Committee is now completed. It is now the responsibility of the AACT to implement what its members have agreed to.

By doing so, steps have been taken to ensure high standards of health care are maintained in a field with a low level of government regulation.

Conclusion

Self regulation is possible in the industry of autologous cell therapies, just as it is practised in others, including in vitro fertilization and the pharmaceutical industry.

Acknowledgements

We wish to thank the following for their input and encouragement:

- A/Prof Megan Munsie, head of Education, Ethics, Law & Community Awareness, Stem Cells Australia
- Executive of NSW Stem Cell Network, especially Drs Kelvin Hopper, Daniella Goldberg, Joanna Knott & Michael Morris;
- International President of ISCT, Dr Kurt Gunter;
- Ms Deborah Monk, Director of Innovation & Industry Policy, Medicines Australia;
- Former Manager, NSW Stem Cell Network, Sarah Mustafa.

The NSW Stem Cell Network acknowledges and appreciates financial support from the NSW Government Office of Health and Medical Research.