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 liposuspirates 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 attended 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).

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
- Megafan Stem Cells
- New Zealand Stem Cell Clinic
- Regenesis
- 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 Autologous Cell Therapy Consortium (AACC);

Website: www.stemcellnetwork.org.au/past_events/workshops/17thW

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

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.

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