

Activity 2.1 - Individual Stakeholder Research

Stakeholder descriptions

Stakeholder Group 1: Patient/consumer advocates

Stem cell therapies have been big news for over 10 years with breakthroughs now being claimed by celebrities and promoted by clinics locally and overseas. The promise of hope for people suffering with diseases such as Multiple Sclerosis, debilitating arthritis, Parkinson's disease and an ever increasing list of health concerns is regularly reported in the media promising improvements unachievable by other therapies.

Enrolling in clinical trials is coveted but opportunities are limited and it takes a long time to amass the research to justify testing a possible treatment in patients. Furthermore, participating in clinical trials may not directly benefit the individual as there is no guarantee that the therapy will provide relief or alleviate the symptoms of the illness. However, stem cell treatment is already being sold in Australia and overseas without evidence that it works or is safe (from clinical trials). These interventions are expensive and websites highlight success stories and down play the risks. Patients often turn to local GPs, physiotherapists or trusted health practitioners for advice but may also decide to pursue treatment based solely on the online marketing claims. For people with a strong religious conviction the use of autologous stem cell therapy (where the treatment uses the patient's own cells) is morally acceptable, as they are not derived from human embryos and therefore assumed to be an 'ethical' alternative. For those who are willing to pursue experimental stem cell treatment, but are unable to participate in clinical trials, they may believe that promised benefits outweigh the risks.

Examples of Patient/Consumer Advocate Stakeholders:

- Person diagnosed with diabetes; MS; Parkinson's Disease; Spinal Cord Injury
- Patient Advocate for Diabetes; MS; Parkinson's Disease; Spinal Cord Injury
- Professional Athlete considering stem cell therapy for injured knee
- Family member of person affected by a disorder potentially treatable by stem cells
- Person successfully treated using bone marrow or cord blood stem cells
- Person who has been unsuccessfully treated using stem cells (cost \$10,000 which was raised by family and friends)
- Person excluded from clinical trial due to illness progression and complications
- Person interested in stem cells but who requires scientific evidence before undergoing therapy
- Person interested in stem cells but only relies on media reports and claims made on websites before deciding
- Person considering purchasing stem cell rejuvenation cosmetics

Stakeholder Group 2: Researchers and Academics

Clinical research requires preclinical evidence to support evaluating an approach on patients and financial support from the Government and Community. Across the world different countries are governed by regulations that stipulate what can and cannot be used as the source of the stem cells and what may constitute sufficient evidence to commence a clinical trial. In some jurisdictions it may be illegal to cells made from human embryonic stem cells; in other countries they may have different laws depending on whether the cells are from a donor (allogeneic) or from the patient (autologous). The discovery of iPS cells has not completely replaced the need for human embryos but does open up a new avenue for research into how diseases develop and a way to possibly identify new drugs to combat illness. For research to continue, funding must be secured either from government, private organisations or community sources. Public funding may be negatively impacted if unproven stem cell treatments (so called stem cell tourism) fails to deliver on its promises resulting in an erosion of

community support. Also by pursuing unproven treatments, patients may not enroll (or be eligible) for clinical trials.

Examples of Researchers and Academic Stakeholders

- University Professor
- Bioethicist
- Biomedical Researcher
- Clinical Trial Coordinator

Stakeholder Group 3: Healthcare Professionals

Doctors and other healthcare professionals are often asked to provide information to patients and their families about the latest scientific breakthrough. They may have some knowledge or know where to go for reliable information (trusted government websites; peer-reviewed publications; pharmaceutical company representatives). However, providing patients and their families with current and accurate information about the research and what this means for their health can be a challenge – particularly in stem cell research where progress is being made quickly and where patients may be desperate for relief from pain or hoping for a cure to alleviate their suffering. Questions about whether there is evidence to support the claims; is the treatment being offered as part of a clinical trial or not; how safe autologous cell therapies are and if it is worth traveling to pursue yet to be proven treatment are some of the points to consider.

Examples of Healthcare Professional stakeholders

- Local GP, Physiotherapist, allied healthcare professional
- Doctor or scientist associated with a registered clinical trial
- Doctor or scientist associated with a clinic selling unproven stem cell treatments outside of a clinical trial

Stakeholder Group 4: Biotechnology company representatives

Worldwide stem cell or regenerative medicine companies are focusing on research, development and commercialization of potential treatments for patients with a wide range of medical conditions. Companies need to adhere to the policy requirements of the country in which they operate, including laws about advertising, manufacturing and fund-raising (ie ASX). Care is taken to ensure the emerging area of regenerative medicine prospers.

Examples of Medical Industry Affiliated stakeholders

- Company Biomedical Researcher
- Drug Company Representative
- Biotechnology CEO
- Owner of Stem Cell Private Clinic
- Health Insurer Representative
- Clinical Trial Head
- Large shareholder in stem cell biotech company.

Stakeholder Group 5: Government and Regulatory

The Government must consider the health of the community as well as individuals, ensuring the public trust the health service. This includes deciding what stem cell therapies are available to the public and ensuring unsafe options are not. They must also decide on the economic cost and benefits, and who pays. Regulations that allow research to advance should be implemented and loopholes that negatively impact patient health and cause harm are to be closed.

Examples of Government and Regulatory stakeholders

- Australian Politician with ability to impact National Stem Cell Policy
- Head of Stem Cell research policy review committee
- TGA Representative TGA are there for manufacturing, advertising standards

Stakeholder Group 6: Community Representatives

Within the community are individuals and groups who actively follow developments in the field. They may be interested in science and its implications for society or perhaps hope to benefit from stem cell treatments one day. Their interests may be influenced by ethical or moral perspectives. Social media and celebrity endorsements are often used to promote stem cell research but claims are not necessarily supported by clinical data and attempts to validate claims can be ignored or ridiculed.

Examples of Community Representative stakeholders

- Religious Leader with influence in the local community
- Advocate for Aging Australians
- High School Students
- Community member of Ethics committee from local hospital network
- Local mother advocating stem cell treatment based on celebrity endorsement and social media campaign
- Member of the local footy club who is asked to help fundraise for a player who can no longer walk following an accidental during a game
- Journalists reporting on issues and ethics of stem cell therapies