Ready or not? A role play on taking stem cells to the clinic
Introduction

Why a role play on stem cells?

Millions of people around the world are excited by the promise of stem cells. Stem cells can potentially be used to replace cells lost in many devastating diseases for which there are currently no cures or very poor treatments, such as Parkinson's disease, multiple sclerosis, leukaemia, diabetes, or in burns. But many people, including scientists themselves, are concerned about the ethical and social issues involved.

One prevailing concern is the use of human embryos to grow stem cells. The most versatile stem cells, embryonic stem cells, need to be taken from 5-6 day old embryos. For many people, this amounts to destroying a life, which they consider totally unacceptable. For others, the medical benefits that may follow from research using these cells outweigh the ethical concerns. Your position might be one of these…or somewhere in between.

Stem cell research raises other issues too. Might this type of research make human cloning more likely? Will it create a "market" for human embryos? Where should we draw the line? Who will own the results of the research and/or the medical outcomes: scientists, companies, the government, you and me? Who will have access to the medical benefits that are promised?

This role-play will allow you to explore some of issues around stem cell research and its medical applications. You will learn a little about the science of stem cells, and how scientists go about their work. The main aim of the role-play is to enable you think about and develop your own views on this very exciting, controversial field.

What will I have to do?

Participants will be asked to take on the role of a particular character, and to defend the interests and concerns of that person or group.

Once the role play is over, everyone will come out of character, talk about their experience of doing the role play and discuss some of the issues that arose concerning stem cell research.

Don't feel pressured to take a stance for or against this research. Even scientists, who are in the thick of it, disagree on many of the issues!

The scene for the role play

Stem Cell Therapeutics is a biotechnology company. The company has recently developed a way of using a type of nerve cell (called oligodendrocytes) made from human embryonic stem cells to repair spinal cord injury in animals. They now want to use these cells to treat patients who have suffered spinal cord injuries.

Stem Cell Therapeutics cannot test their cell therapies on patients at random. They will first have to run a clinical trial on a few selected patients. A clinical trial is a medical research study that involves people. Clinical trials are carried out to assess the safety and efficacy of new treatments or new ways to diagnose a certain disease. Efficacy is the capacity for beneficial change (or therapeutic effect) of a given intervention (a medicine, medical device, surgical procedure, or a public health intervention).

Before embarking on a clinical trial, Stem Cell Therapeutics will have to obtain approval to run the trial from the Research Ethics Committee (REC). This can take up to several years. In fact, you often hear scientists saying that after a major breakthrough in the laboratory, it may take up to 15 years to get a therapy or medicine into the clinic, to be used by all patients.

In this role play, we are going to hold a mock meeting of the Research Ethics Committee assigned the task of deciding whether Stem Cell Therapeutics may or may not go ahead with their clinical trial.

Although it is up to the committee to approve or reject the clinical trial, they are required to listen to the viewpoints of several stakeholders in the matter. Stakeholders are groups or individuals with direct interest in the outcome of the decision. Therefore, we will role play an open public hearing where several stakeholders will present their case. The Research Ethics Committee will consider these accounts when reaching their decision.

Who will I be in the role play?

The role-play has 10 characters:

- A stem cell scientist
- A spinal cord injury patients' group representative
- A neurosurgeon
- A bioethicist
- A student with spinal cord injury
- A pro-life activist
- A representative of a disability rights group
- A biotechnology entrepreneur/ CEO
- A pro-technology activist
- An interested member of the public/ coffee shop owner

One could probably run the role-play with less people, but fewer then eight would not be suggested. This way, participants won't miss the important issues surrounding stem cell research.

Participants will be given sheets with short biographies. All are encouraged to research additional information on the character they will be playing.

The first four characters are members of the Research Ethics Committee. These are experts in their field, scientific or otherwise. We have modelled the make-up of this committee on those of the American Food and Drug Administration (FDA), and the NHS Research Ethics committees, in the UK (see Useful Links section for more information on the FDA and on RECs).

The other characters are in the audience at the open public hearing. These are active, participatory audience members. They have heard about the clinical trial that Stem Cell Therapeutics wants to carry out, have come to this meeting to have their say, and will try to influence the decision of the Research Ethics Committee.

What happens next?

Participants will have received a pack with all the print material necessary to prepare for the role-play.

- Assign the roles
- Elect a Chairperson of the Committee
- Prepare for the open public hearing!

It is very important that participants read: the clinical trials application proposed by Stem Cell Therapeutics, the background information on both stem cells and spinal cord injury and the biography card.

The role play has been planned to last approximately two and a half hours.
Here is a guide to the sequence of events:

- Welcome note by the Chair of the Committee. Introductions are made by all. Chair invites audience members to have their say.
- Audience speakers intervene. All participants enter into dialogue: between the audience and the Committee and amongst themselves.
- The Research Ethics Committee meets to reach a decision.
- The audience meets with the research team members separately for in-character discussion on the issues raised and their expectations of the committee's decision, if time permits.
- The REC announces its decision. The audience reacts to the decision. All participants remain in character.
- Participants come out of character for discussion and debrief.
- Everyone fills out short feedback forms.

It is recommended that this guide is followed. The events build up to the announcement of the decision of the Research Ethics Committee, from which the final discussion will pick up.

We hope that this enlightening, thought-provoking role play will help you to understand and make sense of all the hype around stem cell research. You may even be curious to find out more. Feel free to contact us through www.eurostemcell.org We will be happy to help in any way we can.

Useful links

EuroStemCell
Europe's hub for stem cell research, regenerative medicine and ethics. Features stem cell fact sheets, educational resources, award-winning films, news and FAQ.
www.eurostemcell.org

Institute for Stem Cell Research (ISCR)
To know more about the stem cell research carried out at the ISCR
www.iscr.ed.ac.uk

Innogen - ESRC centre for social and economic research on innovation in genomics
If you want to learn about social research around scientific issues
http://www.innogen.ac.uk/

The Food and Drug Administration (FDA) Advisory Committees
The following sections are of interest: “Committees by Product Type” and “The Open Public Hearing, FDA Advisory Committees”
http://www.fda.gov/oc/advisory/default.htm

NHS Research Ethics Committees
From this page you can download a document describing the standards and principles set out by the Government for Research Ethics Committees. It is quite a lengthy document, but you may find the following sections relevant: “The role of Research Ethics Committees”, “Composition of an REC”, “The process of ethical review of a research protocol”
http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4005727&chk=CNcpyR

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