

# Stem cell research

## FACT SHEET

Ministry of Health  
and Social Affairs

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**Stem cell research is an important field of research, which in the long term can offer the potential to deliver new treatments for serious diseases. To enable further progress in this field, it is essential that research is undertaken in ethically acceptable forms. With the further development of Swedish stem cell research in mind, the Swedish Government has proposed amendments and clarification with regard to stem cell research in current legislation. The proposed date of entry into force of these amendments is 1 January 2005.**

The Swedish Government proposes that research on stem cells from fertilised eggs be permitted under the conditions formulated in the Act concerning research on fertilised eggs. It also proposes that so-called somatic cell nuclear transfer (therapeutic cloning) should be permitted in the context of research. In the initial stage, the same method is used as in cloning human beings. This is why the Government proposes an explicit, unequivocal ban on human reproductive cloning, both in research and in other contexts. All research projects are to be subject to approval by an ethics committee.

### Background

Stem cell research is not a new phenomenon. Researchers have been seeking new methods of replacing diseased or damaged tissue for many years. For decades, blood-forming stem cells from bone marrow have been successfully used in treating patients suffering from leukaemia. Until now, transplantation with blood stem cells has been the only established stem cell therapy. A special field of application for stem cells already in use today is the development of new pharmaceuticals.

### Stem cell research

Stem cell research of the last decade has been notable for a number of major breakthroughs. For example, Swedish researchers have contributed to the discovery of stem cells in various organs of the adult human. The cultivation of embryonic stem cell lines is another breakthrough of vital importance.

At present, stem cell research is being undertaken on a limited scale throughout the world. In Sweden there are research groups at the Sahlgrenska University Hospital and Karolinska Institutet.

### Future treatments

What researchers hope to be able to do in the future is to control stem cells so that they form precisely the cell type needed to treat an injury or disease. The idea is to be able to inject the cell type needed by the patient or to transplant tissue or an entire organ.

It is hoped that stem cell research will be able to lead to new methods of treating serious and currently incurable diseases affecting large sections of the population. These may include Parkinson's Disease and cardiovascular diseases. It is hoped that in the future, it will be possible to repair injuries by replacing dead cells with healthy ones, thus regaining functions that have been lost.

### The patient perspective

From the perspective of the patient, stem cell research is still at a very early stage and continues to be largely a matter of basic research. It will be many years before there are effective methods of treatment based on stem cell transplantation.

### Stem cells

A stem cell is the term for an immature cell that can be described as the body's own raw material. Stem cells have the ability to renew themselves by repeatedly dividing and producing more cells like the original cell. In this way, the body's organs and tissue are replenished and repaired as they age, wear out or are damaged.

The stem cells used in research are collected from individuals who are born (adult), from foetuses (foetal) or from fertilised eggs that are a few days old (embryonic). These categories of stem cells have distinct qualities, including different potential for development.

A stem cell isolated from a fertilised egg, for example, can be cultured by researchers so that a so-called stem cell line is formed. A stem cell line is a cell cultivation with an enormous number of identical cells developing from a single fertilised egg. Each cultivated stem cell line requires considerable effort in terms of research.

## **Ethical principles**

Embryonic stem cells are able to form practically all the tissues of the body, which makes them particularly interesting from the point of view of research. Most controversy has centred upon embryonic stem cells taken from fertilised eggs. This type of research raises fundamental ethical questions involving our attitudes towards people and our values. These questions concern our views on when life begins and the "protection" that should be given to the fertilised egg.

## **Previous legislation**

In Sweden, research on fertilised eggs has been permitted since 1991. The Act (1991:115) concerning research on fertilised eggs was primarily introduced to regulate research focused on improving techniques for test tube (in vitro) fertilisation. The Act provides for research on fertilised eggs under certain conditions. Research is only permitted in the first 14 days after fertilisation. After this, the egg must be destroyed. A fertilised egg that has been subject to research may not be implanted in a woman's body. Nor may the purpose of the research be to create genetic changes that can be inherited.

## **Research on fertilised eggs continues to be permitted**

The Government proposes that research on fertilised eggs continue to be permitted. The parameters of such research have been laid down in the Government decision of 1991 on research on fertilised eggs. Research on fertilised eggs also comes under the provisions of the Act on Ethical Review of Research involving Humans (2003:460). The aim of the Act, which entered into force on 1 January 2004, is to protect the individual in the context of research. According to the Act, research will be permitted only if it is undertaken with respect for human dignity. Research may only be undertaken if the risks it may entail are outweighed by its scientific value. Research may not be approved if the same result can be achieved in some other way that entails fewer risks.

## **Cell nuclear transfer**

The aim of somatic cell nuclear transfer is to produce stem cells that have the same genetic make-up as the patient to be treated. The idea behind somatic cell nuclear transfer is that an unfertilised egg donated by a woman is emptied of its nucleus, or its genetic make-up. The nucleus from, for example, a skin cell from the patient is introduced into the "emptied" egg. An egg with the same genetic make-up as the patient has then been produced. The idea is for stem cells to be cultivated from this egg for use in treating the patient. Since these stem cells have the same genetic make-up as the patient, rejection of the transplanted tissue is avoided. In the Government bill, it is proposed that somatic nuclear cell transfer, sometimes referred to as therapeutic cloning, should not be prohibited but that such research be subject to the same kind of limitations as those applying to research on fertilised eggs.

## **Ban on reproductive cloning**

A condition for permitting cell nuclear transfer is that there is an unequivocal ban on reproductive cloning. The term 'reproductive cloning' means making a copy of another individual by implanting a genetically altered egg into a woman's womb. The Government proposes a ban on reproductive cloning.

## **Donation of eggs for research purposes**

Up to now, most research has been done on surplus eggs after completed treatment with in vitro fertilisation. The couple who have received treatment may then give their consent to the use of these eggs for research purposes. If the embryo has been produced via donated sperm or donated egg, the donors of the egg or sperm must also give their consent.

In the case of research on somatic cell nuclear transfer, a woman has to donate an unfertilised egg and another individual has to donate a human cell. Here too, the Government proposes that donor consent is obtained.



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