

Stem cell policies and regulations globally - an overview of the content and context

August 2011

This rapid response was prepared by the Uganda country node of the Regional East African Community Health (REACH) Policy Initiative.

Key Messages

- The different laws or degrees to which the field of stem cell therapy has been embraced are clearly explained by the contexts that the regions, countries or organizations are working in; the actors or stakeholders like religion, the cultural norms and beliefs, pressure groups that are not or are pro-life and so on, have shaped the direction that different countries have taken on the issue.
- The resources needed like the highly skilled human resource, sophisticated technology and large financial sources for such research are also a clear decisive factor for countries to engage or not, in this field.



Who requested this rapid response?

This document was prepared in response to a specific question from a Senior Health policymaker in the MOH Uganda.

! This rapid response includes:

- Summary of research findings, based on one or more documents on this topic
- Relevance for low and middle income countries

X Not included:

- Recommendations
- Cost assessments
- Results from qualitative studies
- Examples or detailed descriptions of implementation

What is the SURE Rapid Response Service?

SURE Rapid Responses address the needs of policymakers and managers for research evidence that has been appraised and contextualised in a matter of hours or days, if it is going to be of value to them. The Responses address questions about arrangements for organising, financing and governing health systems, and strategies for implementing changes.

What is SURE?

SURE – Supporting the Use of Research Evidence (SURE) for policy in African health systems - is a collaborative project that builds on and supports the Evidence-Informed Policy Network (EVIPNet) in Africa and the Regional East African Community Health (REACH) Policy Initiative (see back page). SURE is funded by the European Commission's 7th Framework Programme.

www.evipnet.org/sure

Glossary

of terms used in this report:

www.evipnet.org/sure/rr/glossary

Background

In reference to policy, this includes laws, rules or regulations, guidelines and policy governing the sources, research, and use in treatment of stem cells in humans. These are drawn by governments or organizations concerned with stem cell research and therapy and they vary significantly. For example in the European Union region, stem cell research using the human embryo is permitted in some countries like Belgium and Britain while it is deemed illegal in others like Austria and Germany. Similarly in the United States, different states subscribe to different laws with some enforcing complete bans and others giving financial support

In 2001, the United Nations General Assembly established a committee on an International Convention against the Reproductive Cloning of Human Beings. This committee was to seek international consensus on a global ban of human reproductive cloning but 2 years later an Islamic conference postponed the debate to 2005 and later this resulted in the entire mission being abandoned. However, similar attempts to ban human reproductive cloning globally have also been attempted by the United Nations Educational, Scientific and Cultural Organization (UNESCO), the Council of Europe, the World Health Organization, the World Medical Association, the European Union and the European Parliament.

The different laws or degrees to which the field of stem cell therapy has been embraced are clearly explained by the contexts that the regions, countries or organizations are working in; the actors or stakeholders like the church, the cultural norms and beliefs, pressure groups that are not or are pro-life and so on. The financial implications and resources like human resource for such research are also a clear decisive factor for countries to engage or not, in this field.

This paper will give a general overview of the content of policies of countries in given regions and will identify a few countries for which the content will be analysed and related to the context in which they operate.

How this Response was prepared

After clarifying the question being asked, we searched for systematic reviews, local or national evidence from Uganda, and other relevant research on the topic. The methods used by the SURE Rapid Response Service to find, select and assess research evidence are described here:

www.evipnet.org/sure/rr/methods

Summary of findings

Africa

In the African region, the only country currently actively engaged in stem cell research activities is South Africa. In 2004, it became the first African nation to create a stem cell bank and prior to this, it had enacted a law maintaining a ban on reproductive cloning other than that that was therapeutic.

The Americas

In 2000, the United States' National Institutes of Health issued guidelines allowing for federal funding of embryonic stem-cell research while Canada took the step and enacted a law permitting research on discarded embryos from in vitro fertilization procedures in 2006. Canada's law however prohibits the creation of human embryos for research.

In the United States, in 2001, the sitting president then implemented a policy limiting the number of stem cell lines that could be used for research. Later in the mid 2000s, there were several laws concerning stem cells that were passed at state level; for instance New Jersey in 2004 enacted a law specifically permitting human cloning for the purpose of developing and harvesting human stem cells, and Missouri in 2006 legalized certain forms of embryonic stem cell research in the state. On the other hand, Arkansas, Indiana, Louisiana, Michigan, North Dakota and South Dakota passed laws to prohibit the creation or destruction of human embryos for medical research. In mid 2006, through a Presidential veto, the Stem Cell Research Enhancement Act was passed. This referred to two similar bills that were vetoed by the president but were not enacted into law. Large amounts of funds have been earmarked for stem cell research in this country; for instance in November 2004, California approved and set up a US\$3 billion state funded institute for stem cell research, the California Institute for Regenerative Medicine which hopes to provide \$300 million a year. Last year the president removed the restriction of federal funding passed in 2001, which originally only allowed funding on the 21 cell lines already created.

In Latin America, Brazil has passed legislation to permit stem cell research using excess in vitro fertilized embryos that have been frozen for a minimum of three years.

Australasia

Australia is partially supportive (exempting reproductive cloning yet allowing research on embryonic stem cells that are derived from the process of IVF). On the other hand, New Zealand prohibits/restricts stem cell research. China prohibits human reproductive cloning but allows the creation of human embryos for research and therapeutic purposes while India banned reproductive cloning and permitted therapeutic cloning in 2004. In the same year, Japan through its Council for Science and Technology Policy permitted

stem cell research for therapeutic purposes, although it has never released the formal guidelines pertaining to this. In South Korea, the government permits and actually promotes therapeutic cloning but only for therapeutic purposes.

Europe

The European Union has no consistent regulations with respect to stem cell research in member states, perhaps because the different member states have embraced stem cell research differently. Germany, Austria, Italy, Finland, Greece, Ireland, Portugal and the Netherlands prohibit or severely restrict the use of embryonic stem cells, while Sweden and Britain have created the legal basis to support stem cell research. Furthermore, Belgium bans reproductive cloning but allows therapeutic cloning of embryos. France prohibits reproductive cloning and embryo creation for research purposes, but has enacted laws to allow scientists to conduct stem cell research on imported surplus embryos from in vitro fertilization treatments. Germany has restrictive policies for stem cell research, but a 2008 law authorizes the use of imported stem cell lines produced before May 1, 2007. Italy has a 2004 law that forbids all sperm or egg donations and the freezing of embryos, but allows, in effect, using existing stem cell lines that have been imported. Sweden forbids reproductive cloning, but allows therapeutic cloning and authorized a stem cell bank.

In 2001, the Parliament in Britain amended the Human Fertilisation and Embryology Act to permit the destruction of embryos for Embryonic Stem Cell harvests but only if the research satisfied one of the following requirements: it increases knowledge about the development of embryos, increases knowledge about serious disease, or enables any such knowledge to be applied in developing treatments for serious disease. They later set up a £10 million stem cell research centre at the University of Cambridge.

Middle East

Israel passed legislation banning reproductive in 1999, exempting only that done for therapeutic cloning and that by leading scientists. Religious officials in Saudi Arabia issued a decree that sanctions the use of embryos for therapeutic and research purposes and Iran has also issued some of the most liberal laws on stem cell research and cloning.

Policy content in context

China's stem cell policy

China's stem cell research is quite interesting considering the context of a strictly regulated environment which some may actually view as restrictive. In fact China has advanced very fast in this field and in 2004, a visiting delegation from Britain's Department of Trade and Industry concluded that Chinese research in the field was already world-class. Several American journals including *Science* and *Nature* have also lauded their work.

Government funding for stem cell research is extremely low in comparison to other countries with the Chinese Ministry of Science and Technology having devoted between US\$33 million and US\$132 million on stem cell research for 5 years between 2009 and 2014 (compared to US\$3 billion for a decade for California State alone). What has advanced the field may be explained by the policies the government has taken on but also by the cultural context China is working in.

China has one of the most unrestrictive embryonic stem cell research policies in the world and in fact because of this in recent years, many expatriate Chinese scientists from the West are returning to China to establish stem cell research centres and laboratories there seeing the research opportunities that China's lax regulations provide.

However due to the influx and increased interest in this field of research, since 2003, the People's Republic of China Ministry of Science and Technology and Ministry of Health has had to issue some official ethical guidelines for human embryonic stem cell research in its territories. The guidelines strictly forbid any research aimed at human reproductive cloning and require that the embryos used for stem cell research come only from: Spared gamato- or blastocyst after *in vitro* fertilization (IVF) procedures; Fetal cells from accidental spontaneous or voluntarily selected abortions; Blastocyst or parthenogenetic split blastocyst obtained by somatic cell nuclear transfer technology; or Germ cells voluntarily donated.

In addition, the cultural and national attitude on stem cell research differs greatly in China than the rest of the world. the commonly held Confucian view or belief is that a person begins with birth; a person is an entity that has a body or shape and psyche, and has rational, emotional and social-relational capacity for a lifetime of learning and innovation, so they do not view the embryo as containing any inherent moral value and as such, a human embryo, lacking the characteristics of a person, cannot be equated morally to a person or a personal life. Stem cell research in China is thus free of the intense moral politicking that characterizes the field elsewhere. This moral and ethical politics has been the reason for most of the restrictive laws seen in the countries.

China's attitude and policies are further complemented by the fact that labor is cheaper in China than it is in the west, it is simply cheaper to produce goods in China than in nearly any other country and in sophisticated sectors such as medical research, the cost advantage is quite high.

Israel's stem cell policies

Israel is the leading publisher of stem cell research per capita in the world, with about 113 articles per 1 million citizens. This reflects on the government's commitment to the field.

Similar to China, Israel does endorse one of the most liberal laws or policies for stem research. In some cases it has in fact been said that Israel has no law regulating stem cell research. However Israel does have laws and in fact in 1999, a law was passed prohibiting cloning humans for five years under the Prohibition of Genetic Intervention Law of 1999, which was extended in March 2004 for another 5-year period. The temporary bans were to give time for the safety and full or potential impacts of stem cell science to be established and that once these were done, there would be no reason to continue with the ban. The lax laws in Israel may also be explained by tradition and religion; the ethical and moral concerns found in many of the Western countries, have no room in the bioethical discourse in Israel. The Jewish religious teachings lead to a conception of ESC research and cloning as morally acceptable. Talmudic tradition or Judaism dictates that life begins significantly after conception. An embryo that has been harvested before reaching 40 days lacks any claim to human rights, it is deemed *maya b'alma*, "mere water." In fact, because of the Jewish imperative to help humans in need of treatment, promoting these advances constitutes a special mitzvah. Other relevant considerations are that embryos outside the uterus are not regarded as human life and therefore do not enjoy a high level of protection; born human life is always given priority over human life in development, such as an implanted embryo; 'interference' with God's creation, if done in a responsible manner, is seen as a virtue rather than as a sinful activity; procreation enjoys a very high status and is regarded as binding for male Jews.

However as the field advances, a few laws are being enacted; there is a law that allows research on embryonic stem cells, but with regulations: For example, the sale of women's eggs and the creation of embryos specifically for stem-cell research is banned but researchers are allowed to use embryos left over from in vitro fertilization, with informed consent.

Scholars have also argued that the Israel situation also lends itself to the prevalent political situation: the 'demographic trend or threat' that the Jewish majority population in Israel will soon be outnumbered by non-Jews provides a context of risk to the discourse on 'Israeli cells'. Contexts of risk extend the scope of self-governing of individuals by predetermining ways of preventing particular risks. Instead of there being a consistent governmental policy on how to regulate medical technologies, the Israeli bioethics discourse shaped the regulations on Embryonic Stem Cell research and human cloning by providing decision-makers with particular understandings of what is acceptable.

Iran's context

Religious beliefs have acted as an obstacle to stem cell research in some countries and states. However similar to the case of Israel, strong religious beliefs do not necessarily mean an obstacle for stem cell research. Iran, a constitutional Islamic republic, is a good example of a country with a strong religion, but

where stem cell research is well embraced. This is probably because there are no laws in Islam regulating stem cell research. Instead what is referred to for regulation, are legislations based on opinions stated by an Islamic scholar founded on Islamic law and its interpretation, also called a Fatwa. Iran's religious leader issued a stem cell fatwa in 2002 stating that experimentation with human embryonic stem cells is consistent with Shiite Islam, thus making stem cell research possible in Iran. Stem cell research therefore got both religious and political backing in Iran, and by this also funding. Muslims believe that life begins after the soul has taken place in the body. This different view of the fetus's intrinsic value makes it possible for the Islamic faith and research on embryonic stem cells to co-exist. Iran can therefore be seen as quite liberal regarding stem cell research.

South Korea's context

South Korea resumed its stem cell research in 2009 following a scandal in which one of its proclaimed researchers was involved in scientific misconduct and fraud, which had led to an informal ban. South Korea had originally been considered a global leader in human embryonic stem cell research until review boards found that key data had been manipulated in some of the studies on cloning stem cells. In 2009 a presidential bioethics committee permitted a medical centre to conduct research on producing human stem cells through cloning, while imposing strict conditions on the team. It also enacted a new Bioethics and Safety Act for Korea prior to this in December, 2008. The act aims to enhance the health of human beings and the quality of human life, by creating conditions that allow for the development of life sciences and biotechnologies that can be used to prevent or cure human diseases. Additionally, the act aims to protect human dignity and to prevent harm to human beings. It ensures that these life sciences and biotechnologies are developed safely and in accordance with the principles of bioethics. It spells out that Somatic Cell Nuclear Transfer (SCNT) will be allowed using human eggs that are left over after IVF; that the use of human Embryo Stem cells is permitted (not derivation of them) for research purposes, but must be approved from an Institutional Review Board. It specifically bans reproductive cloning and interspecies SCNT are banned. It is relatively permissive on various forms of stem cell research from embryonic stem cells, SCNT, iPS generation and adult stem cells.

The relative caution and restriction is fully explained by the scandal that the country's scientist was involved in which brought question to all the work that had been done in that field and took South Korea down from its position as a leader in stem cell research. This however also brings a pressure for performance, South Korea has to prove itself once again not only in terms of being a leader in the field but also in terms of integrity and this may explain the high level of government support.

Conclusion

Reference to policies and regulations in different countries reveal lessons pertaining to the content of the policy which further points to the contexts that those countries are working in. The contexts may be financial, cultural, political, ethical or even social. These have shaped the working environment of stem cell research over the last two decades.

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The logo for REACH (Regional East African Community Health Policy Initiative) features the word "REACH" in large, bold, blue capital letters. Below the letters are three horizontal lines in yellow, green, and blue.

Regional East African Community Health Policy Initiative

The **Regional East African Community Health-Policy Initiative (REACH)** links health researchers with policy-makers and other vital research-users. It supports, stimulates and harmonizes evidence-informed policymaking processes in East Africa. There are designated Country Nodes within each of the five EAC Partner States.

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Conflicts of interest

None known.

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