

# Stem Cell Research and Cloning

by **Michael Asciak MD MPhil MP**  
Chairman Bioethics Consultative Committee

*The use of human stem cells for research purposes has been going on for some time now. It is important to state that there is nothing intrinsically wrong with stem cell research as such. New opportunities in transplanting tissue that is histocompatible and not subject to rejection, is an exciting field which can lead to substantially reducing much suffering and avoid immuno-suppressive treatment that is currently sustained by patients needing a transplant. Research in this area is developing at a fast pace*

The ethical problems with stem cell research are reserved for so-called embryonic stem cell research. There are sources of embryonic stem cells that are available from cord blood (collected from a cut umbilical cord just after delivery) which do not present any problems. The problem arises when researchers harvest stem cells by the destruction of the human embryo. Stem cells are naturally available as tissue found in the embryo in the first few days of development. Unfortunately these cells may only be obtained by the destruction of the embryo itself or by inhibiting the normal development of totipotent cells into an embryo. Some justify this as a necessary price to pay for research to proceed, others argue that spare embryos left over from 'in vitro', fertilization would die anyway, so it would be better to get some positive benefit out of them, before they become worthless. Whichever way one looks at this, two facts are indisputable. The first is, that human life is being used for research purposes and destroyed in the process. The second is, that human beings are being commodified on an increased scale and being rendered an object of financial and economic gain, the demand will increase the supply!

The ethical problems associated with the destruction of human embryos, obtained directly from reproductive technology (IVF) programmes, are not the only ones. Some countries have started the procedure of cloning human embryos first, so that iso-immune cells can be obtained which can be used in transplantation. That is, an individual's cells are first cloned by nuclear transfer (transferring the cell nucleus as happens in reproductive cloning), and the resulting embryo is then destroyed to obtain cells that are immunologically compatible with the cells of the donor, thereby obtaining good tissue for transplantation. Here the ethical and legal problems mentioned in the Additional Protocol on the Prohibition of Cloning of Human Beings of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Convention on Human Rights and Biomedicine / Oviedo Convention) of the Council of Europe are still inherent. Moreover there is a breach of the principles of Liberty, Individuality

and Equality addressed in the Convention for the Protection of Human Rights and Fundamental Freedoms which has been ratified by Malta and is now transposed into Maltese legislation – in the European Convention Act of the same Council of Europe. Reproductive and therapeutic cloning both breach these principles, and the Protocol considers both in the same light, without distinguishing between them, and without even referring to the word cloning, in the relevant article, prohibits the voluntary creation of an individual with the same genetic material.

Other ethical problems that are encountered in human stem cell research are surely those of patenting and ownership. Do the harvested cells belong to the donors or to the researchers? Should they be patented at all? What about the rights of the sacrificed embryo, which is the human being from which the cells originally emanated? These considerations require profound and deep analysis. Having said this, Maltese legislation prohibits the granting of patents for 'processes for cloning the human body, processes for modifying the germ line genetic identity of the human body and uses of the human embryo for industrial or commercial purposes'.

Another problem with embryonic stem cell research, concerns cloning for therapeutic purposes used with derived embryonic stem cells. Cloning, contrary to what has been widely held, is not something new! Nature has been using it for thousands of years to reproduce lesser orders of animals and plants. As evolution progressed slowly, nature developed a different and better way for reproduction to take place, with better mix age of genes and physical features, thereby improving a particular species' resistance to being wiped out by environmental change and improving the evolutionary profile of that particular species. The previous type of reproduction involving cloning was called 'asexual' while the newer revolutionary type was called 'sexual'. In man, sexual reproduction needs no introduction! Asexual reproduction involving cloning also occurs naturally at a particular stage of human development 'in utero' when identical twins are produced.

Man's fixation with cloning, that is

producing an individual whose genes are practically identical to another human being, can be brought about by two processes. One involving the splitting of a developing embryo by the passage of an electrical impulse through that embryo. The other involves the transference of a somatic nucleus into an ovum. This is called nuclear transfer. Once a human being has been cloned successfully and this is now proceeding in several countries of the world, he or she might be implanted into a uterus to develop till birth and allowed to be born naturally. This is termed 'reproductive cloning'. Otherwise the cloned embryo is allowed to develop for a few hours or days inside a dish in a laboratory where it is then cannibalised for its body parts including the much sought after 'embryonic stem cells'. This is termed 'therapeutic cloning', funnily enough.

Probably our obsession with cloning stems from the fact that a duplication of our genetic heritage conjures up profound perceptions or images of our immortality, which is far from the truth, as a particular personal life is not only composed of a genetic component but also of a developmental environmental experience recorded in that particular psyche. Therefore, two identical twins are not the same human beings. They are different human beings with the same genetic code. What fundamental human rights are breached by the act of cloning? Without going into the problem of the wholesale wilful destruction of human embryos for research and other purposes involved in therapeutic cloning, which opens a chapter in its own right, I will now focus lightly on the legal problems concerned with reproductive cloning.

The very act of reproducing or trying to reproduce another human being, either living or dead, breaches the right of every human being of being unique and irreproducible. This breach applies to both the original and the copied clone. Cloning therefore breaches the fundamental right of every human being to his personal freedom and liberty. It also breaches his fundamental right to equality in that every human being has an equal right to free personal development devoid of any shackles to past or present physical or mental predeterminations.

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# Current Status of Avian/Pandemic Influenza

by **Tanya Melillo Fenech MD MSc**

*Principal Medical Officer at Disease Surveillance Unit, Department of Public Health*

The latest epidemiological update by WHO is the following:

1. The number of new countries reporting human cases increased from 4 to 9 after October 2005.
2. Half of the cases occurred in people under the age of 20 years; 90 per cent of cases occurred in people under the age of 40 years.
3. The overall case fatality rate was 56 per cent.
4. Assessment of mortality rates and the time intervals between symptom onset and hospitalization and between symptom onset and death suggest that the illness pattern has not changed substantially during the 3 years;
5. Cases have occurred all year round. However, the incidence of human cases peaked during the winter and spring in the northern hemisphere.

Although media has not been reporting much on the subject, two more human deaths have occurred in July in Egypt and Indonesia. The cumulative number of cases is 229 with 131 deaths as of 4 July. This week Spain has discovered H5N1 in a wild bird and Hungary has discovered the virus in poultry. H5N2 has been discovered in ostriches in South Africa.

## Seasonal Vaccine

It is time to start encouraging our patients to book their seasonal vaccine. We succeeded in vaccinating 62 per cent of the total population last season and this has had an impact on both adult and children absenteeism during winter due to influenza like symptoms. I strongly urge General practitioners and Pharmacists to encourage your clients to take the jab again this year.

Some very interesting news from the Influenza June Market brief: 'New research from St. Jude Children's Research Hospital has suggested that the seasonal flu vaccine could be somewhat effective

in preventing people dying from avian influenza. St. Jude influenza specialist, Robert Webster, has said that the seasonal vaccine will not prevent people becoming sick, but could prevent death. The results of this research has fuelled the argument for broadening the scope of seasonal flu vaccination.'

This season, the Maltese Health Authorities are offering the seasonal vaccination to a wider group including those persons whose occupation is directly involved with poultry and also to front liners including police, armed forces and civil protection staff.

A study in the New England Journal of Medicine published 6 July 06 based on a population based surveillance on disease burden of influenza among children concluded that the average annual rate of hospitalization associated with influenza is 0.9 per 1000 children. Between 50-95 clinic visits and 6-27 emergency visits per 1000 children occur at outpatients. The attack rates of influenza infection vary between 15-42 per cent among school children and these form a reservoir which increases the attack rate in younger children and old persons (both groups being at an increased risk of needing hospitalization for influenza and its complications).

Influenza may be important in the pathogenesis of acute otitis media during the influenza season: 3-5 per cent of children annually experience acute otitis media associated with influenza. Influenza and its complications has been reported to result in 10-30 per cent increase in the number of antimicrobial prescriptions prescribed to children.

The European Vaccine Manufacturers are encountering delays in their production for the coming season due to low manufacturing yield of 1 of the recommended strains H3N2. This will result in fewer doses initially from all suppliers and supply will spread over a longer period so vaccination will start in October and continue till the end of December. ☒

The information is correct as on 13/7/2006.

For further information check the Disease Surveillance Unit Web Portal on <http://www.health.gov.mt/dsu/>.

## N E W F R O N T I E R S I N M E D I C I N E

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Legal instrumentation in a pan-European context, which concerns cloning is found within the remits of two institutions. The Council of Europe and the European Union. The former institution has adopted the Bioethics Convention of Oviedo, with a specific protocol on cloning, as mentioned above, which in effect outlaws both types of cloning (only for those who are signatories to the Convention). The European Union has adopted the Charter of Fundamental Rights which in effect, in article three, (the right to integrity of the person), indicates that the following must be respected: 'prohibition of the reproductive cloning of human beings'. Therapeutic cloning is not addressed in this charter. This charter will form part of the EU Constitution when the latter instrument is adopted by the EU. In the USA, reproductive cloning is forbidden, and President Bush has wisely forbidden the use of public federal funding for research in therapeutic cloning. The EU is still debating the use of EU funding for therapeutic cloning in specific countries. Since our accession to the EU, Malta has consistently voted 'no' to the use of EU funding for therapeutic cloning during the ministerial council meetings of the EU particularly so because it objects to the use of the procedure and also because it objects to any use of the funds which Malta pays into the EU coffers, being used to fund these procedures in other countries where it is allowed. Many countries also have their own national legislation on cloning procedures. For example Germany has very tight restrictions while the

UK has a very liberal legal formulation allowing therapeutic cloning to proceed under the control of research ethics committees.

Incidentally, Malta has no national legislation on the subject (except the abortion law which would prohibit use of embryos for stem cells – therapeutic or research and the patents law). It has not signed the Bioethics Convention at all, nor any of its protocols including the one on cloning (Malta is only bound by the Convention for the Protection of Human Rights and Fundamental Freedoms incorporated into the Maltese European Convention Act, which does not mention cloning at all). All else is fair game barring the arguing in a potential court-case of banning the procedure due to our obligations from our own criminal law and those from our national commitment to the European Convention of Human Rights! Incidentally, the Court of Appeal in the Human Rights Court in Strasbourg has decided not to consider the fundamental rights included in the European Convention, as extended to children who are not yet born, although it does not prevent individual European countries from extending this right to children in utero if they so desire (in Malta, there is some legislation that gives rights to unborn children – mainly Civil Law but also in the latest Domestic Violence Act). Like many other issues in bioethics, Malta is still in its pre-embryonic stage or as a foreigner observed to me, in the Wild West and some effort is needed to remedy the situation soon! ☒