<u>Catholic On Call handbook</u> Chapter 7 - Organ and stem cell transplants

The Catholic MO/HO:

Only some specialists can be affected by this law, being required to certify brain death as defined above for the purpose of kidney removal with the patient's "implied" consent. They will find it difficult to do this licitly, including core cooling under the prevailing circumstances.

Regarding the technique of organ transplants, this means that one can only donate if this act doesn't put one's own health and identity in serious danger, and if it is done for a valid moral and proportionate reason.

The dignity of the human body can be violated when its donated parts are used for financial gain or the remote benefit of others. Any reasons for the buying and selling of organs, or the adoption of utilitarian and discriminatory criteria, would clash in such a way with the meaning of gift that they would be invalidated, qualifying them as illicit moral acts. Abuses in transplants and organ trafficking, which frequently affect innocent persons, such as children, must find the scientific and medical community united in a joint refusal. They should be decidedly condemned as abominable. The same ethical principle must be reiterated in the case of the creation and destruction of human embryos destined for therapeutic objectives.

7.1 Basic Church teaching

"Organ transplants are in conformity with the moral law if the physical and psychological dangers and risks to the donor are proportionate to the good that is sought for the recipient. Organ donation after death is a noble and meritorious act and is to be encouraged as an expression of generous solidarity. It is not morally acceptable if the donor or his proxy has not given explicit consent. Moreover, it is not morally admissible directly to bring about the disabling mutilation or death of a human being, even in order to delay the death of other persons." (Catechism of the Catholic Church, 2296)

"....the respect due to human life absolutely prohibits the direct and positive sacrifice of that life, even though it may be for the benefit of another human being.." (John Paul II to the Pontifical Academy of Sciences, 14 Dec 1989)

The very idea of considering the embryo as "therapeutic material" contradicts the cultural, civil and ethical foundations on which the dignity of the person rests." (Benedict XVI, Vatican City, Nov 2008, address at international congress "A Gift for Life. Considerations on Organ Donation.")

7.2 Issues in clinical practice

7.2.1 Whole brain death vs. brainstem death

1. Machado

During the last decades, three main brain-oriented formulations of death have been discussed: whole brain, brainstem death and higher brain standards. The *whole brain* criterion refers to the irreversible cessation of all intracranial structure functions. It has been accepted by society mainly for practical reasons. Physicians have constructed batteries of bedside tests (and of confirmatory laboratory procedures) to show that this criterion of death has been satisfied. Until recently, whole brain strategists had not provided a conceptual framework to support specific criteria and tests. Moreover, this view has not answered the key point question about the critical

number and location of neurons, subserving the essential brain activities to execute the functioning of the *"organism as a whole*"

The brainstem death view has been powerfully articulated by Christopher Pallis. There were also practical reasons that promoted this view, because according to Pallis "a dead (i. e, irreversibly non-functioning) brainstem can be diagnosed at bedside, without resort of complicated investigations, and it predicts inevitable asystole within a short while". Therefore, so-called brainstem death was adopted in several Commonwealth countries. Pallis emphasised that the "capacity for consciousness" and "respiration" are the two hallmarks of life of the human being, and that brainstem death predicts an inescapable asystole. The physiopathological review of consciousness generation and respiration will provide a framework for not accepting Pallis' definition of death. Moreover, recent clinical cases have shown that brain death will not always predict an "inevitable asystole within a short while".

2. Pallis

Christopher Pallis' book *ABC of Brainstem Death* is a detailed exposition of the diagnosis of death, which however appears to rely on the concept that death occurs when the death *process* seems irreversible. Pallis regards death as a *process* that includes the continuing cellular, tissue and organ death and not as an event Although he agrees that whole brain death does not mean cellular death of all brain cells, neither in his estimation is there a moment of death - his diagnosis of the moment of death is his definition of death, "Irreversible loss of the capacity for consciousness plus irreversible loss of the capacity to breathe," also called brainstem death or apnoeic coma with (some) absent brainstem reflexes. Brainstem death (death of a part) is taken as the necessary and sufficient component of whole brain death. Conversely death of the forebrain alone (anencephalics, PVS) does not constitute death.

His concept that death is an irreversible *process* also permits some chronological disarray, taking *future* inevitable asystole as supportive evidence for his *present* diagnosis of death. In addition, Pallis reaches diagnosis of this *process* with only minimal testing on the grounds that it is impossible to test everything and is in any case sufficient.

The capacity for consciousness is assessed by persistent coma due to irremediable structural brain damage after other pre-conditions are fulfilled including exclusion of metabolic, drug, hypothermic or endocrine causes of coma but excluding post-anoxic cerebral oedema following "successful" CPR. Examples are traumatic physical destruction and intra-cerebral or sub-arachnoid haemorrhage.

Apnoea as the sign of brainstem death (with the same pre-conditions) is supported by 5 or 6 tests for brainstem cranial nerve but does not include tests for all cranial nerves or for brain control of endocrine, autonomic, temperature or cardio-respiratory functions on the grounds that all cranial nerve nuclei are near one another. For example, continued production of arginine vasopressin by the pituitary is not tested for or considered a sign of life. Poikilothermia (unstable temperature control indicating death of the temperature centre in the pons) is not a criterion.

Such minimal testing may thus crudely satisfy the diagnosis of death as a *process* but not as an *event*.

The Pope on the other hand regards death as an *event*. It is marked by the departure of the soul leaving signs of loss of integrative capacity ie loss of vital systems. Certainly a corpse is different from a live person - although both have the same structure, only the latter is animated by the life principle or soul. Dying is the process that precedes the event of death. Death of the organism is followed by disintegration of subsidiary systems, reflex arcs and death of tissues and organs.

The consequence is that the dying and the dead have distinctly different management protocols (these allow the removal of extraordinary means of treatment from the dying but not the removal of unpaired vital organs until dead).

3. The Linacre Centre For Healthcare Ethics

The Linacre Centre's own view is that 'brain death' protocols are insufficient for establishing the death of the body: we have become increasingly convinced by evidence suggesting that integrated bodily activity can continue after 'brain death' has been diagnosed. There have been documented cases of 'brain dead' patients maintaining bodily functions for months or even years: pregnant women have gone through pregnancy, children have grown up and passed through puberty, etc. Moreover, it is well-known to transplant teams that heartbeating donors move when organs are taken, unless they are paralysed by drugs, and that their blood pressure goes up when the incision is made. It is worth noting that some anaesthetists recommend that the supposed 'cadaver' be anaesthetised when his/her organs are taken, and that they may be pink, warm, able to heal wounds, fight infections, respond to stimuli, etc.

We would urge that while the adequacy of brain-related criteria for diagnosing death is fully and fairly investigated, the retrieval of organs from heartbeating donors should be put on hold. Donations from non-heartbeating donors - perhaps after organs have been cooled to preserve them - could continue while this investigation was carried out. At the very least, those who wish to donate their organs should be given the option of being non-heartbeating donors only, and should be fully informed of the state their bodies will be in when their organs are retrieved. Such information requires a proper interview with a medical practitioner who can explain current controversies: simply signing a donor card in no way indicates that the prospective donor understands what organ donation will involve.

Explicit consent by the donor, in addition to consent (or non-objection) by relatives is needed both to safeguard respect for the body, and to protect the interests of the donor in avoiding premature retrieval of organs. We would urge that even if the donor had given fully informed consent to organ donation, objections raised by relatives should be seen as overriding. This is particularly the case with retrieval of organs from heartbeating donors, which can be most distressing for relatives who believe - not without evidence - that their loved one may still be alive.

In the case of non-heartbeating cadavers, we would require consent from the donor him/herself, while relatives should be kept informed and could veto the procedure if they raise strong objections. In the case of children, however, parental consent should be both necessary and sufficient for the retrieval of organs from a non-heartbeating cadaver. Parental consent should also be necessary and sufficient in the case of stillbirth or miscarriage, at whatever stage of pregnancy. Wherever practicable the consent of both parents should be obtained, as generally both will have a legitimate concern for the child, though this will depend on the circumstances of the relationship, contact and custody. However, the deliberate termination of pregnancy and the destruction of human embryos are serious acts of injustice against the child in which the parent or parents are complicit. The use of the body of a child whose life is taken in this way adds insult to injury and is wholly unacceptable.

Apart from the cases of abortion and embryo destruction, where those complicit may not consent to the use of cells or tissue, we would distinguish between retention or use of small tissue samples (for which the relatives' consent need not be obtained) and retention or use of organs and large body parts (for which relatives' consent or non-objection should be essential). Given that the symbolic significance of small body parts is less than that of large

body parts, it seems reasonable to distinguish between the two in terms of the requirement for consent. Again, in the case of hospital post-mortems, although relatives should be informed where possible, we do not believe that explicit consent by relatives, or by the deceased, should be required. If strong objections are raised by relatives, however, or have been raised by the deceased while he or she was alive, these could well be overriding, depending on the urgency of the need to establish the cause of death.

Finally, on the question of live donation, we would urge that cells or tissue not be taken from children or incapacitated adults outside the context of their own medical care. The sole exception to this should be a case where regenerable tissue is removed, with court permission, for the benefit of another person in whose health the donor has a strong interest (normally, a close family member). It is essential to draw a firm line to protect the interests of vulnerable people who could easily be exploited as a source of tissue for transplantation or research.

7.2.2 Stem cells

Stem cells are immature, undifferentiated cells that are capable of developing into many types of cells, which make up different tissues in the adult organism. They are "mother cells" obtained and cultivated for the research and treatment of some illnesses.

Types of stem cells

There are three types of stem cells:

1. Totipotent stem cells

These, from the cells of an embryo up to the morula stage, are capable of generating all types of the organism's cells, including the placenta.

2. Pluripotent stem cells

These are capable of generating all types of the organism's cells, except the placenta.

3. Multipotent stem cells

These are capable of generating a large number of cells but not all.

Sources of stem cells

There are <u>several sources</u> of stem cells: adult, umbilical, placental, foetal, induced pluripotent and embryonic. Of these, only the use of human embryonic stem cells is immoral, because they are obtained by destroying human embryos. The use of foetal cells may also be problematic if obtained through direct abortion.

Adult stem cells are extracted from adults and children (from the skin, muscles, blood, bone marrow, fat etc). Umbilical stem cells come from umbilical cord blood. Amniotic and placental stem cells come from the amniotic fluid and placenta.

Foetal stem cells come from aborted foetuses and from miscarriages. Embryonic stem cells are extracted from so-called surplus embryos conceived through assisted reproductive technologies and then abandoned for use in research. The frozen embryos are thawed and then allowed to develop to the blastocyst stage. They are then destroyed so that their cells can be extracted.

Induced pluripotent stem cells come from an adult's body (from the skin, for example), are deprogrammed and then reprogrammed to become undifferentiated again. They can then be encouraged to develop into many different types of tissue. Their revolutionary discovery by Professor Shinya Yamanaka in 2006 allows researchers to obtain pluripotent stem cells without destroying human embryos.



Taken from A Student's Guide to Bioethics – Jérôme Lejeune Foundation

Stem cell use

1. Cellular therapy

Cellular therapy is cell grafts or implants aimed at restoring the function of a tissue or organ when it is impaired. These therapies have benefitted from recent scientific advances with stem cells.

Adult stem cells are already being used for the treatment of blood diseases (leukaemias etc), to repair wounds and burns, to repair tendons and to engineer tissues (reconstituted trachea). Some adult stem cells, especially from umbilical cord blood, make it possible to restore cells in the walls of blood vessels. Some are now being evaluated for the treatment of infantile cerebral palsy, Krabbe disease and other conditions.

Although these therapies have benefitted from advances with stem cells and hold promise for regenerative medicine (reconstitution of organs), stem cells will not cure all diseases.

2. Research

Huamn embryonic stem cells and induced pluripotent stem cells are being used to treat patients in clinical trials. They serve to model illnesses and to screen molecules, useful in pharmaceutical research.

Recent studies show that induced pluripotent stem cells could also produce therapeutic results (for example, successful repair of a myocardial lesion in a mouse model).



Taken from A Student's Guide to Bioethics – Jérôme Lejeune Foundation

7.2.3 Xenotransplantation

Xenotransplantation, the transplantation of organs, tissues or cells from one species to another, if applied to man, would offer the possibility of a huge supply of organs, tissues and cells for transplantation thereby relieving the "chronic" shortage of human donors.

However, before xenotransplantation becomes a clinical reality, there are practical challenges that must be overcome. One is rejection, the process by which the body of the transplant recipient attempts to rid itself of the transplant. Another is to ensure the correct functioning, across species barriers, of the transplant in its new host. Also, there is the need to minimise the likelihood of the introduction of new infectious agents into the human population via the transplant.

In addition there are concerns about xenotransplantation that require theological, anthropological, psychological and ethical considerations, as well as an examination of legal issues and procedural matters.

In addition to the problems raised by every transplant, there are three issues specifically related to xenotransplantation: 1) the acceptability of man's intervening in the order of the creation; 2) the ethical feasibility of using animals to improve the chances for survival and well-being of human beings; 3) the possible objective and subjective impact that an organ or tissue of animal origin can have on the identity of the human recipient.

There is the ethical requirement that in using animals, man must observe certain conditions: unnecessary animal suffering must be prevented; criteria of real necessity and reasonableness must be respected; genetic modifications that could significantly alter the biodiversity and the

balance of the species in the animal world must be avoided.

Regarding the xenotransplantation of solid organs, it is of course necessary that pre-clinical experiments (from animal to animal) should continue for as long as scientists should require and until repeatable positive results are obtained, results that are considered sufficient to allow trials on man to begin.

When the moment arrives, it will be ethically correct, respecting the rules of informed consent indicated above, to involve initially only a restricted group of patients, patients who cannot be chosen - in the given circumstances - for allotransplantation (whether because of waiting lists or individual counter-indications), and for whom no better alternative treatment is available.

A commensurate moral imperative is that of ensuring careful and detailed monitoring of the individuals who receive a xenograft, a situation which could foreseeably continue for the rest of the patient's life, watching for any sign of possible infection caused by known and unknown pathogenic agents.

In addition, every experimental clinical trial should be carried out in highly specialised centres with proven experience in pre-clinical pig-to-primate models; these centres should be authorised and supervised by the competent health care authorities.

The results thus obtained, if unequivocally positive, would constitute the basis for extending the practice of xenotransplantation, making it an accepted surgical therapy.

The questions and issues related to xenotransplantation have implications of a very wide social character. There is thus an ethical need to acquire correct information on the topics of greatest public interest with regard to the potential benefits and risks. This information should be communicated to as large a segment of the public as possible. Moreover, by means of debates and public discussions in small and large groups, society itself, through its representatives, should help to identify the conditions under which they would find it acceptable to invest resources and hope in this new therapeutic approach, in light of the scientific uncertainties which are still present and the urgent need to increase the availability of organs which can be transplanted.

A serious ethical commitment on the part of scientists should not neglect to explore therapeutic paths which may represent alternatives to xenotransplantation, such as seem to be promised by many recent discoveries in the field of genetics, as in a longer period the therapeutic use of adult stem cells.

7.2.4 Legal issues

7.2.4.1 Human Organ Transplant Act, 1987 (HOTA)

This allows the removal of kidneys from any Singaporean aged 21 to 60 who suffers a road traffic accident and is certified **brain dead** under the Interpretation Act, without his consent if he has not previously "opted out" in writing. The Catholic Medical Guild made a submission on 6 Jan 1987 to the Parliamentary Select Committee and appeared before it to state its disagreement, "This legal manoeuvre effectively abolishes the fundamental right of automatic ownership and stewardship of one's body in favour of a system in which it is necessary to claim one's own body, in default losing it to public use." In 1999, "core cooling" was introduced to cool abdominal organs immediately after cardiac or brain death for transplantation under HOTA or MTA. At its 52nd General Assembly in Edinburgh in Oct 2000, during which it published its 5th Revision of the *Declaration of Helsinki*, the World Medical Association expressed its choice for fully informed consent over presumed consent.

7.2.4.2 Medical (Therapy, Education and Research) Act (Chapter 175)

Act 23 of 1972, revised edition 1985 22 of 1998

An Act to make provision for the use of the bodies of deceased persons or parts thereof for purposes of medical or dental education, research, advancement of medical or dental science, therapy and transplantation, and for other purposes connected therewith. [25th May 1973]

Person may donate his body.

Any person of sound mind and 18 years of age or above may give all or any part of his body for any of the purposes specified in section 7, the gift to take effect upon death.

Relatives may donate body of deceased person.

- (1) Any of the persons specified in the Schedule, in the order of priority stated, when persons in prior classes are not available at the time of death, and in the absence of actual notice of contrary indications by the deceased person, or actual notice of opposition of a member of the same class or a prior class, may give all or any part of the body of the deceased person for the purposes specified in section 7.
- (2) The persons authorised by subsection (1) may make the gift after death or immediately before death.
- (3) Authorised persons
 - 1. The spouse.
 - **2.** An adult son or daughter.
 - **3.** Either parent.
 - 4. An adult brother or sister.
 - **5.** A guardian of the deceased person at the time of his death.

6. Any person authorised or under obligation to dispose of the body of the deceased person.

7.2.5 What to say: questions and answers on organ transplantation and stem cell use/research

Q. I recently declared myself an organ donor. What does the Church teach about organ donation? Is there any difference in teaching for someone who is alive or for someone who has died?

A. Pope John Paul II wrote in *The Gospel of Life* that organ donation is a gesture of selfgiving love when "performed in an ethically acceptable manner, with a view to offering a chance of health and even of life itself to the sick who sometimes have no other hope". Sadly, the demand for organ donors far outweighs the response. The Church's support for this practice is significant and consistent with its value of human life.

The main issue for both live and cadaveric donation is the free and informed consent of the person. In cases of live organ donation (e.g. kidney, liver, bone marrow, stem cells), the donor must be aware of risks involved in the procedure and is obliged ethically not to put herself in unreasonable danger while pursuing the praiseworthy goal of helping someone else. There should also be no economic benefit to donating organs.

When organ donation involves those who have died, the critical moral issue is that the donor has died prior to the process of harvesting organs for donation to others. Due to technological advances, it is possible to keep body organs functioning after a person is declared dead. Preventing the deterioration of organs is most important for successful transplants. A danger, however, is that the demand for organs might move people to begin the process before **the donor has died.** Doing so would not only be an affront to the dignity of the dying person also would place extra burdens on his or her family. One must be absolutely certain that death has occurred according to standard medical criteria before allowing for organ donation; this is especially important if and when someone might make a judgment for another about organ donation, as in the death of an infant or child.

Q. What does the Church say on whether it is licit to donate body remains for scientific and product research?

A. The Catholic Church has taught that it is ethical and even laudable to donate one's body for scientific research if a true need exists.

Pope Pius XII, in his May 14, 1956, allocution to a group of eye specialists, suggested that "The public must be educated. It must be explained with intelligence and respect that to consent explicitly or tacitly to serious damage to the integrity of the corpse in the interest of those who are suffering, is no violation of the reverence due to the dead."

However, the issue of product research raises another and far thornier question.

Common sensibility indicates that since the body is the temple of the Holy Spirit, and since humans live in communion with one another, utilitarian or financial gain is an insufficient basis for donation of organs from a live donor or a cadaver. Rather, the donor should be motivated by generosity, charity and the common good.

While Church teaching does not expressly address product research, one can infer from several Catholic documents that the sale of organs or tissue violates the fiduciary relationship between the individual and caregiver as well as the dignity of the human body. It reduces what can be a laudable act into something that is crassly materialistic and utilitarian.

The Catechism of the Catholic Church speaks about the free gift of organs after death as legitimate and potentially meritorious. Furthermore, the Pontifical Academy for Life, in its "Concluding Communiqué on the Ethics of Biomedical Research for a Christian Vision" on February 26, 2003, recognizes that science and technology can be used for good or for evil ends.

The academy therefore cautions that research be directed toward the "true common good" rather than toward private interest.

Q. Is the selling of the body or body parts morally unacceptable?

A. In Pope John Paul II's address to the participants in a conference on organ transplants he said: "Nor can (the body's) organs and tissues ever be used as items for sale or exchange. Such a reductive materialist conception would lead to a merely instrumental use of the body, and therefore of the person. In such a perspective, organ transplantation and the grafting of tissue would no longer correspond to an act of donation but would amount to the dispossession or plundering of a body."

In light of these statements, the respect due a corpse, and the centrality of the notion of "gift" to organ and body donation, it would seem that selling, buying and profiting from human bodies and their parts would raise serious moral concerns.

There is also something unsavoury about an individual offering his or her organs or body as gift for the well-being or benefit of others and then those who receive the body or its parts turning around and selling them for profit.

This is not to say, however, that those who procure and distribute bodies and body parts

cannot cover legitimate costs. It is commercialization for the sake of profit that is morally troubling.

Q. Why is the Church against stem cell research?

A. The Church is not opposed to all stem cell research. It is one particular kind of stem cell research – embryonic - that is judged to be immoral.

In embryonic stem cell research, the early embryo, sometimes only four or five days old, is destroyed as researchers take stem cells out of the core or nucleus of the embryo for study. As this process destroys the developing, living human being whom we are required to treat as a person, the Church judges this method of stem cell research as wrong. While very much sensitive to the suffering of those afflicted by a variety of diseases that scientists hope may be alleviated or cured through stem cell therapies, the Church judges that the destruction of any innocent human life for whatever good motives and goals is never justified.

However, the Church actively supports adult stem cell research and would welcome other techniques for obtaining stem cells that do not entail the destruction of human embryos. In 2010, the Vatican announced a grant of nearly \$3 million to help fund adult stem cell research. Various reports speak of the success of adult stem cell therapies in treating a variety of injuries and diseases.

Q: Is human cloning okay?

A. No. Cloning is a manipulation aimed at asexually reproducing a human being who is genetically identical to the original. The nucleus of an ovum is replaced by the nucleus of a somatic cell (not a gamete) of the human being who is to be cloned. In theory, scientists distinguish reproductive cloning (which aims to reproduce a human being who is supposed to be born) from therapeutic cloning (whereby the development of the embryo is stopped at the one week gestation mark so as to use his stem cells for research). In reality there is no difference – both are immoral.

7.3 References

- 1. Declaration on the production and the scientific and therapeutic use of human embryonic stem cells Pontifical Academy for Life
- 2. *Prospects for xenotransplantation: scientific aspects and ethical considerations.* Pontifical Academy For Life
- 3. Catechism of the Catholic Church, second edition
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- 5. D. Alan Shewmon. 'The Brain and Somatic Integration: Insights Into the Standard Biological Rationale for Equating 'Brain Death' With Death', *Journal of Medicine and Philosophy* 2001, Vol.26, No. 5, pp.457-478.
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