Republic of San Marino

National Bioethics Committee of Republic of San Marino

Law n° 34 of January 29, 2010

BODY AND BODY PART DONATION FOR THERAPEUTIC OR SCIENTIFIC PURPOSES

APPROVED IN THE PLENARY SESSION OF FEBRUARY 15, 2016

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SUMMARY

PRESENTATION

Since the beginning of its second mandate in 2014, the intention of the *National Bioethics Committee of the Republic of San Marino* (CSB) has been to continue the commitment undertaken in previous years to reflect upon the delicate and complex themes regarding the end of life which began with the document *"The assessment of death",* written in 2013. The work was solicited by the cognizance of the population of the Republic of San Marino through the *Associazione Volontari Sammarinesi del Sangue e degli Organi* (San Marino Volunteer Association of Blood and Organs) and in consideration of the need for a legislative update in the area of the assessment of death and in the sector of body or body part donation.

The CSB wished to dedicate two distinct documents to these topics in order to remark upon the peculiarity of each case. Total or partial body donation, in fact, despite being directly consequent to a meticulous death verification, does not constitute a necessary aim.

The requested scientific rigor in the process of verifying an individual's death is a public guarantee of the procedure and derives from the primary ethical principle of absolutely safeguarding human life in all of its phases.

This respect towards the human person also extends to his/her human body, even after death, is based upon on the principles of inviolability and intangibility that has driven all forms of human coexistence since its most remote expressions.

Aware of the vastness of the subject, the CSB has chosen to realize a document that would be as preparatory as possible for the building of a normative framework by taking into account the specialized literature and the referring national and international debate, and by redirecting the discussion to some future related documents for ulterior specific bioethical problems. In particular, the CSB has contextualized its work on corpse donation (certain that donation between living beings, even if supported by the same principles, has characteristics that require an *ad hoc* dissertation) and has directed its reflection towards the bioethical principles that allow a legitimate use of the corpse both for therapeutic and/or scientific purposes.

The work draws upon principles adopted by the European Countries in a cultural and juridical context accepted by each nation of the union. On one side the CSB immediately identified with these principles and on the other it did not consider it to be opportune to compare the normative framework and different cultural values in this paper (i.e. regarding the possibility of organ trafficking , which is allowed in some countries, and the ongoing debate regarding this topic).

This means that the different and possible ways to approach the problems that belongs to other cultural contexts are not discussed herein.

CSB unanimously recognizes total/partial body donation (for therapeutic or for research objectives) an act of great moral value as long as it is sustained by the principles of **gratuitousness, correct information and expression of a conscious informed consent, traceability, justice and equity in access to care.**

Furthermore the CSB, consistent with what has been recommended in recent European documents, has underlined the important and difficult role of health professionals in the organ donation field and considers it essential to give them continued training from the beginning of their clinical practice.

Finally, even in this document, the CSB has considered it to be fundamental to not discriminate against those with physical, sensory or intellectual disabilities: a basic principle in keeping with its task in the bioethical reflection regarding disability.

The document is supplied with normative attachments reporting the most important San Marino and European references.

The document's draft has been developed by a work group coordinated by dr. Nicolino Monachese, assisted by Deputy President, professor Luisa Borgia and with the fundamental partnership of Professor Assuntina Morresi, as an external expert of CSB.

The group was also joined by: Renzo Ghiotti, Carlo Bottari, Carlo Daniele, Adriano Tagliabracci, Father Gabriele Mangiarotti, Francesco Carinci, Ugo Alonzo and Pier Enrico Gallenga (professor Gallenga as an external specialist to CSB).

Bibliographical and sitographical research has been prepared by Dr. Hhsnija Colombo. We thank her for her kind and precious collaboration.

The CSB expresses a particular gratitude to the following Professors: Alberto Maria Comazzi, neuropsychiatrist and former Director of NIT (Center for the Medical Psychology of Transplants) who, during his audition among the CSB, has elaborated upon consent in the donation field, and Dariusch Atighetchi, Islamic Bioethics professor at the Theology College of Lugano and at the Inter-disciplinary Centre of Studies on Islamic World at the *Second University* of Rome, for his kind written contribution regarding organ donation in the Islamic context. We also thank Dr. Augusto Pocobelli and Dr. Carlo Villani, *Banca degli Occhi di Roma*, *Fondazione Bietti, Ospedale San Giovanni – Addolorata (Eye Bank, Bietti Foundation San Giovanni – Addolorata Hospital)* of Rome, for making available the documents regarding eye donation.

This document has been unanimously approved during the plenary session on February 2, 2016 by the following members: Borgia, Bottari, Alonzo, Monachese, Tagliabracci, Cantelli Forti, Tonelli, Casali, Mangiarotti, Ghiotti. Participant in videoconference, President Sacchini has endorsed the document. Absent from the session, Daniele and Carinci who communicated their endorsement.

CSB's Deputy President
and President of the same committee during 2/15/2016 session.

Luisa Maria Borgia

INTRODUCTION

Among the elements that characterize the course of human civilization, one of the most important is the appearance of funeral rites and burial as a sign of respect for the body, first to counter the consequences of decomposition of corpses and their destruction by wild animals, and later, with the appearance of the sense of transcendence, to allow the soul of the deceased to find peace and the way to the afterlife, avoiding its remaining connected to the place and to the people with whom he had lived.

The cult of the dead and the respect of the body, either by burial or with the subsequent practice of cremation, is the expression of feelings deeply rooted in human nature, following the instinct of preservation, intended to honor the memory of the deceased and to maintain its protection through dedicated respect.

The respect of the body and its inviolability have therefore always been an expression of ethical values, both social and civil, of each culture.

With the birth of civilization that conceived a form of existence after death, the body-corpse took on a meaning of sacredness that demanded respect and inviolability, in order to ensure the passage from one state of existence to another.

The emergence of Christianity did not reject the cult of the dead of the ancient civilizations, but consolidated it, after its purification, giving the true transcendent meaning in the light of the knowledge of the soul and of the dogma of the resurrection; since the body - which during life – is "temple of the Holy Spirit" and "member of Christ" (1 Cor. 6.15 to 9) whose ultimate destiny is spiritual transformation in the resurrection, which always has been, in the eyes of a Christian, so worthy of respect and veneration, as the most Holy of things.

Every religion has always celebrated death as a key step in life, with rites of passage towards a new form of life or toward the resurrection of the body, as found in Judaism, Islam, Buddhism, and Hinduism.

In the Jewish religion the Talmud derives from an explicit biblical reference (according to which even the most depraved beings are created in the image of God and deserve respect in death)[1]. It has strict laws against "dishonoring the dead" in general by means of wrongful exposure, unwarranted, unjustified exhumation, and especially with engravings and disfigurements of various kinds. A category of deceased who enjoy special protection are people who die without having a

[1] *"If a man has committed a sin worthy of death, and you shall be put him to death and hanging from a tree, his body shall not remain all night upon the tree, but you shall surely bury him the same day because the hanged man is a curse of God and you do not defile the land which the Lord your God is giving you as an inheritance "(Deuteronomy 21:23).*

family that can provide for their funerals. The duty of the burial in these cases lies with every Jew. On the whole Jewish law considers the human body as divine property and therefore inviolable.[2]

In the Bible, the damnation is precisely the Gehenna, where the corpses of criminals were burned without burial.

In the Islamic context, the debate on organ donation and the consequent inevitable violation of the integrity of a living body or a cadaver was complex and articulated in several stages, and is not at all concluded. It is not a coincidence that the positions expressed by the doctors of Islamic Law may still diverge on some important issues. If the notion of respect for the human body (alive or dead) is accepted by all the experts, the conception of the human body as *res sacra* appears theologically and legally problematic, though increasingly used in medical and bioethical texts.

In light of all this, it is necessary to understand how, over time, it has been possible to waive these ancestral principles of inviolability and intangibility to allow the lawful use of the whole body or body parts for therapeutic or scientific purposes.

The sole ethically acceptable form of using the body, the *res sacra*, is its donation to enable the realization of a greater good, such as the protection of the health of another human being, or the development of science, in respect for bioethical principles of beneficence, solidarity and subsidiarity.

Literally donation comes from “gift, present, gratuity”, and therefore testifies the gratuity of the gesture, the generosity of the subject and an active action for the good of others.

Legally donation is an act by which one party, the donor, intentionally enriches the other, the donor, who has a right - or binding to dispose of it - without obtaining a fee.

The donation of the body is, after that of life, an act of the highest moral value since the body is the essence of the earthly dimension.

The donation of the body takes place by the will of the subject, and therefore assumes an active action indicating the person's decision. For the profound moral value of the act, it is required that this decision is upheld with the utmost respect, both as acceptance of the will and as a responsibility of the recipient of behaviors, procedures and consistent actions that preserve the rights of the person as though still living

Donation for therapeutic purposes is the most well-known concept. It is thanks to this act that heart, kidney and liver transplants are possible.

Less known, but equally important, is donation for scientific purposes.

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[2] M. Petrini, F. Caretta, The Ancient, R. Bernabei (eds), *The accompaniment of the elderly dying person*, CEPSAG-UCSC, Rome 1994.

Modern medicine has developed from anatomic dissection studies conducted systematically since the Renaissance. It is through the knowledge of the anatomical bases that all other medical disciplines have developed. Today, like yesterday, in-depth knowledge of anatomy and the development of increasingly modern surgical techniques represent an unavoidable step in ensuring competence and the implementation of clinical results.

It is important to distinguish between "respect and integrity" and "inviolability" of the body. It was the identification of these terms at the dawn of modern medicine which caused enormous difficulties in scientific development which is an essential prerequisite to a valid therapeutic approach.

Integrity means to be “whole” or “intact”. The status of an entity that has all of its parts, its elements and attributes, that preserves its unity and nature, or which has not suffered damage, injury, quantitative or qualitative reductions.

The acceptance of body or body part donation should therefore ensure respect, integrity and inviolability of the moral dimension, and therefore all the rights of the subject as if he/she were still alive. However it may not be limited by the inviolability of the body, which effectively prevents the will of the donor.

The lawful use of the body for study and research can only go through the recognition of this particular condition of the human course and in the establishment of a series of rules that protect the body after death.

Even in ancient Rome awareness of the importance of codification with regard to the *status* and use of the corpse (*ca.da.ver*, acronym of *caro data vermibus*, according to the same Romans) had been achieved and a police mortuary embryo can be traced in the Table X in the "Laws of the Twelve tables", compiled by a committee of ten experts (*decemviri legibus scribundi*), whereby among the rules for funerals is stated that "*Hominem mortuum in urbe ne sepelito neve urito*" (No dead may be cremated nor buried in the city). This is the first evidence of a police mortuary standard, which will find full development only after many centuries in different European countries, by the statement of systematic medical necropsy norms aimed at the certain diagnosis of death, the protection of the body and the implementation of sanitation measures to ensure the community against the risk of pathologies connected to cadaveric exposure. The Napoleonic edict of Saint Cloud (June 12, 1804) is the expression and the best known reference, from which modern legislation concerning this issue was drawn. Meanwhile, with the implementation of studies and of medical teaching in European universities, the need to have bodies for research and training in this discipline arose.[3]

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[3] In the arts, the amazing representation of Friar Angelico in the San Marco altarpiece, in Florence (1438-1443) of the miracle of the medical saints Cosmas and Damian (III century AD) with the transplant of the leg of a dead Ethiopian, to save from gangrene the Justinian deacon, is the first document of the hypothesis (''miracle'') to prolong an active life through part of the corpse. The title page of the first edition (1543) of *De humani corporis fabrica libri septem* by Andries van Wesel - Latinized as Vesalius - represented the anatomist in the act of dissecting the arm. Even The

In 1500 Italian universities became an important crossroad for research and teaching in the medical field.[4] During that period there anatomical theaters were built for dissections which could also take place in the home of the deceased or in a teacher's study. However, even at that time, the culture of donating the body for study existed and bodies for dissection were procured , in the absence of a specific regulation of the corpses' protection, in the most diverse of ways ranging from the purchase from the families, to theft or through violent acts.

The first known act of body donation for anatomical studies is that of Francis of Sales, a law and theology student at the University of Padua, who died in 1591 at age 23.

Since the dissection of corpses in Italian Municipalities was prohibited Leonardo, in Tuscany, proceeded with nocturnal anatomical studies by candlelight[5]. The dissecting table of the University

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Anatomy Lesson of Dr. Tulp by Rembrandt van Rijin (1632) is a wonderful testimony of dissecting art and the study of the function: with the forceps in his right hand dr. Claes Pieterszoon (so called Tulp for the coat of arms with golden tulip in a blue field with a star in the fourth left, the tulip was a recent botanical curiosity in the Netherlands) raises the carpal and digital flexors of the left forearm of Adriaen Adriaenszoon, killed for theft- therefore *res nulliuse* available for science - while his left arm imitates physical activity, teaching surgeons learners the wonders of the Creator. The Anatomy book is represented foreshortened in the foreground, on the lectern at the foot of the dissection table, probably opened to the page on which it is addressed the look of Adriaen Slabran, second from left. In the subsequent Anatomy Lesson of Dr. Deyman (1656), partially destroyed by fire, Rembrandt represents the corpse of Joris Fonteyn, who was executed for robbery, emptied of internal organs, while the surgeon proceeds to the cranial dissection, lifting the meninges and highlighting the hemispheres. Curiously, the disciple Gijsbert Kalkoen, holding with religious compunction bone dissected shell, is the son of Matthijs Kalkoen, second from the left in the previous lesson of dr. Tulp. Even in the Protestant Guild of Amsterdam Surgeons the family professional tradition - sanctioned right in the Hippocratic Oath - it was greatly respected. Of relevant educational and artistic importance is the representation in the following centuries of dead body parts in wax which endowed many universities; particularly relevant is that of the Institute of Anatomy of the University of Bologna, reorganized under the direction of prof. Francesco Antonio Manzoli (1981-2011), promoter of initiatives for the testamentary donation of one's body to science.

[4] Scholars came from all over Europe to the Italian Universities of Padua, Bologna, and Ferrara to perfect in anatomy, in the anatomical dissection and in the discovery of the human body.

[5] From Artistic Anatomy to Anatomy-Physiology: to better understand the important contribution of Leonardo to the development of the Anatomy and Anatomy - Physiology, flourished in Italy during the Renaissance, it is necessary to recall at least in broad terms the evolution of the anatomical studies before him. The dissection of corpses was historically considered a sacrilege, also forbidden by Roman law. Only the Medical School of Alexandria, with Herophilus of Chalcedon, had practiced dissections on man. It is not certain if Hippocrates has performed studies on the corpse, but we do know that Aristotle and Galen had studied anatomy in animals, then transposing to man their comments. The Artistic Anatomy starts mainly in Greece during the Hellenistic period, for the search of painters and sculptors in the representation of the human body. Roman civilization which follows the Hellenic is inspired, after the Alexandrian and Galen studies, to the patterns of Greek painters and sculptors. The Church therefore strongly prohibits the dissection of corpses, until 1215, when Emperor and Scientist Frederick II with a special order allows it. However in 1299 Pope Boniface VIII, with the Papal "*De sepolturis*" again prohibits the manipulation of the corpses. It was not until 1300 that at the University of Bologna, Mondino de 'Liuzzi legally resumes such dissection studies, by funding the first School of Anatomy in Europe. Mondino's Anatomy has been published in 1316: his treatise, however, is affected by the influence of the theories of Galen, Aristotle and Avicenna. The book is definitely known to Leonardo and it will remain the fundamental text in European universities for a couple of centuries. After anatomy had been taught at the Bologna Medical School, it was approached by several painters of the 400, who practiced their own dissection studies, to faithfully render the surface anatomy, as in the paintings of Pollaiolo and Signorelli (Taken from: Mingazzini P ., *Leonardo and anatomy*. Il Bassini - Volume XXX - January-June 2010).

of Padua at Palazzo Bo was constructed to rotate and drop the examined body in the canal below, in case the henchmen of the Serenissima were to enter. The cadaver of a dog was tied underneath and was exposed by the rotation, thus deceiving the inquisitors.

Specific rules in the field of the donation of the human body for these purposes appeared centuries later, in 1900, with provisions that favored - or rather, did not hinder - the donation of one's body to the dissecting rooms, in the absence of any action of cultural promotion on the high moral and social value of the act of giving.[6]

Next to the donation of the body for research and teaching purposes, it was only in the second half of the last century, parallel with the development of transplantation from cadavers and living persons[7], in which a thriving legislation began allowing the taking of body parts or from cadavers or organs from living persons for transplantation purposes.

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[6] It may be significant the reference to the Italian law of 1933 (Royal Decree of August 31 1933, n. 1592), still in force, which reserves to the dissecting rooms the dead bodies which do not have family within the sixth degree of relationship who can claim them for funerals.

[7] In the absence of certain data, in addition to the representation of Beato Angelico, on the outcome of Saints Cosmas and Damian, experts indicate more realistically as the date of commencement of transplants 1902, the year when the French surgeon Alexis Carrel (Nobel Prize for Medicine in 1912) invented a technique that allowed to connect to each other and suture blood vessels. Thanks to the sutures the first heart and kidney transplants on animals were performed. During the Second World War, the British doctor Peter Medawar, performing skin grafts in severely burned patients, showed that the biological incompatibility between donor and recipient was of genetic origin . The first real human organ transplant took place, however, in 1954 in Boston, at the hands of the surgeon Joseph E. Murray, who for the first time performed a kidney transplant between two twin brothers, where donor and recipient were, therefore, genetically identical. In 1963 in the United States the first liver transplant was performed, by Professor Thomas Starzl; in the same year the surgeon J.D. Hardy performed the first lung transplant. Three years later, doctors Kelly and Lillehei proceeded to first pancreas transplant. But to raise a stir was Christian N. Barnard, South African surgeon who, in Cape Town, performed the first heart transplant. The event, dated February 3, 1967, astonished the whole world which began to count the patient's survival days of the transplanted patient; they were 18, then the patient died. But the following year Barnard tried another heart transplant and it was clear to the scientific community that transplants of this organ were now a reality. The first perforating corneal transplant was performed on December 7, 1905 in Olmuetz by Eduard KonradZirm on a blind patient for bilateral acid burn by lime: the OD had complications, but with OS the patient resumed his work. Zirm practiced other five transplants (''grafts'') of cornea from a human cadaver, after attempts to allogeneic rabbit, but he was disqualified from continuing opposing religious reasons, and removing him from the role. Transplants are inscribed among the most beautiful pages of Medicine, because characterized by the aspect of extraordinarily solidarity, especially between living relatives; but alongside the extraordinarily noble deeds there could develop ethically unacceptable aspects, albeit regulated: in some countries where there is the death penalty, in case of use of the corpse, in order to allow the multi organ taking that requires a pre-freezing solution, surgeons are proceeding in advance by cannulating the aorta and femoral veins, so to start the process as soon as the executioner executes the prisoner with a blow to the neck, that is, with cerebral and cardiac death. The opinion of Harvard University in Washington has considered the protocol "no beating heart", a not beating heart donor, only for prisoners (From Di Salvo E. *The transplant surgery*, In *New Frontiers of clinical trial: a challenge for bioethics*. Acts of Congress, Napoli 2010, p. 84-87, Editor C. Buccelli. ISBN 978-886651-1-034-5).

BIOETHICAL ASPECTS OF ORGAN AND TISSUE DONATION FOR THERAPEUTIC OR SCIENTIFIC PURPOSES

The availability of human body parts for therapeutic purposes, or more generally scientific and cultural purposes, has always been a major bioethical subject on the international level, involving historical, legal, social, economical, anthropological and ethical fields.

Ethics comes into play when the need to decide which conduct is justifiable or not, and when it is necessary to establish which of two alternatives is the best choice.

The fundamental ethical principles arose from the so-called "civic ethics" consisting in an operational agreement on an issue by accepting the principle that it is a temporary arrangement tied to the culture of the society; based on consensus; and modifiable with the changing culture.

The present document aims to identify the bioethical principles as a reference for a regulation of the donation of organs, cells and tissues of human origin and it must take into account the specialized literature as well as the national and international debates.

Bioethical principles of reference

The donation of human body parts for medical (or therapeutic) purposes is equivalent to organ, tissue and cell transplantation, from a donor to a recipient. The donor may be alive or dead.

It is possible to donate parts of body – organs, tissues and cell – **for scientific and academic purposes, and also for exhibition purpose.** These may be called scientific and educational aims.

The CSB expressed its opinion about the use of corpse parts for educational purposes in 2014[8].

The two objectives of donation involve elements which are very different from each other in ethical, anthropological, scientific, legal and social points of view. For each area it is necessary to make further distinctions – i.e. between living or dead donors.

From the bioethical point of view there are two elements common to the entire issue, which although having to be declared within each specific situation, represent a unitary feature: namely gratuity and informed consent. A third element - traceability - is necessary for organs, cells and tissues donated only for clinical purposes.

Finally, in guaranteeing **the principle of justice and the principle of equity in the access to care** the opportunity to receive organs/tissues/cell samples is guaranteed by the waiting lists that

[8] National Bioethics Committee of Republic of San Marino*, Response to the request for an opinion on the ethical aspects of the use of anatomical parts derived from corps,* October 17, 2014: http://www.sanita.sm/on-line/home/comitato-bioetica/comitato-sammarinese-di-bioetica/pareri-csb.html

must preclude specific forms of discrimination against persons with physical, sensorial or intellectual disabilities as long as they are considered appropriate for the operations[9].

The donation of reproductive cells, which requires a specific reflection, is excluded in the following dissertation.

Furthermore it is necessary to reiterate that the donation, storage, and distribution of human tissues and cells is the first step of the supply chain that it is necessary for the production of so-called advanced therapies: the therapies used for this biological material. This document does not deal with this specific issue.

Gratuity

Oviedo Convention, Article 21 - Prohibition of financial gain

The human body and body parts must not be a source of profit.

The question that underlies this first ethical criteria is: who is the owner of a body?

This is not the place to discuss the issue of availability of one's body and of one's self-determination, however for the purpose of the present document we repeat that the concept of donation is associated with the "body parts" of a person, who renders them available to third parties for therapeutic objectives, such as the common good, and whereby it is impossible to quantify or give a monetary value to the donation itself. It is an asset of the whole community, even though it is the free will decision of the individual who decides to give it freely as a gift to another person. The specific health care authority is in charge of evaluating the pertinence of the donation and giving its approval[10].

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[9] In cases of organ transplant, people with disabilities can be supported and accompanied in the path to the understanding and acceptance of the transplant by competent people in the communication, they are protected from their human rights, in accordance to what stated with the Convention on the Rights of Persons with Disabilities of the United Nations, Art. 25 "*Health*", paragraph a): "*States Parties recognize that people with disabilities have the right to enjoy of the highest attainable standard of health, without discrimination based on disability. States Parties shall take all appropriate measures to ensure their access to health services that takes into account the specific gender-sensitive, including rehabilitation services. In particular, States Parties shall: (a) Provide people with disabilities free or affordable health services, which cover the same variety and that they are of the same quality of health care and programs as provided to other people, including health services in the sexual sphere and reproductive health and public health programs for the people*."

[10] The recent statement of the two Committees of the Council of Europe (Bioethics Committee and Committee for Organ Transplantation) remark the principle that human organs must not be bought or sold, or be a source of profit or similar benefits for the person to be which they are taken or to third parties:
Council of Europe, *Statement on the prohibition of any form of commercialization of human organs*, adopted by the DH-BIO and the CD-P-TO on May 2014.
https://wcd.coe.int/ViewDoc.jsp?id=2215115&Site=COE&BackColorInternet=C3C3C3&BackColorIntranet=EDB021&BackColorLogged=F5D383

Only the absolute gratuity of the donation of one's body parts is a necessary warranty against the exploitation of human beings in the name of therapeutic benefit of third parties or of the progress of research and scientific education.

It is possible to hypothesize health management models which provide forms of cooperation between public health care institutions and for-profit health care facilities when the object of the convention is the "service" of health professionals (doctors, nurses, health workers and administrative) that must take into account management costs. In this case the economic contracting does not directly consider the parts of the human body, but only the work and the human and professional tasks which are used which must be the subject of an economic evaluation.

The no-profit model takes into account only the so-called "living costs" of the donation, that is, the cost of the complete donation procedure, including the cost of clinical tests forecasted for the donor who is declared suitable for donation, as well as the cost of collecting, processing, storing, transporting and distributing the biological material.

These "living costs" must strictly exclude parts of the human body which are destined to be transplanted.

The management model should exclude surreptitious modes of payment, avoid the use of forms of fixed allowances for the "inconvenience", or refunds beyond the support of the living costs as listed above that are closely linked to the treatments and to the work of the donation and the transplantation in the case of clinical purposes.

The management model for a free donation must not therefore accept contracts between donors and third parties, nor the exchange of money involving the donor even in the form of reimbursement, rather it should require methods that ensure that the donor does not have to sustain any costs.

The "bonus" is a form that sometimes is used as a kind of remuneration for any inconvenience on the part of the donor. It necessarily implies and quantifies a cash commitment for the donation thus denying the concept of donation.

As a consequence, any days or hours of work used for the donation, appropriately documented at the department in charge of the donation process, should be recognized to the donor as working days or hours by the Institute for Social Security of the Republic of San Marino (known as ISS), thus avoiding direct and additional refunds to the donor.

It must be reiterated that these are general principles that cannot depend on the invasiveness of the procedures for the donation, nor by the nature of the cells, tissues or organs for transplant: the criteria of gratuity should be universal, and it implies its general applicability.

If this were not the case, that is in the case in which different refunds, bonuses and incentives based on the type of cells, tissues and organ donated would be considered, this would mean that the donation would follow the market criteria, i.e. the supply and demand logic. The act of donating a part of his/her own body should be appreciated and guaranteed, regardless of "what" is given.

The donor will be well informed about the risks may be incurred in and be given a complete framework before the act of self-oblation.

Informed Consent

Oviedo Convention Article 5 - General rule

An intervention in the health field may only be carried out after the person concerned has given free and informed consent.

This person receives complete information on the purpose and nature of the procedure and its consequences and risks.

The person concerned may, at any time, freely rescind the consent.

Informed consent involves both donors and recipients. No type of consent may be implied or inferred, or in the form silence/consent, but must always be free, explicit, fully informed and written. Health care workers must ascertain that the content was reasonably understood by patients, donors and recipients, and ensure that this is the result of an empathic "communication", rather than sterile "information"[11].

The CSB believes that citizens and residents of the Republic of San Marino may express their will regarding donation at the "*Associazione Volontari Sammarinesi del Sangue e degli Organi*" (San Marino Volunteer Association of Blood and Organs)[12] and at the pertinent health services of the Institute of Social Security (ISS), explaining the purpose of the consent .

Concerning the donors:

a. the consent of donation for therapeutic purposes can never limit the audience of recipients, who must be identified only on the basis of clinical appropriateness criteria;

b. the consent of donation for research purposes must be explicit for each specific objective of the research. As part of the donation of biological samples from living persons, if the sample donated will be used for different purposes than the one established in the consent, the donor will be contacted, so that he/she can sign a new informed consent for the newly established aim. If the donor is not able to give his/her consent - with reference to Article. 20 of the Oviedo Convention, dedicated to this type of donation limited to the removal of regenerative tissue sampling for therapeutic purposes- may be allowed, with the

[11] A.M. Comazzi, G. Invernizzi, A. Verdecchia – *"Il consenso informato: riflessi sulla relazione medico-paziente",* in *"Traffico d'organi. Nuovi cannibali, vecchie miserie".* F. Porciani, 1° ed. 2012. Ed. Franco Angeli. ISBN:9788856837063.

[12] The AVSSO ACE was founded in 1959 with 36 donors which were President Pietro Emiliani, Giuseppe Rossi, Giampaolo Rolli, Paolo Mancini, Renzo Ghiotti, Antonio Morri. Today there are approximately 3700 donor members of the Association http://www.avsso.org/new_site/

appropriate authorization, by the legal guardian, as long as the recipient of the donation is a brother or sister of the donor, and as long the transplant is aimed at the preservation of life of the recipient[13];

c. the donation consent for purposes of study, education and training must ensure compliance with the aforementioned provisions recommended above by the CSB in the paper of 2014[14]:

- the person prior to dying has given informed consent to the use provided post mortem of the body or parts of his/her body for the purposes of study, research and training;
- the donation of the body or body parts has taken place in terms of effective gratuity;
- informed consent has been expressed by an adult person, conscious and in the absence of any form of material or psychological coercion;
- that the body parts do not come from prisoners or persons sentenced to death;
- that the body parts are traceable and that the safety of all health professionals and of the community is guaranteed with the full assumption of any responsibility.

For recipients:

The essential element is the full understanding of all clinical tests performed on the donor and the degree of risk that the recipient is aware of, once he/she agrees to receive an organ/tissue/cell sample.

Both donors and recipients:

The need to be detectable and contacted by the health professional (or the competent authority in case of need) in the event of reactions and adverse effects must be clear.

Some EU Member States (i.e. Italy), in order to overcome the shortage of organs, have implemented measures aimed to promote information about the possibility of donation, and to encourage an informed choice about the will expressed during the person's lifetime.

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[13] Oviedo Convention. Article 20 - Protection of persons not able to consent organ removal: "Exceptionally and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to give the consent may be authorized if the following conditions are met:

I. do not have a compatible donor available with the capacity to give consent;
II. The recipient is a brother or sister of the donor;
III. The donation must be performed in order to preserve the life of the recipient ;
IV. The authorization provided in paragraphs 2 and 3 of Article 6 has been given specifically and written form, according to the law and in agreement with the competent force;
V. The potential donor does not object.

[14] National Bioethics Committee of Republic of San Marino, "*Response to the request for an opinion on ethical issues regarding the use of anatomical parts derived from corps*", id.

In the particular social and health context of the Republic of San Marino, the adoption of necessary legislative decisions on taxes would also help to implement the culture of the donation, which is already present in the population and expressed by many citizens through voluntary associations.

Traceability (therapeutic purposes only)

The donor-recipient traceability - and vice versa - must always be guaranteed; the data should be stored, possibly with no time limits, following the same criteria of the relevant documentation for hospital records.

The donor and recipient's health security cannot be subject even to legitimate demands for privacy, still safeguarded by developing a system of collecting, transmitting and storing specifically dedicated sensitive data.

The basic principle for the safe pathway of donor-recipient traceability is that this pathway must always be characterized by an appropriate coding of identification of the donor and of the recipient. The codes and the key for decoding the clinical and sensitive data must be quickly accessible for health interventions, but they should be stored separately, and the whole donor-recipient path must be accessible to a reasonable number of people, that is, as few as possible according to the need.

The procedures for communication of events and adverse reactions to the interventions should be specified in detail to the competent authorities.

The procedures for the implementation of the traceability of the donor-receiver path must respect the basic criteria described below and needs a regulatory framework and an *ad hoc* structure which includes a specific IT system organized with strict security procedures to access the datasets.

Traceability does not necessarily imply providing information about the donor/recipient. On the contrary: it is better that the act of donation remain anonymous, excluding the donations within the family network, for clinical reasons. It means that the donor's identity shall remain unknown to the recipient and vice versa.

The anonymity of the donation is a necessary condition to maintain the oblation of the act itself[15].

[15] The reproductive cells, due to their peculiarities, are not going to be treated in this paper. Unlike the other cells/tissues /organs, the aim of the transplant is the conception of a new human being and for this reason the CSB cannot consider it a normal transplant, despite the fact that some steps – such as the gamete donation - are common with the process of a transplanted organ, tissues and cells. On one side, the principle of the gratuity of the donation includes also the gametes, on the other side, the anonymity of the donation must distinguish between anonymity at the time of the donation and the right of the child to know the origins of the heterologous fertilization. These two sides are totally distinct and theoretically independent. It is clear that the possibility of the heterologous born to

Certification of death (for the removal of the corpse for therapeutic purposes)

The estimation of brain death criteria allowed modern transplantation to arise because it enabled the removal of organs still perfused by cardiac activity in the presence of brain death.

The presence of a national law which recognizes the criteria of brain death as a way of establishing death is an essential prerequisite to meet the bioethical principles of organ and tissue donations while the donor's heart is still beating, and therefore also for the whole process of organ donation for therapeutic purposes.

The CSB has already expressed its opinion on this issue in the document "The assessment of the death"[16], January 21, 2013, identifying the criteria that can combine scientific rigor and certainty of prognosis, in order to provide an ethical and scientific support to the legislative administration in order to update the legislative framework of the Republic of San Marino.

Finally, the presence of a clear ethical and legal framework is an essential requirement to guide health professionals taking care of patients in the final phase of their lives.

know the donor of the gametes - and therefore the horizontal biological parenthood – has consequences on the availability of potential donors, performing as a deterrent both for potential parents and for donors.

16 National Bioethics Committee of Republic of San Marino, *The assessment of the death*, January , 21, 2013: http://www.sanita.sm/on-line/home/comitato-bioetica/comitato-sammarinese-di-bioetica/documenti-csb.html

HEALTH PROFESSIONAL ROLES & TRAINING

Certain health experts, such as doctors working in Intensive Therapy as well as in the Emergency Room cover a crucial role in the organ donation sphere.

Furthermore, they have the delicate task to communicate with a patient's relatives during a critical situation and to present them the possibility of a potential donation, as *extrema ratio* after having exhausted all efforts for rescuing the life of the patient.

The communication toward family members represents in fact a fundamental and particularly delicate moment since only good information allows the relatives to exactly understand what has happened, what occurred to their loved one and what both the medical and the nursing teams are doing.

Such a relationship can be established only by arranging adequate locations which allow relatives to have an intimate space for talking, listening, asking, crying and deciding.

The operation for the donation finalized for organ transplantation requires not only competences and technical capability, but also an ability to interact with the relatives of the potential donor: if the identification and the conservation of the donor follow a scientific path through a correct and objective procedure the dialogue with relatives can be instead strongly influenced by the way the health care professional chooses to conduct the meeting.

Who is leading the dialogue is perfectly aware of leading a helping relationship in that the relative's behavior is focused on the hope of healing his/her loved one, and the process toward accepting the death, and toward the consequent decision for the donation, needs time and methods that are unique for each family even with restrictive time limits.

Therefore it is strictly necessary to clearly separate the different messages so as to allow the relatives to recognize and fully understand what is happening.

Of fundamental importance is the clear explanation of the certainty of the state of death commensurate with the listening and understanding capability of the spokesperson through the elements of authenticity, respect and listening ability.

The conversation must seek the expression of an informed, aware choice which is free from external conditioning and mainly takes into account the will and desires expressed during life.

Considering the peculiarity and the crucial role of these health specialists, the CSB, in line with the recommendations stated in recent European documents[17], considers it necessary that such health specialists get a continuous training from the beginning of their clinical practice,

[17] *Resolution CM/Res (2015)10 on the role and training of critical care professionals in deceased donation* (Adopted by the Committee of Ministers on 10 September 2015 at the 1234th meeting of the Ministers' Deputies): https://wcd.coe.int/ViewDoc.jsp?id=2355079&Site=COE&BackColorInternet=C3C3C3&BackColorIntranet=EDB021&BackColorLogged=F5D383

including both scientific aspects, among which the biological suitability of the donation, the determination of death and the protection of the donor[18], and the psychological/bioethical aspects such as the relationship and the communication with the patient and relatives in critical situations and at the end of life.

[18] Ibidem

CONCLUSIONS AND RECOMMENDATIONS

In conclusion, the CSB recognizes that the body or body part donation for therapeutic, research or educational training purposes is as an act with a very high ethical value, identifying the relevant bioethics principles in protecting all involved persons – both donor and recipient - and pointing out that the updating of regulations is a necessary requirement for guaranteeing the public those procedures that support and incentivize the sensibility of San Marino citizens towards this topic.

Therefore, the CSB recommends the following:

- the CSB recommends identifying a competent Authority which is fully focused on the donation of organs, cells and human origin tissues, both for establishing an expert interlocutor able to communicate with the counterparts of other countries, and for managing any problems linked to the creation of logbooks that are dedicated to each single type of body part and to the relevant personal data management, that require a specific information network compliant with the rigorous safety features for data access. CSB will carry out its proper advisory functions on specific cases/problems;

- the CSB hopes this Authority will promote agreements with the comparable Authorities of other countries, so as to establish protocols for a mutual transfer of organs, cells and tissues of human origin both for an exchange of knowledge and professional development .

With this aim:

- the CSB recommends that the implementation of the regulations chart in Republic of San Marino be compliant especially with the principles of the European Regulations and solicits the adoption of a standards discipline for verifying death and referring to the previous CSB document *"The assessment of death"*[19]*;*

- the CSB recommends that this regulations chart protects the previous mentioned principles relevant to gratuity, traceability, correct information, consent and non discrimination;

- the CSB recommends a public report of activity, organ origins, transplants and relevant results in the short and long term; a similar report is recommended for the use of a body or body parts for research, instructional or educational training purposes, referring to the CSB's previous opinion *"Answer to the request of an opinion on ethical aspects relevant to the use of anatomic parts derived from human corpses"* (*"Risposta alla richiesta di parere su aspetti*

[19] National Bioethics Committee of Republic of San Marino, *The assessment of the death*, January , 21, 2013, id.

etici riguardanti l'utilizzo di parti anatomiche derivate da cadaveri umani"[20]*)*;

- the CSB recommends that the registration of consent expressed during life for some specific type of *post-mortem (after death)* body samples be achieved only if the organization dedicated to develop and maintain the logbooks (containing data relevant to citizens' will toward the *post-mortem* body sample for therapeutic or research/educational purposes) is recognized by law;

- the CSB recommends that the consent to donation for research, instruction and education protects the respect of the features indicated by the CSB in the previous opinion *"Answer to the opinion's request on ethical aspects relevant to the use of anatomic parts derived from human cadavers"* (*"Risposta alla richiesta di parere su aspetti etici riguardanti l'utilizzo di parti anatomiche derivate da cadaveri umani"*[21]*)*.

- In line with the requirements listed in the recent European documents, the CSB recommends that those health experts who cover a crucial role in the sphere of organ donation must receive continuous training since the beginning of their clinical practice including both scientific aspects (such as the biological suitability for the donation, the death certification and the donor's protection) and the psychological/bioethical aspects (as the relationship and the communication with patient and relatives in critical situations and at the end of the life).

[20] National Bioethics Committee of Republic of San Marino, *Answer to the opinion's request on ethical aspects relevant to the use of anatomic parts derived from corps* (*Risposta alla richiesta di parere su aspetti etici riguardanti l'utilizzo di parti anatomiche derivate da cadaveri umani*), id.

[21] Ibidem

ATTACHMENTS

APPLICABLE LAW AND DOCUMENTS THE REPUBLIC OF SAN MARINO[22]

Police Regulation mortuary, March 15, 1910

Law January28, 1975 n. 2*, "Recognition of the right to a day off from work to donor blood transfusion after the drain on the payment of remuneration."*

Law March 27, 2002 n. 48, "Law that recognizes and establishes the San Marino register of bone marrow donors."

Decree October22, 2002 n. 99, "Regulations governing the operations of the register of bone marrow donors in the Republic of San Marino".

Chief Executive Decree February 8, 2007 n. 21, "Amendments to the Regulations governing the operations of the register of bone marrow donors in the Republic of San Marino."

Law January 21, 2010, n.7. "Framework Law on the use of blood, cells, tissues and organs of the human being".

National Bioethics Committee of Republic of San Marino:

The assessment of the death, 21 January2013. http://www.sanita.sm/on-line/home/comitato-bioetica/comitato-sammarinese-di-bioetica/documenti-csb.html

Answer to the opinion's request on ethical aspects relevant to the use of anatomic parts derived from corps October 17, 2014.

http://www.sanita.sm/on-line/home/comitato-bioetica/comitato-sammarinese-di-bioetica/pareri-csb.html

[22] The rules can be downloaded from the Great and General Council website: http://www.consigliograndeegenerale.sm/on-line/home/archivio-leggi-decreti-e-regolamenti.html

EU Directive 2004/23/EC of the European Parliament and of the Council of 31.3.2004 on the definition of a provision of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of tissues and human cells - European Union OJ 7.4.2004.
http://eur-lex.europa.eu/legal-content/IT/TXT/?uri=URISERV%3Ac11573

UE Directive 2006/17/EC of 8 2.2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and control of tissue and cells - OJ European Union 9.2.2006
http://eur-lex.europa.eu/legal-content/IT/TXT/?uri=celex%3A32006L0017

EU Directive 2006/86/EC of 24.10.2006 of the Commission implementing the Directive 2004/23/EC of the European Parliament and of the Council as regards the requirements for traceability, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells - European Union OJ 25.10.2006
http://eur-lex.europa.eu/legal-content/IT/TXT/?uri=celex%3A32006L0086

EU Directive 2012/39/EU of the Commission of 26.11.2012 amending Directive 2006/17/EC as regards certain technical requirements relating to the tests carried out on human tissues and cells.
http://eur-lex.europa.eu/legal-content/IT/TXT/?uri=CELEX%3A32012L0039

EU Commission Directive 2015/565 of 04.08.2015 changed the Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells.
http://eur-lex.europa.eu/legal-content/IT/TXT/?uri=CELEX%3A32015L0565

EU Commission Directive 2015/566 of 8.4.2015 implementing Directive 2004/23/EC as regards the procedures to verify compliance with the standards of quality and safety requirements equivalent of tissues and cells imported.
http://eur-lex.europa.eu/legal-content/IT/TXT/?uri=CELEX%3A32015L0566

EUROPEAN REFERENCE DOCUMENTS

Council of Europe, *Statement on the prohibition of any form of commercialization of human organs*, adopted by the DH-BIO and the CD-P-TO on May 2014.

https://wcd.coe.int/ViewDoc.jsp?id=2215115&Site=COE&BackColorInternet=C3C3C3&BackColorIntranet=EDB021&BackColorLogged=F5D383

Resolution CM/Res (2015)10 on the role and training of critical care professionals in deceased donation (Adopted by the Committee of Ministers on 10 September 2015 at the 1234th meeting of the Ministers' Deputies)

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GUIDELINES

Second Edition of "Guide to the quality and safety of tissues and cells for human application", edited by CD-P-TO (European Committee (Partial Agreement) on Organ Transplantation) del EDQM (European Directorate for the Quality of Medicines & healthcare), Council of Europe.
https://www.edqm.eu/en/organ-tissues-cells-transplantation-guides-1607.html

Guidelines for the retrieval, processing and distribution of tissues for transplantation purposes, edited by National Transplant Center – Ministry of Health (Italy):
http://www.trapianti.salute.gov.it/imgs/C_17_normativa_25_allegato.pdf

Guidelines of the National Transplant Center (Italy):
http://www.trapianti.salute.gov.it/cnt/cntLineeGuida.jsp?id=35&area=cnt-generale&menu=menuPrincipale&sotmenu=normativa&label=norm

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