

LEGAL ASPECT OF ORGAN DONATION AFTER DEATH ACROSS EUROPE IN HUMAN RIGHTS CONTEXT

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Abstract Clinical transplantation has proven to be lifesaving methods since last century. Organ transplants is still subject to ethical evaluation through the prism of basic standards of medical ethics and social phenomena that are not morally neutral. Transplant medicine has a clear social character. It is not only a relationship between a doctor and a specific patient. Authors analyzed existing postmortal donation models in European countries and the most important documents in the European legislation in securing universal rights to freedom and human dignity in transplantation area and identified 15 universal documents valid in Council of Europe and the European Union. Universal legal documents of European law protect human donor right to self-determination and integrity. Postmortal donation in transplantation performed in accordance with the applicable legislation and in the utilitarian dimension does not violate human dignity and the natural right of a person to decide about themselves.

Keywords
transplantation
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cells and organ
donation,
human rights,
consenting,
opt in and
opt out

1 Introduction

Since the last century the clinical transplantation has proven effective and has both saved lives and improved the lives of many others (Linden, 2009, p. 25). Data from the Global Observatory of Donation and Transplantation in 2019 confirmed 153.863 organ transplants worldwide¹ with the actual number of deceased organ donors totaling 40,608. Unfortunately, differences in local donation activities, the broad spectrum of medical contraindications (for example, infections, general conditions, etc.) and long waiting lists (for example three to five years waitlist for kidney transplants in Europe) have posed many challenges for the transplantation processes (Dor et al., 2011).² The shortage of donors and organs for transplantation is an urgent worldwide problem and the subject of both discussion and legislation (Gare et. al., 2017; Lennerling et al., 2013; Merion et al., 2006; Youn & Greer, 2014).³

Due to the extreme delicacy of organ donation for transplantation, it must have a comprehensive legislative basis, but it should also comply with the principles of broadly understood ethics, in particular with respect to the universal right to decide about oneself, which is the foundation of the patient-doctor relationship. Transplantation is undoubtedly a proven method of therapy, providing the recipient with an unquestionable chance to improve his health and even extend life. On the other side, there is no more important issue than the death of another human being. The possibility of a donation after death, makes it possible for death to assume a utilitarian dimension.

It is impossible to analyze the transplant medicine legislation in isolation from legislation relating to the protection of fundamental human rights. The systems that protect and promote human rights can be divided into both universal regional systems, which correlates to geographical divisions.

¹ Summary. <http://www.transplant-observatory.org/summary/>; 2018 (10 June 2020).

² International report on organ donation and transplantation activities.

<http://www.transplant-observatory.org/download/2017-activity-data-report/>; 2017 (10 June 2020).

³ Timely identification and referral of potential organ donors. <https://nhsbtde.blob.core.windows.net/umbraco-assets-corp/1337/timely-identification-and-referral-of-potential-organ-donors-nhsbt.pdf> (12 June 2021).

2 Methods

To assess whether a particular, existing European donation model violates the human rights of donors, the authors critically reviewed the (44 law acts)⁴ universal legal acts; the most important legal instruments in the Council of Europe; and, European Union legislation securing universal rights to freedom and human dignity in the field of postmortem transplantation (see Table 1.) The authors have subjectively assessed the three main donation models: the opt-in model, the opt-out model and the priority model, to determine whether they comply with the assessed legal acts in the context of donor dignity and human rights.

3 Results

The authors identified 15 universal documents valid in the Council of Europe and the European Union guaranteeing human dignity and freedom in the postmortem organ donation context and that adhere to the existing European donation models: opt-in, opt-out and priority (higher necessity) Table 2.

Both the opt-in and opt-out models are fully compatible with the provisions of all 15 analyzed legal acts guaranteeing respect for human dignity and freedom in the context of postmortem donation. The higher necessity model complied with only five of the 15 mentioned legal acts. The level of compliance these three models have with the identified legal acts is listed in Table 2 (in 10 indicated acts the priority model violates the fundamental rights and dignity of donors).

4 Discussion

4.1. Models of Objection or Consent to the Cells, Tissues and Organs Transplantation

The general rule, that donated organs should come not from living donors but from deceased persons, is included in the regulation of the European Convention on Human Rights and Biomedicine. Article 19 clearly indicates the primacy of the postmortem transplant model (*"Removal of organs or tissue from a living person for*

⁴ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness (...)" (Zembala, 2009).⁵ Removal of organs from a living donor for transplantation may only be performed for the therapeutic benefit of the recipient. This is only the case if a suitable organ or tissue from the deceased person is unavailable and no alternative method of comparable effectiveness exists. It follows from the above that *ex vivo* transplantation is only of a subsidiary nature, and the procurement of organs and tissues from a living person is prohibited when an organ from a deceased donor is available.

The possibility of organ explantation is owned solely by the donor, who either expresses consent or objection to organ donation while alive, depending on the model adopted in the legislation of a given country.

Worldwide, there are three legally permissible models for the donation of cells and tissues and human organs after death. The first is the American-Canadian model known as the “opt-in system”. The opt-in model requires consent during life. The opt-in model has two variants, the extended consent version and the strict consent version (model adopted in fourteen European countries) (Kiel-Puslecka et al., 2021). The extended (or soft) consent version applies in the absence of the donor's explicit will. Under this variant, the only source of information about the presumed will of the deceased are eligible persons, most often the closest relatives of the deceased. The second version, the strict (or hard) consent model, presupposes the donor's explicit consent expressed “*pro future*” during his lifetime in oral or written form (Guzik-Makaruk, 2008; Kiel-Puslecka et al., 2021).

The second (French) model, which requires a clear exclusion of such consent, and the presence of presumed consent, is known as the “opt-out system”. Under this system, silence is tantamount to consent. Under a strict objection variant (hard opt-out), all individuals are presumed to be eligible donors in the event of their death unless they have signed an official register to opt out or opposed to donation in other legal form: a signed letter or information left their next of kin, but this wish must be put into writing and presented at the time of death. Under the extended (soft opt-out variant), doctors have to seek consent from a potential organ donor's

⁵ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

family if the individual had died without previously indicating their desire to donate their organs. This is the model adopted in 24 European countries (Kiel-Puslecka et al., 2021). Presumed consent may be withdrawn at any time by identifying whether a given person has raised an objection in the prescribed form during his lifetime – “rebuttable presumption”. Thus, no objection is tantamount to consenting to donation, but it is necessary to establish and confirm potential donor objection to organ donation after his death.

The last model, adopted theoretically only in Bulgaria, is known as the priority rule, or the state of higher necessity. This model is premised on the notion that the life and health of the living person desirous of a transplant takes on a higher value (or status) than that of a human corpse, even in situations where the donor specifically objected to and opposed the possibility of donation while still alive (Guzik-Makaruk, 2008; Kiel-Puslecka et al., 2021).

4.2. International Universal Law in Europe

It is impossible to analyze the legislation on transplant medicine in isolation from legislation relating to the protection of fundamental human rights. The system for the protection and promotion of human rights is divided into a universal system and a regional system, which is related to the geographical division.

The Universal Declaration of Human Rights (UDHR) and the International Covenants on Human Rights are considered the bases of the universal system, which together constitute the overall Constitution of Human Rights (International Bill of Human Rights) (Guzik-Makaruk, 2008).⁶

The UDHR found its juridical development in the International Covenant on Civil and Political Rights (ICCPR)⁷ and the International Covenant on Social, Economic and Cultural Rights (ICSECR).⁸

⁶ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

⁷ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

⁸ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

The UDHR was adopted by the UN General Assembly in Paris on December 10, 1948.⁹ It is the basis of the international legal system for the protection of human rights, and has become the primary impetus for the creation of further documents at both the universal and regional levels. The basic factor that contributed to its creation was inhumane activities during World War II, caused by the failure to respect human rights. The UDHR consists of 30 Articles dealing with fundamental human rights and freedoms, with particular emphasis on dignity, as well as the equal and inalienable rights of all people, which constitute the foundation of freedom, justice and peace in the world. Although the UDHR does not contain regulations regarding medical transplantation procedures, Article 3 of the UDHR indicates that every human being has the right to life, liberty and security of his person, and thus to respect for his bodily integrity (*'Everyone has the right to life, liberty and security of person'*). It is not expressed directly, but the interpretation of this article allows us to postulate that the general principle of freedom applies to the prohibition of medical experiments and interfering with the bodily sphere with medical procedures.

The ICCPR is an Act that the United Nations adopted in New York on December 16, 1966; it duplicates and clarifies the principles set out in the UDHR.¹⁰ Article 6 of the ICCPR guarantees the inherent right to life and further recommends that this right should be protected statutorily (*"every human being has the inherent right to life. This right should be protected by statute. No one may be arbitrarily deprived of life."*). Article 7 ensures that "no one will be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one will be subjected to any medical or scientific experiments without his or her consent".

The last act comprising the International Bill of Human Rights is the ICSECR¹¹ of December 19, 1966. It contains second generation rights. In the field of medicine, attention should be paid to Article 12, which ensures that every human being has the right to the highest possible level of physical and mental health protection, including through prevention, treatment, eradication of disease, and professional care in the event of disease (*"The States Parties to the present Covenant recognize the right of everyone to enjoy the highest attainable level of protection for their physical and mental health. Steps that States Parties to the present Covenant should take to achieve the full implementation of this*

⁹ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

¹⁰ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

¹¹ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

right, will include the measures necessary to: a) ensure the reduction of stillbirths and infant mortality and ensure the healthy development of the child; b) improving environmental hygiene and industrial hygiene in all aspects; c) the prevention and treatment of epidemic, endemic, occupational and other diseases and combat; d) create conditions which would provide assistance to all and medical care in case of illness.”).¹²

The first international dedicated document, WHA 40.13 of the Forty World Health Assembly of 1987, concerning in particular the ethical system of therapeutic organ transplantation, was an important step in safeguarding the interests of donors and recipients (Duda, 2011). The document sets forth nine guiding principles on human organ transplantation. The first principle stipulates that as conditions for organs to be removed from a deceased person for the purpose of transplantation the authorities removing the organ(s) must have obtained “any consents required by law” and further, those authorities must have “no reason to believe that the deceased person objected to such removal, in the absence of any formal consent given during the person’s lifetime.” The second adopted principle is a kind of guarantee, that the personnel directly involved in the determination of death remain impartial, do not engage in the donor's therapeutic process and are not involved in the organ explantation and transplant procedure.

In the guiding principles, the World Health Assembly promotes postmortal (*ex mortuo*) transplants as the primary method of transplantation, and recommends the use of ex vivo transplantation only for family donors and then only in the case of regenerating tissues. Moreover, it recommends that all measures should be taken to remove cultural and religious barriers to this form of treatment, and discusses in detail the organs trade – with an order not to perform transplant operations if there is any suspicion of an illegal source of organs.

The Convention on the Rights of the Child (CRC)¹³ adopted in 1989, reaffirms the rights guaranteed by the Convention for the Protection of Human Rights and Fundamental Freedoms of Council of Europe. The CRC contains 54 Articles detailing the specific rights afforded to children. The preamble to the CRC highlights the importance of providing children with special care. In the CRC, there is a provision that the best interests of the child should be of paramount importance;

¹² <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

¹³ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

this also applies to transplant procedures. Activity should be taken “*that will not cause long-term disruptions and damage to the child's health*”. Although the CRC does not contain detailed regulations on transplantation activities, in a situation where a child is one of the participants of the procedure, the decision about a possible explantation of the child's organs should be made by his parents or legal guardians, taking into account the child's views. Consideration also should be given to the child's age and maturity, in line with “concern for the best protection of the child's interests”.¹⁴

4.3. Council of Europe Law

In addition to the universal system of human rights protection, there are also regional divisions. The Council of Europe (COE)¹⁵ system is comprised of two basic documents: the Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) and the European Social Charter. The ECHR was signed in Rome on November 4, 1950.¹⁶ Creating an exceptionally effective control system, the ECHR is the fundamental and most important Act that was established within the Council of Europe. The values embodied in it are based on those recognized by the acts covering the scope of protection at the universal level, mainly the provisions of the UDHR. Therefore, with respect to the regulation of transplant medicine, it does not contain any explicit provisions. The European Social Charter¹⁷ complements the ECHR in the area of economic and social rights. Opened for signature on October 18, 1961, it entered into force in 1965. The Revised European Social Charter has been in force since 1996. One of the regulations contained in this Act mandates parties to the Act to take “appropriate measures” to promote and to achieve the best possible state of health (Article 11 – the right to health protection).

¹⁴ <http://www.transplant-observatory.org/by-regions/> (12 June 2021); 5. “European Treaty Series” CETS Nr 164. <https://rm.coe.int/168007cf98> (12 June 2021).

¹⁵ The Council of Europe was founded on 5 May 1949 by Belgium, Denmark, France, Ireland, Italy, Luxembourg, Netherlands, Norway, Sweden and the United Kingdom, Greece, joined three months later, and Iceland, Turkey and West Germany the next year. It now has 47 member states. Article 4 of the Council of Europe Statute specifies that membership is open to any "European" State. This has been interpreted liberally from the beginning, when Turkey was admitted, to include transcontinental states (such as Georgia and Azerbaijan) and states that are geographically Asian but socio-politically European (such as Armenia and Cyprus). Nearly all European states have acceded to the Council of Europe, with the exceptions of Belarus (human rights concerns including active use of the death penalty), Kazakhstan (human rights concerns), and the Vatican City (the independent state ruled by the Holy See), as well as some of the territories with limited recognition. Besides the status as a full member, the Council of Europe has established other instruments for cooperation and participation of non-member states: observer, applicant, special guest, and partner for democracy.

¹⁶ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

¹⁷ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

The resolution of the Council of Europe of May 11, 1978, introduced the regulations on transplantation in Europe. The resolution called for the consolidation and harmonization of the legislation of the Member States relating to donation and human tissue and organ transplantation (Jasudowicz, 1998). The main goal of the resolution was to coordinate legislative efforts to help ensure the maximum protection of both donors and potential recipients of tissues and organs of human origin. At the same time, the Council of Europe has excluded other forms of use of substances and materials of human origin that is transfer of embryos, use of ova and sperm, as well as the removal and transplantation of testes and ovaries.

The international regulations discussed above form the nucleus for most of the laws of the COE Member States. The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (European Bioethical Convention, hereinafter the EBC),¹⁸ for example, attempts to systematize national laws and create a binding international document on the subject matter; it has been opened for signature April 4, 1997, in Oviedo (Spain).¹⁹ The EBC is a framework treaty defining the scope of protection of an individual against the possible consequences of the development of biomedicine. This document, based on the most important resolutions concerning human rights, including the UDHR and the CRC, is designed to guarantee the protection of the dignity and identity of every human being, without any discrimination, respecting the integrity of the individual, his fundamental rights and freedoms related to the fields of biology and medicine. The EBC obliges the Member States to effectively enforce its provisions. The issues of transplantation were regulated in Chapter VI of the EBC²⁰ entitled “Organ and tissue removal from living donors for transplantation purposes” while the regulation of postmortem donation was included in the Additional Protocol (Protocol Two) to the EBC, which was completed in 2000. The Committee of Ministers adopted the Act entitled “Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin” on November 8, 2001; the Act was opened for ratification on January 24, 2002.²¹ With regard to donation after death, Article 2 of the EBC states that “The interests and welfare of the human being shall prevail

¹⁸ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

¹⁹ „European Treaty Series” CETS Nr 164. <https://rm.coe.int/168007cf98> (12 June 2021).

²⁰ <https://www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168007cf98> (12 June 2021).

²¹ European Treaty Series” CETS Nr 164. <https://rm.coe.int/168007cf98> (12 June 2021).

over the sole interest of society or science”, and Article 21 EBC emphasizes that “The human body and its parts shall not, as such, give rise to financial gain or comparable advantage”. The issue of consent to perform a medical intervention (also in relation to postmortem donation) is discussed extensively, with the emphasis that “An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it”, and such consent may be withdrawn at any time pursuant to Article 5 of the EBC (general provisions) Chapter II – Consent. Article 20, point 1 of the Protocol to the EBC contains the general principle of donation after death, namely that the assumption is that the removal of organs from the deceased is prohibited (*“No organ or tissue removal may be carried out on a person who does not have the capacity to consent”*). A derogation from the above prohibition is obtaining the consent or authorization required by law. Article 20, point 2 sets the minimum standard of protection of the human right to self-determination, and prohibits the donation of an organ or tissue if the deceased objected to postmortem donation during his lifetime.²²

On May 3, 2005, the Committee of Ministers of the Council of Europe adopted the text of the Convention on Action against Trafficking in Human Beings, which entered into force in 2008.²³ The text of Article 4(a) inherited the definition of trafficking in human beings from the Palermo Protocol (on the prevention, suppression and punishment of trafficking in human beings, in particular women and children, supplementing the United Nations Convention against Transnational Organized Crime), which states “the exploitation of another person for the purpose of obtaining cells, tissues or organs in breach of the provisions of the Act of trafficking in human beings”.²⁴ On March 25, 2015, fourteen European countries, including Poland, signed the Council of Europe Convention against Trafficking in Human Organs (CETS No. 216).

²² <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

²³ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

²⁴ <http://www.transplant-observatory.org/by-regions/> (12 June 2021); “European Treaty Series” CETS No. 164. <https://rm.coe.int/168007cf98> (12 June 2021); <https://www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168007cf98>, (12 June 2021); Council of Europe Convention against Trafficking in Human Organs, Santiago de Compostella, (CETS No. 216) <https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/216> (12 June 2021).

It is the first act of this type to regulate procurement of organs for transplantation and to restrict organ trafficking. According to the provisions of the Convention (CETS No. 216), the donation of organs without the donor's consent, living or deceased, or when it has brought profit to the donor or a third person, will be treated as a crime (Article 4). Each party to the Convention agreed to enact the necessary legislative and other measures to criminalize, under its domestic cases, situations where the removal of human organs from living or deceased donors is performed “a. without the free, informed and specific consent of the living or deceased donor, or, in the case of the deceased donor, without the removal being authorized under its domestic law; b. where, in exchange for the removal of organs, the living donor, or a third party, has been offered or has received a financial gain or comparable advantage; c. where in exchange for the removal of organs from a deceased donor, a third party has been offered or has received a financial gain or comparable advantage.” Article 7(2,3) of the Convention (CETS No. 216) explicitly imposes an obligation on the part of each member party to enact necessary legislation (and other appropriate measures) “to establish as a criminal offence, when committed intentionally, the request or receipt by healthcare professionals, its public officials or persons who direct or work for private sector entities, in any capacity, of any undue advantage with a view to performing or facilitating the performance of a removal or implantation of a human organ performed or facilitated, where such removal or implantation takes place under the circumstances described in Article 4, paragraph 1, or Article 5 and where appropriate Article 4, paragraph 4 or Article 6.”

In addition, it provides for compensation for victims of these crimes, the protection of donors and the introduction of preventive measures aimed at ensuring equal access to transplantation. In addition to strictly procedural powers, the Convention (CETS No. 216) obliges states to take steps to ensure the safety of victims and their families against intimidation and retaliation. Protection is also to extend to witnesses, their families and other relatives (Article 20). The Convention also is instructive on methods to strengthen training both for healthcare professionals and other relevant officials to assist them in preventing and combatting illegal trafficking in human organs. At least five countries must ratify the Act for it to enter into force (Zembala, 2009).²⁵ The development of transplant medicine, despite the presence of the above-

²⁵ Council of Europe Convention against Trafficking in Human Organs, Santiago de Compostella, (CETS No. 216) <https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/216> (12 June 2021).

mentioned conditions, has forced the introduction of modern, country-specific legislation regulating the admissibility of the procurement and transplantation of cells, tissues and organs.

4.4. European Union law

The constitutional values on which the European Union is based are: respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights. These values are inextricably linked with pluralism, tolerance, justice, solidarity and non-discrimination.²⁶

However, the European Union lacks the competences to adopt measures leading to the harmonization of the laws of the Member States in the field of organ, cell and tissue transplantation. Member States therefore must introduce legislation at the national level that set high standards of quality and safety for organs and substances of human origin, blood and blood derivatives. It stays without prejudice to national provisions relating to the donation or medical use of organs and blood. Actions taken at the Union level may only be of a subsidiary nature (Guzik-Makaruk, 2008).

The Charter of Fundamental Rights of the European Union (Charter of the EU) of December 2000 (the Charter was declared in 2000, and came into force in December 2009, along with the Treaty of Lisbon) assumes that human dignity is the source of all rights and freedom, is inviolable and is subject to respect and protection (Article 1). Article 3(2) on biology and medicine presupposes, in particular, the observance of: the informed consent of the person, the prohibition of selecting people and eugenic practices, and the use of parts of the human body for financial gain. It prohibits reproductive human cloning for the purpose of obtaining organs (“*2. In the fields of medicine and biology, the following must be respected in particular: (a) the free and informed consent of the person concerned, according to the procedures laid down by law; (b) the prohibition of eugenic practices, in particular those aiming at the selection of persons; (c) the prohibition on making the human body and its parts as such a source of financial gain; (d) the prohibition of the reproductive cloning of human beings.*”).²⁷

²⁶ Art. 2 Constitution for Europe, The Lisbon Treaty. <http://www.lisbon-treaty.org/wcm/the-lisbon-treaty/treaty-on-european-union-and-comments/title-1-common-provisions/2-article-2.html> (12 June 2021).

²⁷ Timely identification and referral of potential organ donors. <https://nhsbtde.blob.core.windows.net/umbraco-assets-corp/1337/timely-identification-and-referral-of-potential-organ-donors-nhsbt.pdf> (12 June 2021).

The latest documents on transplantation are Directive 2004/23/EC of the European Parliament and the EU Council of March 31, 2004,²⁸ and Directive 2010/45/EU of the European Parliament and the EU Council of July 7, 2010.²⁹ Together, these two Directives establish the quality and safety standards for donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.³⁰ The main purpose of the Directives is the harmonization of the laws of the Member States, which will guarantee high standards and safety of transplantation operations, respect for the dignity of the deceased donor, and support national and European information campaigns. These Directives emphasize the “no-profit” principle of donation and tissue and cell transplantation. The Directive 2004/23/EC contains a provision on respect for fundamental rights and complies with the principles contained in the EU Charter, and recognizes as appropriate the EBC. In addition, in the context of the dignity of the deceased donor, it imposes due respect by reconstructing the donor's body in such a way that it is as close as possible to the original anatomical shape.

In 1993, the European Parliament, in a special resolution, adopted the principle of prohibiting the payment organs trade, as well as the prohibition of the import and use of organs derived from criminal activity (Duda, 2011). Attention should be paid to the provisions of the Council Framework Decision of 19 July 2002, on combating trafficking in human beings. These provisions complement the actions taken on the basis of the United Nations Convention against Transnational Organized Crime and the Palermo Protocol. Unfortunately, the definition utilized by the Council in its Decision concerning trafficking in human beings, although very similar to the definition contained in the Palermo Protocol, completely ignores trade for the removal of organs for transplantation.³¹

²⁸ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

²⁹ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

³⁰ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

³¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32002F0629> (12 June 2021).

4.5. Donation Models and Compliance with European Law

As general rules, in a country with an opt-out system, the failure to submit an objection declaration on organ donation is tantamount to presumed consent to the donation, while in a country with an opt-in system, the failure to submit a declaration of consent to organ donation means that procurement is prohibited.

Postmortal transplantation performed in accordance with the applicable European legislation and in the utilitarian dimension does not violate human dignity and the natural rights of a person in most common opt-in and opt-out models. The third theoretical model, the priority rule – also known as the state of higher necessity – is the most controversial, mainly because it does not respect the right to decide about the donor's person and assumes that the social goods of the recipient are more important than the will of the deceased donor.

Under the third theoretical model, the competent authority unbundles the organs, acting as the primary decision maker, and the will of the donor is basically irrelevant. This authority has the sole discretion to decide whether or not organs for transplantation should be taken and to whom they should be allocated. This is a perfect situation for transplant medicine in the sense that under this model a near perfect balance may be struck between supply and demand. However, this model is not a viable option and is unsuitable in democratic states where core democratic values are premised on observing and protecting the fundamental rights of individuals. Most often, institutions designated by the state make secondary decisions, accepting and thus carrying out the will of the deceased donor. In fact, that model adopted theoretically in Bulgaria, because of controversies surrounding it, is in practice functioning as would be the case under a traditional opt-out model.

In postmortal organ donation only, the recipient is beneficent. The Immanuel Kant concept of human dignity does not allow the use of a person for purposes other than the ones he/she consents to (Rachels, 1986). Unfortunately, the failure to object is not always the equivalent of giving consent. In a hierarchy of acceptability in so far as transparency is concerned, the opt-in model is more transparent than the opt-out model, while the priority model quite simply is unacceptable. The EBC is the basic document that specifies and regulates the legal and ethical minimum for postmortal donation in determining the consent or non-contradiction requirement

for donation. In 1978, the Committee of Ministers of the Council of Europe and the Parliamentary Assembly of the Council of Europe indicated in “Resolution (78) 29 on the harmonization of the legislation of the Member States relating to the procurement and transplantation of human tissues and organs”, that the removal of organs from a deceased person is unacceptable if it is evident that the deceased person has objected to the collection (explicit or implied) – opt-out.³²

The authors of the Additional Protocol to the EBC recognized the need to introduce regulations to respect the will regarding postmortal donation. Article 17 of the Additional Protocol prohibits the removal of organs from a deceased person, unless consent to the donation was given during the lifetime of the donor or a permit required by national law was obtained. This regulation should be interpreted as an obligation on COE Member States to create a system that defines the conditions for the admissibility of donating organs or tissues from deceased persons.

Thus, while the Resolution (78)29 stipulates the need to take into account the patient's possible objection (open or presumed objection), in contrast Article 10 § 1 explicitly uses the concept of objection. Article 10 § 2 expands upon the concept of an objection, and more broadly takes into account the wishes expressed by the deceased. The authors of the EBC decided to use the concept of consent, which emphasizes the respect for the human's autonomy. The patient may therefore either consent or refuse to express consent directly or implicitly. Moreover, respecting Article 8 of the Additional Protocol, the Member States should undertake activities aimed at informing the public about the principles of donation, including donation of organs and tissues after death.³³

The EBC does not prejudge the superiority of the opt-in vs. opt-out models that Member States should adopt in the field of postmortal organ donation, although it has emphasized that if the deceased person failed to clearly express his will during his lifetime, there must be a viable procedure established by local domestic law that makes it possible to ascertain this will. The EBC's explanatory report indicates some

³² Resolution (78)29 of the Committee of Ministers of the Council of Europe on the harmonization of the legislation of the Member States relating to the procurement and transplantation of human tissues and organs. [https://www.coe.int/t/dg3/healthbioethic/texts_and_documents/Res\(78\)29E.pdf](https://www.coe.int/t/dg3/healthbioethic/texts_and_documents/Res(78)29E.pdf) (12 June 2021).

³³ <http://www.transplant-observatory.org/by-regions/> (12 June 2021); Resolution (78)29 of the Committee of Ministers of the Council of Europe on the harmonization of the legislation of the Member States relating to the procurement and transplantation of human tissues and organs. [https://www.coe.int/t/dg3/healthbioethic/texts_and_documents/Res\(78\)29E.pdf](https://www.coe.int/t/dg3/healthbioethic/texts_and_documents/Res(78)29E.pdf) (12 June 2021).

countries utilizing a system of presumed consent opt-out provide the legal means for the person to express an objection(s) (that is an objection register). The authors of the EBC also considered the system in which the will of the deceased is established on the basis of an interview conducted among the family and friends of the deceased regarding what the deceased's will was (soft opt-in and soft opt-out).

While it is true that at the time of organ donation there is no entity whose autonomy should be protected, nevertheless, pursuant to the Convention standard, the issue of respecting the patient's will in deciding on postmortal organ donation must be given the utmost attention. Article 17, sentence 2 of the Protocol, emphasizes that no donation may take place if the deceased person objected to its during his lifetime. Although the EBC recognizes the permissibility of systems providing for presumed donation consent (that is opt-out), one may seriously question whether this type of "consent" is consistent with the meaning of the word "consent" as used and understood in the Convention and whether the opt-out model guarantees respect for the deceased person's (actual) will expressed during his lifetime.³⁴

Only in an exceptional situation, when the patient's will cannot be ascertained, does the Additional Protocol allow for the possibility of establishing it based on the beliefs of relatives, assuming this is allowed pursuant to national regulations (soft opt-in and soft opt-out). However, it is difficult to rationalize the justification for transferring to the deceased's family the competence to decide on the removal of organs from his corpse. The assumption that the proximity of the relationship between the deceased and his relatives will somehow ensure the deceased person's will is adhered to is highly questionable. This solution seems to be not only insufficient, but even counterfactual.³⁵

5 Conclusion

The possibility of organ explantation after death is owned by the donor himself, who expresses consent or objection to organ donation during his lifetime, depending on the model adopted in the legislation of a given country. Both the opt-in and opt-out models seem to be in harmony with human freedom and dignity. The theoretical priority model is not. Legislative acts in Europe (including COE and EU) are clearly

³⁴ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

³⁵ <http://www.transplant-observatory.org/by-regions/> (12 June 2021).

pro-transplant. “*Pro futuro*” decisions by the patient/donor (consent or objection) fully comply with human freedom rights. The basic moral rule provides there is a willing donor on the one side and a recipient eligible to receive an organ on the other side. Willingness, however, demands the requirement of consent.

Postmortal transplantation performed in accordance with the applicable legislation and in the utilitarian dimension does not violate human dignity and the natural right of a person to decide about themselves.

Legal Sources

Universal Declaration of Human Rights

The General Assembly of the United Nations adopted the Declaration on 10 December 1948, available: <https://humanrights.gov.au/our-work/what-universal-declaration-human-rights>.

International Covenant on Civil and Political Rights

Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966, entry into force 23 March 1976, in accordance with Article 49, available: <https://www.ohchr.org/en/professionalinterest/pages/cpr.aspx> (1 September 2021).

International Covenant on Social, Economic and Cultural Rights

Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966 entry into force 3 January 1976, in accordance with article 27, available: <https://www.ohchr.org/en/professionalinterest/pages/cesr.aspx>.

European Social Charter

The European Social Charter was adopted within the framework of the Council of Europe in 1961, available: <https://www.coe.int/en/web/european-social-charter>.

Convention for the Protection of Human Rights and Fundamental Freedoms

The European Convention on Human Rights (ECHR) (formally the Convention for the Protection of Human Rights and Fundamental Freedoms) is an international convention to protect human rights and political freedoms in Europe. Drafted in 1950 by the then newly formed Council of Europe, the convention entered into force on 3 September 1953, available: <https://www.refworld.org/docid/3ae6b3b04.html>.

WHA 40.13 of the Forty World Health

Fortieth World Health assembly, Geneva 4-15 MAY 1987. WHA40.13, available: <https://www.who.int/transplantation/en/WHA40.13.pdf>.

The Charter of Fundamental Rights of the European Union (EU Charter of the EU)

The Charter of Fundamental Rights of the European Union: OJ C 326, 26.10.2012, pp. 391–407, available: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012P/TXT&from=EN>.

Convention on the Rights of the Child

Adopted and opened for signature, ratification and accession by General Assembly resolution 44/25 of 20 November 1989 entry into force 2 September 1990, in accordance with article 49, available: <https://www.ohchr.org/EN/professionalinterest/pages/crc.aspx>.

Additional Protocol to The Convention On Human Rights And Biomedicine

Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, Strasbourg 25.I.2005, available: <https://rm.coe.int/168008371a>.

Additional Protocol to The Convention On Human Rights And Biomedicine Concerning Transplantation of Organs And Tissues Of Human Origin

Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, Strasbourg, 24.I.2002, available: <https://rm.coe.int/1680081562>.

Convention For The Protection Of Human Rights And Dignity Of The Human

The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine is an international instrument aiming to prohibit the misuse of innovations in biomedicine and to protect human dignity. The Convention was opened for signature on 4 April 1997 in Oviedo, Spain and is thus otherwise known as the Oviedo Convention, available: <https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164?module=treaty-detail&treatynum=164>.

Convention Organ Trafficking

Council of Europe Convention against Trafficking in Human Organs Santiago de Compostela, 25.III.2015, available: <https://rm.coe.int/16806dca3a>.

Council Of Europe Convention On Action Against Trafficking In Human Beings

Council of Europe Convention on Action against Trafficking in Human Beings, Warsaw, 16.V.2005, available: <https://rm.coe.int/168008371d>.

Council Of Europe Convention On Action Against Trafficking In Human Beings Explanatory Report
Explanatory Report Beings to the Council of Europe Convention on Action against Trafficking in Human, Warsaw, 16.V.2005, available: <https://rm.coe.int/16800d3812>.

European Agreement on the Exchange Of Therapeutic Substances Of Human

European Agreement on the Exchange Of Therapeutic Substances Of Human origin of 15 December 1958 (ETS No. 26, entered into force on 1 January 1959), available: <https://rm.coe.int/1680902946>.

Explanatory Report Organ Trafficking Convention

Council of Europe Convention against Trafficking in Human Organs Explanatory Report, The Committee of Ministers of the Council of Europe took note of this Explanatory Report at a meeting held at its Deputies' level, on 9 July 2014, available: <http://www.transplant-observatory.org/download/explanatory-report-organ-trafficking-convention/>.

Trafficking in Organs In Europe, Parliamentary Assembly Recommendation 1611

Assembly debate on 25 June 2003 (21st Sitting), available: <https://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=17125&lang=en>.

Committee of Ministers Council of Europe Recommendation No 2003 (10) On Xenotransplantation
Adopted by the Committee of Ministers on 19 June 2003 at the 844th meeting of the Ministers' Deputies, available: <https://rm.coe.int/16805dj8df>.

Committee of Ministers Council of Europe Recommendation No 2003 (12) On Organ Donor Registries

Adopted by the Committee of Ministers on 19 June 2003 at the 844th meeting of the Ministers' Deputies, available: https://www.edqm.eu/sites/default/files/recommendation_no_2003_12_of_the_committee_of_ministers_to_member_states_on_organ_donor_registers.pdf.

Committee of Ministers Council of Europe Recommendation No 2004 (7) On Organ Trafficking
Adopted by the Committee of Ministers on 19 May 2004 at the 884th meeting of the Ministers' Deputies, available: <https://rm.coe.int/16805dcf59>.

Committee of Ministers Council of Europe Recommendation No 94 (1) On Human Tissue Banks

Adopted by the Committee of Ministers on 14 March 1994 at the 509th meeting of the Ministers' Deputies, available: <https://rm.coe.int/09000016804dd7ee>.

Committee of Ministers Council of Europe Recommendation No 97 (15) On Xenotransplantation
Adopted by the Committee of Ministers on 30 September 1997 at the 602nd meeting of the Ministers' Deputies, available: [https://www.coe.int/t/dg3/healthbioethic/texts_and_documents/Rec\(97\)15E.pdf](https://www.coe.int/t/dg3/healthbioethic/texts_and_documents/Rec(97)15E.pdf).

Committee of Ministers Council of Europe Recommendation No Rec (98) 2 On Provision Of Haematopoietic Progenitor Cells

Adopted by the Committee of Ministers on 12 February 1998 at the 620th meeting of the Ministers' Deputies, available: <https://ekea.gr/wp-content/uploads/Rec982-Provision-of-haematopoietic-progenitor-cells.pdf>.

Committee of Ministers Council of Europe Recommendation Rec 2004 (8) On Autologous Cord Blood Banks

Adopted by the Committee of Ministers on 19 May 2004 at the 884th meeting of the Ministers' Deputies, available: <https://rm.coe.int/16805dcf59>.

https://www.edqm.eu/sites/default/files/recommendation_no_2004_8_of_the_committee_of_ministers_to_member_states_on_autologous_cord_blood_banks.pdf.

Committee of Ministers Council of Europe Recommendation Rec 2005 (11) On The Role And Training Of Professionals Responsible For Organ Donation

Adopted by the Committee of Ministers on 15 June 2005 at the 930th meeting of the Ministers' Deputies, available: <https://rm.coe.int/09000016805b025f.pdf>.

Committee of Ministers Council of Europe Recommendation Rec 2004 (19) On Criteria For The Authorization Of Organ Transplantation Facilities

Adopted by the Committee of Ministers on 7 October 2020 at the 1385th meeting of the Ministers' Deputies, available: <https://rm.coe.int/09000016809fdedd.pdf>.

Committee of Ministers Council of Europe Recommendation Rec 2006 (15) On The Background, Functions And Responsibilities Of National Transplant Organization (NTO)

Adopted by the Committee of Ministers on 8 November 2006 at the 979th meeting of the Ministers' Deputies, available: https://www.edqm.eu/sites/default/files/recommendation_no_2006_15_of_the_committee_of_ministers_to_member_states_on_the_background_functions_and_responsibilities_of_a_national_transplant_organisation_nto1.pdf.

Committee of Ministers Council of Europe Recommendation Rec 2006 (16) On Quality Improvement Programmes For Organ Donation

Adopted by the Committee of Ministers on 8 November 2006 at the 979th meeting of the Ministers' Deputies, available: <https://rm.coe.int/09000016805d7409.pdf>.

Committee of Ministers Council of Europe Resolution CM Res 2008 (4) On Adult-To-Adult Living Donor Liver Transplantation

Adopted by the Committee of Ministers on 12 March 2008 at the 1021st meeting of the Ministers' Deputies, available: <https://rm.coe.int/09000016805d3da0.pdf>.

Committee of Ministers Council of Europe Resolution CM Res 2008 (6) On Transplantation Of Kidneys From Living Donors Not Genetically Related

Adopted by the Committee of Ministers on 26 March 2008 at the 1022nd meeting of the Ministers' Deputies, available: http://www.xxoo156.com/medias/fichiers/Resolution_CMRes20086_on_transplantation_of_kidneys_from_living_donors_who_are_not_genetically_related_to_the_recipient.pdf.

Committee of Ministers Council of Europe Resolution CM Res 2013 (56) On The Development And Optimisation Of Live Kidney Donation Programmes

Adopted by the Committee of Ministers on 11 December 2013 at the 1187th meeting of the Ministers' Deputies, available: https://www.edqm.eu/sites/default/files/medias/fichiers/resolution_cmres201356_on_the_development_and_optimisation_of_live_kidney_donation_programmes.pdf.

Committee of Ministers Council of Europe 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, available: https://www.edqm.eu/sites/default/files/resolution_cmrs_201510_role_and_training_critical_care_professionals_in_deceased_donation.pdf.

Committee of Ministers Council of Europe Resolution CM Res 2015 (11) On Establishing Harmonised National Living Donor Registries

Adopted by the Committee of Ministers on 15 September 2015 at the 1235th meeting of the Ministers' Deputies, available: https://www.edqm.eu/sites/default/files/resolution_on_establishing_harmonised_national_living_donor_registries_september_2015.pdf.

Committee of Ministers Council of Europe Resolution CM Res 2015 (11) On Establishing Harmonised National Living Donor Registries Explanatory Memo

CM(2015)128 add final 18 September 2015, available: https://www.edqm.eu/sites/default/files/explanatory_memorandum_resolution_cm_res201511_on_harmonised_national_living_donor_registries_2015.pdf.

Committee of Ministers Council of Europe Resolution CM Res 2013 (55) On Establishing Procedures For Collection And Dissemination Of Data Outside Domestics

Adopted by the Committee of Ministers on 11 December 2013 at the 1187th meeting of the Ministers' Deputies, available:

https://www.edqm.eu/sites/default/files/medias/fichiers/resolution_cmres201355_on_establishing_procedures_for_the_collection_and_dissemination_of_data_on_tr.pdf.

Committee of Ministers Council of Europe Resolution CM Res 2013 (56) On The Development And Optimisation Of Live Kidney Donation Programmes Explanatory Memo

Adopted by the Committee of Ministers on 11 December 2013 at the 1187th meeting of the Ministers' Deputies, available:

https://www.edqm.eu/sites/default/files/medias/fichiers/resolution_cmres201356_on_the_development_and_optimisation_of_live_kidney_donation_programmes.pdf.

Committee of Ministers Council of Europe Resolution CM Res 78 (29) On Harmonisation Of Legislations Relating To Removal, Grafting And Transplantation

Adopted by the Committee of Ministers on 11 May 1978 at the 287th meeting of the Ministers' Deputies, available:

[https://www.coe.int/t/dg3/healthbioethic/texts_and_documents/Res\(78\)29E.pdf](https://www.coe.int/t/dg3/healthbioethic/texts_and_documents/Res(78)29E.pdf).

Commission Directive 2003/63/EC Of 25 June 2003 Amending Directive 2001/83/EC Of The European Parliament And Of The Council On The Community Code Relating To Medicinal Products For Human Use

On 25 June 2003, amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, available: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003L0063&from=EN.

Commission Directive 2006/17/EC Of 8 February 2006 Implementing Directive 2004/23/EC Of The European Parliament And Of The Council As Regards Certain Technical Requirements For The Donation, Procurement And Testing Of Human Tissues And Cells

On 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, available: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:038:0040:0052:EN:PDF.

Commission Directive 2006/86/EC Of 24 October 2006 Implementing Directive 2004/23/EC Of The European Parliament And Of The Council

On 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells, available: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006L0086&from=EN.

Commission Implementing Directive 2012/25/EU Of 9 October 2012 Laying Down Information Procedures For The Exchange, Between Member States, Of Human Organs Intended For Transplantation

On 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation, available: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012L0025&from=EN.

Directive of the European Parliament and of the Council 2004/23/EC of 31 March 2004 On Setting Standards Of Quality And Safety For The Donation, Procurement, Testing, Processing, Preservation, Storage And Distribution Of Human Tissues And Cells

On 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, available: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:102:0048:0058:en:PDF.

Directive of the European Parliament and of the Council 2010/45/EU of 7 July 2010 On Standards Of Quality And Safety Of Human Organs Intended For Transplantation.

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Directive 2012/39/EU Amending Directive 2006 (17) EU As Regards Certain Technical Requirements For The Testing Of Human Tissues

On 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells, available: <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:327:0024:0025:en:PDF>.

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*Appendix***Table 1: Universal acts and most important legal aspects in the Council of Europe and European Union legislation in postmortal transplantation subject.**

Universal acts	Council of Europe documents
<ol style="list-style-type: none"> 1. Universal Declaration of Human Rights 2. International Covenant on Civil and Political Rights 3. International Covenant on Social, Economic and Cultural Rights 4. WHA 40.13 of the Forty World Health 5. Convention on the Rights of the Child 	<ol style="list-style-type: none"> 1. European Social Charter 2. Convention for the Protection of Human Rights and Fundamental Freedoms 3. Additional Protocol To The Convention On Human Rights And Biomedicine 4. Additional Protocol To The Convention On Human Rights And Biomedicine Concerning Transplantation Of Organs And Tissues Of Human Origin 5. Convention For The Protection Of Human Rights And Dignity Of The Human 6. Convention For The Protection Of Human Rights And Fundamental Freedoms 7. Convention Organ Trafficking 8. Council Of Europe Convention On Action Against Trafficking In Human Beings Explanatory Report 9. European Agreement On The Exchange Of Therapeutic Substances Of Human 10. Explanatory Report Organ Trafficking Convention 11. Trafficking In Organs In Europe, Parliamentary Assembly Recommendation 1611 12. Committee of Ministers Council of Europe Recommendation No 2003 (10) On Xenotransplantation 13. Committee of Ministers Council of Europe Recommendation No 2003 (12) On Organ Donor Registries 14. Committee of Ministers Council of Europe Recommendation No 2004 (7) On Organ Trafficking 15. Committee of Ministers Council of Europe Recommendation No 94 (1) On Human Tissue Banks 16. Committee of Ministers Council of Europe Recommendation No 97 (15) On Xenotransplantation 17. Committee of Ministers Council of Europe Recommendation No R982 On Provision Of Haematopoietic Progenitor Cells 18. Committee of Ministers Council of Europe Recommendation Rec 2004 (8) On Autologous Cord Blood Banks 19. Committee of Ministers Council of Europe Recommendation Rec 2005 (11) On the Role and Training of Professionals Responsible for Organ Donation
European Union documents	
<ol style="list-style-type: none"> 1. The Charter of Fundamental Rights of the European Union (EU Charter of the EU) 2. Commission Directive 2003/63/EC Of 25 June 2003 Amending Directive 2001/83/EC Of The European Parliament And Of The Council On The Community Code Relating To Medicinal Products For Human Use. 3. Commission Directive 2006/17/EC Of 8 February 2006 Implementing Directive 2004/23/EC Of The European Parliament And Of The Council As Regards Certain Technical Requirements For The Donation, Procurement And Testing Of Human Tissues And Cells. 4. Commission Directive 2006/86/EC Of 24 October 2006 Implementing Directive 2004/23/EC Of The European Parliament And Of The Council. 	

5. Commission Implementing Directive 2012/25/EU Of 9 October 2012 Laying Down Information Procedures For The Exchange, Between Member States, Of Human Organs Intended For Transplantation. 6. Directive of the European Parliament and of the Council 2004/23/EC of 31 March 2004 On Setting Standards Of Quality And Safety For The Donation, Procurement, Testing, Processing, Preservation, Storage And Distribution Of Human Tissues And Cells. 7. Directive of the European Parliament and of the Council 2010/45/EU of 7 July 2010 On Standards Of Quality And Safety Of Human Organs Intended For Transplantation. 8. Directive 2012/39/EU Amending Directive 2006 (17) EU As Regards Certain Technical Requirements For The Testing Of Human Tissues	20. Committee of Ministers Council of Europe Recommendation Rec 2004 (19) On Criteria For The Authorization Of Organ Transplantation Facilities 21. Committee of Ministers Council of Europe Recommendation Rec 2006 (15) On The Background, Functions And Responsibilities Of National Transplant Organization (NTO) 22. Committee of Ministers Council of Europe Recommendation Rec 2006 (16) On Quality Improvement Programmesfor Organ Donation 23. Committee of Ministers Council of Europe Resolution CM Res 2008 (4) On Adult-To-Adult Living Donor Liver Transplantation 24. Committee of Ministers Council of Europe Resolution CM Res 2008 (6) On Transplantation of Kidneys from Living Donors Not Genetically Related 25. Committee of Ministers Council of Europe Resolution CM Res 2013 (56) On the Development and Optimisation of Live Kidney Donation Programmes 26. Committee of Ministers Council of Europe Resolution CM Res 2015 (10) On the Role and Training Of Critical Care Professionals In Deceased Donation 27. Committee of Ministers Council of Europe Resolution CM Res 2015 (11) On Establishing Harmonised National Living Donor Registries 28. Committee of Ministers Council of Europe Resolution CM Res 2015 (11) On Establishing Harmonised National Living Donor Registries Explanatory Memo 29. Committee of Ministers Council of Europe Resolution CM Res 2013 (55) On Establishing Procedures for Collection and Dissemination Of Data Outside Domestics 30. Committee of Ministers Council of Europe Resolution CM Res 2013 (56) On the Development and Optimisation Of Live Kidney Donation Programmes Explanatory Memo 31. Committee of Ministers Council of Europe Resolution CM Res 78 (29) On Harmonisation of Legislations Relating To Removal, Grafting And Transplantation
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Table 2: 15 universal documents valid in Council of Europe and the European Union guaranteeing human dignity and freedom in postmortal organ donation context in adherence to existing in Europe donation models: opt-in, opt-out and priority.

Legal Act		opt-in	opt-out	priority
1	Universal Declaration of Human Rights	Y	Y	N
2	International Covenant on Civil and Political Rights	Y	Y	Y
3	International Covenant on Social, Economic and Cultural Rights	Y	Y	Y
4	WHA 40.13 of the Forty World Health Assembly of 1987	Y	Y	N
5	Convention on the Rights of the Child	Y	Y	N
6	Convention for the Protection of Human Rights and Fundamental Freedoms	Y	Y	N
7	European Social Charter	Y	Y	N
8	Convention for the Protection of Human Rights and Human Dignity	Y	Y	N
9	Convention on Action against Trafficking in Human Beings	Y	Y	Y
10	Council of Europe of Convention on Counteracting Trafficking in Human Organs	Y	Y	Y
11	Additional Protocol to The Convention On Human Rights And Biomedicine	Y	Y	N
12	Additional Protocol to The Convention On Human Rights And Biomedicine Concerning Transplantation Of Organs And Tissues Of Human Origin	Y	Y	N
13	Charter of Fundamental Rights of the European Union	Y	Y	N
14	Directive of the European Parliament and of the Council 2004/23/EC of 31 March 2004 on Setting Standards Of Quality And Safety For The Donation, Procurement, Testing, Processing, Preservation, Storage And Distribution Of Human Tissues And Cells.	Y	Y	N
15	Directive of the European Parliament and of the Council 2010/45/EU of 7 July 2010 on Standards Of Quality And Safety Of Human Organs Intended For Transplantation.	Y	Y	Y

Y – harmonized with document, N – dissonant with document.