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ORGAN TRANSPLANTATION - DIFFERENT CONTROL STRATEGIES[1]

SUMMARY

Transplantation of human organs and tissues for therapeutic purposes has been practiced since the middle of the last century. It began in a very primitive way back in ancient India (and today one method of transplantation is called the "Indian method"), through the 16th century (1551), when the first free transplantation of part of the nose was performed in Italy, and has developed to this day into an irreplaceable medical procedure aimed at saving and prolonging human life. Thousands of pages of professional literature, notes, polemical discussions, atypical medical articles, notes in the margins of read magazines or books in philosophy, sociology, criminal law literature... even representatives of the church have taken their position on events of this kind.

Understanding our view of this complex and very complicated issue requires that certain solutions on the international stage be given greater attention, especially where there are certain overlaps, certain overlaps but also divergences. It is always good to hear a different opinion, because it makes you think. Therefore, in the following considerations, we have tried to answer some of the numerous and diverse questions in which these touch, but often diverge, both from the point of view of real regulations, and from the angle of medical and judicial practice, this time from the perspective of some EU member states (Germany, Poland, also expressing the position of the Catholic Church) on the one hand, and from the perspective of different moral, spiritual, cultural and other values - India and Iraq, on the other.

Key words: *organ transplantation, changed situations, new requirements, normative frameworks*

1. INTRODUCTION

»Long live death« - someone must die so that someone can continue to live - this sad motto looms over the concept of transplantation and poses for many a major bioethical question mark about the fundamental meaning and essence of »giving one's own vital part of the body to another being«.

In the overwhelming human »dependence« on imposed dangers and limitations, on the one hand, and the effort to save one's life »at all costs« with this therapeutic approach, on the other, a multitude of problems arise. For example, is it right to base patients' hope of survival on the expectation that someone else will die? Is it ethical for a surgical team to wait for the death of one patient in order to save another? Is it right to take an organ from a healthy and living donor when the extension of the patient's life after the procedure is limited to one, two or three years? Will transplantation contribute to the good? In general, is the right to experiment a fundamental right of doctors? What are the limitations? How should a recipient be chosen when there is a shortage of donors and equipment? On what basis should this choice be made? For example, should the life of a child or a person without skills and qualifications be prolonged? Who is qualified and has

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the right to judge the value of someone's years of life? To what extent is a surgeon in a position to choose between the risks borne by the donor of the organ to be transplanted and the value of the recipient's life? Is organ transplantation a question of positive morality? Is therapy based on human death ethically correct? Is it in accordance with religious dogmas, etc.?

In the answers - great disorder and fierce frustration, pressure, forced decisions, fear and disgust, enormous stumbling blocks, but also abuse.

From this reference, following only some of the questions raised, i.e. in their complexity and diversity, the central thing is recognized - the solution to this problem lies in the problem itself.

And the problem itself is subject to ambiguous answers.

Sometimes it is not good to take everything into account.

Omnipresence depresses.

And disarms.

But it also knows how to give hope... and offer solutions!

And in this field they are original, historically interesting, universally valuable, exemplary... From state to state, from legislation to legislation. In this way, our position on the need to explain some of them is also clarified.

2. SEEING THE PROBLEM FROM THE OUTSIDE

I will start with what is essentially important and decisive for the transplantation of parts of the human body and by pointing out the fact that this is a form of treatment in modern medicine thanks to which many people who were previously condemned to premature death, live with quality and dignity and are active at work.

Today, this type of medical surgery has become the practice of top medical institutions throughout the world. In this context, it is interesting to point out that the emergence of solutions in the field of transplantation medicine was preceded by decades of dealing with all the complexity and difficulties that this method of treatment brought.

Since the early 1950s, surgical dilemmas related to transplantation have begun to be successfully resolved. The best results in transplantation were first achieved on identical identical twins, on whom the first kidney transplant was performed (Joseph Murray, 1954). A few years later, Murray successfully performed the first kidney transplant from a deceased person, thus »paving the way« for hundreds of thousands of such procedures.[2] Somehow at the same time, problems of an internal nature were also solved (1956). In the early 1960s, the first insights and discoveries of tissue typing (HLA typing) and knowledge of the necessary immunological compatibility, necessary for the successful performance of organ and tissue transplantation, came to light.[3]

On March 16, 1968, Philip Blaiberg, at that time the only survivor of a heart transplant, left Grotte Schuur Hospital in Cape Town (South Africa). He was escorted to the hospital's front door by Dr. Cristian Baernard, the leader of the transplant team that had transplanted the heart of Clive Haupt, a twenty-four-year-old black man who had died of brain damage after collapsing on the beach, to a 43-year-old dentist.[4]

2 Peličić, D., Ratković. M., Radunović, D., Prelević, V., *Etički aspekti transplantacije tkiva i organa,* Inspirium, 2015, p. 36, https://scindeks-clanci.ceon.rs/data/pdf/2217-656X/2015/22117-656X1514035P.pdf, access date: 10.09.2024.

3 *Ibid*

4 On this occasion, it must be admitted that in the history of medicine, no event has attracted so much attention and interest not only from medical circles that deal with this issue professionally, but also from the general public, as well as from experts in the fields of law, ethics, philosophy, and sociology. The Nuremberg Trials clearly demonstrated the dangers associated with experiments performed on healthy people. »Science turned us into Gods before we were worthy of becoming humans.« Castel, J.-G., *Some Legal Aspects of Human Organ Transplantation in Canada*, Canadian Bar Review, vol. XLVI, september, no. 3/1968, p. 346; Ford, J. T., *Human Organ Transplantation: Legal Aspects*, Chatolic Lawyer, spring 1969, p. 136.

Just a month later, Norman Shumway performed a similar transplant in California. The first successful liver transplant was performed by Thomas Strazl in 1967 in Denver, USA.[5]

Today, kidneys, hearts, corneas, livers, pancreases, skin parts, etc. are successfully transplanted. One day it will be possible to transplant someone's reproductive organs or brain...

A significant increase in the »demand« for transplant medicine services and its very dynamic development, as well as the lack of alternative treatment methods for the terminal stage of organ failure, makes transplantation still a »hot topic for discussion«.

3. STUDYING THE SITUATION FROM THE PERSPECTIVE OF CHANGED SITUATIONS AND NEW REQUIREMENTS

Modern legislation regulating the transplantation of human body parts, from country to country, does not show significant oscillations. In almost all countries (except Japan), brain death has been accepted as the legal definition of death.[6] From that moment on, the removal of organs for transplantation to another is considered permissible. The law prohibits, in various ways, the trade in organs intended for treatment. The prohibition is also sanctioned by punitive measures. Transplantation can only be performed by a qualified person, and certain institutions are responsible for the distribution of organs. Regarding whether and in what form a potential donor should approve organ donation, the donor's prior consent has been adopted as a general rule, i.e. as a prerequisite for a valid transplantation. However, as regards the question of the form in which the donor should approve post mortem organ donation, the existing legal regulations differ from country to country. In fact, there are two basic models for regulating the removal of organs from a deceased donor: the model of explicit consent of the deceased (option in system) and the model of presumed consent (option out system).

For our consideration, which we have made in the context of a comparative presentation of more or less detailed provisions on the conditions under which the removal of organs from deceased persons is permitted, the following can be stated: depending on the applicable legal solutions, some countries proceed from the presumed consent of the deceased person, some from his explicit consent, some normative concepts contain features of both the explicit and tacit consent system, and finally, in certain legislations the option of opposition is accepted (from giving a statement of disagreement to giving a written statement of disagreement to transplantation).[7]

But let's simplify. We will begin our research into alternatives in the direction of the most adequate normative regulation of this increasingly common medical procedure in modern medicine, as we have already indicated, with a brief explanation of each of the above-mentioned solutions.

Opposition is adopted as a valid principle by the majority of the laws on transplantation of the European Union member states. From this position, the removal of organs from a deceased person for the purpose of transplantation is considered permissible if the deceased person did not object to it during his lifetime. His silence is considered as consent, i.e. consent to the request is presumed. In addition, the removal of body parts is permitted even in cases where there is doubt about the will of the deceased. As can be seen, the removal of organs from deceased persons is not prohibited in principle, but rather permitted. This solution is in line with all the efforts being made to increase the number of potential donors (which means eliminating the need to carry a donor card), because they also include those who have not declared themselves at all.[8]

5 Peličić, D., Ratković. M., Radunović, D., Prelević, V., *op. cit.,* p. 36.

6 See more about that: Klajn Tatić, V., *Uzimanje organa od umrlih davalaca - medicinski, etički i pravi problemi*, Zbornik radova Pravnog fakulteta u Novom Sadu, no. 3/2007, pp. 273-278.

7 https://www.www-drze.de/in-focus/organ-transplantation/legal-aspects, access date: 22.01.2025.

8 Klajn Tatić, V., o*p.cit.,* p. 282.

The concept of dissent, which envisages the taking of organs from deceased persons in the event that the donor did not explicitly declare himself against organ donation during his lifetime (dissent solution), is applied, for example, in Italy,Slovenia, the Czech Republic and Hungary. In Belgium, Finland, Norway, the extended dissent solution is applied, i.e. a solution according to which the closest relative can also oppose the organ donation process. Denmark, Greece, the United Kingdom, the Netherlands, Switzerland and Germany accept the broad consent solution, according to which the organ donor must give consent during his or her lifetime, in the form of a donor card »narrow or the extended consent solution«.[9]

Where this is not the case, the decision is made according to the wishes of the deceased expressed before death, or based on an assumption of what the wishes of that person would have been. In Japan, a »specific form of consent« is necessary for a valid transplant. The removal of organs from a deceased person for the purpose of transplantation can only be carried out with the consent of the person who is the closest relative of the deceased donor. In France and Sweden, the so-called »information solution«[10] - organs can be donated, unless the person in question refused such a procedure while alive. The donor's silence is considered a lack of opposition, or rather, acceptance.[11]

4. "GERMAN TRANSPLANT LAW"

The European Union has a contractual obligation to set quality and safety standards for organ transplantation. This follows from Art. 168, point IV, par. A) of the Treaty on the Functioning of the European Union (TFEU). On the basis of this Treaty, Directive 2010/45/EU on standards of quality and safety of human organs intended for transplantation was adopted on 7 July 2010. The Transplantation Directive primarily aims to assimilate quality and safety standards throughout Europe and to develop more efficient transplantation systems in order to improve exchanges between the Member States of the Union. Since the Directive is binding on all EU Member States, it was implemented into German national law on 1 August 2012 through amendments to the provisions on transplantation. This Directive does not apply to regulations on the donation, procurement and distribution of organs, which are legally regulated individually by the Member States.[12]

In addition to this directive, the European Parliament has tabled an Action Plan on Organ Donation and Transplantation (2009-2015). The 10-point plan encourages the introduction of a central transplant registry and the appointment of specially trained coordinators in hospitals.[13]

In Germany, human organ transplantation is regulated by the Act on the Removal, Donation, and Transplantation of Organs and Tissues (*Gesetz über die „Spende, Entnahme und Übertragungvon Organen und Gewebe"* or: Transplantation Law – *TPG*). The law was adopted by the German Bundestag on November 5, 1997, and entered into force on December 1, 1997.

The provisions of this law were amended and supplemented by the versions of September 4, 2007, and August 1, 2012. Depending on whether the organs are taken from deceased or living donors, the Law contains two different sets of regulations that are determined in detail according to these significantly different situations. Providing a broader framework for understanding, the TPG prescribes the so-called »extended consent solution«, so that the taking of organs from a deceased person is possible, not only in the case when the person has expressly consented to

9 Presumed strong consent advocates the "doctrine of cadaver socialization." Presumed weak consent, on the contrary, requires explicit opposition to the medical procedure. In the absence of this explicit opposition (a statement on an ID card or driver's license), any person can appear in the role of donor. https://www.www-drze.de/in-focus/organ-transplantation/legal-aspects, access date: 22.01.2025.

10 *Ibid*.

11 See more about that: Klajn Tatić, V., *op. cit.,* p. 282.

12 https://www.www-drze.de/in-focus/organ-transplantation/legal-aspects, access date: 22.01.2025.

13 *Ibid*.

it during his or her lifetime (prior permission given in the form of an »organ donor card«), but also when close relatives give their consent to this donation after his or her death. In April 2014, amendments to the Transplantation Act were adopted, which provide for the removal of organs or tissue from a deceased donor only if death has been established: in accordance with the rules of medical science (§3. para. 1. item 1. TPG), by two independent, qualified doctors who may not be involved in the process of organ removal and transplantation itself (§ 5 TPG). The operation itself must be performed by doctors who are »specially qualified« for this type of intervention (§ 3. para. 1. item 3. TPG). Likewise, the removal and donation of organs or tissue from a dead embryo or fetus requires the consent of a woman who was pregnant (§ 4a para. 1. TPG).

The amendments to the TPG, which came into force on 1 August 2012, require that all health insurance holders aged 16 or over be asked whether they wish to donate their organs after death. Proponents of this regulation expect an increase in the number of donors. In addition, existing control mechanisms in health centres and hospitals where organ removal and transplantation are carried out must ensure strict implementation of these rules. The relevant expert and independent inspection carries out testing and monitoring by a Commission established within the German Medical Association. Clinics are legally obliged to provide the board with information on decisions relating to the distribution of organs.

Organ donation from a living donor is permitted in Germany if the donor is of legal age, capable of giving consent to this intervention, is adequately informed, agrees to the removal of the organ (informed consent to the operation) and is considered a medically adequate donor; in addition, it must be ensured that the donor is not exposed to risks greater than those of the operation (§8, para. 1 TPG).[14] While organs or tissues that are renewable can be donated to an unknown recipient, the donation of organs that are not renewable (e.g. kidneys, parts of the liver) is only permitted for the purpose of transplantation to first- and second-degree relatives, spouses, registered life partners, fiancés or fiancées with whom the donor has a clearly very close relationship (§8, para. 1, item 4 TPG). The amendments to the TPG and the accompanying changes to the general law (SBG V) state that the donor has broad rights to use the health insurance of the donation recipient in terms of medical treatment, rehabilitation, travel expenses and sick leave compensation. In addition, the donor has the right to salary compensation in the event that he is unable to work due to the consequences of organ donation.[15]

In addition to the detailed regulations on the procurement of organs from deceased or living donors, the provisions of this law also contain a set of general principles and procedural requirements. Organ donation is a joint task in which several different institutions participate. The so-called TPG commissioners play a key role in this process: the National Association of Compulsory Health Insurance *(GKV- Spitzenverband),* the Coordination Center for Organ Procurement (§11 *TPG*), the German Medical Association (*BAK* association), the German Hospital Federation *(OKG)* are jointly assigned to the Coordination Center for Organ Procurement (§12 *TPG*). Organ transplantation in which the objects of allocation (»vermittlongspflichtige Organe«) are the heart, kidneys, liver, pancreas, intestines (§3, 4 *TPG*) may only be carried out in precisely designated authorized hospitals (so-called transplant centers) (§9, 10 *TPG*); the organs must only be allocated by the Allocation Agency (§11 *TPG*). The law also stipulates that these centers maintain

14 Establishing the rank of persons who can be considered close to an organ donor, the German legislator specifies: spouse, adult children, parents or guardians, adult brothers or sisters, grandparents. The listed persons can decide only if they have had personal contact with the potential donor in the last two years before his death. When there are several close persons of the same rank, the consent of one of them is sufficient, but the opposition of each of them must be taken into account. In the event that a close person of a high rank is not available, the decision of the closest person who is available is sufficient. Finally, if the deceased has transferred his right to decide on organ donation to a designated person, that person takes the place of the closest person. Cited by: Klajn Tatić, V., *op. cit.,* p. 281.

15 https://www.www-drze.de/in-focus/organ-transplantation/legal-aspects, access date: 22.01.2025.

waiting lists for organ donation. However, not all patients in need of new organs can be found on these lists - where the risks associated with transplantation and postoperative treatment are high and the prospects for success are low, transplantation is not considered an option. Doctors must adhere to the guidelines of the German Medical Association when deciding which patient to put on the waiting list. In addition, they must document the reasons for such a decision and inform the patient accordingly (§16 TPG). Based on §12 TPG, donated organs are distributed at national level in accordance with the guidelines of the German Medical Association for organ donation. The guidelines and opinions of the German Medical Association are binding on the Chamber (§16 TPG). These guidelines were developed by the Standing Committee on Organ Transplantation of the German Medical Association (Ständige Kommission Organtransplantation der Bundesärztekammer), and are updated at certain intervals in accordance with new findings in medical science. The interdisciplinary committee includes experts from the fields of medicine, law and philosophy, as well as patients and relatives of organ donors. In terms of the provisions of the TPG, the German Medical Association has issued the following guidelines: 1) on the determination of brain death; 2) on the management of waiting lists and the allocation of organs; 3) on the medical assessment of organ donors and the preservation of organs; 4) on the implementation of insurance measures to guarantee appropriate quality.

These guidelines are legally binding for all actors in the transplantation process (as defined in (§16 TPG). The law does not cover xenotransplantation. Namely, the German Medical Association decided in 1999 that the necessary prerequisites for performing xenotransplantation in a reasonably low-risk manner were not yet met. Since the TPG does not regulate this area, the provisions of the Medicinal Products Act (Arzneimittelgestz - AMG) are relevant for xenotransplantation. According to §2. Para. 1. Item. 1 AMG, medicinal products are substances or preparations made from a substance which, when applied to or in the human body, treat, alleviate, prevent or eliminate diseases, suffering, injuries or medical conditions (conditions). According to § 5. Para. 2 AMG, medicinal products are considered unsafe if, in the light of current scientific knowledge, there is reason to suspect that, when used in accordance with their intended purpose, they have harmful consequences that exceed the limits considered tolerable. Regardless of whether this is the case with organ transplantation from animals to humans, this issue is very controversial, i.e. it is subject to contradictory interpretations, assessments and evaluations.[16]

5. POLAND

In Poland, the first successful transplantation from a deceased donor (kidney) was performed in 1966, when there was no legal regulation that would regulate the conditions and procedures in this area. In fact, this was done much later, only in 1995, when the Act on Donation and Transplantation of Cells, Tissues and Organs was passed - which specifies when and from whom cells, tissues and organs can be taken, what conditions must be met when taking organs and transplanting, and who has the right to allocate and transplant human organs, cells and tissues. Today, the Act on the Proclamation of the Marshal of the Polish Sejm of 11 May 2017 is in force in this country, with a refined legal text on the procurement, storage and transplantation of cells, tissues and organs.[17]

According to the provisions of this Act, human organs, cells and tissues from a deceased person may be taken for transplantation, if the donor did not object to this during his lifetime. The objection must be expressed in writing and entered in the central register, or orally - by a statement in the presence of at least two witnesses who certify their presence with their signatures. The objection (oral or written) can be withdrawn at any time. Therefore, Poland has adopted pre-

16 *Ibid.*

17 https://www.www-drze.de/in-focus/organ-transplantation/legal-aspects, access date: 19.02.2020.

sumed consent or registered opposition as the basic principle.[18] In this case, the family's consent to organ donation is not mandatory, although family members should always be informed about it. However, the express objection of the deceased's family is - despite the existing legal solutions - respected, and in that case it is not withdrawn from the transplantation procedure.[19]

Article 12. 1. of the Act on Transplantation of Cells, Tissues and Organs, taking from a living donor is permitted only if the recipient is a direct relative regardless of the degree of kinship, spouse, adoptive parent or adoptee and that persons, if they justify it with exceptional personal reasons. This provision allows for kidney transplantation from a living donor with whom you are not related within the »Exchange Program Par«. Donation of cells, tissues and organs from a living donor is permitted only with the consent of the court with jurisdiction over the place of residence, or seat of the donor, conducted in an out-of-court procedure, after taking a statement from the recipient and after the Ethics Committee of the National Transplantation Council has given an opinion based on the previously obtained consent of the district court for the collection of bone marrow, regenerative tissues or cells, etc.[20]

In Poland, in 2017, 1.531 organs were transplanted from deceased donors; the most common were kidneys (1,004), livers (349) and hearts (98). There were also 1,290 cornea transplants. In contrast, 80 organ transplants were performed from living donors (56 including kidney and liver parts 23).[21]

Due to the significant gap between the number of patients waiting for kidney transplantation and the availability of organs, the National Program for the Development of Transplant Medicine of the Ministry of Health for 2011-2020 was established,whose goal is to increase the number of kidney transplants from living donors. It is expected that after this program, the number of people who will receive a kidney from a living donor will increase to at least 115 per year, or at least five times more than the number of transplants in 2009, when 23 patients in Poland received a kidney from a living donor.[22]

Although the Paired Exchange Program was created in 1989 in the USA, the first cross-transplant was performed in 1991 in South Korea, where this method has become a common method of kidney transplantation. In Europe, the first transplant within the framework of the Paired Exchange Program was performed in Switzerland in 1999, then in Romania in 2001, and in 2004 in the Netherlands. Poland joined the countries that have been implementing this transplantation method since 2015 (when the first cross-linked kidney transplant was performed at the »Baby Jesus Clinical Hospital« in Warsaw.[23]

6. THE POSITION OF THE CATHOLIC CHURCH

The Catholic Church takes a positive attitude towards transplantation treatment, evidence of which can be found in the Catechism of the Catholic Church. Pope John Paul II, a representative of the ideology of personalism, has repeatedly emphasized the importance of organ donation in the name of Christian love. During an audience, members of the World Transplantation Society stated: "A person who expresses his consent to donate organs after his death demonstrates Christian

18 Mattioli, M. C., Legal Aspects oof Transplantation of Organs, http://www.hottopos.com/ harvard3/matti.htm, access date: 15.07.2024.
19 *Ibid.*
20 *Ibid.*
21 http://www.poltransplant.org.pl/statystyka_2017.html, access date: 02.02.2025.
22 http://www. zywydawcanerki.pl, access date: 02.02.2025.
23 The person who lived the longest after an organ transplant in Poland is 91-year-old Tadeusz Zytkiewicz. He passed away last year, on September 18, at the age of 92. Prof. Religa made the decision to transplant in 1986, even though the patient was already 61 years old and the treatment seemed to have little chance of success. Glowala, S., Lergal and moral aspects of Transplantation, Journal of Education, Health and Sport, No. 8(11)/2018, p. 18-31, available at http://ojs.ukw.edu.pl/index.php/johs/ article/view/6150, accessed 12.05.2025.

love, which gives life to others." A few years later, during a session of the World Transplantation Society, the positive attitude of the Catholic Church regarding this type of specialized treatment was reaffirmed. It was clearly stated that the Church accepts the medical criterion of death and recognizes the idea of brain death, assuming that death occurs when the brain dies, i.e. when the brain as a whole stops working.[24]

Despite this expressed position, the transplantation world expects greater engagement of the Catholic Church (through the work of church chaplains, parish priests) in activities that promote organ donation, so that the Church's position on this issue is clear to every believer.[25]

The media play an important role in shaping social attitudes, placing an excessive emotional burden on individuals, rather than influencing essential social problems.

7. IRAN

According to Islamic belief, every individual has a soul and a body. The human condition depends on the eternal soul. God endowed man with the basic knowledge of "good" and "bad" at the time of creation. On the other hand, human actions have value if they are performed with information and freedom. Solutions to ethical problems are derived from Islamic principles and are actualized in the Holy Quran, which includes the traditions of the Prophet of Islam and his successors (Sunna and Hadith), the consensus of scholars (Ijma), and wisdom (Aqul). Islam supports helping others and saving lives. The Holy Quran says: "and whoever saves the life of a soul, it is as if he has saved the life of all mankind" (5:32). According to religious prohibitions (fatwa), vital organs (such as the heart) must not be donated before death. Donating other organs is permissible but should not be harmful to the donor. The consent of the donor and recipient is necessary.[26]

CURRENT STATUS OF ORGAN TRANSPLANTATION IN IRAN

Transplantation has a long history in Iran. Avicenna (981–1037 CE), a great Iranian physician, performed the first nerve repair. Modern organ transplantation dates back to 1935. Currently, Iran has one of the most successful transplant programs in the Middle East. The overall survival rate of patients and grafts is comparable to other centers around the world.

Since the Iranian people are predominantly Islamic, ethical issues are a frequent topic of discussion among physicians, legal experts, and religious scholars. A positive fatwa is required for any law to be passed by parliament. Consensus among physicians and religious leaders has opened the door for the advancement of the transplant program in Iran in recent years. The "Law on Transplantation and Brain Death" was approved by the parliament in 2000. According to this law, brain death must be established and confirmed by four doctors: a neurologist, a neurosurgeon, a general practitioner, and an anesthesiologist. Members of the team that diagnoses and establishes brain death may not be part of the transplant team. After confirmation of brain death, organs and tissues from the deceased person are used for transplantation with the consent given during life (e.g., a written will or a signed donor card), or from close relatives. Since the end of 2000, only 84 kidney transplants have been performed in Iran, i.e. <0.8% of the total. Although the donation of organs from deceased donors has increased in recent years due to people signing organ donation cards, effective organ donation from deceased donors requires increased social awareness as well as better equipment and laboratory conditions. In 2002, only about 6% of all kidney transplants

24 *Ibid*.

25 St. Basil, a Doctor of the Church, who lived in the 4th century, said: "Would it not be inappropriate to surrender the gift of God, which is medical knowledge, because of its misapplication by a few (…), but we must shed light on what they have defiled." Ford, J. T., *Human Organ Transplantation: Legal Aspects*,Chatolic Lawyer, spring 1969, p. 26.

26 Larijani, B., Zahedi, F., Taheri, E., et. al., Ethical and Legal Aspects of Organ Transplantation in Iran, Transplantation proceedings, No. 35/2004, pp. 1241-1244, available at: https://www.researchgate.net// publication/8458635, date of access 5.07.2024.

were from deceased donors. Similarly, the shortage of deceased donors is the biggest obstacle to liver transplants in Iran.

In Iran, until 1988, living donors were always related to the recipient. However, due to the increasing national demand for patients, a controlled program for living unrelated kidney transplants (LURD) was adopted in 1988. As a result, the waiting list for kidney transplantation was eliminated in 1999. In Iran, organ transplantation is encouraged by a government-sponsored reward. The Law on Gifted Organ Donation was approved by the Iranian government in 1997. The "gifted" donation is implemented through the Charity Foundation of Special Diseases (CFSD), which is a non-governmental organization.[27]

8. INDIA

In India, the Transplantation of Human Organs (THO) Act was passed in 1994, with the aim of simplifying the procedure for donating and transplanting human body parts. According to the provisions of this Act, in terms of determining the concept of death, the criterion of brain death was adopted. Human organs cannot be sold. The ban is also sanctioned by criminal measures. With the acceptance of the definition of brain death, i.e. from that moment on, transplantation was allowed not only of kidneys, but also of liver, heart, lungs and pancreas. Despite the aforementioned Act, affairs and scandals related to the trade in human organs, and above all, the trade in kidneys, are regularly present in the Indian media. In most cases, the provisions of the THO are incorrectly applied and seriously abused. »MOHAN Foundation« (MOHAN Foundation - NGO based in Tamil Nadu and Andhra Pradesh), has provided donation and transplantation of 1300 organs from deceased donors in the last 14 years alone. Otherwise, India currently has a rate of 0.05-0.08 deceased donors per million inhabitants. In order to increase the supply of cadaveric organs needed for transplantation, the Government amended the existing Law with seven new provisions, and on July 30, 2008, new amendments came into force, which were supposed to reformulate the work of the Chamber and introduce certain innovations in the actions of its bodies (which suffered terrible criticism from international bodies).[28]

Despite the Law (THO), neither the number of organs for sale has decreased, nor has the number of organ donations from deceased persons increased, and therefore the shortage of cadaveric organs has not been overcome. The concept of brain death has never been promoted to the general public. The largest number of transplants on a commercial basis is carried out »under the guise« of approvals given by the Committee (AC); the primary role of the Committee is, according to a precisely prescribed procedure, to ensure the donation of organs without compensation. It is clearly defined which of the living donors can donate an organ: mother, father, brother, sister, son, daughter and spouse. They are required to provide evidence of a close relationship: genetic tests and certain legal documents. In the event that there are no close relatives, the donor and the recipient request a special permit from the Committee (AC) whose members are appointed by the Government before whom they conduct an interview, from which the motive for organ donation should be determined and at the same time, the donor is examined to see if he understands the potential risks of the operation. The decision to accept or reject the request for organ donation and transplantation is sent by mail to the hospital. The competent authority (AA) carries out inspections, grants permission to register the hospital as a transplant hospital, monitors compliance with the prescribed standards, conducts regular inspections in hospitals regarding quality testing, suspends or cancels registration on waiting lists (fraud), conducts investigations into complaints

27 *Ibid.*

28 Govermment of India, Transplantation of Human Organs Act, 1994. Central Act 42 of (cited 2007 Mar 9) Available from: http://www.medindianet/tho/thobill1asp, access date: 19.02.2025.

due to violation of any provision of the Law, etc. The purpose of this body is to precisely regulate the collection, storage and transplantation of human organs. Hospitals are allowed to perform transplantation only after they have been licensed by the competent authority.The removal of an eye as an organ of vision from a deceased donor for transplantation is not as such within the competence of this Committee, and it does not require any special procedure for issuing a permit for the hospital premises in which it can be performed. A separate permit is required for each organ.

Before removing the organ, the doctor should ensure that the donor has approved the removal of the organ in Form 1(a), if he is a close relative in the direct line, i.e. father, mother, brother, sister, son or daughter. Form 1(b) is used for a spouse and Form 1(c) is used for other relatives. He should also confirm that the donor is in good health and fit to donate the organ. The authorized doctor signs the certificate (Form 2). The relationship between the donor and the recipient should be examined and approved by the authorized doctor at the transplant center.

When the proposed donor and recipient are not close relatives, the Approval Committee (AC) will assess whether there is a financial transaction between them and will specifically examine and evaluate the explanation of the relationship between them and the circumstances that led to the offer; the reasons why the donor wants to donate; written proof of the relationship, e.g. proof that they lived together (old photos showing the recipient and the donor together); that there is no intermediary; a detailed examination of the financial status of the donor and the recipient with financial statements for the previous three years; the donor must not be a drug addict or a person with a criminal record.[29] However, as has been repeatedly pointed out, the provisions of this law in practice turn into their opposite, causing catastrophic consequences for the life and health of donors and their family members. The law, which was supposed to prevent the acquisition of material benefits from the sale of organs, now provides protection for actors in this type of commercial business.

After the revelation of major scandals about the sale of kidneys and livers, the Department of Health issued a statement in the form of a »Government Decision«, in which it tried to absolve itself of any responsibility for any connection with the Committee (AC) on organ trafficking. It shifted the responsibility to the doctors in the hospitals (interview request), which is why it is planned to record the entire interview in the future. The striking impoverishment of the middle class, the lack of national health insurance, the drastic increase in inequality between the rich and the poor, the presence of new technologies that make this process simpler and faster, etc., seem »attractive« to those interested (both on the side of donors - organ sellers, and on the side of recipients - organ buyers). Even where there are relatives in good health who could donate organs, the main argument is »why should the donor take the risk when a kidney can be bought«!?[30]

Organ trafficking is a complex social problem in India (as is the case with the exploitation of children for labor and prostitution), but unlike other forms of exploitation, organ harvesting for transplantation requires an invasive surgical procedure that can lead to serious physical and psychological disorders (although it is a relatively safe method,diabetes and hypertension are recorded, which endangers the health of young donors in the long term). In some studies, it has been observed that when the motive for donation is purely commercial, donors are in poor health in the postoperative period. And when organ donation is exclusively on an altruistic basis, the feel-good factor acts as an incentive for a quick and successful recovery. In this interesting study on the economic and health consequences of organ sales, it was found that 96% of respondents sold their organs due to debts, at a price of about $ 1070. The average family income fell by a third after organ removal, so the number of these people, who already live below the poverty line, increased

29 *Ibid.*
30 *Ibid.*

significantly. In total, three-quarters of the respondents, even after »earning« money from the sold kidney, are still in debt. About 86% of them reported a deterioration in their health after this intervention, and 79% of those surveyed would not recommend this step to someone else. Lorens Koen, an anthropologist from Berkeley, found that in most cases the donors were women who were forced to sell their own organs due to huge debts incurred by their husbands (gambling).[31] In this study, the author goes further and talks about the kidney trade in the »belt region« in southern India, as a »trading route« from organs - usually poor rural women, to recipients in transplant centers - often wealthy people from Sri Lanka and Bangladesh, but also from the Gulf States.[32] He found that these people sold their kidneys to repay debts or to support their families. But most of them very quickly »returned« to a life of misery, poverty, debt, but this time impoverished for their organ. When asked if they would do it again, the answers were mostly similar: »I would do it again! I have a family to support. I have to help them. It was my choice.«[33]

The growth of »health tourism« for transplant medicine treatments and other advanced procedures has increased the old divisions between »the haves and the have-nots.« In principle, the movement of organs, tissues and body parts follows the flows of capital: from South to North, from the Third to the First World, from the poor to the rich... In its most drastic form, this market has led to theft and coercion (as in China), in the belief that the rich have a right to »spare parts« from the poor (human organs are sent to patients in Saudi Arabia, from North America to Turkey...), where kidney sellers are recruited from prisons, unemployment offices and urban slums.[34] A few years ago, a group of doctors and legal experts, in order to prevent the trafficking of human organs, tried to build appropriate control mechanisms to protect against intermediaries or brokers in the illegal organ market (as was done in Iran). The global shortage of organs,The high demand and shortage of organs (kidneys) in the US has led to an increasing number of patients traveling abroad for kidney transplants (India, Iran, China, Pakistan, Philippines, Brazil, Moldova, Romania, Bulgaria, Ukraine...). In its statement on the sale of organs, the WHO clearly stated: »The human body and its parts cannot be the subject of financial transactions. Therefore, the giving or receiving of money ... for organs is prohibited«. The WHO advises doctors not to transplant organs »if they have reason to suspect that these have been the subject of a financial transaction«.[35]

The editorial in »The Lancet« points out: »The success of transplantation as a life-saving treatment does not justify the sacrifice of poor people as a source of organs for the rich«.[36] In India, the percentage of organs taken from deceased donors is extremely low, and therefore it is necessary to explore this option and find real solutions to overcome the problem of organ shortage and prevent organ trafficking. The emphasis is, first of all, on »replacing« organs from living people, by taking organs from deceased donors as a viable alternative. Currently, there are 120 transplant centers in India, in which 3500-4000 kidney transplants are performed annually. Within this, 150-200 cases of liver transplants were performed in 4 transplant centers, while heart transplants were occasionally performed in some of these centers. For 50 patients, livers were taken from dead people, and the rest from living donors. In 1998, India had 1% of road vehicles and 6% of traffic accidents in the world. The number of these accidents increased to 10% in 2006. The total number of road accidents is estimated at around 90,000 annually. In Tamil Nadu alone, 13,000 fatalities were re-

31 Cohen, L. R., *Where it Hurts: Indian Material for an Ethics of Organ Transplantation*, Daedalus, 1999, p. 128, pp. 135-165.

32 "Kidney colony" in India is used as a metaphor for a kind of health transfer from the poor to the rich, because the former, in order to survive, were forced to sell their kidneys, creating a settlement of "donors" of these organs.Клајн Татић, В., Легитимност донорства људских органа на комерцијалној основи, Анали Правног факултета у Београду, year LVI, no. 1/2008, p. 109.

33 Cantarovich, Persons and Their Bodies: Rights, Responsibilities and the Sale of Organs, Philosophy and Medicine, 2002, pp.1-32.

34 Delmonico, F. L., Arnold, R., Sheper-Hughes N., Siminoff, L. A., Kahn, J., Youngner S. J., *Ethical incentives - not payment - for organ donation*, N. Engl. J. Med. 2002 Jun, 20; 346(25): 2002-5. doi: 10.1056/NEJMsb013216.

35 Available at: http://www.who/int/ethic/topics/transplantation_guiding_principles/en/ index1.htmal, access date: 17.04.2025.

36 The Lancet, *Organ Trafficking and Transplant Tourism and Commmercialism: the Declaration of Istanbul,* 2008 Jul 5;372(9632):5-6. doi: 10.1016/S0140-6736(08)60967-8.

ported in 2005. In 40-50% of fatal road accidents, the cause of death is head injury (potential donor), and other causes of brain death, such as hemorrhage and brain tumors, could also increase the number of potential donors. Even if only 5-10% of deceased people donated their organs, this would mean that living people would not have to donate their organs. By promoting a program for organ donation from deceased people, the illegal market in human organs would be significantly limited, if not eliminated.and therefore it is necessary to explore this option and find real solutions to overcome the problem of organ shortage and prevent organ trafficking. The emphasis is, first of all, on »replacing« organs from living donors by taking organs from deceased donors as a viable alternative. Currently, there are 120 transplant centers in India, where 3500-4000 kidney transplants are performed annually. Within this, 150-200 cases of liver transplants have been performed in 4 transplant centers, while heart transplants have been performed occasionally in some of these centers. For 50 patients, livers were taken from dead people, and the rest from living donors. In 1998, India had 1% of road vehicles and 6% of traffic accidents at the global level. The number of such accidents increased to 10% in 2006. The total number of road accidents is estimated at around 90,000 annually. In Tamil Nadu alone, 13,000 fatalities were reported in 2005. In 40-50% of fatal road accidents, the cause of death is head injury (a potential donor), and other causes of brain death, such as hemorrhage and brain tumors, could also increase the number of potential donors. Even if only 5-10% of deceased people donated their organs, this would mean that living people would not have to donate their organs. By promoting a program for organ donation from deceased people, the illegal market in human organs would be significantly limited, if not eliminated.and therefore it is necessary to explore this option and find real solutions to overcome the problem of organ shortage and prevent organ trafficking. The emphasis is, first of all, on »replacing« organs from living donors by taking organs from deceased donors as a viable alternative. Currently, there are 120 transplant centers in India, where 3500-4000 kidney transplants are performed annually. Within this, 150-200 cases of liver transplants have been performed in 4 transplant centers, while heart transplants have been performed occasionally in some of these centers. For 50 patients, livers were taken from dead people, and the rest from living donors. In 1998, India had 1% of road vehicles and 6% of traffic accidents at the global level. The number of such accidents increased to 10% in 2006. The total number of road accidents is estimated at around 90,000 annually. In Tamil Nadu alone, 13,000 fatalities were reported in 2005. In 40-50% of fatal road accidents, the cause of death is head injury (a potential donor), and other causes of brain death, such as hemorrhage and brain tumors, could also increase the number of potential donors. Even if only 5-10% of deceased people donated their organs, this would mean that living people would not have to donate their organs. By promoting a program for organ donation from deceased people, the illegal market in human organs would be significantly limited, if not eliminated.[37]

9. NORMATIVE BASIS FOR ACTION IN OUR COUNTRY

In analyzing the question posed, with the conclusion that statements of this type, by the nature of things, should have found their place at the beginning of our text, we have decided on a different approach - by indicating certain general guidelines or established frameworks that directly concern this matter at the international level, but in the context of considering the legal conditions in which it is carried out in our country (because they represent an integral part in considering this

37 In this regard, several such programs of organ donation and exchange from deceased persons have been implemented in India so far. Five hospitals in Tamil Nadu and eight in Hyderabad, in the period from 2000 to 2008, successfully exchanged 450 organs, at the initiative of a non-governmental organization (NGO), called MONAH Foundation. It is interesting to note that this approach has been known for a long time, so mention is made of Gujarat, which has had significant success with its eye transplant program, because the majority population of the Yuan community believes that eye donation is a form of supreme charity, and believes that there is a strong connection between "daan" (charity) and "moksha" (salvation).

complex issue). The above procedure could perhaps lead us to some more answers to the numerous questions that arise in connection with this matter. Therefore, we will address the justification of this conclusion from the beginning.

When it comes to the transplantation of parts of the human body, it must be admitted that the legal profession and science have not managed to keep up with scientific achievements in this field of medicine. Court decisions are rare and of little help, as case law and legal regulations contain a large number of outdated rules, especially when it comes to the bodies of deceased persons, which are also the main source of organs for transplantation. In many cases, the progress of science has been stopped by current legal restrictions. Rigid legal thinking had to adapt to new conditions. This observation by L. G. Castel refers, first of all, to the regulations regulating the conditions and procedure of transplantation in the 1970s.[38]

Has anything changed in this direction since then?

To answer the question posed, let us first recall that more intensive and systematic regulation of this matter has marked the period of the last twenty years or so. The changes that have occurred during this period at the international, regional and national levels indicate a greater scope and importance of legal regulation in this direction and an increasing presence of international legal norms and practices - moving towards universal solutions that states at the next (national) level of legal competence will apply, i.e. »put into practice«. We will not here deal with a detailed consideration of all the regulations governing this area, but will only indicate the general direction in their explanation by simply listing the most important ones. First of all, we are talking about the Universal Convention on Human Rights and Biomedicine with the related Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being (Paris, 1998), and the Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine in Relation to Transplantation of Organs and Tissues of Human Origin (Strasbourg, 2002). In this context, we also underline the importance of the Declaration on the Advancement of Patients' Rights in Europe, which stipulates the patient's right to information as one of the most important rights of the patient. The right to self-determination requires that the patient can freely and responsibly decide whether to undergo a certain medical procedure.[39]

In the legislative concept of our country, there are two laws in force that regulate the issue of transplantation, namely, the Law on Human Organ Transplantation[40] and the Law on Human Cells and Tissues.[41] The above laws,[42] in addition to general provisions on the transplantation of human body parts, also contain criminal law provisions (»VIII Penal Provisions, Art. 63-65. of the Law on Organ Transplantation, and »XII Penal Provisions« Art. 98-100) of the Law on Human

38 Castel, J.-G., *op.cit.,* pp. 346-347.

39 Declaration on the Promotion of Patients Rights in Europe, the so-called "Amsterdam Declaration" of the World Health Organization and the World Medical Association (1994). In the USA, the right to refuse medical treatment is considered a constitutional right derived from the right to self-determination and the right to bodily integrity, which are derived from the Duo Process Close contained in the 14th Amendment. In Europe, the right to self-determination and bodily integrity are derived from the right to human life, contained in Art. 8, paragraph 1 of the European Convention on Human Rights. Ivančić Kačer, B., *Medicinske usluge - informirani pristanak kao jedno od temeljnih prava pacijenata i transplantacija,* Zbornik radova: Uslužni poslovi, Kragujevac, 2013, pp. 688-689. When it comes to our legislation, see more about that: Petrović, D., *Eutanazija, nove dimenzije*, Beograd, 2010, pp. 18-19.

40 Official Gazette of the Republic of Serbia, No. 57/2018. of July 25, 2018 and 111/2021 of November 25, 2021, decision of the Constitutional Court.

41 Official Gazette of the Republic of Serbia, No. 57/2018, 111/2021-2024 decision of thConstitutional Court.

42 Our previous legal text regulated the transplantation of organs, tissues and cells in a simple way. This refers to the Law on the Removal and Transplantation of Human Body Parts of the SFRY (Official Gazette of the SFRY, No. 63/1990). With the entry into force of this Law, based on Art. 83, Paragraph 1 of the Law on Health Care (Official Gazette of the RS, no. 17 of 31 March 1992), the following ceased to be valid: the Law on the Removal and Transplantation of Human Body Parts for the Purpose of Treatment (Official Gazette of the RS, no. 21/81), the Law on the Removal and Transplantation of Human Body Parts for the Purpose of Treatment (Official Gazette of the RS, no. 44/91) and the Law on the Removal of Human Body Parts for the Purpose of Transplantation (Official Gazette of the SAP Vojvodina, no. 26/86).

Cells and Tissues. This means that the criminal law provisions of these laws are of a special nature and that they provide penalties for violations only of the provisions of these laws. However, this is not enough for a complete criminal law view of transplantation; it is necessary to bear in mind the provisions of criminal law that regulate the practice of medical practice in general. From this perspective, it is clear that the provisions of criminal law have a general nature, that is, they can be applied only in cases where the provisions of medical legislation cannot be applied (Lex specialis derogat legi generali).[43]

It should be emphasized that the Law on Organ Transplantation and the Law on Human Cells and Tissues represent a significant step forward in this area, because they systematically and comprehensively regulated several issues that were controversial from the aspect of existing legal solutions. At the same time, they introduced certain novelties (improvements and harmonization with modern tendencies), which, with certain limitations, implemented a more modern concept in the approach to this matter - we have come closer to the legislation of most European countries, adapted to the needs, circumstances and social reality of the RS.

Briefly, in terms of these observations.

Of the important novelties, certainly, in the first place is the simplified procedure for consent, taking organs from a deceased person for transplantation, because every adult, capable person is defined as a potential donor. However, the role of donor cannot be played by someone who opposed this during his life (explicitly - in written or oral form), i.e. if at the time of death no one of the family members explicitly opposed it (Art. 23 - a parent, spouse, common-law partner or adult child of the deceased).[44]

The law defines in detail the conditions for donation (activities of donation, testing, processing, collection, allocation, preservation, distribution, exchange ... Art. 10, Art. 11, Art. 12.[45]

It also provides for the adoption of a national organ transplantation program with clear procedures and actions, with a unified information system, and the implementation of the law is placed under the supervision of the Biomedicine Administration (Art. 41-44).[46] Health institutions and institutions for performing transplantation are precisely determined and defined (Art. 3, paragraphs 12-17). A Medical Inspector has also been introduced to carry out inspection supervision over the performance of health institutions in the field of transplantation (Art. 46-47), and the conditions for implementing safety and quality standards for human organs for transplantation have also been established. (Art. 44), for the implementation of safety standards and monitoring of the quality of human organs for transplantation (Art. 44).

The principle of unpaid donation is one of the fundamental principles of this law (»Organ donation is voluntary and without financial compensation«, Art. 5). In addition,The Transplantation Act stipulates that any procedure related to organ removal and transplantation shall be performed only if it is medically justified, i.e. if it is the most favorable treatment method (Art. 6), under equal conditions for registration on the waiting list, without discrimination (Art. 7), with the duty to respect the dignity of the organ donor (Art. 4) and the protection of personal data (Art. 36-37).[47]

43 Čejović, B., *Transplantacija delova ljudskog tela i pravo na život - krivičnopravni aspekt*, Pravni život, no. 91/1995, p. 86, 90.

44 According to previous regulations, it was stipulated that the donor: 1) during his lifetime, he consented in writing to donation in the manner prescribed by law (except if, according to a statement by family members or a close person, he changed his position afterwards); 2) during his lifetime, he did not explicitly prohibit it, and family members or another close person, in cases prescribed by law, agree to the donation in writing (Art. 50 of the Law on Organ Transplantation: 72/2009 - 180. Therefore, let us repeat here, or emphasize, that the conditions for the donation of human organs from a deceased person have been significantly changed by the new regulations. See more about this: Planojević, N., Živojinović, D., *Promet delova čovečijeg tela u našim novim propisima,* Pravni život, no. 10/2019, pp. 426-431.

45 The law specifies (Art. 24) that before removing human organs from a deceased person, the identity and the manner in which this is done are checked, as well as whether the deceased person objected to the donation of their organ for the purpose of transplantation during their lifetime.

46 Art. 8 of that law and Art. 41-44.

47 French law stipulates that doctors are obliged to perform "corpse restoration" after removing organs from a deceased person's body

The Human Cells and Tissues Act should also be interpreted in this perspective. We are therefore faced with a new concept of regulations that precisely define which healthcare institutions can submit a request to perform work in the field of human cells and tissues (procurement, processing, preservation, storage, distribution, testing), as well as which conditions cell and tissue banks must meet (Art. 3, items 26-27, l. 8). It is envisaged to simplify the issuance of permits to health institutions for performing work in the field of human cells and tissues, as well as to establish an information system in the aforementioned field (Article 19). Also, one of the novelties is the simplification of the procedure for granting consent for the use of human tissue, with the effect of avoiding unnecessary financial costs by introducing a prohibition on donation (Article 29). The law gives every adult the opportunity to prohibit the donation of their cells and tissues in writing or orally, as well as the opportunity for family members to do so at the time of death if the deceased person did not declare this during his or her lifetime (Article 28).

The main reason for adopting these legal solutions is to increase the number of organs from deceased donors needed for transplantation, i.e. to increase the number of successfully performed organ transplants for patients for whom this is the only way to cure them, while reducing waiting lists.

Precisely, by shaping such a legal procedure, it would be possible, or at least provide an opportunity, to overcome the problem of the permanent shortage of transplanted organs and increase their supply. Whether the aforementioned laws will really redirect events in that direction remains to be seen. Finally, let us conclude that although our legislation in this area is in line with the actions of the majority of European countries, there are still certain limitations in terms of goals, means and subjects in achieving this important task.as well as the establishment of an information system in the aforementioned area (Art. 19). Also, one of the novelties is the simplification of the procedure for giving consent for the use of human tissue, with the effect of avoiding unnecessary financial costs by introducing a prohibition on donation (Art. 29). The law gives every adult the opportunity to prohibit, in writing or orally, the donation of their cells and tissues, as well as the opportunity for family members to do so at the time of death if the deceased person did not declare this during his or her lifetime (Art. 28). The main reason for adopting these legal solutions is to increase the number of organs from deceased donors needed for transplantation, i.e. to increase the number of successfully performed organ transplants for patients for whom this is the only way to cure them, while reducing waiting lists. Precisely, by shaping such a legal procedure, it would be possible, or at least provide an opportunity, to overcome the problem of the permanent shortage of transplanted organs and increase their supply. Whether the aforementioned laws will really redirect events in that direction remains to be seen. Finally, let us conclude that although our legislation in this area is in line with the actions of the majority of European countries, there are still certain limitations in terms of goals, means and subjects in achieving this important task. as well as the establishment of an information system in the aforementioned area (Art. 19). Also, one of the novelties is the simplification of the procedure for giving consent for the use of human tissue, with the effect of avoiding unnecessary financial costs by introducing a prohibition on donation (Art. 29). The law gives every adult the opportunity to prohibit, in writing or orally, the donation of their cells and tissues, as well as the opportunity for family members to do so at the time of death if the deceased person did not declare this during his or her lifetime (Art. 28). The main reason for adopting these legal solutions is to increase the number of organs from deceased donors needed for transplantation, i.e. to increase the number of successfully performed organ transplants for patients for whom this is the only way to cure them, while reducing waiting lists.

for transplantation. Attacks on the integrity of a corpse are also punishable by criminal sanctions. Kandić Popović, Z., *Donatorstvo organa - primer francuskog prava*, cit. according to Klajn tatić, V., *Uzimanje organa ..., op. cit.,* p. 285.

Precisely, by shaping such a legal procedure, it would be possible, or at least provide an opportunity, to overcome the problem of the permanent shortage of transplanted organs and increase their supply. Whether the aforementioned laws will really redirect events in that direction remains to be seen. Finally, let us conclude that although our legislation in this area is in line with the actions of the majority of European countries, there are still certain limitations in terms of goals, means and subjects in achieving this important task.[48]

10. CONCLUSION

Although much has been written about the transplantation of human body parts from various aspects, it is important to note that there is still a whole series of confusing tendencies, mixed explanations, justifications and criticisms. But what is important is that when this extremely complex issue is broken down into parts, when one begins to think point by point, from the perspective of the application of solutions in practice to date, it can be concluded that the regulations governing this area of medicine (historically and comparatively observed) are getting better, to which extent their future effectiveness should also be recognized.

In this context, we should also consider our new transplantation regulations, the Organ Transplantation Act and the Human Cells and Tissues Act, which, with certain limitations, have introduced significant innovations (improvements and harmonization with modern tendencies in the approach to this matter). However, although it is important for practice that transplantation is procedurally precisely regulated, events from individual lives offer as a reality the sad statistics according to which, currently, a million people in the world are waiting for an organ transplant, waiting for years, and of the total number of patients on waiting lists, according to official data - more than one third of them die while waiting for an organ, another third remain on the waiting list, and only one third receive a transplanted organ

How to solve the increasing demand for organs for transplantation on a global level and the simultaneous shortage of suitable organs? Is there a »right« solution? Perhaps, after all, »another way« must be found for the solution!? And only in this sense, our position on the need for further improvement of ideas in the direction of overcoming the striking differences between the set goals and the achieved results, i.e. between the projected tasks related, on the one hand, to increasing the supply of cadaveric organs needed for transplantation, and on the other, to preserving the autonomy of each deceased person as a potential donor.

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48 In the majority of countries with successful transplantation programs, presumed consent is applied, which was also introduced in our country by the new law. This model, for example, is also applied by Croatia, which has emerged as the first in Europe in terms of the number of potential donors - 40 per million inhabitants. Serbia currently has 4-6 donors per million inhabitants, which places our country at the very bottom of the European organ donor rankings (available on the portal: novosti.rs, date of access 18.04.2021). Spain and Italy stand out in terms of the success of these programs, and more than a thousand patients are waiting for a diseased organ replacement (available on the portal: DMN dmn/rtvvesti.vojvodina, Novi Sad, date of access: 02. 01.2020).

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TRANSPLANTACIJA ORGANA - RAZLIČITE STRATEGIJE KONTROLE

REZIME

Transplantacija ljudskih organa i tkiva u terapijske svrhe praktikuje se od polovine prošlog veka. Započela je na vrlo primitivan način još u staroj Indiji (i danas se jedan metod transplantacije naziva "indijskom metodom"), preko 16. veka (1551), kada je u Italiji izvedena prva slobodna transplantacija dela nosa, da bi se do danas razvila u nezamenljiv medicinski postupak u cilju spašavanja i produžavanja ljudskog života. Hiljade stranica stručne literature, beleške, polemičke rasprave, atipični medicinski članci, zapisi na marginama pročitanih časopisa ili knjiga iz filozofije, sociologije, krivičnopravne literature... o događajima ove vrste, svoj stav su zauzeli i predstavnici crkve.

Razumevanje našeg pogleda na ovu kompleksnu i veoma komplikovanu problematiku nalaže da se određenim rešenjima na međunarodnoj sceni posveti veća pažnja, posebno tamo gde postoje izvesna prožimanja, određena ppklapanja ali i razilaženja. Uvek je dobro čuti i drugo mišljenje, jer ono stavlja na razmišljanje. Upravo stoga, u razmatranjima koja slede pokušali smo da odgovorimo na neke od mnogobrojnih i raznovrsnih pitanja u kojima se ova dodiruju, ali često puta i razilaze, kako sa gledišta pravih propisa, tako i iz ugla medicinske i sudske prakse, ovog puta iz perspektive nekih zemalja članica EU (Nemačke, Poljske, iznoseći i stanovište Katoličke crkve) na jednoj strani, i u perspektivi drugačijih moralnih, duhovnih, kulturnih i drugih vrednosti - Indije i Iraka, na drugoj.

Ključne reči: *transplantacija organa, "option in sistem", "option out sistem", postignuti rezultati.*