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## International standards and domestic legislation on human organ donation and transplantation

### Міжнародні стандарти та вітчизняне законодавство про донорство та трансплантацію людських органів

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#### Abstract

The article analyzes international standards for the quality and safety of organs for transplantation. Azerbaijan, like other countries, strictly prohibits organ trade. It criminalized the forcible removal of organs, fraud or coercion, and the buying or selling of organs. The objective of the work is to analyze the Oviedo Convention and the Council of Europe Convention on Combating Trafficking in Human Organs, as well as other legal acts, in comparison with the criminal and administrative laws of Azerbaijan. To achieve the objectives of the research, the author of the article used such methods as analysis and synthesis, the formal-legal method and the comparative-legal method. As a result of the research carried out, it was concluded that Azerbaijan should improve its relevant legislation taking into account the norms of these conventions. In particular, the State's priority should be to emphasize the donation of artificial organs and tissues instead of human donation.

**Keywords:** transplantation, trafficking in human organs, human rights, the principle of dignity, Azerbaijani legislation.

#### Introduction

Human organ transplantation entered a new stage of development that has created a new field of science – transplantology. Despite the transplantation research was conducted for the first time in Europe (Grigoriev et al., 2001), the first successful kidney transplant was performed in the United States in the 50s of the last century.

#### Анотація

У статті проаналізовано міжнародні стандарти якості та безпеки органів для трансплантації. В Азербайджані, як і в інших країнах, суворо заборонена торгівля органами. Він криміналізував примусове вилучення органів, шахрайство чи примус, а також купівлю чи продаж органів. Метою роботи є аналіз Ов'єдської конвенції та Конвенції Ради Європи про боротьбу з торгівлею органами людини, а також інших правових актів у порівнянні з кримінальним та адміністративним законодавством Азербайджану. Для досягнення поставленої мети дослідження автор статті використав такі методи, як аналіз і синтез, формально-юридичний метод та порівняльно-правовий метод. В результаті проведеного дослідження було зроблено висновок, що Азербайджану необхідно вдосконалити відповідне законодавство з урахуванням норм цих конвенцій. Зокрема, пріоритетом держави має стати акцент на донорстві штучних органів і тканин замість донорства людини.

**Ключові слова:** трансплантація, торгівля людськими органами, права людини, принцип гідності, законодавство Азербайджану.

For the first time a heart was transplanted from a dying person to a patient in the 60s of the last century. Transplantology, as one of the promising fields of medical science, was formed with regard to the transplantation of human organs and tissues.

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Since then, transplantology has turned into a powerful branch of medicine, but criminal activity related to transplantology has also gained serious scale.

The international legal fight against crime in this field should be ensured together with organizational, economic and educational measures, as stated in the National Action Plan for 2020-2024 on the fight against human trafficking in the Republic of Azerbaijan. A more appropriate policy should be the donation of artificial organs and tissues, which should be established in light of the objectives of the Oviedo Convention and its Protocol, rather than human donation.

The research tasks:

Evaluate the Discrepancies Between National Legislation of Azerbaijan and the Protocol on Transplantation:

Conduct a comprehensive analysis of the Protocol concerning Transplantation of Organs and Tissues of Human Origin.

Compare the provisions of the Protocol with the applicable Law of the Republic of Azerbaijan related to organ and tissue transplantation.

Assess the extent to which the internal legislative act aligns with the Protocol and identify any areas where the Protocol provides superior regulation.

Addressing the "Right to Personal Inviolability" and Prevention of Criminal Interests:

Propose amendments to Article 17 of the Protocol to include a provision stating that human organs and tissues transplantation is prohibited in the absence of the deceased person's will.

Examine the implications of such an amendment on preventing criminal interests and protecting the "right to personal inviolability" of the deceased person.

Critical Examination of Protocol Wording for Safeguarding Human Dignity:

Evaluate the wording of Article 21.1 of the Protocol and its implications in safeguarding human dignity.

Recommend changes to Article 21.1, specifically proposing a modification to broaden the scope of

the norm to include various aspects such as social and physiological factors.

Addressing Gaps in National Legislation Against Illegal Organ Trafficking:

Analyze the existing criminal and administrative legislation of the Republic of Azerbaijan related to illegal organ transplantation.

Identify gaps in coverage and propose amendments to strengthen the legal framework, considering the transnational nature of organ trafficking.

Assess the need for and implications of recognizing the Convention against Trafficking in Human Organs by the Republic of Azerbaijan. Promoting International Legal Cooperation in Combating Organ Trafficking:

Evaluate the effectiveness of international legal cooperation in combating illegal transplantation of human organs and tissues.

Analyze the role of criminal and administrative legislation in the Republic of Azerbaijan in supporting international efforts.

Propose strategies for enhancing international legal cooperation against transnational crimes related to organ trafficking.

Exploring Comprehensive Approaches to Prevent Organ Trafficking:

Examine the limitations of relying solely on international legal cooperation in addressing the increasing pace of trade in human organs.

Identify additional measures beyond legal frameworks, such as public awareness campaigns or ethical guidelines, to prevent and combat illegal organ transplantation.

Assess the feasibility and potential effectiveness of these additional measures in complementing legal efforts.

### **Theoretical Framework or Literature Review**

This section delves into the multifaceted challenges surrounding organ donation and trafficking globally. The authors shed light on diverse issues, ranging from the lack of standardization in defining brain death and organ donation criteria to the role of healthcare professionals in perpetuating illegal organ transplantation. The findings underscore the

urgency for international cooperation, legal reforms, and responsible AI frameworks to address these challenges and enhance organ donation practices while curbing illicit organ trafficking.

In the article «Worldwide Barriers to Organ Donation» Ivan Rocha Ferreira Da Silva and Jennifer A. Frontera (2015) claim, that the lack of standardization of brain death and organ donation criteria worldwide contributes to a loss of potential donors. Major barriers to donation include variable clinical and legal definitions of brain death; inconsistent legal upholding of brain death criteria; racial, ethnic, and religious perspectives on organ donation; and physician discomfort and community misunderstanding of the process of donation after cardiac death. Limited international legislation and oversight of organ donation and transplant has contributed to the dilemma of organ trafficking. The authors sum up, that an urgent need exists for a global standard on the definition of brain death and donation after death by cardiac criteria to better regulate organ donation and maximize transplantation rates. Unified standards may have a positive effect on limiting organ trafficking.

In the article «A Responsible AI Framework for Mitigating the Ramifications of the Organ Donation Crisis» Salih Tutun, Antoine Harfouche, Abdullah Albizri, Marina E. Johnson & He Haiyue (2022) proposed a responsible AI framework that integrates network science and artificial intelligence to identify consent outcomes for organ donation. The proposed framework includes three phases: collecting and pre-processing data, creating new features and identifying root causes of family refusal, and training and testing models to predict the probability of families granting consent for organ donation. The designed artifact included collaborative decisions and network measures, increasing explainability through network science. It integrated human reviews and assessment of risks which increases correct and interpretable predictions. The authors believe that results can help encourage organ donations and reduce the illegal organ trade.

In the article «Formula to Stop the Illegal Organ Trade: Presumed Consent Laws Formula to Stop the Illegal Organ Trade: Presumed Consent Laws and Mandatory Reporting Requirements for Doctors and Mandatory Reporting Requirements for Doctors» Sheri R. Glaser (2005) claims that currently the international community has not adequately responded to this problem. To reduce or eliminate organ trafficking, countries should

(1) strengthen their laws against this crime and remove any loopholes that encourage corruption; (2) adopt presumed consent laws to increase organ supply legally, which would reduce the number of organs obtained on the illegal black market; and (3) impose mandatory reporting requirements on doctors who suspect that a patient has obtained an organ from a trafficked person. If these recommendations are not followed, organ trafficking will continue to persist, exploiting the less fortunate and violating the autonomy of its victims.

In his article «Organ Trafficking: Why Do Healthcare Workers Engage in It?» Trevor Stammers (2022) considers organ trafficking in all its various forms is an international crime which could be entirely eliminated if healthcare professionals refused to participate in or be complicit with it. Types of organ trafficking are defined and principal international declarations and resolutions concerning it are discussed. The evidence for the involvement of healthcare professionals is illustrated with examples from South Africa and China. The ways in which healthcare professionals directly or indirectly perpetuate illegal organ transplantation are then considered, including lack of awareness, the paucity of both undergraduate and postgraduate education on organ trafficking, turning a blind eye, advocacy of organ commercialism, and the lure of financial gain.

In her article «Understanding the challenges to investigating and prosecuting organ trafficking: a comparative analysis of two cases» Frederike Ambagtshee (2021) aims to explain the legal, institutional and environmental factors that affected the investigation and prosecution of two organ trafficking cases: the Netcare case, exposed in South Africa and the Medicus case, exposed in Kosovo. Both cases constituted globally operating criminal networks involving brokers and transplant professionals that colluded in organizing illegal transplants. Recommendations to improve enforcement of organ trafficking include improving identification of suspicious transplant activity, strengthening cross-border collaboration and enhancing whistleblower protection laws.

Summary of Main Findings:

"Worldwide Barriers to Organ Donation":

Authors Ivan Rocha Ferreira Da Silva and Jennifer A. Frontera (2015) emphasize the need for standardized criteria for brain death and organ donation globally. Barriers include variable definitions of brain death, legal inconsistencies,

and cultural perspectives. They argue for unified international standards to regulate organ donation, reduce physician discomfort, and address the organ trafficking dilemma.

"A Responsible AI Framework for Mitigating the Ramifications of the Organ Donation Crisis":

Salih Tutun et al., (2022) propose an AI framework integrating network science to predict consent outcomes for organ donation. The three-phase framework enhances explainability and incorporates collaborative decisions and risk assessment. The authors believe this approach can encourage organ donation, mitigate the crisis, and combat illegal organ trade.

"Formula to Stop the Illegal Organ Trade":

Sheri R. Glaser (2005) argues for legal reforms to combat organ trafficking, advocating for strengthened laws, presumed consent, and mandatory reporting by doctors. The author warns that failure to implement these measures may perpetuate organ trafficking, exploiting vulnerable populations and violating individual autonomy.

"Organ Trafficking: Why Do Healthcare Workers Engage in It?":

Trevor Stammers (2022) explores the involvement of healthcare professionals in organ trafficking, discussing types of organ trafficking and the role of professionals in perpetuating illegal transplantation. Factors such as lack of awareness, inadequate education, and financial motives contribute to this issue. Stammers suggests that healthcare professionals refusing to participate could eliminate organ trafficking.

"Understanding the challenges to investigating and prosecuting organ trafficking":

Frederike Ambagtshee (2021) analyzes two organ trafficking cases, the Netcare case in South Africa and the Medicus case in Kosovo, highlighting legal, institutional, and environmental factors affecting investigation and prosecution. Recommendations include improving identification of suspicious activity, enhancing cross-border collaboration, and strengthening whistleblower protection laws to combat organ trafficking globally.

## Methodology

This article undertakes a comprehensive examination of the legal framework governing

organ transplantation in the Republic of Azerbaijan, employing a range of scientific research methods. The primary focus is on evaluating the adequacy of domestic legislation concerning organ transplantation in comparison to the international standards outlined in the Protocol on Transplantation of Human Organs and Tissues. The author utilizes analysis and synthesis, formal legal methods, and the comparative legal method to scrutinize existing laws, identify deficiencies, and propose specific amendments to enhance the legal landscape for organ transplantation.

Analysis and synthesis:

Analysis: The author conducts an analysis of the Protocol on Transplantation of Human Organs and Tissues and the legislation of the Republic of Azerbaijan. The analysis reveals that, despite the initial conclusion about more complete regulation of the domestic legislation, there is a higher level of regulation in the Protocol.

Synthesis: Based on the analysis, a conclusion is made about the need to adapt the national legislation of Azerbaijan to the Protocol, in particular, the article states that the adaptation should continue.

Formal and legal method:

The author uses the formal legal method to argue for making specific changes to the text of the Protocol. For example, the author proposes to include the rule that transplantation of human organs and tissues is prohibited in the absence of the donor's will. This approach is supported from the point of view of the "right to personal integrity" of the deceased person.

Comparative legal method:

The author compares the provisions of the Protocol with the internal legislation of the Republic of Azerbaijan and concludes that the regulation in the Protocol is superior. It also compares the provisions of specific articles with changes that, in the author's opinion, can improve the protection of the rights and dignity of individuals in the context of organ transplantation.

These methods allow the author to identify shortcomings in the current legislation, point out the advantages of the Protocol and propose specific changes to improve the situation in the field of organ transplantation. Analysis and synthesis help to reveal the problem and

highlight the need for changes, the formal-legal method is used to substantiate specific proposals, and the comparative-legal method helps to establish the differences between various norms and determine the optimal way to achieve the goal.

#### Rigor of the Study:

**Source Selection:** The study relies on primary sources, including the Protocol on Transplantation of Human Organs and Tissues, and the domestic legislation of Azerbaijan. The selection of these sources is crucial for a thorough understanding of the legal framework.

**Quality Evaluation:** The quality of sources is assessed based on their relevance to the topic and the authority of the legal documents. The use of internationally recognized standards, such as the Protocol, adds credibility to the study.

**Results Interpretation:** The author interprets the results by critically evaluating the identified shortcomings in domestic legislation, highlighting the Protocol's advantages, and proposing specific changes. The conclusion underscores the urgency of continuous adaptation to international standards in the field of organ transplantation.

In essence, the combination of analysis, synthesis, formal legal methods, and comparative legal methods employed in this study offers a robust foundation for identifying, understanding, and rectifying deficiencies in the current legal framework for organ transplantation in Azerbaijan.

## Results and Discussion

### 1. Transplantology and the legal aspects

Transplantology is a field of biology and medicine that studies the problems of transplantation and develops methods of preservation of organs and tissues, creation and use of artificial organs. As a field of science, it covers surgery, resuscitation (restoration), anesthesiology (sedation, pain relief), immunology (medicine that studies inviolability), pharmacology and other biomedical and medical technologies. It mainly involves the regeneration of diseased organs and tissues as a form of fighting against human diseases.

As human organs and tissues transplantation also covers the problems having legal, as well as

personal, somatic (comes from the Greek) nature, so its legislative solution has also emerged as a special problem. Since many legal and criminal problems arise in the process of transplantation, its complex legislative regulation and issues of international legal cooperation in a transnational context should also be resolved. Since the transplantation and donation of human organs and tissues is a matter of human rights and freedom, dignity and privacy, the norms of the Universal Declaration of Human Rights (United Nations, 1948), the International Covenant on Economic, Social and Cultural Rights (1966b), the International Covenant on Civil and Political Rights (1966a), which contain universally recognized standards must be taken into consideration for the creation and interpretation of special rights. Norms containing universally recognized standards determine the direction of other, specific areas by creating international human rights law (Guseinov, 1998; Toebes, 2001). The right to receive health and medical care, which is expressed in international acts (e.g., Article 25 of the Universal Declaration of Human Rights; Article 12 of the International Covenant on Economic, Social and Cultural Rights, etc.) has led to the adoption of new international acts.

Since it is mainly in the category of economic and social rights, states participate in international cooperation in this field (e.g., the 1981 Declaration of Lisbon on the Rights of Patients on the ethical criteria of doctors regarding the rights of patients; the 2005 UNESCO Universal Declaration on Bioethics and Human Rights, etc.) under the norms that do not create a binding obligation. In the personal rights category, conventional norms on personal rights, personal integrity, respect for human dignity, etc. could not achieve comprehensiveness. For example, the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine has not been ratified even by the member states of the Council of Europe (UK, FRG, etc.) up to this date. In this field, universal recognition of adopted international obligations is delayed.

Only 28 countries have met the legislative requirement set by the 2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (World Health Organization, 2016).

In terms of adoption of binding legal documents, the main exceptions are acts of the European

Union (e.g., the 2002 European (Brussels) Charter on Patients' Rights). Currently, one of the international legal acts that stands out for its unifying importance is the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of April 4, 1997 (the Republic of Azerbaijan is not a signatory to the Convention). It is also known as the Oviedo Convention because it was adopted in Oviedo, Spain. The Convention (Art.1) specifies the necessary legislative measures to be implemented for the safeguard human rights and dignity (Council of Europe, 1999). During the application of biology and medicine, the concerned parties can define more comprehensive rules compared to the Convention regulation (Art.27). The application of biology and medicine not only benefit humanity, but may lead to acts endangering human life, wellbeing or dignity through genetic processes (Sollie, & Duwell, 2009).

Another important aspect of the Convention is the obligation of states to be open to public discussions and consultations during the application of biology and medicine. For fulfilling this obligation, the concerned parties can establish their own procedures. In particular, the domestic legislation (Constitution of the Republic of Azerbaijan, 1995, Art.29) envisages increasing the role of medical personnel, teachers, and society in the application of biology and medicine by establishing ethical commissions for organ donation and transplantation (Art.28). Subordination of professional standards in the healthcare system to human interests, safeguard rights and dignity, the primacy of human dignity with regard to any commercial or scientific interest should find its expression in the domestic legislation. The primacy of human rights and dignity in the Convention (Art.2); ensuring equitable access to health care (Art.3); development of professional standards (Art.4), protection of each individual as a representative of the human race should be ensured in the course of research (Mammadov, & Mustafayeva, 2013). The Convention only regulates preventive, diagnostic, therapeutic and scientific research activities covering human biology and medicine.

The activity of European international judicial bodies (the "Sunday Times" case of the European Court of Human Rights, 1979 (Janis et al., 2008; R.R. v. Poland-HUDOC, 2011) and the "Brustle v. Grenpes" case of the European Court of Justice, 1997 (European Union, 2011) pertaining to the primacy of human health in biotechnology

and medicine over any scientific research and commercial activity is expanding the general practice on the need to safeguard rights and freedoms.

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine was enacted as an act of the Council of Europe in the context of the 1950 European Convention for the Protection of Human Rights and Freedoms (Council of Europe, 1997). It means that the limit of individual rights expressed in Article 8.2 of the 1950 European Convention for the Protection of Human Rights and Freedoms is also valid for the Oviedo Convention. It is true that in the Oviedo Convention (Art.7) these exceptions have particularity. In this sense, the exceptions stated in Article 8 of the European Convention for the "protection of the country's economic stability, public order or morality and national security" are not covered by the general exceptions of the Oviedo Convention (Art.7.1). It appears that, in the context of the Oviedo Convention, it is not appropriate to make the realization of fundamental rights mainly relating to the protection of human rights in the field of health, dependent on the country's economic well-being, public order or morals, and national security.

The Oviedo Convention establishes the framework principles for the realization of human rights and human dignity of the human being with regard to the application of biology and medicine. For this reason, it has specific annexes according to the subject of regulation, one of which is the 2002 Protocol to the Convention on Transplantation of Human Organs and Tissues (the Protocol entered into force in 2006, the Republic of Azerbaijan is not a signatory to this Convention).

This Protocol applied to the transplantation of human organs and tissues carried out for therapeutic purposes and also haematopoietic stem cells (Art.2). Reproductive organs and tissues, embryonic organs, blood elements are not regulated by the Protocol (Council of Europe, 2002). In this field, the Republic of Azerbaijan is also in the stage of development of its own legislation. For example, the 1997 Law of the Republic of Azerbaijan "On Protection of Population Health" coincided with the adoption of the Oviedo Convention. Subsequently, the 1999 Law "On Transplantation of Human Organs and Tissues" (Law No. 360-IQ, 1997; Law No. 726-IG, 1999), which was replaced by a new legislative act, established a specific legal

regulation in this area. Given the application of biotechnology development in the field of medicine, on October 20, 2020, a new Law of the Republic of Azerbaijan "On Donation and Transplantation of Human Organs and Tissues" was adopted. The new law was enacted as of January 1, 2022. Article 3.3 of the Law prescribes the areas covered by it as per the subject of regulation of the Protocol.

Besides some legal instruments (the Constitution of the Republic of Azerbaijan, the Law of the Republic of Azerbaijan "On Protection of Population Health", this Law, along with other regulatory acts), Article 2 of the Law mentions the international agreements on organ donation and transplantation that the Republic of Azerbaijan is a party. Although the Republic of Azerbaijan is not bound by the Oviedo Convention and its Protocol, it ensures the harmonization of its domestic acts with international norms. In particular, scientific and technical cooperation with foreign countries and international organizations in organ donation and transplantation in accordance with international law; the organs and tissues exchange arrangements are specified in the Law (Art.33).

2. The rights of a living donor, the problem of donation of a deceased person (non-living or deceased donors) and the principle of dignity.

Both domestic legislation and international legal norms have set specific rules and conditions for the removal of donor organs for transplantation from a living donor. One of the issues of special importance of the Protocol and not established in the legislation is the risk assessment mechanism for the donor. Article 12 of the Protocol specifies the right to have access to independent advice by a competent health professional having appropriate experience and who is not involved in the transplantation, on the assessment of possible risks during organ transplantation. Specifically, information on the "right to independent advise" is defined as an international legal obligation for the concerned parties in the Protocol. Although the rights and duties of the living donor are listed in Article 19 of the Law and the right to "receive complete and objective information about transplantation from a health care institution, including possible complications" is established in Article 19.1.1, it cannot be considered the same as the "right to receive independent advice" provided for by the Protocol.

It is true that Article 19.1.1 of the Law specifies to "...get complete and objective information about complications." However, it has substantive legal content. An "independent expert" is needed for its provision. In this sense, the Law should include the rule "to receive complete and objective information about complications from an independent professional having medical ability and knowledge." The relevant rule is one of the procedural conditions before transplantation. The next issue is that the right to "...informed consent" in Article 17 of the Law is given as the right to "consent of the living donor" in Article 13 of the Protocol. "Consent" should mean that it is not only against legality or personal rights, but also not against morality (Koru, 2021). Note that, a detailed definition of "informed consent" is expressed in the Law (in the Article of basic concepts, Art.1.1.10) compared to the Protocol.

Subject to this article, the following are the absolute conditions:

- prohibition of forcing the removal of any personal organs;
- complying with the principle of voluntariness in the transplantation of organs from the living donor;
- certified application of the informed consent of the living donor in writing;
- special form of the informed consent application;
- notarized testimony of close relatives during organ transplantation from the living donor;
- entering information on the informed consent of the living donor into the register of living donors (Art.17.2).

As an established part of the right to informed consent of the living donor, Articles 19 and 20 of the Law also cover the living donor's medical (Art.19.1.4; Art.20), labor (Art.19.1.5), social (Art.19.1.6) and other state guarantees. The right to informed consent of the living donor is one of the basic somatic (medical) rights and is generally guaranteed by the individual's constitutional right to "freedom of information." The right to "informed consent" in the field we have studied ensures the safeguard rights of donors in the donor-doctor relationship by determining the doctor's responsibility (Law No. 360-IQ, 1997). The exception to this right in special cases is compatible with the convention norm (Art.26) (Council of Europe, 1999) and the legislative norm (Art.28).

The legislation of the Republic of Azerbaijan on the organs and tissues transplantation of the

living donor envisages a more comprehensive regulation than the Convention, with very few exceptions (for example, the "right to independent advice" in Article 12 of the Protocol).

### 3. The problem of deceased person (corpse) donation and the principle of dignity

As mentioned, since the human organs and tissues transplantation is related to a number of serious ethical, psychological, and religious issues, its legal and legislative solution also has diversity in the legislation of individual states, and this diversity is changing day by day. For example, in the Swiss Confederation, the previous Law of 2004 established the exact opposite concept with a new amendment. With the new Law "On Transplantation and Donation of Human Organs" adopted as a result of the referendum held on May 15, 2022 (60.2% vote), donation is based on the presumed "silent consent". This trend is also found in other countries. The United Kingdom, which stands out for its conservatism, with the recent 2020 (Carey and Max law) legislative change, automatically considers people aged 18 and over to be organ donors, provided that the person has not expressed objection to organ donation in writing before their death.

According to anti-donation model applicable in the vast majority of states (e.g., Swiss Transplant Act of 1988; US National Organ Transplant Act of 1984; the Federal Law of Germany on Donation, Collection and Transplantation of Organs and Tissues of 1997 as amended on May 25, 2012, if a person has not given voluntary consent for donation before his/her death, his/her organs cannot be taken even after his or her death.

The presumed "silent consent" in donation, which we can express as the Swiss model, is established in the legislation of the states mentioned, including the legislation of the Republic of Azerbaijan (e.g., the 1997 Law of the Republic of Azerbaijan "On Protection of Population Health"; the 1999 Law "On Transplantation of Human Organs and Tissues, etc.) against the presumed "consent" or "requested consent." The presumed "consent" or "requested consent" requires the documented consent of the persons before their death and of their relatives after their death for organ and tissue transplantation. For example, under the US National Organ Transplant Act of 1984 (US Congress, 1984), the consent document is known as a "donor note." According to the "presumed

consent" applied in the United States and Australia, it is considered an objection to donate if it cannot be proven otherwise (e.g., there is no registration in the donor database, registration of consent for donation in the passport) according to the "presumed consent" applied in Australia.

The main argument of the initiators of the 2022 Act of the Swiss Confederation, which should enter into force no earlier than 2024, as well as the recent 2020 Carey and Max Act of Great Britain, is that there are serious problems in securing donations. For preventing abuses, the new Swiss legislation has also significantly enhanced the role of relatives of deceased persons in relation to donation. However, these arguments cannot be considered fair in terms of safeguard personal rights and dignity. Until recently, in some countries (Latvia) clandestine removal of tissues and organs from corpses for commercial purposes in exchange for medical equipment (from Germany) was observed as well (Neethu R. Elberte v. Latvia, 2015). At the beginning of 2005, the European Parliament announced a list of countries where trafficking in human organs is widespread (Moldova, Ukraine, Romania, Estonia, Central Asia). In the current chaos caused by Russia's military aggression against Ukraine, it is possible that this problem will deepen.

As a rule, relatives do not give consent to the donation of a dying person, but wish for his/her recovery. The last thing they may think about is the "obligation" of the relatives to inform the competent authority about the donation consent. Of course, cases of consent to the removal of organs from a person (potential donor) whose death is obvious (for example, in cases of serious accidents) may constitute an exception. In this sense, the provision of data privacy in the secure national online registry, which allows access to donation consent before the death of all persons who have reached the age of 16 in the Swiss legislation we have described, also seems problematic. The inability to express objection in advance for various reasons, the existence of cases of abuse, including criminal cases, does not exclude that this model leads to more serious dangers in societies where democratic values and human rights have not been fully established. Murder for organ removal is also seen in legal states. As proof of this is the "Doctor's case" in the U.S. California Supreme Court in 2008 (Mustafaeva, & Mamedov, 2010). Illegal transplants have also been found in India, Brazil, Ukraine, Croatia, Bulgaria, Venezuela and other countries.



As a rule, there are no unloved relatives at the hospital, and what beloved relative would think about a transplant at this moment? They are praying for healing at this time. That is what is ethical.

The European Court of Human Rights, in a number of its decisions, drew attention to the uncertainty in the legislation of the states in the decision mechanism of relatives. For example, in 2015, the European Court of Human Rights (ECHR) in its decision on the case "Petrova v. Latvia" noted the non-realization of the right of relatives to consent due to the absence of the obligation to ask the consent of the medical personnel in the legislation (Petrova v. Latvia, 2014; Neethu R. Elberte v. Latvia, 2015).

We believe that (as noted by the Non-Party Committee of the Swiss Parliament (Swissinfo, 2022) "silent donation" contradicts the principle of inviolability of human dignity. It is not inconceivable that in this way the commercial removal of organs from people who did not consent to donation *Elbert v. Latvia* (Neethu R. Elberte v. Latvia, 2015) will not be carried out, and this situation will not lead to the creation and increase of criminal cases.

The inviolability of a person is related to his/her dignity. Dignity is a person's right to respect...quality. It is achieved by the development of a personality that has realized its freedom, equality and protection. Dignity is the right of a person to be valued and respected for their own sake, and to be treated ethically. The donation problem should be solved taking into consideration of the general position of the European Court of Human Rights on "inviolability of personality", as well as international acts (The International Covenant on Civil and Political Rights (Art. 7): ... no one shall be subjected without his free consent to medical or scientific experimentation; the norms on dignity of the Oviedo Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Art.1; 2) (the Republic of Azerbaijan is not a signatory to this Convention) and the 2002 Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin.

The new Law of the Republic of Azerbaijan "On Donation and Transplantation of Human Organs and Tissues" adopted on October 20, 2020 is based on the "requested consent" model. The legislation of the Republic of Azerbaijan was

established based on the content of the 1997 Oviedo Convention and its Protocol on the Transplantation of Human Organs and Tissues to solve this problem. The new legislation of the Republic of Azerbaijan has undergone a conceptual change in accordance with the Oviedo Convention and its Protocol. Thus, in the new Law, the institution of donation of human organs and tissues envisages "removal of organs from a deceased person." And organ donation from a living person contains a special case.

The Protocol specifies the cases in which it is not allowed to remove an organ from a deceased person. However, the new legislation of the Republic of Azerbaijan regulates "removal of organs from a corpse" in more detail than the Protocol. Subject to the first part of Article 16 of the Protocol, organs or tissues shall not be removed from the body of a deceased person unless that person has been certified dead in accordance with the law. Subject to the second part of Article 16 of the Protocol, the next restriction condition is provided. According to that article, the doctors certifying the death of a person shall not be the same doctors who participate directly in removal of organs or tissues from the deceased person, or subsequent transplantation procedures (Council of Europe, 2002). Article 25 of the Law "On Donation and Transplantation of Human Organs and Tissues" further expands the scope of restrictions on organ and tissue donation. The Protocol does not specify the mechanism for determining biological death or brain death. The rules for solving this issue are provided in the 1997 Law of the Republic of Azerbaijan "On Protection of the Population Health." (Law No. 360-IQ, 1997) In accordance with the Law "On Protection of Population Health", the decision of the medical council and the consent of the health care institution are taken as the basis for biological death. For excluding abuse or any illegal interest factor, as in the relevant article of the Protocol, the Law prohibits the participation of the transplant doctor and transplant coordinator in confirming the moment of death of the donor.

As per Article 17 (consent and authorization) of the Protocol on transplantation of human organs and tissues, the appropriate wording of the Law attracts attention due to its wider content. Legislation of the Republic of Azerbaijan does not rely on the "silent consent" or "soft model" formula established in European countries, but on the "presumed consent." It is Article 21.1 of the Law that states the principle of consent to the removal of donor organs from a deceased person for transplantation. If a person during his/her

lifetime gives his/her written consent to the transplantation of his/her organs, for educational and scientific purposes, in accordance with Article 22.1 of this Law, after his/her death, his/her donor organs can be used for transplantation, educational and scientific purposes. Article 22 specifies the position of a person regarding his/her consent to the removal of his/her organs and tissues for transplantation after death or his/her objection to remove his/her organs.

Note that subject to the requirement of Article 22.1 (the consent to the removal of organs for transplantation after the death of a fully functional adult during his/her lifetime or the objection to remove organs is executed by an application approved in accordance with Article 22.6 of this Law...) donation institution is based on the "presumed consent." Why "consent"? Such a form of consent to the removal of a person's organs after death for transplantation or the objection to the removal is subordinated to the requested consent form. That is, there is a necessity of formalization for the waiver application. Subject to the previous legislation, it was possible to become a donor by registering a person with the national health care bodies based on an approved official donor document. Donation was not possible if there was no such document.

What does the non-declaration of will on donation mean? Article 21.3 of the Law states that if a person refuses to donate in writing during his/her lifetime, it is not allowed to take organs from his/her corpse for transplantation after his/her death. Contrary to this norm, if a person did not refuse donation in writing during his/her lifetime, if it is possible to remove his/her organs from his/her corpse for transplantation after his/her death? Non-declaration of will on donation replaces the former "strict" or "requested consent" model by the new one (e.g., according to the Swiss model), which "automatically becomes a donor if there is no written objection to donate organs."

This situation is also confirmed by Article 21.4 of the Law (In case of brain death as a result of an accident and natural disaster, it is allowed to take organs for transplantation from the deceased persons who did not object donation in writing during their lifetime and who are not relatives specified in Article 21.2 of this Law). Such a rule is based on the written "presumed consent" specified in Article 21.1 of the Law, as well as the Constitution of the Republic of Azerbaijan (... medical, scientific and other experiments cannot

be carried out on anyone without their voluntary consent) (Constitution of the Republic of Azerbaijan, 1995). It contradicts Article 46.III and can be considered as an unethical, moral aspect of the Law. Thus, there is a tendency of discrimination in relation to the deceased persons who did not consent to donation during their lifetime or did not declare their will about it or did not have the opportunity to do so. Universal international law (e.g., Article 130 of the 1949 Fourth Geneva Convention relative to the Protection of Civilian Persons in Time of War requires detaining authorities to ensure that internees who die while interned are honorably buried, if possible according to the rites of the religion to which they belonged...) (International Humanitarian Law Databases, 1949) expressed to respect the deceased persons after their death in the context of universally recognized human rights. Acceptance of the deceased person's body as a donor despite the absence of a direct expression of will contradicts Article 2 of the Oviedo Convention (the interests and ... of the human being shall prevail over the sole interest of society or science). Article 18 of the Protocol states that during removal the human body must be treated with respect. However, this obligation cannot be considered sufficient in terms of the protection of human dignity. The "presumed consent" in the Protocol should be safeguarded against all abuses. Note that although donation is considered normal for health care institutions, being a donor is related to a psychological process. The original basis of the principle of informed consent can be linked to the inseparability of human rights and freedom established by the French bourgeois revolution. According to the Civil Code of France (Napoleonic Code) (chapter on the inviolability of the person, Art.16.3) (Trans-Lex, 2016), there may be no infringement of the integrity of the human body. The consent of the concerned person must be obtained beforehand.

According to the Protocol (Art.19), parties may take all appropriate measures to promote the donation of organs and tissues. As mentioned, the Protocol is based on the principle of respect for human dignity in the legal regulation of organs and tissues transplantation (Art.1). Although some legal issues of human organs and tissues transplantation (e.g., "human organs and tissues transplantation in the absence of a declaration of will) are within the competence of the domestic legislation of individual states. In this regard, the Oviedo Convention (Art.36) does not interfere with the unilateral regulatory authority of states. However, in terms of ensuring the content richness of the principle of respect for human

dignity in the Protocol, there is also a need for a law-making process. In Article 17 of the Protocol (except for "the removal shall not take place if the deceased person had objected to it"), the rules and conditions of "consent and authorization" are left to the domestic legislation.

For preventing the criminal interests in the human organs and tissues transplantation and ensuring the "right to personal inviolability" of the deceased person, the norm "human organs and tissues transplantation is prohibited in the absence of will" can be included as part 2 of Article 17 of the Protocol. Such a norm would also serve the principle of dignity.

In accordance with the principle of respect for human dignity, as in Chapter VII of the Oviedo Convention, Protocol (21.1) states that "the human body and its parts shall not, as such give rise to financial gain or to obtain a comparable advantage." Here, the formula "... as such give rise to obtain a comparable advantage " should also be considered flawed. It should be noted that "...to obtain any, including social, physiological etc. comparative advantages."

Both the Protocol (Art.22) and the domestic legislation prohibit the commercialization of human organs and tissues transplantation, and state that the human organs and tissues transplantation is free of charge. Article 4 of the Law of the Republic of Azerbaijan "On Donation and Transplantation of Human Organs and Tissues" states that legality, humanism, volunteerism, solidarity, compassion and disinterestedness are the principle directions of organ donation and transplantation. However, as mentioned, organ donation is often accompanied by moral and ethical problems. According to the position of experts, although the human organs and tissues transplantation from one relative and implantation of them into another person is legally free, it is also a transaction. There are different theories on the fair distribution of these scarce resources, and sometimes preference is given to individuals of "higher" social importance (Mustafaeva, & Mamedov, 2010). As stated in the Council of Europe Convention Against Trafficking in Human Organs (Council of Europe, 2015), enacted in 2018, and Article 22 of the Protocol ("prohibition of financial gain"), trade in organs is prohibited in the legislation of the Republic of Azerbaijan. Article 32 of the Law states that the purchase and sale, as well as advertising the need for donor organs is prohibited. Organ trafficking has a number of inexcusable moral ugliness.

The purchase and sale of the human body, with its transformation into an object, leads to the violation of the special social status of the person in the society, depersonalization and demoralization of the person. Trade in organs as a new form of exploitation increase social injustice in society and the rich literally survive at the expense of the poor. Since it is impossible due to various objective and subjective reasons, it should be a matter of special legislation not to eliminate this injustice, but to ensure control over it.

In world practice, there are several legal types of organ removal from a deceased person (corpse). As noted in the literature the cultural, religious, etc. specifics of the region taken separately while establishing the states' domestic legislation on transplantation should be taken into consideration. Mainly, the form of organ collection based on the consent given by the potential donor during his/her lifetime, which is used in some American states, as well as in the Netherlands, Portugal and several other European countries, contains moral and ethical values. It is based on the fundamental rights of the individual, such as self-determination and independence, with informed consent. A person retains the right to dispose of his life and body even after death. In medicine, this is considered a more democratic method. Doctors do not have the right to use the body of a deceased person at own discretion. In medicine, this is considered a more democratic method. In this case, the flexible preparation and transplantation of organs and tissues, the establishment of rapid, stable relationships of mutual trust between the doctor and the patient's relatives and the time required lead to psychological difficulties for doctors. In this case, the doctor collects the organs not by his/her personal will and desire, but according to the law. In terms of prevention of criminal cases, inviolability of personality, and the principle of dignity, as stated above, this form may be deemed as a form of universal regulation based on the rule of international law.

The main points of legislation related to the removal of organs from the corpse for transplantation are:

- the principle of written consent in contradictory (exceptional) form to the removal of donor organs from the corpse for transplantation;
- use of donor organs for transplantation, educational and scientific purposes;

- donation is a declaration of will during the lifetime of a fully functional person who has reached the age of majority;
- formalization of consent to removal of organs or objection of removal of organs with a special application form;
- inclusion of donation information in the register of persons who consented to donation, in the unified state database;
- the possibility to change the expression of will regarding donation at any time after the person's death;
- responsibility of the medical setting and the coordinating institution should be stated for ensuring the confidentiality of information related to the consent to organ transplantation or the objection of removal of organs.

### Conclusions

In case of comparison of the Protocol concerning Transplantation of Organs and Tissues of Human Origin with applicable Law of the Republic of Azerbaijan, despite the initial conclusion that the internal legislative act has a more comprehensive regulation, there is a superior regulation in the Protocol. In this sense, the adaptation of the legislation to the Protocol (Article 12) should be continued.

For preventing criminal interests in the transplantation of human organs and tissues and in terms of ensuring the "right to personal inviolability" of the deceased person, the norm "human organs and tissues transplantation is prohibited in the absence of will" can be included as part 2 of Article 17 of the Protocol. The wording of Article 21.1 of the Protocol ("...cannot be taken to gain comparable advantage") should also be considered flawed. Changing this norm as "...any, including social, physiological, etc. cannot be taken to gain comparable advantage" would be more logical in terms of safeguard human dignity.

Since the trafficking in human organs is a transnational crime that violates human rights and freedoms, human dignity, and threatens public and national security, the fight against it can only be effective with international legal cooperation. Criminal and administrative legislation of the Republic of Azerbaijan is being developed for toughening of punishments. Analysis of criminal legislation shows that all forms of illegal organ transplantation are not fully covered. Therefore, recognition of the Convention against Trafficking in Human Organs by the Republic of Azerbaijan would

make the fight against the criminal donation and transplantation effective and promote international legal cooperation against this transnational crime.

On the background of international legal cooperation against the illegal transplantation of human organs and tissues, establishment of the norms of responsibility in the domestic legislation of the states, including criminal liability, and toughening the punishments are of course important in preventing criminal activity. However, these measures are not the only way out. It seems impossible to prevent the problem using the international legal fight due to the increasing pace of trade in human organs.

### Bibliographic references

- Ambagtshee, F. (2021). Understanding the challenges to investigating and prosecuting organ trafficking: a comparative analysis of two cases. *Trends Organ Crim*, 2, 37-59. <https://doi.org/10.1007/s12117-021-09421-2>
- Constitution of the Republic of Azerbaijan [Const.]. Art. 46.3. November 12, 1995 (Azerbaijan). Retrieved from <https://e-qanun.az/framework/897>
- Council of Europe. (1999). *Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164)*. Retrieved from <https://acortar.link/18TNjx>
- Council of Europe. (2002). *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186)*. Retrieved from <https://acortar.link/Zj34Rh>
- Council of Europe. (1997). *Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*. Retrieved from <https://rm.coe.int/1680a8e4d0>
- Council of Europe. (2015). *The Convention against Trafficking in Human Organs*. Retrieved from <https://rm.coe.int/16806dca3a>
- European Union (2011). *Judgements C-34/10, Oliver Brustle v. Greenpeace e.v. Court (Grand Chamber) of 18 October 2011*. Retrieved from <https://acortar.link/j7gf6m>
- Ferreira Da Silva, I.V., & Frontera, J.A. (2015). Worldwide Barriers to Organ Donation. *JAMA Neurol*, 72(1), 112-118.

- <https://doi.org/10.1001/jamaneurol.2014.3083>
- Glaser, S. R. (2005). Formula to Stop the Illegal Organ Trade: Presumed Consent Laws and Mandatory Reporting Requirements for Doctors. *Human Rights Brief*, 12(2), 19-22. Retrieved from <https://acortar.link/9ZTo1r>
- Grigoriev, Yu., Grigoriev, I., & Istomina, L. (2001). Legal aspects of conducting some types of biomedical and clinical experiments. *Bulletin of new medical technologies*, 8(3), 79-81. (In Russian)
- Guseinov, L. G. (1998). *International obligations of states in the field of human rights*. Baku: publishing house "Legal Literature". (In Russian)
- International Humanitarian Law Databases. (1949). *Convention (IV) relative to the Protection of Civilian Persons in Time of War*. Retrieved from <https://ihl-databases.icrc.org/en/ihl-treaties/gciv-1949>
- Janis, M., Kay, R., & Bradley, E. (2008). *European Human Rights Law*. Oxford: Oxford University Press. ISBN: 9780199277469
- Koru, O. (2021). Legality of medical intervention: indication requirement. *Inönü University Faculty of Law Journal*, 12(2), 491-500.
- Law No. 360-IQ, On Protection of the Population Health. *Republic of Azerbaijan*, 1997. Retrieved from <https://cis-legislation.com/document.fwx?rgn=5809>
- Law No. 726-IG, On Transplantation of Human Organs and Tissues. *Republic of Azerbaijan*, 1999. Retrieved from <https://cis-legislation.com/document.fwx?rgn=2727>
- Mammadov, V., & Mustafayeva, A. (2013). *Bioethics, law and human rights*. Baku: Law.
- Mustafaeva, A.I., & Mamedov, V.K. (2010). *Transplantology: legal and ethical problems*. Baku: Echo. Retrieved from <https://acortar.link/4f0N3h>
- Neethu R. Elberte v. Latvia. *Application no. 61243/08*. European Court of Human Rights, 2015. Retrieved from <https://hudoc.echr.coe.int/fre#%22itemid%22:%22001-150234%22>
- Petrova v. Latvia. *Judgment 24.6.2014*. Case 4605/05. European Court of Human Rights, 2014. Retrieved from <https://hudoc.echr.coe.int/fre#%22itemid%22:%22002-9531%22>
- R.R. v. Poland-HUDOC. *Application no. 27617/04*. European Court of Human Rights, 2011. Retrieved from <https://acortar.link/4eEbEV>
- Sollie, P., & Duwell, M. (2009). *Evaluating New Technologies: Methodological Problems for the Ethical Assessment of Technology Developments*. (Vol. 3). Springer Science & Business Media.
- Stammers, T. (2022). Organ Trafficking: Why Do Healthcare Workers Engage in It?. *Cambridge Quarterly of Healthcare Ethics*, 31(3), 73-89. Retrieved from <https://acortar.link/OsEsVw>
- Swissinfo. (2022). *Amendments to the Law "On Human Organ Transplantation"*. Retrieved from <https://acortar.link/N9tKFi>
- Toebe, B. (2001). The right to health. *Economic, Social and Cultural Rights*. London: Law. Retrieved from <https://acortar.link/5Dir80>
- Trans-Lex. (2016). *French Civil Code*. Retrieved from [https://www.trans-lex.org/601101/\\_/french-civil-code-2016/](https://www.trans-lex.org/601101/_/french-civil-code-2016/)
- Tutun, S., Harfouche, A., Albizri, A., Johnson, M.E., & Haiyue H. (2022). A Responsible AI Framework for Mitigating the Ramifications of the Organ Donation Crisis. *Inf Syst Front*, 25, 2301-2316. Retrieved from <https://doi.org/10.1007/s10796-022-10340-y>
- United Nations. (1948). *Universal Declaration of Human Rights*. Retrieved from <https://www.refworld.org/docid/3ae6b371c.html>
- United Nations (General Assembly). (1966a). *International Covenant on Civil and Political Rights*. Treaty Series, 999, 171. Retrieved from <https://www.refworld.org/docid/3ae6b3aa0.html>
- United Nations (General Assembly). (1966b). *International Covenant on Economic, Social, and Cultural Rights*. Treaty Series, 999, 171. Retrieved from <https://www.refworld.org/docid/3ae6b36c0.html>
- US Congress. (1984). National Organ Transplant Act of 1984. Retrieved from <https://acortar.link/vDEhTC>
- World Health Organization. (2016). *Implementation of the Nagoya Protocol and pathogen sharing. Implications for healthcare*. Retrieved from <https://acortar.link/d30I2H>