

REVIEW ARTICLES

Analysis of the legal framework on donation and transplantation of organs and cells in the Republic of Moldova**I. Codreanu**

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Abstract

Background: Due to rapid advances in transplantation medicine, the use of human organs, tissues and cells for transplantation has steadily increased during the past decades. Nevertheless, the success of organ transplantation has led to a huge imbalance between the scarce supply and the abundant demand for available organs for transplantation. The imbalance is one of the main reasons for illicit activities in this domain. The aim of this article was to review the most important legislative acts which regulate the activities in the field of donation and transplantation of organs, tissues and cells in the Republic of Moldova. The development of an appropriate transplant system in the Republic of Moldova represents a priority for the Government and specifically for the Ministry of Health to ensure high standards of quality and safety as to the procurement, testing, processing, preservation, storage and distribution of human organs, tissues and cells.

Conclusions: In the Republic of Moldova there is an ongoing development in law enforcement and implementation of quality assurance standards. The law on transplantation of organs, tissues and cells of human origin was adopted by the Parliament of the Republic of Moldova in March 2008. According to the new legislation the Transplant Agency was created as a public body in May 2010. Despite multiple efforts made by the Ministry of Health, Transplant Agency and other state institutions to improve the legal framework there are still some deficiencies to be overcome by adopting normative acts to prevent cases of trafficking in organs and tissues or other illicit activities in this area.

Key words: transplantation, donor, organs, legislation.

Introduction

Transplantation of organs, tissues and cells is one of the top areas of modern medical practices, which saves thousands of lives and contributes considerably to the improvement of the quality of life of hundreds of thousands patients around the world every year. During the past 5 decades, transplantation has become a well-developed medical procedure and in case of many illnesses it often represents the only possible treatment.

It's a paradox, but namely the transplant development has contributed to the extension of the waiting lists. According to the Global Observatory on Donation and Transplantation data, 112,631 solid organ transplants were performed in 2012 around the world [1]. This accounts to 10% of the global demand for organs. Simultaneously, each year approximately 13,961 patients pass away, while waiting for a transplant graft. The mortality rate on the waiting list for a heart, liver or lung transplant varies between 15 and 30%. The European

Union (EU) records significant differences with regards to the number of cadaveric and living donors. These differences cannot be explained easily. Even in the EU countries, where well-developed services are available, there are significant differences related to organ donation and transplantation and it seems that certain organizational systems are more efficient than others.

The transplantation includes the organ, tissue and cells donation and their subsequent implantation, the two processes being fully interdependent. Organ procurement does not concern only the transplantation teams. More and more health professionals, working in teams and international organizations are trying to strengthen the cooperation between doctors and management structures. It is vital for the entire medical community to acknowledge the problem and to be directly and indirectly involved in the donation and transplantation process. The medical staff can contribute

indirectly to the education of the general public, chase away the fears and encourage a positive attitude towards donation. All medical staff can directly support the identification of potential donors, with their subsequent evaluation and maintenance therapy. Like any medical activity, the overall success of the transplantation depends on the responsibility of all representatives of the health system, and on the whole society. The use of substances of human origin for treatment raises serious ethical concerns for the society [2,3]. Any transplantation program has the major goal to increase the number of transplant operations by optimizing the number of altruistic donors and by ensuring transparent and equitable, but also medically efficient allocation of organs and tissues. The donation and transplantation activity must be based on the rigorous compliance with the general ethical norms.

By Law No 261-XVI of 06.12.2007, the Republic of Moldova ratified the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, adopted by the Council of Europe on 24 January 2002 [4,5]. The protocol urges states to provide equitable access to transplantation services for patients, to protect the rights and freedoms of donors and recipients of organs and tissues of human origin, and to eliminate the misuse of transplantation that may lead to acts endangering human life, well being and dignity. According to the Protocol, the states will cooperate by exchanging information on the demand for organs and tissues, and by offering mutual support for organ and tissues transportation to and from their territory.

The Republic of Moldova has committed to take the necessary measures in order to prevent and curb immediately any violation of rights in organ transplantation and to introduce adequate sanctions in its legislation.

Alignment of the Republic of Moldova to the international and European standards on human rights and biomedicine. National Regulatory Framework

The organ procurement and transplantation was regulated for the first time in the Republic of Moldova with the enforcement of Order of the Ministry of Health of USSR No 153 of 22 February 1982 on the "Right to procure and preserve kidneys for transplantation" and the decision of the Scientific Council Board of the Science Academy of USSR of 29 June 1982 on the "Right to perform kidney transplantation operations in the Republican Clinical Hospital".

Law No 473-XIV on Transplantation of Human Organs, Tissues and Cells of 25 June 1999 was the first law that regulated the donation and transplantation of organs and tissues in the Republic of Moldova [6].

The evaluation of the Moldovan system for transplantation of organs, tissues and cells of human origin, performed by the Council of Europe experts under the Joint Programmer between European Commission and Council of Europe for Moldova 2004-2006, confirmed the topicality of this issue and the need for immediate interventions. To overcome this situation various workshops and round tables were organized with the participation of Council of Europe experts. These meetings addressed the current situation related to organ

transplantation and the fight against organ trafficking in the Republic of Moldova. The Council of Europe experts drew the attention to the deficiencies of the current legislation - cadaveric procurement only in case of brain death, prohibition of organ exchange within an international cooperation, non-acceptance of spouses or other relatives, except first kinship, as living donors - which were the key factors preventing the development of this field. The Council of Europe experts recommended to adopt a new Law on Transplantation of Human Organs, Tissues and Cells, aligned to Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [7,8,9]. Authorities of the Republic of Moldova have carried out a series of legislative and regulatory actions with the view to adjust the legal framework to the international legislative norms and EU requirements, facilitate the transplantation of human organs, tissues and cells, help save lives and improve significantly the quality of life, and prevent the trade in parts of human bodies [10,11,12,13]. Respectively, the following national legal framework on transplantation of human organs, tissues and cells is in place today:

- Law on Transplantation of Human Organs, Tissues and Cells No 42-XVI of 06.03.2008 (Official Gazette No 81/273 of 25.04.2008);
- Government Decision No 386 of 14.05.2010 establishing the Transplant Agency;
- Government Decision No 1207 of 27.12.2010 approving the Regulation on the Organization and Modus Operandi of the Independent Approval Commission under the Ministry of Health and authorization criteria for the performance of procurement and transplantation activities.

These laws and regulations were enforced, further developed and elaborated with the approval of a series of orders by the Ministry of Health. They regulate the requirements, procedures, and techniques for the authorization of healthcare facilities and medical staff in procurement and transplantation and the quality of organs, tissues and cells for transplantation [14,15].

Law No 42-XVI of 06.03.2008 on Transplantation of Human Organs, Tissues and Cells is the main internal law [10]. It regulates the transplantation of all human organs (a vital differentiated part of the human body, consisting of different tissues that maintain its structure, vascularization and physiological functions with an important level of autonomy), tissues (all parts (anatomical formations) of the human body, consisting of cells) and cells (individual cells or cell conglomerates, which are not linked by any form of tissue).

Article 2 of Law No 42 -XIV defines the transplantation as "a medical process intended to restore certain functions of the human body by transferring equivalent organ, tissues, and cells from a donor to a recipient. Transplantation might be from a person to another (allogenic) or from a person to himself (autologous)".

In order to perform the transplantation of organs, tissues or cells it is necessary to comply with certain clear rules and principles imposed by the law.

These are stated expressly in Article 3 of Law No 42-XVI of 06.03.2008 on Transplantation of Human Organs, Tissues and Cells, as follows:

a) protection of dignity and identity of human beings, without discrimination, and respecting the integrity and other fundamental rights and freedoms related to transplantation of organs, tissues and cells;

b) The therapeutic benefit for the recipient by timely transplantation of an organ, tissues and cells from a living or cadaveric donor, unless there aren't any therapeutic methods with a similar efficiency;

c) Ensuring quality, by observing the professional standards and obligations, during any intervention related to transplantation of organs, tissues and cells;

d) Traceability, by guaranteeing the identification of organs, tissues and cells intended for transplantation, during the procurement, storage and distribution, from the donor to the recipient and vice-versa;

e) Protection of human rights and freedoms and prevention of trade in parts of the human body;

f) Fair access of patients to transplant services.

Procurement of Human Organs, Tissues and Cells

Procurement represents the process by which the donated organs, tissues or cells become adequate for transplantation. A difference is made between the procurement of organs, tissues and cells from living donors (*ex vivo*) and procurement of organs, tissues and cells from cadaveric donors (*ex mortuo*). This procedure, both from living and cadaveric donor, can be performed only under certain conditions, set by the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin [15] and Law No 42 of 06.03.2008 on the Transplantation of Human Organs, Tissues and Cells.

Violation of any of the conditions set by the Law is an assault to the dignity and integrity of the human being.

Conditions for the Procurement of Organs, Tissues and Cells from Living Donors

Chapter III of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin sets the conditions for organ and tissue removal from living persons.

In its turn, Article 15 of Law No 42-XVI of 06.03.2008 on the Transplantation of Human Organs, Tissues and Cells lists expressly the following conditions for procurement from a living donor. But these are not exhaustive, as a series of other conditions are stipulated in several other articles such as Article 9, 19 and 20 of the Law. Also, it is important to mention that both the Protocol and the Law stipulate additional conditions for organs procurement compared to the tissue and cells procurement from living donors, as well as for the tissues and cells procurement from persons, who do not have the capacity to express their consent.

Based on the above-mentioned documents, we can specify the following conditions:

1) Organs, tissues and cells procurement from a living donor is allowed only when compatible organs, tissues and

cells from a cadaveric donor are missing and only for the therapeutic benefit of the recipient;

2) Human organs, tissues and cells procurement, for therapeutic purposes, can be performed from living donors who have reached the age of majority, who have full legal capacity, after receiving in advance their written, unforced, preliminary and express consent. The donor may reverse the consent until the moment of the procurement;

Human organs, tissues and cells cannot be procured from persons, who lack capacity to express their consent. However, the law makes an exception to this: tissues and cells procurement is allowed in the case of regenerative tissues and cells, provided that the following conditions are met cumulatively:

a) To have the agreement of the legal representatives of the donor or of the guardianship. This requirement is applicable for minors as well;

b) The procurement must be authorized by the Independent Approval Commission;

c) The donor must be a relative of first kinship of the recipient (for the minor donor this has to be a sibling);

d) The procedure to cause a minimal risk for the donor;

e) Procurement from a minor donor cannot be performed if he/she has expressed his/her refusal in writing, verbally or in any other form.

The Ministry of Health Order No 885 of 18.11.2011 approving the documents for the Independent Approval Commission on the consent for or refusal from procurement of organs, tissues and cells from living donors, Annex 3, approved the informed consent form for regenerative tissues and cells in the case of minors or incapacitated persons.

3) The donation consent shall be signed only after the donor was informed by the physician on the potential risks and physical, psychic, family and professional consequences that could be caused by the procurement;

4) The consent to donate shall be expressed according to the legislation on the rights and responsibilities of patients and shall be prepared as an informed consent form. The informed consent form for living donor donation of organs, tissues and cells was approved by Government Decision No 1207 of 27.12.2010, in Annex 3.

5) In case of organ procurement from a living donor it is mandatory to have the approval of the Independent Approval Commission.

The Independent Approval Commission's approval of the donation from a living donor is not required for the procurement of stem cells, sperm, femoral head (after endoprosthesis), placenta, umbilical cord blood or amniotic membrane for therapeutic purposes. However, in this case the procurement must comply with the bioethics rules and patient's rights.

In addition, procurement and transplantation of organs, tissues and cells must meet these restrictive requirements:

a) Procurement and transplantation of human organs, tissues and cells as a result of any physical or moral coercion is forbidden;

b) Donation and transplantation of human organs, tissues and cells cannot be object of certain judicial actions or documents, aiming at obtaining material or any other type of gain.

Conditions for the procurement of organs, Tissues and Cells from Cadaveric Donors

Certification of the moment of death is an issue in the case of procurement of organs, tissues and cells from cadaveric donors. According to Article 10 of Law No 42 of 06.03.2008, the legal procedure of cadaveric donor procurement can be initiated only when the person's death was declared, after it was certified according to certain criteria set by the Ministry of Health. Currently these criteria are not stated expressly in a separate regulation.

According to Article 11 of Law No 42 of 06.03.2008 in the case of a potential donor, it is necessary to confirm the death of the donor before the launching the legal procedure of donation, following one of these procedures: after a respiratory cardiac arrest or as a consequence of brain death.

In case of irresuscitable and irreversible respiratory cardiac arrest, the death is confirmed in at least 5 minutes after the performance of all intensive care measures, with all tests proving unambiguously the lack of blood circulation towards the brain and vital organs.

In case of brain death, the death is confirmed after the occurrence of irreversible changes in the vital centers of the brain, confirmed by specific tests, while the cardio-respiratory function is maintained artificially.

The brain death diagnosis is set according to the Ministry of Health Order No 260 of 05.04.2011 approving the "Standardized Clinical Protocol on Brain Death". This Protocol presents the criteria of clinical and instrumental diagnosis of brain death in adults (persons over 18 years old) and the relevant tests in order to facilitate the recognition and diagnosis of brain death and justification of the actions taken by the medical staff in case of suspected brain death.

Brain death diagnosis shall be established by a medical council consisting of three specialists: neurologist/neurosurgeon, anesthesiologist/intensive care physician, and manager of the institution. The brain death shall be confirmed by determining the clinical signs and performing the mandatory paraclinical tests. Brain death diagnosis shall be recorded in the Brain Death Determination Statement, according to the form presented in Annex 2 to the above-mentioned Protocol. As an essential condition for the determination of brain death, the physicians that certify the death of the person should not be the physicians, who are involved directly in the procurement of organs or tissues from the deceased person, who are involved in the subsequent transplantation, or who are in charge of providing care to the potential recipient [10].

At the same time, organs, tissues and cells are procured from cadaveric donors only if the clinical and laboratory tests exclude any communicable diseases, a potential contamination or other affections that represent a risk to the recipient.

The consent to donate is an important element in the procurement of organs, tissues and cells from cadaveric donors.

Article 17 of the Protocol is quite laconic on this subject, stating that organs or tissues shall not be removed from the body of a deceased person unless consent or authorisation required by law has been obtained. The removal shall not be carried out if the deceased person had objected to it.

Based on the legal regulations we can conclude that there are two types of consent: the presumed consent and the informed consent.

More explicit regulations on this subject are provided in Article 13 of Law No 42 of 06.03.2008 on the Transplantation of Human Organs, Tissues and Cells.

Thus, procurement is possible only when the person has expressed the consent to donate before death or during his/her lifetime. This is the express manifestation of the agreement to donate, according to the law, i.e. the express consent of the donor to donate.

Also, the procurement cannot take place, if during her/his lifetime the deceased person has rejected the donation in writing or in any other legal form. In such a situation, the manifestation of refusal to donate organs or tissues can have the form of a written document, with the signature of the refusing person, or a notarized statement.

After the death of the person, if he/she did not manifest the agreement to donate during the lifetime, donation is possible only if there is no written refusal to donate from at least one member of the family, from other relatives of first kinship or from the legal representative of the deceased. This is an informed consent and the emerging issue consists in the time period when the refusal can be expressed. Considering that the procurement should be performed timely, the relatives or legal representative of the deceased shall express their refusal within a very limited time period.

Also, donation is possible if after the legal certification of death, none of the close relatives or the legal representative have expressed their position regarding donation, and the contact data of the close relatives or the legal representative of the deceased person are lacking.

In forensic cases, cells, tissues and organs shall be procured from cadaveric donors with the consent of the coroner, provided that it does not compromise the forensic autopsy results.

Prohibition of Financial Gains from the Donation of Cells, Tissues and Organs. Criminal Liability for Trafficking in Organs

The low number of organs available for transplantation raises various moral and bioethics issues concerning their procurement and distribution. All international human rights documents state that the human body is sacred, intangible, must be respected both during the lifetime and after death and cannot be the object of any trade [16,17,18,19]. In order to avoid violation of human rights, in the international legislation, the specialized bodies adopted norms that set the general principles for donation of organs, with the most important being: principle of respecting the human dignity and prohibition of any violations thereof, principle of donors' anonymity, of gratuity, etc. Any action of procurement of organs from a living human body, which affects severely the life and integrity of the human body, is sanctioned by the Criminal Code. The failure to comply with the legal requirements for the selection and follow up monitoring of organ donors can lead to severe consequences for their health. In order to avoid these consequences, the organ transplantation shall to be planned and implemented as a grand gesture of dedication of a hu-

man to another human, an action of humans who, though have inalienable rights over their bodies, are members of the society and thus can bring a service to their peers, under the conditions of a healthy and reasonable generosity.

A Declaration on Human Organ Transplantation was adopted in October 1987 by the 39th World Medical Assembly. This Document criticizes strongly the donation of organs for commercial purposes. Subsequently, The World Health Organization (WHO) developed a set of guiding principles in the field of transplantation. WHO approved these principles at the 44th session in 1991 and recommend to states to use them in the development of policies in this area. According to Guiding Principle no.5 „Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin of deceased persons, should be banned.” A similar position was adopted also in 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 of 4 April 1997. By ratifying this Convention, the Republic of Moldova assumed the obligation to prevent any human rights violations, provided in this Convention. Law No 42 of 06.03.2008 is a necessary legal support in this sense, which details the principle of prohibiting trade in parts of the human body, and simultaneously incriminates the trafficking in human organs, tissues and cells.

Thus, Article 27 of the Law prohibits earning any financial profits from the donation of human cells, tissues and organs and stipulates that the donation and transplantation of cells, tissues and organs cannot be the object of a material transaction. In this sense, the Independent Approval Commission controls if the donation is made with a humanitarian purpose, if it has an altruistic character and if it does not represent the object of a material transaction. Upon the evaluation of the legal motivation and procurement procedure, the Commission verifies if the donor is informed that accepting any monetary compensation for donation is illegal.

The sui generis act of tissues/organs donation is free of charge and respectively, does not depend on any transaction that aims at selling the respective organ/tissues or cells or the acceptance of a material benefit or of a benefit of any other nature.

Gratuity is the essence of the tissues and organs donation. It should not be regarded as the lack of a patrimonial advantage, but as the lack of any advantage, regardless of its nature.

Also, the legislator prohibits any advertising of human organs, tissues and/or cells transplantation for purposes of obtaining financial gains or related advantages, these actions being subject to criminal liability.

Article 29 2) of Law No 42 of 06.03.2008 states that the cost of the transplantation, investigations, hospitalization, surgery, drugs, sanitary materials, post-surgical care and any other expenses linked to transplantation can be covered by:

- a. Funds from the National Health Insurance Company;
- b. The state budget;
- c. Payments (fees) incumbent on the patients, according to the law, for medical services;

d. Donations from charity organizations and other legal entities, as well as from private persons, that are not linked directly to a certain transplant activity.

However, donors can receive an indemnification that is strictly limited to covering the expenses and of the following inconveniences:

- a. Compensation of living donors for the lost income and other justified expenses, caused by the donation and related medical check-ups;
- b. Payment of justified expenses for the medical services or technical services related to donation. Living organ donors benefit of compulsory health insurance policy for life, funded from the state budget.

By these regulations, the legislator does not exclude the possibility to provide some compensation for the act of donation, but totally excludes the legal possibility to provide compensations that would generate sales relationships between the donor and recipient or another interested person.

The Government has the main role in this case and should assume all the responsibilities towards the donor by providing a benefit for the temporary incapacity to work and providing health services from the state budget, as well as offering certain facilities for the provision of health services.

Article 28 of Law No 42 of 06.03.2008 prohibits the trafficking in human organs, tissues and cells, and obtaining any financial profits or advantages from trafficking in human body and its parts.

Trafficking in human organs, tissues and cells is a form of trafficking in human beings, which violates the human dignity and physical integrity.

According to the law of the Republic of Moldova, the human body cannot be viewed as an asset and cannot be the object of a patrimonial legal relationship. This conclusion is a general principle, though it is not provided expressly in the current law, it can be deducted from Article 27(1) from Law No 42 of 06.03.2008. At the same time, Article 28(2) from Law No 42 stipulates expressly that trafficking in human organs, tissues or cells is a crime, punishable in accordance with the criminal law.

The incriminated criminal facts, contained in the Criminal Code of the Republic of Moldova on the trafficking in human organs, tissues or cells, are stated in Article 158 - Trafficking in Human Organs, Tissues and Cells, Article 165 - Trafficking in Human Beings, Article 206- Trafficking in Children and Article 213¹ - advertising for illegal procurement of human organs, tissues and cells or their illicit donation [21]. The objective side of trafficking in human organs, tissues or cells from Article 158 includes plenty of actions, such as illegal procurement of human organs, tissues or cells by removing them from the living or dead human body of another person by unauthorized persons and/or unauthorized institutions according to the current law or in non-compliance with the legal provisions on the person's consent to donate or in order to earn income from this, as well as their illegal selling, procurement, use, storage, possession, transmittal, receipt, import, export, or transportation. There are the following aggravating circumstances for these actions: a) committal by a person

who committed previously a similar act; b) by physical or psychic coercion; c) against two or more persons; d) against a pregnant woman or a child; e) by two or more persons; f) by a public person, by a person in position of liability, by a public dignitary, by a foreign public person or by an international official; g) committed by an organized criminal group or by a criminal organization; h) resulting in severe damage to the corporal integrity or health, with the death or suicide of the person. It is worth noting that prior to the adoption of Law No 270 of 07.11.2013 on Amendments and Addenda to some Legal Acts, Article 158 used to incriminate only coercion of a person into procurement of organs or tissues for transplantation or for other purposes, committed by applying violence or threatening to apply violence.

From this perspective, in the spirit of Article 19 of the Convention on Human Rights and Biomedicine and Articles 27-28 of Law No 42 of 06.03.2008, the legislator intervened in the regulation of such social relations by sanctioning those who do not comply with the principles of gratuity of donation of organs, tissues and cells, stipulating exhaustively in the new version of Article 158 the actions for trafficking in organs, tissues and cells that constitute crimes.

Actions of recruitment, transportation, transfer, housing or receipt of a person, with or without his/her consent, for purposes of organs or tissues procurement, are part of the crimes stated in Article 165- Trafficking in Human Beings.

The objective aspect of the crime stated in Article 206 - Trafficking in Children, incriminates the recruitment, transportation, transfers, housing or receipt of a child, and offering or receipt of some payment or benefits to obtain the consent of a person, who detains control over the child in order to procure human organs, tissues and/or cells as socially dangerous acts, punished by the criminal law. An aggravating circumstance is if these actions were accompanied by procurement of human organs, tissues and/or cells.

Article 27(4) of Law No 42 of 06.03.2008 on Transplantation of Human Organs, Tissues and Cells prohibits advertising the need for transplantation of human organs, tissues and/or cells for purposes of obtaining financial gains or related advantages. Or, incriminating it as a criminal action and the sanction that would come to support the respective regulation did not exist. The legislator eliminated the legal gap by amending the Criminal Code with Article 213¹, that foresees the advertising for illegal procurement of human organs and/or tissues and/or cells or on their illegal donation. Therefore, only the advertising for illegal procurement of human organs, tissues or cells and advertising for illegal donation for purposes of getting some financial benefits, are criminally sanctioned. The authors of the announcements, as well as the individuals or legal entities, who make this information public, are subject to criminal liability.

The European experts jointly with other international organizations, such as the Council of Europe and World Health Organization recommend close monitoring of the issue of trafficking in organs. In addition, it is important to ensure periodic update on this topic for press and general public. In order to prevent trafficking in organs, in May 2012

the Ministry of Health and the Ministry of Internal Affairs of the Republic of Moldova signed the Cooperation Agreement on combating trafficking in human beings for the purpose of organs and tissues procurement. At the same time, to monitor the donation and transplantation of human organs, tissues and cells and to develop the waiting lists, the Transplant Agency jointly with the Ministry of Health established the Information System TRANSPLANT in February 2013, which is part of the Integrated Medical Information System (IMIS) and a component of the "Automated registry of social and demographic resources" of the State Informational Resources of the Republic of Moldova. During the implementation of some components of the information system, organizational and financial difficulties have been encountered. Thus, the collection and storage of data about the patients with scheduled dialysis treatment was troublesome, due to the shortage of medical staff in dialysis centers, and shortage of computers or their Internet connection.

At the same time, so far, no method of registering data on persons who refuse to donate organs, tissues and cells in the Registry for Refusal was set, the register being thus not operational. The implementation of this register requires significant financial efforts.

With the enforcement of Law No 103 of 12.06.14, in order to ensure traceability for all organs, tissues and cells, the process of establishing a single encoding system that will provide information on the main characteristics and properties of organs, tissues and cells was initiated. The traceability requirement shall be also applied to all the pertinent data on products and materials that get in contact with these organs, tissues and cells.

According to the law in force, all the data on the transplantation shall be recorded, stored and archived in electronic form for 30 years in the information systems designated for transplant activities [10,13,22].

Conclusions

In the Republic of Moldova, the donation and transplantation of human organs, tissues and cells are regulated by a series of national legal acts and, also, by international conventions signed by Moldova, as well as the European Directives, which the national legislation shall be aligned to. Law No 42 of 06.03.2008 on the Transplantation of Human Organs, Tissues and Cells forms the basis of the national regulations on transplantations. Despite the plenty of efforts made by the Ministry of Health, Transplant Agency and other state institutions aimed at improving the legal framework, there are still some deficiencies that have to be eliminated by approving some regulatory documents that would allow preventing the trafficking in organs and tissues or other illicit activities in this field.

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