

LEGAL ASPECTS OF TISSUE TRANSPLANTATION

Nigmatullin R.T., Chernov N.V.

State Institution - Russian Eye and Plastic Surgery Centre of the Russian Public Health Ministry, Ufa-city

Life and death enjoy equal rights,
they can not get along without each other.

After the publication of widely known works by N.I. Pirogov (1835), I.A. Golianitsky (1914-1922), V.P. Filatov (1961) and some other authors, it became obvious that the problem of tissue transplantation must be put on a firm legal basis.

Our compatriots scientifically proved the necessity of transplantology development (V.P. Filatov, 1937), and the first legislative acts permitting the use of cadaverous tissues for medical purposes appeared in our country.

The legislative acts on transplantation appearing in our country are associated with the resolution “On the procedure of performing surgeries” issued by the Council of the People’s commissars of the USSR dated September 15, 1937. In accordance with this documents the Health Ministry was given the right to issue regulations to be followed by all the institutions, organizations and persons on the procedure of performing surgeries dealing with the transplantation of cadaver cornea, blood transfusion and transplantation of separate organs etc. The starting point of the legal regulation of medical problems in our country was the “Instruction on the use of cadaver eyes for cornea transplantation to the blind” (worked out in the Ukraine in 1932).

Since the transplantation of cadaverous cornea was quite spread in the hospitals of our country, on March 4, 1935 there was worked out a draft instruction for harvesting cadaverous cornea. The government decree and instruction of the People’s Commissariat of Public Health not only made it easier the harvesting of the cadaverous cornea for clinical transplantation but also considerably advanced the development of the cadaverous material harvesting problem and preservation of organs and tissues.

A special order № 88 issued by the Ministry of Health dated February 15, 1954

“On the cornea transplantation surgeries to be in common practice of the ophthalmologists”, permitted the cadaverous eyes harvesting without the relatives’ consent inclusively.

In accordance with order № 482 issued by the Ministry of Health of the USSR on July 14, 1972 “On better provision of prophylactic institutions and clinics with cadaverous tissues, marrow and blood” harvesting of cadaverous tissues, marrow and blood should be performed of cadavers who died suddenly from the acute cardiovascular collapse or other reasons that led to a quick death (myocardial infarction, cerebral hemorrhage, electric trauma, ethyl alcohol poisoning etc.).

In accordance with this order the decision of whether the harvesting of blood marrow or other tissues is permissible is up to the forensic medical expert who preliminary examines the body. The cadaver in this case should have no external injuries accompanied by huge loss of blood and there should be also no contraindications revealed during the forensic medical examination of the cadaver.

At present in our country there functions law № 4180-1 dated 22.12.1992 of the Supreme Soviet of the Russian Federation “On organs and tissues transplantation of the human”. The law regulates all basic legal aspects of transplantatology and functions together with order № 189 of August 10, 1993 “On further development and improvement of the transplantological help to the people of the Russian Federation” and order № 387 of November 21, 1996 “On making amendments into the above order” (Drgonets I. 1991).

Order № 407 of December 10, 1996 “On introducing into practice the rules of the forensic medical examination procedure” (paragraphs 7.1.5, 7.4.5 – 7.4.7) allows to harvest human organs and tissues for transplantation if the Law of the Russian Federation “On transplantation of organs and tissues of the human”, chapter 2, “Harvesting of the cadaverous organs and (or) tissues for transplantation is observed.”

According to Article 8 “Consent presumption for harvesting of organs and (or) tissues”, the harvesting of cadaverous organs and (or) tissues is not allowed in case the Public Health institution by the moment of harvesting was informed that when alive a man or his close relatives or lawful representative stated about the disagreement to harvest his organs and (or)

tissues after death for transplantation to the recipient (Pokrovskii V.I., 1997).

The Russian Federation Law “On transplantation of organs and (or) tissues of the human” in Chapter 1, Article 6 states that the recipient’s consent for the transplantation of organs and (or) tissues of the human is required. It also considers the case when getting such a consent is impossible which reads: “The transplantation of organs and (or) tissues to the recipient without his consent or his parents’ consent or lawful representative is performed only in exceptional cases when a delay may threaten the life of the recipient and getting the consent immediately is impossible”.

Unfortunately the legislation of the Russian Federation does not distinguish between the tissues and organs harvesting and practically speaking it imposes one and the same requirements to the solution of two completely different biomedical tasks.

In our opinion the law which is being worked out at present about the biomedical ethics should clearly distinct two problems of donation:

- harvesting of the viable organs and tissues;
- harvesting of the tissues not requiring the preservation of their viability.

It is the first problem which is connected with harvesting of the viable organs for allotransplantation (heart, lungs, kidneys, etc.) or tissues (cells) for cryopreservation with the purpose of their further transplantation in the viable condition (marrow, islet cells of pancreas, fetal tissues) that raise debate. The legal aspects of this problem regulation are especially acute since they require to establish the exact time of death to minimize or fully exclude the postmortal changes of the organs. And the regulation of donation in the given aspect is the subject of a special discussion both on the level of the legislative power and medical community.

Harvesting of donor tissues not requiring the preservation of their viability is quite another medico-biological and social problem. Harvesting of tissues in this case is carried out during a standard medico-legal autopsy or post-mortem examination. The regulation of such an activity should be performed by special law provisions on biomechanical ethics. We consider it interesting to compare laws on transplantation in different countries.

Many countries began to adopt legislative acts specifying the conditions

under which the application of the nontraditional forms and methods of the medical intervention is admitted (Drogonets Ya., 1991). It is understood that there can be no universal law for all the countries and every state. The law should take into account all the aspects of the public opinion, historical and cultural traditions of every nation and confession. In his book “Biomedical ethics” Pokrovsky V.I. writes: “Can it be called humane to initiate a permission for donation addressed to the next of kin right after the unexpected news of his death? Can it be called humane to ask of the resuscitation department doctor about his duty to ask the relatives these questions?” This situation is extremal for both sides and goes far beyond the possible psychological loads. That is why not only in Russia but also in such European countries as Austria, Belgium, Spain, Hungary, Switzerland, Czechia, there has been legally accepted the form of the supposed consent for donation.

In other words the laws of the given countries are based upon the presumption of the potential donor’s consent for harvesting of tissues. The only thing that should be absolutely unacceptable in the authors opinion is the market formation of organs and making profit from it. Commercialization contradicts a supreme humanistic idea of transplantology: “Death serves the prolongation of the human being’s life” (Pokrovsky V., 1997).

The main ethical principal in transplantology is the priority of the recipient’s interest and it is to be taken into account while working out the legal acts in the field of Public Health.

All these questions were touched upon at the International symposium under the name of “Bioimplantation on the threshold of the 21-st century” on the problems of tissue banks held in Moscow in 2001. This problem was several times discussed in the Russia’s State Duma. It is known that the law “On transplantation of organs and tissues” of 1992, establishes the presumption of the donor’s consent, the consent of a man to harvest his tissues. It means that if a man when alive didn’t refuse his tissues to be harvested, then after his death either during the medicolegal autopsy or postmortem examination there can be performed harvesting of his these or those tissue transplants. This conception has

been in act since 1932 and served as an example for many European countries.

However the consent presumption for the harvesting of donor tissues doesn't suit some public figures, certain representatives of the confessions who come out in favour of the enactment of the law similar to that one in the USA. In the USA a provision is made for the dissent presumption for harvesting the donor tissues, which means that if a man when alive didn't make a written statement that he wanted to be a donor then no harvesting of his tissues is possible. However human this law may sound it didn't make the work of the donation services more intensive (Pokrovsky V.I., 1997). In a number of cases it makes harvesting of tissues impossible.

According to the results of the public opinion the population in different western countries is essentially informed of the problems relating to the transplantation of organs. 60% in Canada and 75% in the USA of the whole number of people taken part in the poll approve the conception of donation. At the same time only 24% of those people remarked that they would mind becoming donors of the organs themselves and only 10-17% (in different states of the US actively filled in the donors' charts and 50% of those who did it didn't inform their families of it.

Unfortunately mass media consider the presumption of discord for harvesting of donor tissues as an indication of the legal state. If the constitutional law of the country envisages the presumption of consent for the harvesting of donor tissues then this state is considered as an illegal one, as Russia for example.

At the same time the legislations of such European countries as Belgium, Spain, Hungary, Czechia are known to envisage the presumption of consent to harvest the donor tissues. These states could hardly be called illegal but in these countries as well as in Russia the presumption of consent to harvest the donor tissues is envisaged and what is more the law in these countries has been adopted later than in the Russian Federation. The laws of each country should take into account the experience of the experimental and clinical transplantation and that is why they can not be universal. The mentioned European countries took the Russian laws as an example and followed our progressive experience which envisages the presumption of consent to harvest the donor tissues. The Russian law and the

supplements to it are in this sense one of the most advanced and allow to develop theory and practice of tissue transplantations keeping parity of the donor's and recipient's interests. All should be interpreted through public consciousness. Then why today are some public figures, making use of the problem's urgency, so willing to gain political image, saying that our state is not a lawful one precisely due to the fact that in its law there is in it a presumption of consent to harvest donor tissues?

First of all we should give up the perverse interpretation of the problem, presumption consent or discord as an indicator of the constitutional state's level of development, since the fact itself of the donor tissues harvesting and all appropriate conditions is stipulated in the Russian Federation law of transplantation of organs and tissues. It is based upon the most humane attitude to the dead since harvesting of tissues is performed of only those cadavers when this procedure may be carried out by medical indication. This is a very insignificant part of the cadavers. Besides, harvesting of tissues is performed only during the autopsy and when doing it no additional damage is inflicted on the dermal cover. During this procedure harvesting of certain tendons, serous tunics, fasciae, aponeuroses and dura mater is performed. It is also necessary to take into account that many tissues irrespective of donation are harvested during autopsy to carry out diagnostic investigations. And harvested tissues for conservation are in fact not a bigger intervention than harvesting of tissues for the postmortem or medicolegal examination.

The problem of the embryonic and fetal tissues harvesting requires a separate consideration since it is connected with obtaining the embryonic stem cells, regional stem cells and somatic cells. From the legal and ethical points of view these three types of transplantation should be considered as independent ones. The transplantation of embryonic tissues is in fact a technology of cloning and requires a special discussion of the whole scientific and medical community involving specialists of different fields. They should be represented by geneticists, embryologists, specialists in biomedical ethics, transplantologists. Juridically the problem of embryonic tissues harvesting is to this day practically unsolved. It is regulated by the Russian Federation's Ministry of Health order No.189 of 10.08.1993 on

transplantation of organs and tissues and also by a few clauses of the Russian Federation's criminal code (clause 105^m, 118 ^{2g}, 120), Appendix 2, clause 472.

Zilber A.P. (1998) writes the following on the subject: "The embryo is a personality though an inanimate one. There is a similarity between a cadaver and embryo in this respect, they can not express their own will. But there is a principal difference between them, i.e. an embryo is alive. Obtaining the embryo's tissues and organs for transplantation may be a consequence of only medical actions (abortion, etc.) carried out according to the medical indications and in no case for obtaining the transplantational material".

The World Health organization admits the use of the embryonal tissue only in case of experiments when:

1. The Declaration of the World Health Organization and Declaration on transplantation of the human organs are compatible with since they refer to the donor and recipient of the embryonal tissue transplant.

2. The embryonal tissue is not to be bought and sold and is to be exchanged for the money reward not exceeding the amount necessary to cover the admissible expenses.

3. The recipient of the tissue is not marked as a donor.

4. There is established and guaranteed an absolute independence between a team of doctors who carry out harvesting and a group of doctors using an embryo for therapeutic purposes.

5. The decision is made taking into account the state of health of both mother and embryo with respect to gestational age being safe for a pregnant woman.

6. Public health employees do not draw any profit from the transplantation of the abortion tissues of the same pregnancy.

7. The consent for transplantations received on behalf of the donor and in accordance with the law (Boer G.J., 1994; Bakay R.A., 1990; Burd L., 1998; Fine A., 1994).

In conclusion we would like to point out that no matter what approaches could be in the decision of the legal aspects of tissues transplantation, they could not be regarded

as certain dogmatic assertions of the lawful state. Each country should establish its rules in the decision of the given problem taking into account historical traditions of the people, most widely spread confessions, level of the public consciousness and eventually the population being kept informed of the donation problems. There are no universal legal decisions acceptable for each state. National legislations should conceptually be based on the well-known international legal norms regulated, for example, by the Geneva convention or convention of the European Council adopted in the city of Oviedo (04.04.1997). The adoption of the specified legislations should first of all proceed from the parity of interests of the donor and recipient.