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Tissue banks. World experience. The history of development and current approaches

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Abstract

The article outlines the main stages of the formation, development and specialization of medical institutions associated with the harvesting and procurement of allogeneic tissues, considers the global practice in the field of tissue institutions, taking into account medical and legal aspects. In the second half of the XX century, the tendency has developed towards the consolidation of tissue banks and the expansion of their functional capabilities within individual states. The development of this trend in the late XX - early XXI centuries led to the establishment of international tissue banking associations. The goal of international associations of tissue banks has been to develop cooperation, standardize procedures at all stages of tissue harvesting and procurement, and form an effective legislative framework. In the Soviet Union, the procurement of donor tissues was widely developing, but in the 90s, in our country there was an abrupt decline in this field. To date, in Russia, the harvesting and

procurement of allogeneic tissues is carried out in only a few institutions; the development of tissue institutions is difficult due to the lack of an adequate legal framework. The article proposes to legally differentiate the concepts of "organ transplantation" and "tissue transplantation"; as an example, the US experience in this area is discussed.

Keywords: allogeneic tissues, grafts, tissue bank, standardization, association

Conflict of interests Authors declare no conflict of interest

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AATB, American Association of Tissue Banks

APASTB, Asia Pacific Association of Surgical Tissue Banking

APNOTS, Asia-Pacific Network of Organ and Tissue Sharing

ALABAT, Latin American Association of Tissue Banking

ATBF, Australasian Tissue and Biotherapeutics Forum

BAA, Biotherapeutics Association of Australasia

CBER, Center for Biologics Evaluation and Research

EATB, European Association of Tissue Banks

FDA, US Food and Drug Administration

HRSA, The Health Resources Services Administration

IAEA, International Atomic Energy Agency

JSTT, Japan Society for Tissue Transplantation

WUTCBA, World Union of Tissue and Cell Banking Associations

Introduction

The idea of replacing damaged or lost human tissues with healthy ones appeared a long time ago. The first attempts at tissue transplantation were made in the Middle ages, but scientific knowledge and surgical methods did not allow for successful engraftment for a long time for a long time. Publications about successful tissue grafting appeared only in the 19th century. Initially, for the replacement of the damaged tissues, the native ones were used with the preserved blood supply of the grafted flap. Further attempts were made with using allogeneic tissues. So, in 1869, the Swiss physician Jaques-Louis Reverdin made a report at the Royal Surgical Society in Paris on the possibility of allografting skin flaps to the granulating wound of a recipient [1]. The method described by him is still used today with some modifications. In 1881, William Macewen first used a bone allograft from a child's tibia to reconstruct the humerus of another young boy [2]. In the same year, 1881, the possibility of using cadaveric tissue for transplantation was demonstrated. George Girdner published a report on the successful use of cadaveric skin for the treatment of a burn wound [3]. In the 80s and 90s of the XIX century, some tissues were shown to remain viable for 24 hours after the onset of human death, so for many years cadaveric tissues used to replace the damaged and lost ones were called "surviving".

Thus, by the beginning of the XX century, the possibility of successful use of allogeneic tissues, including those obtained from cadaveric donors, for clinical use had been postulated. The problem was the lack of donor material in the required amount by the time of use, which forced scientists to search for methods of long-term preservation of living tissue. The next important milestone in the development of tissue transplantation was the study by Wentzer in 1903 who reported that a skin graft stored in a refrigerator after its removal retained its viability for up

to 14 days [4]. This concept has been the main idea for the development of tissue banks (tissue institutions). Thus, the basis for the idea of tissue banking was laid at the beginning of the XX century. Harvesting, processing, and storing human tissue for clinical use are the main activities of tissue banks today. Storage of the processed tissue at low temperatures remains one of the best preservation methods.

Replacement therapy using allogeneic tissue grafts has shown its effectiveness in the treatment of injuries or diseases accompanied by a deficiency of native tissue (Table).

Table. Clinical effect and economic benefits of using tissue grafts as based on the experience of N.V. Sklifosovsky Research Institute for Emergency Medicine

Graft type	Pathology	Clinical effect	Economic benefits
Type 1 collagen-based dressing	2nd degree burn Photochemical dermatitis	40% faster wound epithelialization	Reduction of in-hospital length of stay in a Burn Unit by 10-14 bed-days
Acellular dermis matrix	3rd degree burn Wound deficient in tissue	30% reduction in wound preparation time for autodermoplasty Reduction of plasma and electrolyte losses Decreased bacterial contamination of the wound	Reduction of in-hospital length of stay in Burn or Trauma Units by 10-12 bed-days Reducing the cost of transfusion and antibiotic therapy
Bone tissue grafts	Fractures, including those with bone tissue loss	Osteoconduction and osteoinduction Biodegradation and replacement with native tissues	Reducing the time of fracture union No need for additional interventions

The most commonly used allogeneic tissues include: the cornea, skin, bones, cartilage, joints, heart valves, fascia, and tendons (Fig. 1).

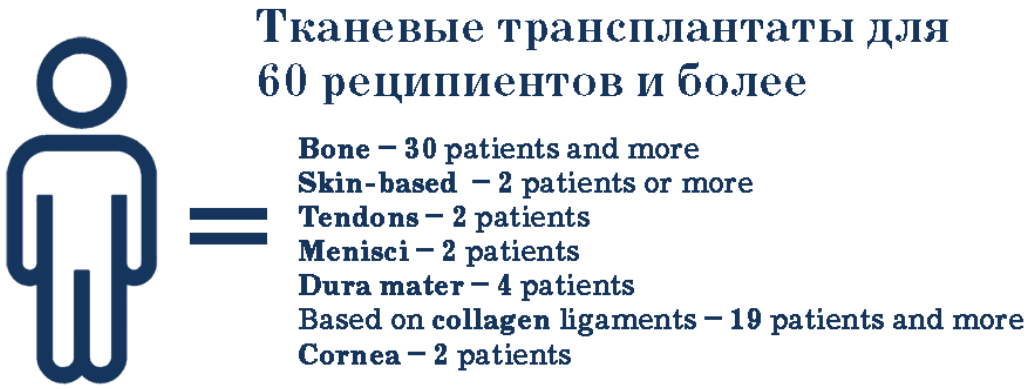

Fig. 1. The number of tissue grafts that can be obtained of tissue from one donor

Tissue banks are developing institutions all over the world. At the same time, the tissue banking arrangement is a rather complex system and requires high technical expertise, qualified personnel, and modern equipment for proper and effective functioning. A deviation from the established protocols leads to donor tissue losses and/or inflicting harm to patients, and carries the risk of transmission of fatal diseases and tumors.

The purpose of this review is to review the world experience in the establishing and development of tissue institutions and the up-to-date approaches to organizing a tissue bank.

History of establishing tissue banks in the world

In the world, the first tissue banks were created in the late 40s-early 50s of the XX century in North America and Western Europe. The main purpose of tissue banking at that time was to provide military hospitals with allogeneic tissue material, primarily, skin and bone grafts. By the

beginning of the 60s, many tissue grafts (bones, skin, heart valves) had already been tested in clinical practice, and the first guidelines for tissue preservation had also been developed. Initially, the tissue banks were formed on the base of individual laboratories that were functionally unrelated to one another. In the 1980s, individual laboratories in the United States began to gradually merge with larger structures that had specialized premises designed exclusively for a certain type of work, trained medical personnel, including mobile field teams performing tissue harvesting, a quality management system, and a system for keeping the accounting-and-reporting records. Currently, large non-profit (national, state) Tissue Banks in the United States, as a rule, perform the entire cycle of work from the moment of donor examination, including the donor selection, removal of tissues, biosafety assurance, quarantine, modification, storage, quality assurance, providing a strategic reserve and deliveries to clinical departments of Medical centers in the country (Fig. 2).

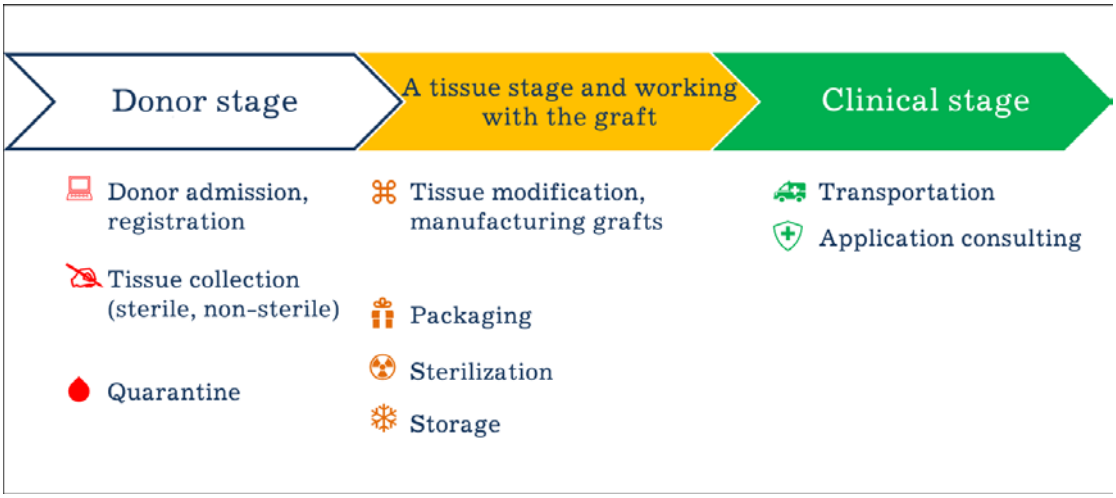

Fig. 2. A "complete" cycle of working with the donor, tissues and grafts

Since the 1970s, a rapid development of transplantation alongside with the population growth and an increased proportion of elderly people has significantly increased the demand for tissue grafts. There arose a need to standardize all stages of work with donors and tissues, as well as the interaction of tissue banks with each other and with clinical departments. For this purpose, the American Association of Tissue Banks (AATB) was established in 1976 [5]. In the late 1980s, the Food and Drug Administration (FDA) announced its intention to regulate "banking operations" with human tissues and at the end of 1993 began to exercise this supervision [5]. This regulation was developed to reduce the likelihood of infectious disease transmissions by setting standards for screening and testing donors. Additional rules also apply to record keeping, labeling, and tracking of tissues and tissue biomedical products [6]. In 1998, the US legislature required the registration of all processes of working with tissue. The Legislation proposed in 1999 included the regulation of all human tissue- and cell-based products, additional donor screening, and reproductive technologies.

In Europe, the problem of implementing uniform international standards for tissue banking is also relevant [7, 8]. In this regard, in 1991, the European Association of Tissue Banks (EATB) was established, which initially included 280 participants from 18 European countries [9, 10]. Representatives of European countries agreed that the organization should report on all its activities in the field of tissue banking. Currently, EATB includes more than 50 countries and more than 10,000 specialists from all over the world.

In Asia, the development of tissue transplantation was delayed due to legal, religious and national characteristics. To speed up this process, in the early 1980s, a group of medical scientists from Asian countries held a series of meetings led by the International Atomic Energy Agency

(IAEA) aiming at organization of a Tissue Bank. In the future, it is the IAEA that will act as one of the main coordinators for the development of tissue banking in the Asian region [11-14]. In many Asian countries, tissue banking started from the preparation and modification of the amniotic membrane for use in the treatment of burns. Despite the large population, many Asian countries experienced a shortage of cadaveric material. To solve this problem, the Asia Pacific Association of Surgical Tissue Banking (APASTB) was established in 1988, which has been coordinated by the Japan Society for Tissue Transplantation (JSTT) [15]. We can say that currently there is an industry orientation of Asian countries for the production of tissue grafts of a certain type. For example, India and Sri Lanka are major producers of corneal grafts [16]. Currently, Sri Lanka plays a key role in providing donor cornea grafts to clinics not only in its region, but also to clinics around the world. In Japan, Thailand, Singapore, and the Philippines, bone allogeneic grafts intended for orthopedic surgery have mainly been produced; China is a major manufacturer of skin-based grafts [18]. At the present stage of tissue allograft development in India and China, with the support of the IAEA, some of the largest tissue banks in the world have been established, which provide their countries with modern allogeneic tissue biomedical products [17, 18]. The establishment of the Asia-Pacific Network of Organ and Tissue Sharing (APNOTS) is currently being discussed to strengthen a closer regional cooperation.

In Latin America, as in Asia, the development of tissue banks was fraught with difficulties due to socio-political, economic and religious aspects. In Brazil, until 2000, tissue banks were only minor repositories within orthopedic surgery services. Only after the IAEA supported the implementation of tissue banking programs in the city of Sao Paulo (Brazil), a modern HC-Tissue Bank was established in 2001 on the base

of the Skin Bank of the Plastic Surgery Department of Das Clinicas Hospital. At the same time, with the help of the IAEA programs, tissue banks were created in Peru, Chile, and Argentina [19-21]. In the 1990s, these countries actively promoted the idea of creating a single Association for tissue banking within the South American continent. As a result, in 2000, the Latin American Association of Tissue Banking (ALABAT) was established in Sao Paulo, Brazil [22]. ALABAT activities also include the exchange of allogeneic grafts between national tissue banks, providing professional capacity support, establishing links with various international scientific organizations, and establishing a network of tissue (skin) Banks to ensure the supply of allografts to any country in the region in the event of a major disaster. Currently, about 200 tissue banks are successfully operating in Latin America. In Latin America countries, bone grafts are intensively harvested and procured, including bone chips, wedges, and powders; and wound coatings based on skin and amniotic membrane are produced [23, 24].

In Cuba, the first tissue bank was founded in Havana in 1957 on the base of the Franco Pais International Scientific Orthopedic Complex [25]. At that time, the Bank used freeze-drying as a preservation method, as well as sterilization of bone tissue, heart valves and other transplants by radiation. Currently, the range of tissue allografts has significantly expanded, and there has been an increase in the production of sterilized tissues using ionizing radiation, which has led to an improved production quality of bone tissue, pig skin and amnion. At the same time, the tissue import has reduced due to the increase in local production.

In the African region, the key manufacturer of tissue transplants is currently the Republic of South Africa based on Tissue Bank. The establishment of the Tissue Bank in South Africa began in the 1960s, and today this Tissue Bank continues developing [26, 27]. The current focus

is on delivering viable bone products that have been manufactured under the best possible quality assurance conditions, in collaboration between various organ donation organizations.

Thus, in the second half of the 20th century, there was a tendency in the field of tissue procurement to enlarge the tissue banks and expand their functionality within individual states. The development of this trend in the late XX–early XXI centuries led to the creation of international associations for tissue banking, which goal, among others, was to standardize the work performed at all stages of operations. The logical result of these processes is the creation of worldwide tissue banking associations. However, given that it is not possible to completely overcome the differences between the regions of the world, including in the medical and socio-legal spheres, it is still important for many countries to improve the professional and legal framework for donor tissue harvesting at the national level.

The creation of a global cooperation in tissue banking

The World Union of Tissue and Cell Banking Associations (WUTCBA) was established in 2005 within the framework of the joint efforts of international organizations in the field of tissue and cell banking to ensure the access to safe and high–quality donor tissues by future recipients around the world [28]. WUTCBA comprises the American Association of Tissue Banks (AATB), the Asia Pacific Association of Surgical Tissue Banks (APASTB), the Biotherapeutics Association of Australia (BAA), formerly: the Australasian Tissue and Biotherapeutics Forum (ATBF), the EATB, and ALABAT. Most recently, the South African Association of Tissue Banks has joined WUTCBA as an observer member. These associations make up 90-95% of globally active tissue manufacturing institutions and production centers; they include

laboratories, testing centers, cell therapy groups, and other industry participants. The World Union of Tissue and Cell Banking (WUTCBA) has the following tasks:

- create a free Association of the world's leading organizations specialists of tissue banks;
- support ethical practices regarding tissue donation and transplantation and oppose the tissue trade;
- work on the harmonization of global practices in the field of donor screening, human tissue procurement/restoration and processing;
- exchange information about events, activities, standards, regulations, education, and research;
- coordinate meeting schedules and promote scientific programs (conferences, seminars, etc.) of member associations;
- organize world scientific meetings and seminars on a regular basis;
- create a global registry of tissue institutions;
- to collect and publish data on the donation of tissues;
- cooperate in the development of quality and biosafety monitoring systems for tissue transplants;
- to support the efforts of universal coding of allograft tissue;
- act as a global and scientific partner in tissue banking for the World Health Organization.

Homeland experience

Our country has extensive historical experience in the field of tissue allotransplantation. Since the middle of the 19th century, scientists in our country have attempted to perform tissue transplantation in order to replace the damaged site. In 1852, N. I. Pirogov, a great Russian surgeon, developed an osteoplastic method for amputation of the foot using non-free autograft and implemented it in Russian medicine as a standard

operation [30]. In 1861, E. I. Bogdanovsky and his collaborators experimentally confirmed the possibility of the engraftment of animal's native bone and the bones taken from other animals. And in 1862, I.Bredikhin expressed the idea of using cadaveric tissues for medical purposes.

The first skin grafting operations using the Reverdin method in Russia were performed in 1870 by S. M. Yanovich-Chainsky, who suggested using small pieces of the epidermis containing the papillary layer. This method of free grafting small in size, but full-thickness skin pieces is called Riverdin–Yanovich-Chainsky method. In 1890, Dr S. S. Ivanova, who used cadaveric skin for transplantation, noted that individual tissues of the body could remain viable for some time after its death, and she based her method on that concept [29].

In the late 1920s, Professor V. N. Shamov was the first to scientifically substantiate the possibility of using cadaveric blood in Transfusiology [31, 32]. In 1930, S. S. Yudin, together with N. V. Sklifosovsky Institute staff, performed the world's first successful transfusion of cadaveric blood to a patient [33-35]. At the same time, V. P. Filatov showed the possibility of the human cadaveric cornea preservation in a wet chamber and performed the first successful transplants of donor corneas. By the end of the 1940s, the number of corneal transplants performed by V. P. Filatov and his trainees exceeded the total number of operations performed in all other countries [36, 37]. In the 50s–60s of the XX century, the widespread development of tissue allotransplantation in the USSR began: new laboratories and departments for tissue harvesting were established, the range of harvested tissues was expanded, new methods of harvesting and storing grafts were implemented, which in fact was the prototype of modern "tissue banks". From 1963 to 1965, more than 200,000 tissue allografts were implanted

in the Soviet Union. In 1965, there were departments designated for tissue transplantation in almost all the USSR cities with a population of one million or more. The largest laboratories were located in Rostov-on-Don, Kiev, Kharkov, Yerevan, Novosibirsk, Saratov, Donetsk, Minsk, Dnepropetrovsk, Odessa, Sverdlovsk, Gorky, Leningrad, Kuibyshev, Baku, Khabarovsk, Alma-Ata and many others. In the late 60s, the N.V.Sklifosovsky Institute developed innovative bone allografts that brought trauma surgery technology to a fundamentally new level [38]. I.N.Kulagin wrote a unique manual on mechanical processing of bone allografts in sterile conditions [39].

In the 70s–80s, there was an active search for optimal methods of preserving tissue grafts [40, 41]; methods of graft chemical modifications, in particular, bone demineralization, were developed [42-44]; and the clinical efficacy of modified bone grafts in clinical practice was demonstrated [43-45]. Until the end of the 80s, the work in the field of tissue transplantation was carried out in accordance with the USSR Health Ministry Order No. 482 of June 14. 1972, "On improving the provision of medical institutions and clinics with cadaveric tissues, bone marrow and blood", which regulated the work with human tissues, including the tissue donor selection, tissue explantation, quarantine, modification, sterilization, ensuring biosafety, and delivery for clinical use. That Order regulated the work with tissues, and also laid the basis for the standardization of allogeneic grafts. Unfortunately, the Order was canceled in 1988, and no other similar regulatory document was developed in its place (Fig. 3).


МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ СССР

ПРИКАЗ
от 14 июня 1972 г. N 482

ОБ УЛУЧШЕНИИ ОБЕСПЕЧЕНИЯ ЛЕЧЕБНО-ПРОФИЛАКТИЧЕСКИХ УЧРЕЖДЕНИЙ И КЛИНИК ТРУПНЫМИ ТКАНЯМИ, КОСТНЫМ МОЗГОМ И КРОВЬЮ

Приложение
к Приказу Министра
здравоохранения СССР
от 14 июня 1972 г. N 482

ИНСТРУКЦИЯ
ПО ЗАГОТОВКЕ ТРУПНОЙ КРОВИ,
КОСТНОГО МОЗГА И ТКАНЕЙ

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ
РОССИЙСКОЙ ФЕДЕРАЦИИ

ПРИКАЗ

от 10 августа 1993 года N 189

О дальнейшем развитии и совершенствовании трансплантологической помощи населению Российской Федерации

(с изменениями на 20 апреля 2001 года)

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ И СОЦИАЛЬНОГО РАЗВИТИЯ
РОССИЙСКОЙ ФЕДЕРАЦИИ

РОССИЙСКАЯ АКАДЕМИЯ МЕДИЦИНСКИХ НАУК

ПРИКАЗ

от 25 мая 2007 года N 357/40

Об утверждении Перечня органов и (или) тканей человека - объектов трансплантации, Перечня учреждений здравоохранения, осуществляющих трансплантацию органов и (или) тканей человека, и Перечня учреждений здравоохранения, осуществляющих забор и заготовку органов и (или) тканей человека

(с изменениями на 24 мая 2011 года)

Fig. 3. Canceled regulatory documents

From the 1990s, there was a clear decline in research and application of cadaveric tissues in the Russian Federation due to certain reasons. Units dealing with this issue suffered closures throughout the country. To date, there are only a few operating units in Moscow, Samara, Ufa and Novosibirsk. Units working with human tissues, "tissue banks", in Samara and Novosibirsk are located on the base of educational institutions, the Unit in Ufa is a completely commercial structure. We can draw a sad conclusion that, despite the unconditional historical success of our country in the field of tissue banking, currently this branch of medicine is in an unsatisfactory state, and the scale of donor tissue production in the Russian Federation is comparable neither with Western countries, nor with the fast-growing countries of the Asia-Pacific region. The official sources do not indicate the volume of the demand for tissue grafts in medical institutions of the Russian Federation. However, taking into account the number of population in the Russian Federation, the structure and rates of morbidity, we can conclude that the annual need for tissue grafts in our country makes several tens of thousands. Therefore, the problem of restoring allogeneic tissue banks in the Russian Federation is extremely urgent.

Legal difficulties of tissue banking development in the Russian Federation and possible ways to overcome them

One of the most important causes for the lack of tissue transplantation development in Russia is a disagreement of some regulatory and legal documents guiding the industry. In the 90s of the previous century, organ transplantation began rapidly developing in Russia. Federal Law No. 4180-1 dated 22.12.1992, "On transplantation of human organs and (or) tissues" was adopted for the legal regulation of the developing field of medicine. (Fig. 4) The Law was aimed primarily at the development of organ transplantation. An important aspect of the Law was the issue of organ and tissue donation. Subsequent RF Health Ministry Orders on organ and tissue transplantation also regulated the work of medical institutions mainly related to organ transplantation. Note, Order No. 357/40 of the Ministry of Health and Social Development of Russia and the Russian Academy of Medical Sciences dated 25.05.2007, "On approval of the List of human organs and (or) tissues - objects of transplantation, the List of health care institutions performing transplantation of human organs and (or) tissues, and the List of health care institutions engaged in harvesting and procurement of human organs and (or) tissues" (Fig. 3) allowed harvesting the tissues most in demand in clinics, but the Order effect was canceled by Order No. 355n issued by the RF Health Ministry on June 8, 2016, "On approval of the procedure for keeping records on donor organs and human tissues, organ and tissue donors, patients (recipients), the forms of medical documentation and the statistical reporting forms to keep records on donor organs and human tissues, organ and tissue donors, patients (recipients) and the procedure of filling them in" where the List missed mentioning the main tissues used in clinical practice, such as the dura mater, bone, skin, ligaments, and

tendons (Fig. 4). Thus, in Russia, tissue grafts and their use are not legally defined nowadays, which dramatically complicates both the process of their production and application in clinical practice.

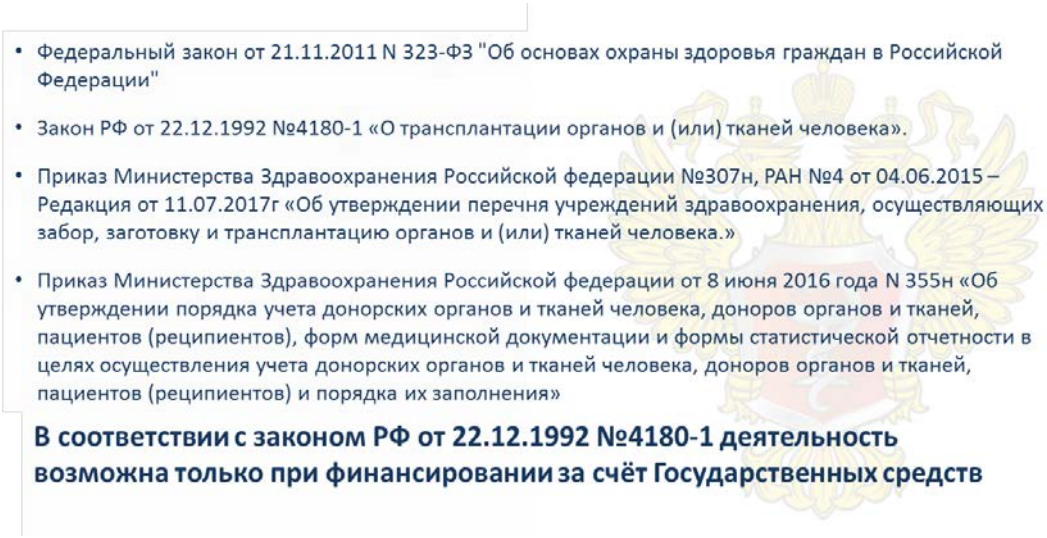

Fig. 4. Regulatory and legal acts in force

It seems reasonable to propose a format in which donor organs and tissues will be legally differentiated i.e. their production, storage and use will be regulated by different structures. From a medico-biological point of view, all grafts removed from a donor can be divided into two categories: vascularized grafts, which are directly connected to the patient's circulation and non-vascularized grafts, whose use does not imply their direct connection to circulation The first group of grafts includes all donor organs, as well as autologous fragments of skin, bone, and cartilage on the musculo-vascular pedicle. The second group of grafts consists of the allogeneic tissue grafts described above, as well as blood cells, collagen, other components of the intercellular matrix and products based on them. If the transplantation of vascularized grafts requires specially equipped transplantation departments and trained personnel, then the transplantation of non-vascularized grafts can be

performed on the basis of conventional medical institutions and clinics without the involvement of professional experts in transplantation. This approach is implemented in almost all countries. In the United States, the FDA on its website emphasized that organ transplantation is regulated by the Health Resources Services Administration (HRSA), whereas all the issues on the tissue banking, starting from the selection and testing of donors, are regulated by the Center for Biological Evaluation and Research (CBER) [46]. The purpose of CBER's work is primarily to ensure biological safety, reduce the risk of blood-borne infection transmissions, to evaluate donors, control ready-made tissues, as well as deal with the legal aspects of tissue graft registrations [6, 46, 47]. At the same time, an information and digital database of available tissue grafts is being created, which allows quickly finding the necessary medical product that is approved for use. This approach seems to be very effective and relevant for implementation in our country, especially in the framework of the updated digitalization process for the entire economic sphere of Russia.

Conclusion

Tissue donation is a complex of activities aimed at examining a potential donor, harvesting tissues, their transportation and quarantine. At all stages of this process, clear regulations are required that would define acceptable and unacceptable actions, as well as the conditions under which they can be carried out within the framework of tissue harvesting. It is obvious that surviving tissues (capable of maintaining their viability for a certain period of time) can be removed from a donor at a later period, in contrast to the tissues that are not capable of vital activity after the donor's death. In this case, the possibility to perform an emergency or

urgent operation to remove the tissue is extremely essential. In the absence of a specialized team for the removal of donor tissues in medical institutions, it is relevant to involve mobile field teams, which requires close cooperation between various medical disciplines. In this regard, the development of legislative acts aimed at regulating the activities of tissue banks becomes particularly important.

In the world practice, there is a clear tendency to create professional communities in the field of development of tissue institutions, both at the national and international levels. Most likely, the extent of this process will increase in future. The development of cooperation in tissue banking is extremely relevant for our country. It is necessary to create national associations for a close cooperation in the field of tissue procurement, regulation and standardization of all stages of working with donors and donor tissues, for assessing the quality and safety of tissue grafts and biomedical products based on them.

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