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LEGAL REGULATION OF BONE BANKS IN THE RUSSIAN FEDERATION

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Autologous bone grafts are considered the gold standard for bone grafting, but in cases where their use is limited or impossible, allogeneic bone tissues become the first alternative. To date, the legal status of the activity on manufacturing bone grafts from femoral heads after total hip replacement surgery has not been defined. This somewhat hampers the development of this technology in Russia. Specialized institutions typically use internal instructions developed and approved taking into account existing legal norms in various fields. The creation of uniform operating rules, standards, instructions, clinical guidelines for working with donor tissues, as well as relevant sufficient regulatory and legal support would promote the development of tissue transplantology, bioimplantology and tissue engineering. This, in turn, would open up wide opportunities for the development of new methods of treatment of diseases, injuries, traumas and their consequences.

Keywords: tissue, medical activity, regulations, allogeneic bone tissue, femoral head, procedure legal status.

According to the Russian transplantation law, transplantation of human organs and (or) tissues is a means of saving life and *restoring the health of a person* and should be done in compliance with the laws of the Russian Federation and human rights in accordance with humane principles proclaimed by the international community, *while the interests of the individual must prevail over the interests of society or science* [1].

Proceeding from this, Article 1 of the said law provides that *transplantation* of organs and (or) *tissues from a living or deceased donor is applied* only *if other medical means cannot guarantee* preservation of the patient's (recipient's) life or *restoration of his/her health*; removal of organs and (or) tissues from a living donor is admissible only if his/her health will not be significantly harmed based on a report from a medical council and can take place only with the consent of the living donor; human organs and (or) tissues cannot be sold or purchased; the sale and purchase of such organs and (or) tissues, as well as advertising of these actions is a criminal offense under the laws of the Russian Federation.

To confirm the relevance of this issue, let us consider clinical examples from the specialized scientific literature presented by Majoor et al. [2].

Clinical example #1

A 17-year-old patient. DS: fibrous dysplasia of the left proximal femur. ***Surgical treatment:*** *resection of the mass, plasty with two* ***cortical allografts*** *from the fibula (Fig. 1).*

The patient was removed from further follow-up with good function and no pain [2].

Clinical example #2

A 15-year-old patient. DS: fibrous dysplasia of the right femoral neck (Fig. 2).

Surgical treatment: *resection of the mass, plasty with a* ***cortical autograft*** *from the tibia [2].*

In clinical cases #1 and #2, an alternative to the gold standard (i.e. optimal set of characteristics) was used for bone grafting and restoration of patient's health – cortical allograft from the fibula, an allobone, an osteoplastic material.

Clinical examples are summarized in one publication. Even though the surgical treatment was performed in compliance with similar approaches and surgical technique, a directly opposite result was obtained under a control period. In case #1, treatment was effective and bone graft remodeling was determined radiologically, while in case #2, there were allograft resorption and disease recurrence in the same localization [2].

Clinical examples were given by authors from the Netherlands, where legal issues on allogeneic bone use have been addressed. Is it possible to use allogeneic bone on the territory of the Russian Federation? And can this be done in a way to comply with all regulations in Russia?

The concept of "medical activity" stipulates that providing medical care, conducting medical and physical examinations, sanitary and anti-epidemic (preventive) measures and professional activity related to transplantation of organs and (or) tissues, circulation of donor blood and (or) its components for medical purposes constitute a professional activity (Article 2 of Federal Law No. 323-FZ) [3].

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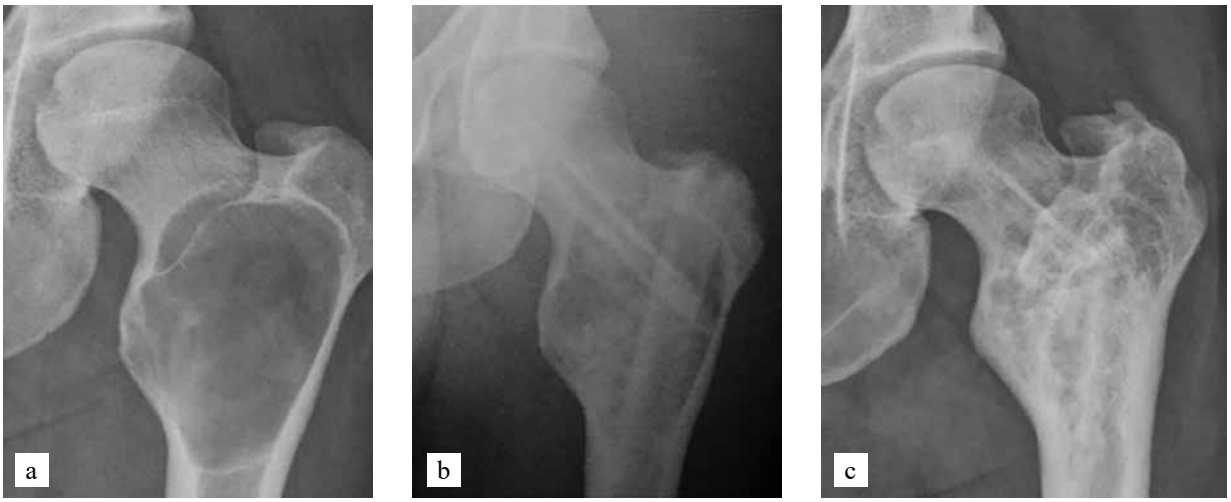
According to Article 12 of the Federal Law No. 99-FZ of May 4, 2011 "On Licensing of Certain Types of Activities", medical activity is subject to licensing [4].

Thus, for a state/municipal institution to be allowed to provide medical care for organ and (or) tissue transplantation, to carry out medical activities related to organ and (or) tissue donation for transplantation, that institution must meet the following requirements:

– obtain a license for the relevant work (services);
– be included in the lists of healthcare institutions that harvest, prepare and transplant human organs and (or) tissues, which are approved by the Russian Ministry of Health (RMH) jointly with the Russian Academy of Medical Sciences (RAMS) [5].

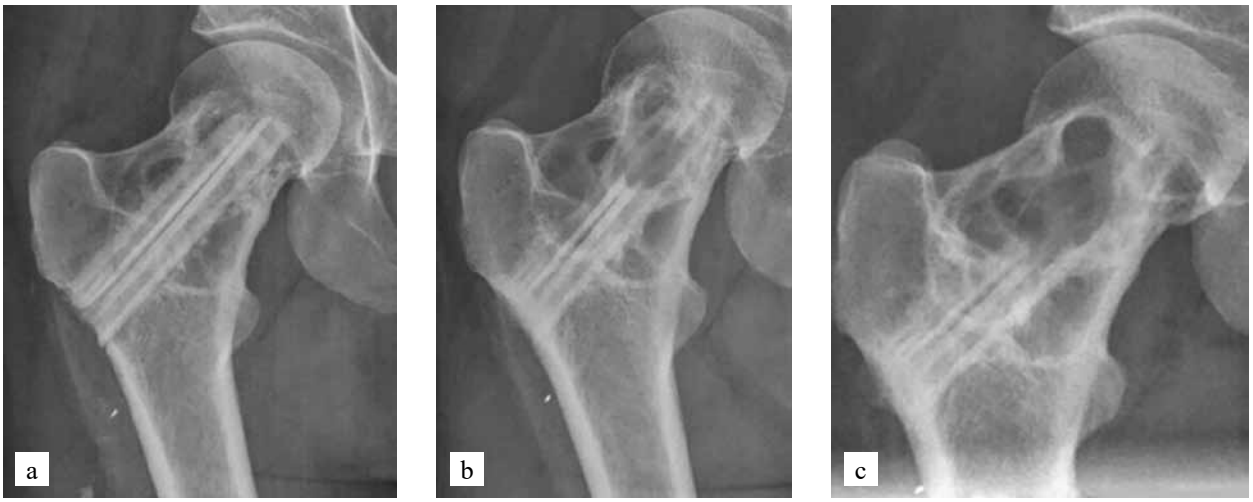
In addition, one of the main requirements for obtaining a license for medical activity is that the medical institution must comply with the Healthcare Procedure, approved by the authorized federal executive body and mandatory for all medical institutions in the territory of the Russian Federation (Article 37 of Federal Law No. 323-FZ) [3].

If we apply the transplant laws of the Russian Federation in full to the activity of manufacturing bone grafts from femoral heads after total hip replacement surgery, then it is necessary to license medical institu-



Preoperative **Control at 3 months** **Control at 7 years**

Fig. 1. Radiographs of a patient with an expansive lesion in the proximal femur with a ground glass aspect and cortical thinning: a, preoperative condition. the diagnosis of fibrous dysplasia was histologically confirmed, and the patient was treated with implantation of two fibular strut grafts; b, control at 3 months: strut grafts gradually incorporated in vital bone with intact (undamaged) bone; c, 7 years after surgery: radiologically positive dynamics with the formation of bone architectonics in the area of surgery [2]



Postoperative **Control at 12 months** **Control at 7 years**

Fig. 2. Dynamic radiographs of the right femoral neck: a, the radiograph is made postoperatively and shows two fibular strut grafts that cross the dysplastic lesion but have minimal contact with vital bone proximally; b, after 1 year, graft resorption gradually increases; c, after 7 years, strut graft is resorbed over the full length of the diameter, losing its stabilizing function

tions for work (services) on procurement and storage of human organs and tissues for transplantation (Table 1). Moreover, the licensing requirements for preparation of removed femoral heads are not defined in Transplantation Procedure No. 567n. In addition, inclusion of medical institutions in Lists No. 738n/3 is required. In this case, contradictions have long been eliminated, as all institutes and centers of traumatology and orthopedics are present in the lists of organizations that perform both procurement and transplantation of organs and (or) tissues.

While these changes are implemented to some extent in multidisciplinary hospitals, it is a problem for single-profile hospitals and federal centers, because it requires large resource costs, whose feasibility is not obvious (Tables 1, 2).

If we apply to these activities Federal Law No. 323-FZ and medical waste regulations, then it is not required to license medical institutions for works (services) on procurement and storage of human organs and tissues for transplantation and include them in Lists No. 738n/3. The activity will be carried out within the framework of a license for work (services) on "traumatology and orthopedics".

In the Russian Federation, medical care in surgery (transplantation of human organs and (or) tissues) and medical activities for removal and storage of human organs and (or) tissues for transplantation may be carried out by state and municipal medical institutions that have been licensed for these types of medical activities in accordance with the established procedure.

In addition, in accordance with the Law No. 4180-I of the Russian Federation "*On Transplantation of Human Organs and (or) Tissues*" of December 22, 1992 (Article 4), such medical institutions should be included in the List of health care institutions engaged in collection, procurement and transplantation of human organs and (or) tissues, approved by RMH and RAMS [5–7]. At the same time, the procedure for their inclusion and exclusion in the List is not defined in the laws of the Russian Federation. This is why medical institutions that decide to run a donor and (or) transplantation program face a well-known legal conflict: in what order should they be licensed and included in the List? The new List of healthcare institutions was approved by RMH and RAMS on November 10, 2022 (order No. 738n/3). It includes 210 medical institutions that harvest and prepare human organs and (or) tissues and 106 medical institutions engaged in transplantation of human organs and (or) tissues.

In accordance with Article 2 of the Law of the Russian Federation "*On Transplantation of Human Organs and (or) Tissues*", RMH and RAMS jointly determine the List of human organs and (or) tissues – objects of transplantation. The current List was approved on June

Table 1

Challenges with the licensing of works (services)

License for transplantology Full implementation of the requirements of the current Regulation (Order No. 567n of the Ministry of Health of the Russian Federation, dated December 21, 2012	**Changing the staffing and organizational structure of the institution** Creation of new units: – Transplantation Department; – Hemodialysis Department; – Pathologoanatomic Department; – Therapeutic Departments; – Organ Donation Coordination Department; – Clinical Immunology Laboratory
	Additional equipment: – Angiography system – Hemodialysis and Hemofiltration Machine – Mass Spectrometer
	Training of highly specialized doctors (orthopedic traumatologists, ophthalmologists, cardiac surgeons) under the following additional specialties: – Surgery – Organ and (or) tissue transplantation

Table 2

Challenges with the licensing of works (services) depending on type of donation

Donation type	
Living	**Deceased**
• Licensing requirements on procurement of removed femoral heads are **not defined** (transplant). • Licensing for type of medical activity is **not required** (medical waste)	• Licensing for this type of medical activity lies under the Office of the Chief Medical Examiner • Licensing for this type of medical activity of the institution lies under the anatomical pathology departments of medical institutions (if the institution has no such department)

4, 2015 via order No. 306n/3 [8], which contains only 25 items (Table 3). Seven items in the List correspond to the types of solid organ transplants that are performed under the state guarantee program for free provision of medical care to citizens (*VMP2*), another 1 is bone marrow and hematopoietic stem cell transplantation (*VMP2*). The remaining 17 items in the List are tissues that can not only be transplanted but also be used for production of medical devices and their application in reconstructive plastic surgery, traumatology and orthopedics, dentistry, and ophthalmology [7, 9].

It is the "tissue part" of the List that raises the most questions among specialists, since the legal status and quantity of tissues may change significantly depending on the technology of their production, processing, registration, and use. Tissues that are not in the List fall out of the legal regulation for clinical use; for example, cartilage, bone, ligaments, dura mater, pericardium, vessels and others.

The wording of paragraphs 4 and 12 – "upper limb and its fragments" and "lower limb and fragments" – is also confusing, since transplantation of the upper limb as a tissue complex was hardly what was meant here. Most likely, this refers to fragments of various tissues topographically located in a given skeletal segment. However, lack of clarifications in the regulatory documentation is a limitation to systematic activities in this direction.

One of the approaches to solving this problem can be to enlarge the positions of the List taking into account global practice, classifiers of human organs and tissues for transplantation existing in other countries. The List of transplant objects, compiled taking into account the classification of the European Committee on Organ Transplantation (CD-P-TO), is presented in Table 4 [9].

In accordance with Article 37 of Federal Law No. 323-FZ of November 21, 2011 "*On the Fundamentals of Public Health Care in the Russian Federation*", health care is organized and provided:

Table 3

List of human organs and (or) tissues – objects of transplantation

No.	Organs (tissues)
1.	Amniotic membrane
2.	Tunica albuginea
3.	Vascularized soft tissue complex, including skin layer, fatty tissue and muscles
4.	Upper limb and its fragments
5.	Temporal fascia
6.	Eyeball (cornea, sclera, lens, retina, conjunctiva)
7.	Intestine and its fragments
8.	Cardiopulmonary complex
9.	Cranial vault bones
10.	Bone marrow and hematopoietic stem cells
11.	Lungs
12.	Lower limb and fragments
13.	Lower jaw
14.	Liver
15.	Pancreas with duodenum
16.	Subcutaneous fatty tissue of the plantar region
17.	Kidneys
18.	Spleen
19.	Heart
20.	Serous capsule of the liver
21.	Vessels (sections of the vascular bed)
22.	Trachea
23.	Renal capsule
24.	Endocrine glands (pituitary, adrenal, thyroid, parathyroid, salivary gland, testis)
25.	Cells intended to replace (perform) their inherent functions in the body, which are obtained (prepared) from biological material as a result of its grinding, homogenization, enzymatic treatment, removal of undesirable components, selective selection of cells and (or) their treatment to remove preservatives in case of their storage and which do not contain other substances (objects), except for water, crystalloids, sterilizing, preservatives, as well as biological material for their preparation

Table 4

List of human organs and (or) tissues according to the CD-P-TO Registry, published annually in the Newsletter Transplant Journal [9]

No.	Organs
1.	Kidney
2.	Liver
3.	Heart
4.	Lung
5.	Cardiopulmonary complex
6.	Pancreas
7.	Pancreas with duodenum
8.	Intestine and its fragments
	Tissues
9.	Bones
10.	Ligaments
11.	Tendons
12.	Fascia
13.	Cartilage
14.	Skeletal muscles
15.	Eye tissues (cornea, sclera, lens, retina, conjunctiva)
16.	Skin
17.	Vessels
18.	Heart valves
19.	Amniotic membrane
20.	Placenta
21.	Bone marrow and hematopoietic stem cells
22.	Adipose tissue
23.	Pancreatic tissue
24.	Endocrine glands
25.	Trachea
26.	Unclassified tissues

– in accordance with the regulations for providing health care by types of health care;
– in accordance with the Healthcare Procedure;
– based on clinical guidelines;
– considering healthcare standards.

Healthcare for organ transplantation, medical activity related to organ and (or) tissue donation for transplantation is regulated by the Healthcare Procedure in the "*Surgery (Transplantation of Human Organs and (or) Tissues)*" Profile, approved by RMH on October 31, 2012 (order No. 567n) (hereinafter referred to as "Healthcare Procedure" or " Procedure") [10]. This Procedure needs to be updated.

The following phrase appears in a piece published in a specialized scientific journal in 2022 [11]:

"The action of the Procedure does not apply to:

– Health care for transplantation of eyeball fragments (cornea, sclera, lens, retina, conjunctiva), which is provided in accordance with the Healthcare Procedure in the "*Ophthalmology*" profile in medical institutions licensed to carry out medical activities, including works (services) in ophthalmology;
– Health care for transplantation of musculoskeletal fragments (bones, cartilage, ligaments, fascia, tendons, muscles, skin), which is provided in accordance with the Healthcare Procedure in the "*Traumatology and Orthopedics*" profile, in medical institutions licensed to carry out medical activities, including works (services) in traumatology and orthopedics [12];
– Health care with the use of medical products that were prepared using tissue components;
– Medical activities related to the procurement of human cadaveric tissues at the thanatology departments of forensic medical examination bureaus and pathology departments of medical institutions;
– Medical activities related to the procurement of human cadaveric tissues for preparation of medical products" [11].

However, there are no references or interpretations in the regulatory documents (Fig. 3), which again can be interpreted at present only as the opinion of the head of a specialized department at RMH and the RMH chief freelance specialist for that field.

Thus, at present there are certain "scissors" in the laws of the Russian Federation, consisting of the following:

Health care should be provided in accordance with the standards and procedures for provision of health care, i.e. with registered medical products, and the registration of allogenic products is not possible because the source of "raw materials" and the legitimacy of obtaining allogenic bone tissue and its use have not been fully addressed.

According to Sergey Gautier, Fellow, Russian Academy of Sciences, chief freelance transplant specialist at RMH, the key issue is actualization of the regulatory and legal framework in the field of donation and transplantation of human organs and tissues *at the level of federal subjects of the Russian Federation*.

As an example of a systemic regulatory and legal act in the field of organ donation and transplantation at

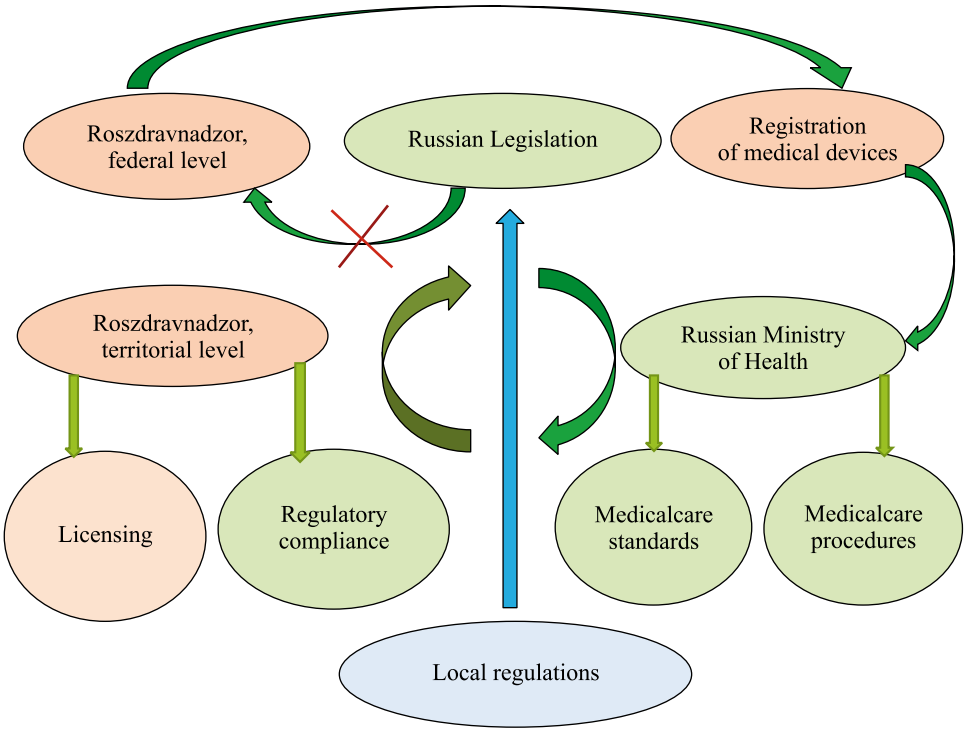


Fig. 3. Tissue bank regulatory challenges. Roszdravnadzor, Federal Service for Surveillance in Healthcare

the level of federal subjects is an Order (No. 737) of the Department of Health of Moscow of October 19, 2017 "On Medical Activities Related to Donation of Human Organs and the Provision of Medical Care in the "Surgery" (transplantation of human organs and tissues) profile in the city of Moscow". However, despite its title, this document is devoted exclusively to organizational issues of organ donation, contains gaps in the part of tissues and could be transferred to the level of a federal subject of the Russian Federation.

It is recommended to transfer a number of issues subject to legal regulation to the level of a federal subject of the Russian Federation, for example:

1. Procedure for implementation of medical activities related to tissue donation for the purpose of tissue transplantation and (or) manufacturing of medical devices.
2. Procedure for interaction with the forensic medical examination bureau when conducting activities related to organ and (or) tissue donation for the purpose of transplantation.
3. Procedure for maintaining a waiting list and distributing donor tissues for transplantation and (or) manufacturing of medical products.
4. Regulations on regional coordination centers of organ and (or) tissue donation.
5. Regulations on interaction with medical institutions carrying out activities in the field of organ and (or) tissue donation and (or) transplantation on the territory of other federal subjects of the Russian Federation.
6. Registers of medical institutions carrying out medical activities related to organ and (or) tissue donation and (or) transplantation.
7. Standard forms of documentation in implementation of medical activities on organ and (or) tissue donation and (or) transplantation [13].

We would like to note that this statement is in contradiction with Federal Law FZ-323, which states that *all citizens of the Russian Federation have the right to quality healthcare regardless of their place of residence*. Transferring the regulatory framework to the regional level allows for regional differences in such an important area of activity and makes the need for regulatory and legal regulation vital for the industry as a whole, and for specialists and patients in particular.

Back in 2016, we analyzed the legislation of the Russian Federation regarding the legal norms regulating tissue donation and transplantation; we also analyzed the appeals received by the chief freelance transplant specialist at RMH on this issue.

Based on the study, it was concluded that "*gaps and conflicts in the legal regulation of tissue donation and transplantation in the Russian Federation exist, are significant and should be eliminated. This is one of the basic conditions for further development of tissue transplantology in the Russian Federation*" [14].

The following tasks were formulated as priority tasks for improving the legal framework:

1. Remove the legal conflict "licensing – lists" in Decree No. 291 of the Government of the Russian Federation of April 16, 2012 (see item 4, sub-item 3, paragraph 2).
2. Clarify the list of licensed works and services in the "*Transplantation*" profile in accordance with the object (type) of transplantation. Study the issue of state supervision over production and circulation of medical products using human tissues (part 5 of Article 38 of Federal Law 323-FZ).
3. Develop and approve the Regulation on procurement of donor tissues, including requirements for the standard of equipment and staffing of specialists of medical institutions to carry out this activity. Clarify the legal regime for the procurement of donor tissues (Article 47 or Article 68 of Federal Law 323-FZ).
4. Develop and approve Regulations on the activity of tissue banks, make appropriate changes to the Healthcare Procedure in the "Ophthalmology" (eye banks) profile, to the Healthcare Procedure in the "traumatology and orthopedics" (bone banks) profile.
5. Clarify the legal status of the activity on manufacturing bone grafts from femoral heads after total hip replacement surgery.
6. Develop and approve separate accounting and reporting forms for human tissue donation and transplantation, make appropriate changes to Order No. 355n of the Russian Ministry of Health.
7. Develop methodological guidelines on procurement of donor tissues and on the operation of tissue banks.
8. Supplement the state program of the Russian Federation "Health Care Development" with measures on tissue transplantology, including the activity of forensic medical examination bureaus on procurement of donor tissues and the activity of tissue banks.

These tasks remain relevant today.

Till now, the legal regulation is undergoing changes, but, unfortunately, it concerns only organ donation. At the same time, the word "tissues" always appears in the title of regulatory documents. That is why the release of each Order or supplement to Orders of the Russian Ministry of Health arouses interest among specialists dealing exclusively with the issues of tissue procurement and use within the framework of separate surgical specialties.

A vivid example is such a direction as "Traumatology and Orthopedics".

In the Russian Federation, 30,000–35,000 total hip arthroplasty operations are performed annually, and the need, according to expert estimates, is at least 100,000 operations per year [15]. After such surgeries, a valuable biomaterial – removed femoral heads – remains. After several manipulations, it can be used in reconstructive and plastic surgeries to replace bone tissue defects.

To date, the legal status of the activity on production of bone grafts from femoral heads after total hip arthroplasty has not been defined. This somewhat complicates development of this technology in the country.

The entire donor tissue workflow can be divided into three main steps [16, 17]:

– Donation;
– Storage, processing and sterilization;
– Clinical application.

It should be remembered that human tissue is a unique biological structure. By its structure and functional properties, any tissue is unique, and in cases of massive lesions or pathological changes, it can be irreparable using its own regenerative resources.

Autologous tissues for transplantation are considered the gold standard, but in cases where their use is limited or impossible, allogeneic tissues become the first alternative.

In contrast to organ transplantation, where the main principle is preservation of organ viability, the preservation of their biological activity and structure (after processing and sterilization), which ultimately leads to positive treatment outcome, is of crucial importance in allogeneic tissue transplantation [18, 19].

In world clinical practice, the femoral head is singled out as a separate unit among donor tissues of living donors. A resected femoral head is an available donor material suitable for further use both as a native (fresh frozen) graft and as other biomaterials made from it, different in shape, processing method and sterilization.

On the territory of the Russian Federation, an organizational and functional model of femoral head procurement with the compilation of process flowcharts and provision of mandatory documentation was proposed in 2009 [20]. For the first time in national literature, a system based on the process approach is presented, covering organizational, ethical and technical issues, taking into account the existing regulatory and legal framework. Development of this process made it possible to preserve valuable bioplastic material necessary not only for revision interventions on large joints, but also for other pathologies associated with bone tissue deficiency in a separate institution.

The above-mentioned phasing of donor tissue processes is given for a better understanding of the fact that different phases are currently under the responsibility of different professional communities and legal regulations [17, 19].

Under current legislation, tissue extraction is permitted for scientific, educational and therapeutic purposes; these purposes are different in nature. Working with donor tissues requires government regulation.

According to the chief transplant specialist at RMH, *it is inappropriate to apply the human organ/tissue transplantation laws of the Russian Federation* to this biomaterial since in this case, there are no operations involving tissue harvesting from the donor and tissue transplantation to the recipient. The material is obtained as a result of a hip replacement surgery performed on a patient for medical indications and is used after deep processing as a medical product in several patients when performing reconstructive plastic surgeries to replace bone tissue defects. In essence, this biomaterial is a medical waste, since, according to Russian law, medical waste includes anatomical waste generated in the course of medical activities. Unfortunately, Federal Law 323-FZ in Article 49 does not provide for the possibility (does not establish rules) of processing anatomical medical waste into medical products [21].

On this issue, we agree with Sergey Gautier and believe that the legislation on transplantation approaches the direction only selectively. Any biomaterial, taken even during surgery, before undergoing technological processing, must be diagnosed to ensure there is no risk of transmitting bloodborne infections. Specialists have no alternative method of diagnostics other than additional examination of the patient as a tissue donor. It is this tissue procurement stage that falls into the zone of regulation in accordance with the "*Transplantology*" profile, since in the preoperative period, the patient's blood is collected for PCR (polymerase chain reaction) and ELISA (enzyme-linked immunosorbent assay) diagnostics of infectious processes. Even though hospitalization is scheduled and compulsory examinations, including for bloodborne infections, have already been conducted, infections are detected in 10–15% of cases even at this stage of additional examination of the patient as a donor.

For patients from whom femoral heads removed after prosthetics remain, the rules on informed voluntary consent (Article 20 of Federal Law 323-FZ) to use their biomaterial for medical products should be applied. Regarding the production and use of bone grafts, the rules of Article 38 of Federal Law 323-FZ on medical products apply [21].

At present, there are no uniform guidelines in Russia that would regulate the handling of this donor material, there is no clear definition classifying this biomaterial, and there is no objective information on the number of primary hip replacement surgeries and the number of resected heads and their further use. Nevertheless, attempts are constantly being made to standardize technological processes by different institutions at their bases.

Proposals for standardization of Russian tissue banks were prepared based on the concept of mass allotissue procurement in any conditions, not only in the aseptic conditions of the operating room, which was proposed by Vladimir Savelyev, the head (1962–1973) of the laboratory of biotissue procurement and preservation at Novosibirsk Research Institute of Traumatology and Orthopedics. However, further development of the standardization process with the formation of regulatory legal

acts throughout the Russian Federation, unfortunately, did not happen [20, 22, 23].

Specialized institutions, as a rule, use internal instructions developed and approved taking into account the existing legal norms.

Emerging publications [17–20, 24] and methodological guidelines [25] can serve as a confirmation. Methodical guidelines "*Safety and Quality Control of Allogeneic Human Tissue Transplants*" of the Moscow City Department, dated 2022, agreed upon by the chief freelance transplant specialist at Moscow City Health Department, fully describe the processes and approaches used in the tissue banks of the Russian Federation. These guidelines are based on various regulatory documents that have not yet been formed into a coherent system but ensure maximum safety and efficiency. At the same time, some of the documents relate to legislation on donors, and some to the regulatory documents on medical products. But, again, everyone should realize that it is not possible to use regulations concerning medical products in isolation. This is because "raw materials" here are not metals and plastics that can be standardized, but are human tissue fragments, i.e. standardization can only concern the criteria for donor selection, infectious safety, structural integrity, processing technology, including final sterilization and bacteriological control.

Currently in the Russian Federation, tissue grafts are outside the legal field, which dramatically complicates both the process of their production and their use in clinical practice [24].

Thus, working with donor tissues implies complex interprofessional interaction, all stages of which should be regulated [17, 19]. Creation of unified rules, standards, instructions, clinical guidelines for working with donor tissues, as well as having sufficient regulatory and legal support will contribute to the development of tissue transplantology, bioimplantology and tissue engineering, which, in turn, will open up wide opportunities for the development of new methods for the treatment of diseases, injuries, traumas and their consequences [25].

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