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# Setting up clinical and production-based biobanks in the healthcare system of the Russian Federation

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**Abstract**

***Background.*** *The therapeutic efficacy of skin grafts and various tissue equivalents in the treatment of many diseases is known. Special clinical biobanks are engaged in the procurement of such products, their processing, storage, provision of their safety measures, and preparation for use. The purpose of such biobanks is both the storage of tissues and cells and their subsequent delivery to medical institutions for the clinical use. The production-based biobanks allow the use of biomaterial for the manufacture of drugs and medical devices and are also an important component in the organization of medical care in many countries of the world.*

***Objective.*** *To summarize the current concepts on the role of clinical and production-based biobanks in the system of providing medical care to the population in various countries of the world; to present the organizational and legal mechanisms of the tissue banking system using the example of the USA and the EU; to present solutions for creating the first biobanks of viable tissues in the Russian Federation using the example of a skin biobank.*

***Material and methods.*** *The review includes world literature publications on tissue banks, references to legal acts and documents regulating tissue donation in Russia and other countries, as well as issues of organizing the work of biobanks.*

***Conclusion.*** *This article introduces an overview of biological banking practices, the main types of grafts and tissue equivalents of skin, the areas of their possible use and the peculiarities of processing and storage technology. The discussion presents an opinions on what types of tissue banks can be created now to meet urgent medical needs, what products can be processed and stored in such banks, and what regulatory framework is required for their creation and operation.*

**Keywords:** biobanks, tissue donation, tissue equivalents, allogeneic skin, skin substitute, manufacture of cellular products, high-tech drugs, wound treatment

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## Abbreviations

AATB, American Association of Tissue Banks
BMCP, biomedical cell product
BSE, biological skin equivalent
CBER, Center for Biologics Evaluation and Research
Combi-BSE, combined biological skin equivalent
DSE, dermal skin equivalent
EUTCD, European Union Tissue and Cells Directives
HTMP, high-tech medicinal product
LSE, living skin equivalent
MSCs, multipotent stem cells

## Introduction

The clinical experience of using human skin and its components for wound treatment accumulated in the world is enormous. This experience has shown that the use of both autologous and allogeneic (from the Greek Allos, other, different) skin as a wound covering material can have a stimulating effect on the cell proliferation processes and the wound healing course, and also can partially replace the functions of lost integumentary tissues. The need for the widespread use of human tissues for therapeutic purposes has led to setting up the biological tissue banks

in the world, which harvest and store various human tissues, including viable skin and skin-based bioproducts.

Biological banks can be classified by their main or primary purpose: to support scientific activities, exclusively for the purpose of storing particlular objects, for medical purposes (subsequent transfer of biological objects for use in medical purposes), for special accounting purposes (forensic), and production (of medicines and medical devices) [1]. The biobank objects of storage and processing can be both tissues and cells.

The existing clinical tissue banks in the Russian Federation make it possible to provide clinics with material for transplantation of eyeball fragments (cornea, sclera, lens, conjunctiva), which is performed in the field of ophthalmology [2], for transplantation of fragments of the musculoskeletal system (bones, cartilage, ligaments, fascia, tendons) in the field of trauma surgery and orthopedics [3], to carry out cryopreservation of blood components, germ cells and embryos [4], as well as adipose tissue with the possible production of multipotent stem cells (MSCs) or stromal vascular fraction [5].

However, the vast majority of tissue banks in the Russian Federation produce devitalized products made of donor tissues, which is associated with greater ease of manufacture. In Russia, the examples of such institutions are the banks that mainly procure bone material: the Department of Tissue Transplantation and Transfusiology of the "National Medical Research Center of Traumatology and Orthopedics named after Academician G.A. Ilizarov" in the system of the RF Ministry of Health and located in the city of Kurgan, the Bank of Allogeneic Tissue (bone material, dura mater, fascia-lyophilized forms) and the "BIOTECH" Research Institute of the Samara State Medical University in Samara, as well as tissue banks of the Central Institute of Traumatology

and Orthopedics (Moscow) (bone material, costal cartilage, tendon, dura mater) and the Russian Research Institute of Traumatology and Orthopedics named after Academician R.R. Vreden (St. Petersburg), Eye Bank of the "Eye Microsurgery" Scientific and Technical Complex (Moscow) and the "Alloplant" Tissue Bank (Ufa) based on the All-Russian Center for Eye and Plastic Surgery of the Bashkir State Medical University of the Ministry of Health of the Russian Federation.

At the same time, the Russian healthcare system has an unmet need for the use of donor skin and products that can be made of it, but there is not a single skin biobank that would have been organized for healthcare needs, although various scientific and medical institutions in the Russian Federation have repeatedly attempted to create such biobanks, and technologies for processing donor skin have been developed to ensure its safety and viability [6].

**The core part**

The first report of skin grafting dates back to the 2nd century BC, when the Indian surgeon Sushruta used autologous skin grafting for rhinoplasty [7]. Over the following millennia, along with the development of medical science and surgery, clinical experience in using human and animal skin to treat the wounded and sick had been gained. Significant experience in the use of skin grafting and plastic surgery was accumulated during the armed conflicts of the 19th and 20th centuries, which made it possible to transfer these technologies to the treatment of patients with burns and skin damage and to establish indications for the use of banked bioproducts based on human skin [7–9]. As can be seen from Table 1, the use of products manufactured of viable and non-viable skin covers almost the entire spectrum of clinical needs in the treatment of various types of skin damage.

**Table 1. Indications for use of skin bank bioproducts: classification and clinical use**

| Cryopreserved skin | Cryopreserved de-epidermized dermis | Glycerol-preserved skin | Glycerol-preserved dermis/de-epidermized dermis | Lyophilized acellular dermis |
|---|---|---|---|---|
| Contain viable tissue | | Contain nonviable tissue | | |
| Preparation of the wound bed, skin regeneration | Composite graft, temporary covering | Analgesic effect of glycerol-preserved skin | | |
| Composite graft, temporary covering, possible engraftment of dermal component<br>Extensive burns<br>Non-healing ulcers of the lower extremities<br>Diseases associated with epidermolysis (Stevens-Johnson syndrome)<br>- toxic epidermal necrolysis (Lyell's syndrome)<br>- staphylococcal scalded skin syndrome<br>Healing of post-traumatic, surgical wounds | Post-traumatic wounds<br>Ulcers of the lower extremities | Temporary covering, composite graft<br>Extensive burns, skin wounds,<br>Lyell's syndrome<br>Extensive ulcers<br>Temporary covering for donor sites | Composite grafts, possible engraftment of dermal matrix<br>Bedsores, post-traumatic wounds, ulcers<br>Full-thickness burns<br><br>Skin wounds | Dermal matrix engraftment<br>Full-thickness skin wounds (venous ulcers, bedsores, diabetic/trophic ulcers)<br>Burns (thermal, chemical), surgical (post-traumatic full-thickness) wounds, orthopedic surgery, ear, nose, throat surgery, maxillofacial and plastic surgery |

Technologies for storing viable and nonviable skin, as well as products made of it, differ: cryopreservation using a special preservative is required for storing viable skin, while glycerol and lyophilization, which cause cell death, are usually used for nonviable skin. Viable allogeneic skin and biological products made of it are of key importance in the treatment of patients with burns, since they are used for temporary closure of wounds and stimulation of wound processes [10]. Clinical indications for the use of allogeneic human skin grafts in the treatment of burns are: the closure of extensive full-thickness wounds; covering skin

autografts with a high perforation coefficient; healing of partial-thickness wounds; preparation of the wound bed before autografting [9].

Various types of these products are stored in biobanks in the US, EU, UK, Asian Pacific and other countries worldwide. Perforated allografts are indispensable when there is a need to cover large burns of more than 50% of the total body surface area when it is impossible to obtain autologous skin in the required quantity, and the patient has a high risk of death [11]. Viable skin allografts have important clinical applications for wound healing worldwide, despite the availability of a variety of commercially available synthetic and semi-synthetic dermal matrices and skin equivalents [10, 12]. Compared to nonviable allografts and synthetic wound dressings, the viable skin allografts can improve clinical outcomes in patients with partial- and full-thickness burns and slow-healing wounds dressings [13, 14]. In addition, they are used to cover wounds with exposed bones, joints and tendons, in reconstructive facial surgery, surgical dentistry, in the treatment of extensive full-thickness ulcers, wounds and bedsores [15-17]. In situation of mass disaster and many casualties, allogeneic grafts are effective, physiological and affordable means to temporary cope with skin graft deficiency. This explains the increased demand for allogeneic skin from tissue banks and the demand for human skin products and the presence of a developed system of skin banks throughout the world. Many world countries and regions (North America, Europe, Southeast Asia) have built systems for the operation of skin banks, developed a detailed regulatory framework in the field of ensuring biosafety of donation, processing, storage, distribution, and the efficacy of using skin grafts [18]. Technologically advanced countries have either one large service bank with branches in the regions (USA), or several private banks in the country (EU), or a unified network of banks (Southeast Asia). According to expert estimates,

in various countries, the volume of skin reserves makes thousands (USA, Canada) or hundreds of square meters stored in skin banks (EU, China).

In almost all regions of the world, donor skin banks have been created at the national and regional levels and are functioning, which store, among other things, an irreducible and renewable reserve. They are integrated into the systems of medical care and their activities are regulated by national legislation, taking into account the guidelines of international specialized organizations. However, not all of the technological and economic opportunities that such donor skin biobanks provide for healthcare in general are currently available in the Russian Federation. The need to create a system of such biobanks, both clinical and production-affiliated, is obvious, and its relevance is growing. To accomplish this task, it is necessary to solve a number of technological and regulatory problems.

Biobanks in the Russian Federation mainly collect and store donor material without significantly modifying it and do not have a unified legal regulation [19]. In the Russian Federation, there are no clinical or production-affiliated biobanks of viable donor skin whose activities would be regulated at the federal legislative level, but the storage of skin samples and their use is exercised at the level of some scientific and medical organizations based on internal regulations and standard operating procedures. In connection with the inclusion of high-tech medicinal products (HTMPs), as well as tissue-engineered materials, in the list of biological medicinal products, there is a need to create production-based biobanks of viable tissues that would receive donor material from medical institutions, and would isolate, control, and store cell lines. Such biobanks would be able to give out the tissues containing viable cells and individual biomedical cell products (BMCPs) to the enterprises producing HTMPs, significantly increasing the safety of the

manufactured products. From the practical application point of view, cellular HTMPs and individual BMCPs for the treatment of various skin defects can be called “skin equivalents”, i.e. tissue-engineered constructs that combine a biocompatible medical device as a “matrix” and cultured allo- and (or) autologous cellular elements [20].

Russian scientists have extensive experience in developing tissue equivalents containing viable human cells [21], but in actual clinical practice in the Russian Federation, devitalized products are mainly used. Sometimes medical institutions use products containing live cells, which are cultivated in these same clinics. Due to changes in regulatory frameworks, according to which many tissue-engineered structures containing human cells, except for those manufactured in a clinic for a specific patient, are classified as medicinal agents; the products with live skin cells remain unavailable for third-party medical institutions until a licensed production appears. Thus, the creation of industrial biobanks of viable tissues and cells in the Russian Federation is currently of great importance for improving the provision of medical care, since it will allow scientific and clinical institutions of the country to create effective therapeutic products based on human cells and tissues. To plan the organization of industrial and clinical skin biobanks, it is necessary to clarify what types of bioproducts can be stored there and what types of therapeutic agents can be manufactured using these bioproducts.

***Potential areas of using viable-cell-containing human skin as a biobank product in the Russian Federation:***

1. Allogeneic cadaveric skin can be used to make frozen grafts (with preservation of viable cells). A common disadvantage of such grafts is the preservation of cells or cell membranes carrying antigens of the major histocompatibility complex, which can lead to the development of

a rejection reaction 10–21 days after application [22]. The most common use of allogeneic cadaveric skin in world practice is in patients with burns of more than 30% of total body surface area [16, 23]. The patients with extensive burns are known to be in a state of immunosuppression, and also, the patients with the most severe injuries would reject the allograft slowest of others [24]; this means that the autoimmune reaction will be less pronounced in patients in weakened general condition. The allograft can be used for up to 3 weeks, until signs of rejection appear, and can be removed before using technologies for the final wound closure: autodermoplasty and/or living-cell-containing tissue equivalents. In patients with grade III (deep dermal and full-thickness) burns of more than 30% of total body surface area, a graft of cultured autokeratinocytes is indicated for use [25]. The time to produce such a graft, for example, Epicel, is approximately 3 weeks, which would give burn treatment centers the chance to successfully combine the use of allogeneic cadaveric skin with the subsequent use of autologous grafts [23]. In some countries, the use of allogeneic skin is included in the guidelines for the clinical treatment of burns [9, 25–28]. In the Russian Federation, though allogeneic skin is not used for grafting, but it might be in demand for the purpose of producing various types of devitalized (acellular) dermal matrices [10, 29].

2. Allogeneic skin of a living donor to be used to obtain cell lines for the production of tissue equivalents such as individual BMCPs or HTMPs;

3. Patient’s autologous skin for autotransplantation or for the purpose of producing tissue equivalents such as individual BMCPs or HTMPs.

To date, a total of about one hundred tissue equivalents made of skin or its components have been developed, registered, and used or are undergoing clinical trials worldwide as intended for the treatment of

various skin defects [30, 31]. Many of them are widely used in reconstructive surgery to restore organs and tissues. The resource for their production is usually donor material from biobanks. Table 2 presents the most often used and well-studied products based on human skin components.

## Table 2. The products based on human skin components developed and used worldwide

| Product name | Manufacturer | Product composition | Indications |
|---|---|---|---|
| **Contain viable cells** | | | |
| **Apligraf®** | Organogenesis Inc.<br>USA<br>www.organogenesis.com | A two-layer bioengineered skin equivalent consisting of a dermal (allogeneic fibroblasts on a collagen gel matrix) and epidermal (keratinocytes grown on a pre-formed dermal layer) layers. | Treatment of chronic non-healing wounds (including venous ulcers of lower extremities and ulcers associated with diabetic foot syndrome).<br>It has been reported to be used in the treatment of burns, including in combination with autodermoplasty |
| **Epicel®** | Vericel Corporation<br>USA<br>https://www.vcel.com | Composition: a cultured epidermal autograft, which consists of sheets of autologous keratinocytes (ranging from 2 to 8 cell layers thick) | Treatment of extensive burns (comprising a total body surface area greater than or equal to 30%). Can be used in combination with split-thickness autografts or alone in patients for whom split- thickness autografts may not be an option due to the severity and extent of burns |
| **JACE®** | Japan Tissue Engineering Co., Ltd. (J-TEC)<br>Japan<br>https://www.jpte.co.jp/en/ | Autologous cultured keratinocytes obtained using the Green's method, arranged in several layers | JACE is indicated for use in patients with extensive grade III burns where donor sites for autologous skin grafts are insufficient and deep dermal and full-thickness burns comprise a total body surface area greater than or equal to 30%. JACE is applied to the reconstructed dermis of a full-thickness burn wound to facilitate the wound closure. Dermal reconstruction with allografts is recommended. JACE is indicated for use in deep burn wounds of the skin only when full-thickness and deep dermal burns coexist and are difficult to treat separately |
| **StrataGraft®** | Stratatech Corporation USA<br>https://www.mallinckrodt.com | Full-thickness skin substitute with dermal and fully and completely differentiated epidermal layers | For wound closure and enhancing the defect regeneration in the treatment of adult patients with untreated thermal burns containing intact dermal elements and for whom surgical intervention is indicated. Reduces the need for autologous skin in the treatment of deep burns |
| **TheraSkin®** | LifeNetHealth<br>USA<br>https://www.lifenethealth.org | Viable split-thickness allogeneic human skin graft | It can be used for temporary skin replacement, including but not limited to the treatment of diabetic ulcers, venous ulcers, pressure ulcers, open surgical wounds, consequences of necrotizing fasciitis, thermal and radiation burns. Can be used on exposed bones, tendons, joint capsules and muscles |
| **Acellular** | | | |
| **AlloDerm®** | LifeCell Corporation<br>USA<br>www.lifecell.com | Cryopreserved acellular dermal matrix derived from human skin obtained by US tissue banks by means of removing the epidermis and cells that cause a rejection reaction | For the purpose of reconstructing the skin in case of burns, wounds, and for use in plastic surgery. |

As of 2011, 62% of tissue engineering companies were based in the United States [32].

There are also products developed in Europe, but they have not been as well studied in clinical trials and are not as well known [33, 34]. The Table presents the trade names of the products the most widely used in the wounded, patients with burns, including deep and extensive burns, slow-healing wounds; some of the products are used as material for reconstructive plastic surgeries, and also cover a wide range of needs of clinical medicine for hundreds of thousands of patients per year. An advanced system of the development and production of human-skin-based medical products functions thanks to the available tissue biobanks and well-coordinated legislative regulation of their activities.

**Skin banking regulations in the USA and the European Union**

Today, there are several dozen tissue banks in the United States that operate in accordance with the recommendations of the American Association of Tissue Banks (hereinafter referred to as AATB) and federal laws [35]. The AATB was established as the need emerged to standardize all stages of biobank work with donors and tissues, as well as the interaction of tissue banks with each other and clinical facilities. The FDA exercises supervision aimed at regulating the "banking operations" with human tissues. This regulation was developed in order to reduce the likelihood of transmitting infectious diseases by establishing the standards for screening and testing donors. Separate rules govern the accounting, labeling, and tracking of tissues and products containing viable cells. Currently, in the United States, all processes of working with tissues are legislatively regulated; the specific rules stipulated in the Code of Federal Regulations (CFR) (Current Good Tissue Practice (CGTP) requirements and Additional Requirements for manufacturers of human

cells, tissues, and cellular and tissue-based products (HCT/Ps), Guidance for Industry) are used to regulate the manufacture of cellular and tissue-based products, as well as the additional testing of donors. In the United States, tissue banking issues, from the selection and testing of donors, are regulated by a special division of the FDA, the Center for Biologics Evaluation and Research (CBER). The CBER purpose is, first of all, to ensure biological safety, reduce the risk of blood-borne infection transmission, evaluate donors, control prepared tissues and deal with legal aspects of tissue graft registration. CBER protects and improves public health by ensuring the safety and efficacy of biological products, as well as their availability to patients. Having a unified informational and digital database allows fast finding a necessary medical product approved for use, which facilitates the provision of medical care to patients in the US healthcare system.

Europe probably has the most comprehensive tissue banking regulations, some of which are mandatory and some of which are advisory. In Europe, the European Association of Tissue Banks (EATB) was created to introduce uniform international tissue banking standards, and it receives reports on all activities of biobanks in EATB member countries. European Tissues and Cells Directive (EUTCD) requirements are legal documents that allow control over the processing of human tissues and cells intended for use in patient treatment. The directives are based on the European Union Public Health Program within the EU, with the exception of blood and blood-based products. The aim of the EUTCD is to establish a common standard for the safety and security of donation, extraction, testing, processing, preservation, storage and distribution of human tissues and cells in all EU countries. Biobanks must mandatory comply with EATB and EUTCD, quality standards such as ISO 9001. In addition, the EU countries have developed and implemented the

European Quality Systems for Tissue Banks, the European Directorate for the Quality of Medicines & HealthCare (EDQM), the Euro-GTP II Guide, the biosurveillance and surveillance programs: the European Union Standards and Training for the Inspection of Tissue Establishments Project (EUSTITE). The Euro-GTP II Guide sets out good practices for the assessment of the quality, safety, and efficacy of new tissue and cell products, as well as therapies using these products. The ultimate goal of Euro-GTP II is to improve the quality of health care when using tissues and cells.

Associations of tissue banks have worked out issues of screening and selection of donors, rules and methods of skin collection, processing, handling of skin samples, quality control, assessment of viability of skin grafts and cells, possible storage methods, cryopreservation methods, the relationship between the storage temperature modes and graft viability, issues of short-term and long-term storage and other issues that are stated in the above mentioned regulatory documents and guidelines of the USA and EU on biobanking. In order to advance with clinical and industrial tissue biobanks in the Russian Federation, it is advisable to amend the current legislation for more precisely defining the legal status of biobanking and regulation of biobank activities.

The main regulatory acts of the Russian legislation that currently comprehensively regulate the activities of biobanks and manufacture of cell-based products are the following.

1) Federal Law No.180-FZ of June 23, 2016, "On Biomedical Cell Products" that regulates the relationships pertinent to the development of biomedical cellular products, their preclinical studies, examination, state registration, clinical trials, procurement, sale, storage, transportation, use, destruction, their import into the Russian Federation and export from the Russian Federation.

2) Order No. 842n of the Russian Federation Ministry of Health dated October 20, 2017, that establishes requirements for the organization and activities of biobanks, as well as rules for storing biological material, cells for the preparation of cell lines intended for the production of biomedical cell products.

3) Order No. 512n of the Russian Federation Ministry of Health of the dated August 8, 2018 "On approval of the Good Practice Rules for working with biomedical cell products" that defines the rules of good practice for working with biomedical cell products, including requirements for preclinical studies, production and quality control of biomedical cell products.

4) Federal Law No. 61-FZ dated 12.04.2010 "On the Circulation of Medicines" as amended on 30.01.2024 based on the amendments introduced by Federal Law No. 1-FZ of 30.01.2024, which entered into force on 30.01.2024 that establishes the definitions of "biological medicinal products" and "high-tech medicinal product" (HTMP). Biological medicinal products include medicinal products based on human somatic cells. HTMPs include drugs based on somatic cells or tissue-engineered medicinal products.

Today, the skin biobanks in the Russian Federation should be given a legal status and incorporated into the unified system of tissue biobanks regulated at the state level, designated to establish the rules for processing activities, provide and coordinate the work of biobanks and manufacturers in compliance with the principal rules of Russian legislative acts, ensure consistency with regional and local regulations and promote the manufacture of viable tissue- and cell-based therapeutic agents made of biobank products.

**The ways of establishing biobanks in Russia and regulating their work**

The material for storage in a biobank can be donor skin (cadaveric or obtained from a living donor), or cell lines for the production of individual BMCPs or HTMPs being tissue-engineered structures, or technologically processed (manipulated) donor skin. Currently, in the Russian Federation, these types of products differ significantly in their production, storage technologies, and also in regulatory framework. The practice of working with these tissue sources in Russia has some specific features different from those in other countries.

*1. Allogeneic skin from a living donor*. Rules for obtaining, procurement and processing of skin from living donors for biobanks have been developed in the World Union of Tissue Banking Associations Members. Such skin grafts are removed during surgical interventions [7, 37]. The availability of allogeneic skin from living donors becomes especially relevant when the use of cadaveric skin is not legalized [38] or its availability is limited. Skin grafts from living donors can be obtained by a medical organization that performs an intervention aimed at excising a flap of soft tissue or skin. This can be either a surgical intervention or plastic surgery for aesthetic purposes performed in a certified clinic by a surgeon of an appropriate profile. The skin tissue material must be collected under sterile conditions and packed in a container with a preservative. There are no special regulations for harvesting this type of material in the Russian Federation. However, given the rules of tissue and organ donation in the Russian Federation, after the donor's informed voluntary consent has been issued, allogeneic living donor skin must be transferred free of charge to the organization which the tissue bank is affiliated to. The biobank may pay for the clinic's services for the medical examination of the donor. The Russian legislation should differentiate

between the concepts of organ and tissue donation, since the scope of examination and the procedure for collecting biomaterial for these types of donors will differ significantly, making organ donation more complicated.

*2. Autologous skin from the patient*. The biobank can store the autologous skin of the individual patient, for whom it is planned to manufacture an individual BMCP or HTMP or who is scheduled to undergo a skin grafting procedure with a high grafting ratio (1:5 or more) combined with a product made of his/her native cells (fibroblasts, multipotent stromal cells of adipose tissue, keratinocytes) to save his skin resource. The patient's skin sample can be stored cryopreserved for a long time (up to 5 years) without the loss of its quality when defrosted [39]. During the storage period, therapeutic products can be manufactured of it for the patient multiple times [40]. The conditions for obtaining autologous skin from a patient are similar to the conditions for obtaining a skin graft from a living donor of allogeneic skin. Before collecting the skin, the patient must undergo a medical examination.

*3. Allogeneic cadaveric skin*. Its procurement is possible owing to the presumed consent for posthumous donation legally adopted in the Russian Federation. Viable cell-containing cadaveric skin, when used in a patient, will essentially be a graft, but its use as a graft is currently impossible from the point of federal legislation, since skin is not included in the list of objects for transplantation in the Russian Federation. In most countries of the world, donor skin is the main object of clinical tissue banks. However, in order to procure allogeneic cadaveric grafts, medical institutions must have the legal right to render surgical care, for which they must be licensed to provide such care and be included in the "List of healthcare institutions entitled to extract, procure and transplant human organs and (or) tissues" approved by the Ministry of Health of the

Russian Federation and the Russian Academy of Sciences. In accordance with Article 2 of the Law of the Russian Federation "On Transplantation of Human Organs and (or) Tissues", the Ministry of Health of the Russian Federation and the Russian Academy of Sciences jointly determine the "List" of human organs and (or) tissues as transplant objects. The current valid List was approved by Order No. 306n/3 of June 4, 2015, which does not include skin. Of 25 transplant objects presented on the List, 17 are tissues that can both be transplanted, and also can be used to produce medicinal products to be applied in reconstructive and plastic surgery, trauma surgery and orthopedics, dentistry, ophthalmology, etc. [41]. It is the “tissue” part of the List that raises many questions among specialists, since the legal status and quantity of tissues can vary significantly depending on the technology of their production, processing, registration, and use. Tissues not presented in the List for example, skin, cartilage, ligaments, pericardium, and others, may not be clinically used. One approach to solving this problem may be to consolidate the items in the List taking into account the global practice, the classifiers of human organs and tissues for transplantation as developed in other countries, for example, based on the List of objects for transplantation compiled taking into account the European Committee on Organ Transplantation (CD-P-TO) regulations, which include skin and other tissue grafts [42]. Medical care for organ transplantation, medical activities related to the donation of organs and (or) tissues for transplantation, are regulated by the "Procedure for the provision of medical care in the field of "Surgery" (Transplantation of human organs and (or) tissues)", approved by the Order No. 567n of the Ministry of Health of the Russian Federation dated 31.10.2012, which also needs to be revised and supplemented so that not only medical institutions licensed for transplantation, but also other clinics could use viable allogeneic donor skin from biobanks as grafts for

transplantation. Koltzov Institute of Developmental Biology of the Russian Academy of Sciences (hereinafter referred to as IBR RAS) has conducted a number of scientific studies aimed at determining the timing to recover the viable cadaveric skin after the donor death, as well as developing the methods for assessing its viability [39, 43]; clinical results have been obtained by using the studied method [44]. The results of these studies can form the basis for the processing (technological) activities of a biobank. At present, there are no legislatively established clear regulations for harvesting donor cadaveric skin, requirements for the donor selection, nor criteria for the viability and suitability of donor material for subsequent use, harvesting conditions or rules of transportation to the biobank. It is assumed that cadaveric skin can be harvested from medically examined donors by a surgeon in a medical institution licensed for surgery. If the examination has not been passed at the time of organ harvesting, then it is necessary to take blood tests for community acquired infections, exclude oncological diseases based on the autopsy results and, after collecting the samples, wait for the examination results. Sending skin samples for further processing will be possible only after the examination is complete.

Thus, the issue of including allogeneic skin in the list of transplantation objects is relevant. Inclusion in the list will allow using allogeneic skin as a minimally manipulated material for wound closure (before the main stage of treatment). Clinical banks of cryopreserved skin created in the Russian Federation will be able to provide it as an independent therapeutic product, or as s biological material for the production of HTMPs, individual BMCPs, and acellular dermal matrices.

Currently, a biobank can be established as a structural division of a non-profit medical or educational organization engaged in scientific research activities, as a scientific center (institute) affiliate without the

rights of a legal entity. The creation of a biobank as a commercial organization or division of a commercial organization (except for blood banks) does not contradict Russian legislation. At the same time, the work of skin biobanks in Russia with the subsequent production of tissue equivalents can be started with working with living donor materials (allogeneic or autologous tissues); the technological process should be organized taking into account the decisions of the Eurasian Economic Union, international principles of banking organization, which, ultimately, will require licensing of the clinical biobank activities. Setting up the uniform standards for the activities of biobanks and the system for their licensing or certification will be supported by the Russian scientific medical community, since such standards are necessary to ensure the correct and safe storage of tissues and cell cultures with the possibility of subsequent manufacture of cellular products [45]. Scientific and medical institutions of the Russian Federation have created a large reserve in the development of cellular products and technologies for the treatment of the wounded and burned using cellular products; there are opportunities and a need to implement them into clinical practice, since the number of casualties of armed conflicts and terrorist attacks in recent years has remained high. The need to use allogeneic skin and its components has been proven many times: leading clinics and research institutes in the Russian Federation (A.V. Vishnevsky National Medical Research Center of Surgery, N.V. Sklifosovsky Research Institute for Emergency Medicine, I.I. Dzhanelidze Research Institute for Emergency Medicine and others) and clinics in other countries have studied the use of these therapeutic products and the products made of them [28, 46–48]; and the Clinical Guidelines for their use have been developed and followed in many countries [9, 10, 25–27].

In Russia, private skin banks, as an exception, have been organized at large medical centers with pathological anatomy departments and are regulated exclusively by the regulatory documents of the medical center itself. But even in this case, they will be able to made products only for use within the institution, since the manufacture of viable cell-containing products, namely individual BMCPs or HTMPs will require obtaining the appropriate licenses [49–52]. Based on the intended areas of the allogeneic skin application or manufacturing therapeutic products of it, the development of technology for banking and quality control of donor skin should include an analysis of potential complications (bacterial, viral, fungal contamination) when using allografts (donor examination methods, microbiological studies, sterilization methods, discard criteria), the risks and timing of transplant rejection (methods for reducing graft immunogenicity).

Using the biobanking technologies from the world experience and the results of its own research, the IBR RAS has developed laboratory technologies for processing, preparing the preservation, and the preservative per se [53], a technology for storing donor skin, the short-term and long-term storage modes, methods of defrosting and monitoring the viability of donor skin at different stages of storage, methods of defrosting and monitoring the cultured tissue equivalents, a draft of technological documentation for storing the donor skin, a technological scheme for obtaining, storing, and preparing biomaterial for use, an equipment scheme for the production, a scheme of the technological process, sanitary preparation for production, a technology for preparing personnel and equipment for work, a technology for processing and harmless utilization of production wastes, and production control methods. The IBR RAS has also developed dermatotropic high-tech medicinal products containing viable human skin cells: a combined

biological skin equivalent (Combi-BSE), and biological and dermal skin equivalents (BSE and DSE), which precursor is a living skin equivalent (LSE) [44, 54]. Combi-BSE and BSE contain cultured keratinocytes and MSCs on a scaffold matrix, wherein BSE contains allogeneic keratinocytes, while Combi-BSE contains autologous keratinocytes. DSE contains only MSCs on a scaffold matrix. The creation of Combi-BSE was preceded by work with a culture of autokeratinocytes, which showed good clinical results [55, 56]. Clinical trials investigating all of the above products have been planned. This group of medicinal products will help treat many types of acute and chronic (non-healing) wounds, donor sites after taking skin flaps for autografting, trophic ulcers, burns, epithelial-mesenchymal damage to various organs (for example, the urethra, larynx, pharynx, and others) [57, 58]. Establishing a tissue banking system will provide clinics with therapeutic products and the manufacturers with raw materials for their production. Research and scientific teams will be able to receive safe and high-quality biomaterial from biobanks for the development of new therapeutic products. The implementation of viable cell-containing products into clinical practice will ensure an up-to-date treatment for the patients within the system of Russian healthcare.

## Conclusion

Currently, in the Russian Federation, allogeneic skin grafts are outside the legal framework, which considerably complicates both the process of their procurement and storage, and their use in clinical practice. It is necessary to set up clinical biobanks of tissue grafts, first, to ensure the planned work of medical institutions (short-term reserves) and, second, to ensure the safety of the population, effective elimination of the consequences of man-made disasters and other emergency situations associated with the emergence of a significant number of wounded and

burned (long-term reserves at a storage temperature of -196° C). Thus, the advantage of creating a skin biobank system is the ability to supply burn centers and clinics with allogeneic grafts manufactured in accordance with a uniform standard and to ensure the availability of a permanent supply of skin in case of emergencies and armed conflicts, following the example of many countries in the world.

2. In order to organize clinical and production-based tissue banks, it is necessary to legislatively define the legal status of biobanks and prepare a regulatory framework for their creation and operation. It is necessary to define technological standards for skin banking that would allow creating short-term and long-term reserves. It is necessary to organize post-transplant surveillance procedures. When setting up the Russian standards for organizing the biobank activities, in addition to the current norms of Russian legislation based on the ISO 20387:2018 Biobanking Standard, it is necessary to use the decisions of the Council of the Eurasian Economic Commission, the standards of the Euro-GTP II Guide, and the practices of the International Society for Biological and environmental repositories (ISBER). The EUTCD, the standards of the European Quality Systems for Tissue Banks and the European Association of Tissue Banks, the norms of Current Good Tissue Practice (CGTP), some sections of the Code of Federal Regulations (CFR), as well as the AATB standards can be used as recommendatory sources. Such a systematic approach will allow developing legislation for many groups of tissue grafts at the national level.

3. In order to create independently functioning skin banks that would be able to supply allogeneic grafts for the treatment of the wounded and burned in the near future, it is necessary to supplement the regulatory List of Transplantation Objects with donor skin; approve the list of institutions authorized to procure and (or) store allogeneic skin,

develop rules for its storage and transportation; approve the procedure for voluntary skin donation from a living donor. For the time while the use of donor cadaveric skin for transplantation and production has not been legalized, the manufacturers should be permitted to use the living donor material obtained as a result of surgical interventions provided that the patient has signed an informed voluntary consent to donate such biomaterial for the manufacture of high-tech medicinal or biomedical cell products.

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