TERMINOLOGY AND CONCEPTUAL APPARATUS OF TISSUE DONATION AND TISSUE BANKING: INTERDISCIPLINARY EXPERT CONSENSUS (PART 1)

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An interdisciplinary consensus of experts has been formed in the area of medical activity such as tissue banking. An analysis and attempt was made to systematize some of the terms and definitions used by tissue bank specialists in the process of their work and presented in the Federal laws and orders of the Ministry of Health of the Russian Federation regulating medical activities in the field of tissue donation and their clinical use.

Key Words: tissue banking, consensus, terms and definitions.

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Operation with donor tissues implies a technological process involving interprofessional cooperation, all stages of which should be regulated [1, 2]. A unified multi-stage technology of procurement, processing, and storage of donor tissues is successfully implemented under a number of factors. Significant of them are the complex cooperation of highly qualified professionals of different medical specialties, availability of a universal terminology, the evidence base for the effectiveness of tissue use in clinical practice, and a unified federal legislative framework adapted for tissue banks that can prevent discrepancies in the understanding of regulatory documentation. All this will allow standardizing both the individual stages of the tissue banks functioning and the overall process.

The creation of single operating rules, standards, instructions, clinical guidelines for the operation of tissue banks, as well as their statutory support will promote the development of activities for the procurement of biomaterial that, in turn, will open great opportunities for the development of new techniques for the treatment of diseases, injuries, traumas and their consequences [3].

A common understanding of most of the used terms has developed at the stage of interaction with tissue donors, whereas at the following stages, different sources use various interpretations of the same object/process, including those of fundamental significance, or, on the contrary, a conceptual apparatus is absent [4].

The translation of terms in the medicine speciality “donation and transplantation of organs and/or tissues” presented by foreign associations, for example, the European Association of Tissue Banks, can be treated differently. This further promotes a different understanding of the meaning of these terms and

their use in describing identical materials and processes. For example, depending on the context, the term "graft" can have different semantic meanings when translated into Russian [5].

The objective is to update the terminology and develop a unified terminology standard in the field of tissue donation and tissue banking.

Methods and Stages

The solution to the problem of wording for a unified expert consensus has been realized in four stages:

The first was to form a register of leading professionals with published works and experience in the organization or implementation of the technological process of tissue banking.

The second was to compile a list of the main terminological definitions with their translation and transliteration, then further mailing to experts for review and suggestions.

The third was to perform a face-to-face open discussion of the proposed formulations of the terms.

The fourth was to prepare a project with subsequent publication in a scientific print periodical.

The first stage of consensus development

A group of highly qualified professionals in the field of procurement and transplantation of tissues, as well as related fields of medicine of the leading healthcare facilities of the Russian Federation decided on the need to formulate a common expert consensus on the development and adoption of a unified glossary in the field of donation and use of human tissues in medicine. The authors of this article analyzed the terms found in federal laws and other legislative and scientific literature regulating activities relating to donation and transplantation of organs and/or tissues, which can be used in respect to tissue donation and for clinical purposes, research, educational processes, and the creation of tissue components, pharmaceutical products, and medical devices.

The second stage of consensus development

It has been determined that the same term may have significant semantic differences when it is used on the pages of the same core publication. For example, such terms as "implant", "implantation", and "transplant", "transplantation" in the Oxford Concise Medical Dictionary have the following definitions [4]:

• *Implant, graft:* 1) a drug, a prosthesis, or a radioactive source that is introduced into the body; 2) in dentistry, a dental implant is a rigid structure that is attached to a bone, embedded into a bone, or under its periosteum instead of teeth to anchor a crown, a bridge, or a denture.

• *Implantation* (Latin *im* means in or inside; *plantatio* means planting): 1) the attachment of the early embryo to the lining of the uterus; 2) the placing of a substance (e.g. a drug) or an object (e.g. an artificial pacemaker) within a tissue; 3) the surgical repair or replacement of damaged tissue with healthy tissue (i.e. transplantation).

It turns out that, the word "implantation" is broader and includes, among other things, a transplantation. In other way, a transplantation is one of the types of implantation associated with the surgical replacement of damaged tissue with healthy tissue.

• *Transplant, graft* is any organ, tissue or part of the body used for transplantation to replace a faulty part of the body.

• *Transplantation* (Latin: *trans* – across, over, or beyond, and *plantatio* – planting) is the implantation of an organ or tissue.

The third stage of consensus development

The task of the third stage was to distinguish between these terms. The concepts separating the term "implant" and "transplant" have been formed.

• *Implant* is an embedded or grafted (implantable) product of artificial origin, as well as biomaterials that have been processed and/or sterilized, and medical devices. In this regard, all medical devices implemented into the human body (hardware, stents, pacemakers, neurostimulators, etc.) and biomaterials related to materials of xenogeneic origin are included in this concept.

According to the first term, the concept of implantation has been changed.

Implantation is the surgical restoration or replacement of damaged or lost tissue with healthy tissue using artificial products, as well as biomaterials that have been processed and/or sterilized, and medical devices.

• *Transplant* is any organ, tissue, or part of the body used for transplantation to replace an injured part of the body. For transplantation, only organs and tissues are used that are not related to the human reproduction process and do not include reproductive tissues, in particular the ovum, semen, ovaries, and embryos [6].

• *Transplantation* is the replacement of organs or tissues. Therefore, an organ or tissue (tissue component) can be transplanted. At the same time, the content of cells and/or antigens is not essential, and the viability of cells is irrelevant. This is due to the fact that cell fragments and the cytoplasm of non-viable cells are, in fact, biologically active substances that have a regulatory effect on tissues and cells in the area of transplantation.

Moreover, it is important to adopt a single conceptual interpretation of such a term as "tissue." Currently, the unity of understanding of some terms in the field of tissue donation is due to the morphological and physiological characteristics of the object.

• *Tissue* (Latin *textus*, Greek *ιστός*) is a collection of cells and intercellular substance united by common origin, structure and functions performed (e.g. epithelial, connective, muscular, or nervous).

• *Tissue component (component of a tissue)* is an integral part of a tissue. If any component of a tissue is removed, we may talk about a tissue component rather than the tissue itself, e.g. a tissue component of an eye, bone, etc.

In terms of implantable materials or transplantable tissues, and/or tissue components, such terms as bio-inertia and bioactivity is yet another point to bear in mind. The type of connection of materials with surrounding tissues, the type of

regeneration, and their stability in the bed depend on the physical and chemical profile of the material, which define its bio-inertia or bioactivity [7–10].

• *Bio-inertia* is the ability of a material to retain the invariance of its composition and structure for a long time due to the lack of local and systemic interaction with the body or to its minimally pronounced chemical, electrochemical, and surface- catalytic manifestations.

A bioinert material replaces the lost tissue or its fragment, performing a certain function. For example, a hip endoprosthesis performs a supporting function and for a long time maintains the constancy of its composition and structure due to the lack of local and systemic interaction with the body.

• *Bioactive material*s are materials that are a matrix for the formation of tissue on their surface; they have an effect on the cells and tissues of the recipient's body.

The term "biocompatibility" is most concisely reflected in the glossary of international terms used in biomedicine [11].

• *Biocompatibility* is the ability of a material to integrate into the host body without causing adverse effect and to induce a cellular or tissue response necessary to achieve an optimal therapeutic benefit.

In reviewing the regulatory documentation of the Russian Federation and the Ministry of Health of the Russian Federation governing medical activities in the field of organ and/or tissue transplantation, it is essential to refer to a number of documents with established terminology. The Federal Law No. 180-FZ of June 23, 2016, "On Biomedical Cell Products" [12], specifies a number of terms for general use in the field of high-technology medical care in specialized medical facilities in Russia and the carrying out of medical activities on the profile of "surgery (transplantation of organs and/or tissues) of a human being".

Accordingly, a biological material (biomaterial) is defined as body biological fluids, tissues, cells, secretion and excreta, physiologic and pathologic waste, smears, scrapes, swabs, and biopsy specimens.

In the context of the conceptual apparatus of tissue banking activities, the definitions are as follows:

• *Biomaterial* is tissues and/or cells, as well as excreta after separation from the human body. The key point is that this is a material of biological origin. This aspect is principal. It is not competent to use the term "bioceramics" for the sole reason that this ceramic is the raw material for the production of human implantable medical devices. It is true to talk about ceramics with bio-inertia or bioactivity, since in this case we will describe the effect of ceramics on the human body.

• *Donor of biological material* (hereinafter also referred to as the donor) is a person who provided biological material during his/her lifetime or a person from whom biological material was collected after his/her death, determined in accordance with the procedure prescribed by the legislation of the Russian Federation.

• *Donation of biological material* is the process of cadaveric donation of biological material (hereinafter referred to as deceased donation) or living donation of biological material (hereinafter referred to as living donation).

The Federal Law No. 125-FZ of July 20, 2012, "On Donation of Blood and Its Components," provides more precise terminological wording adapted for the processes of donation, procurement, storage, and transportation of blood and its components [13]. We have substituted the word "blood" for the word "tissue," while we understand that blood is also a tissue. Nevertheless, at the legislative level, everything related to donation of blood and its components is regulated separately from other tissues, while all the principles applied to blood can also be used for tissues.

• *Donor of tissue and/or tissues* (hereinafter referred to as the donor) is a person who voluntarily underwent a medical examination and voluntarily donates tissue and/or tissues.

• *Donor tissue* is a tissue collected from a donor and intended for clinical use as a biomaterial, as well as for use in research and educational purposes.

• *Donation of tissue and/or tissues* is the voluntary donation of tissue and/or tissues by donors, as well as measures aimed at organizing and providing safety for the procurement of tissue and/or tissues.

• *Procurement of donor tissue and/or its components* is a set of measures including the selection of a donor and the tissue collection, testing procedures for suitability and infectious safety, banking or processing of donor tissues and/or their components [14].

• *Recipient* is a person who, for medical grounds, requires or has undergone a transplantation of donor tissue and/or its components.

The following term is formulated in the guidelines [15], but clarified in the course of discussion by the expert group.

• *Waste biomaterials (waste tissues)* are tissues which excision is planned or performed in a capable person as part of treatment for an underlying disease and not subject to replantation (fragments of extremities, bone tissue, skin graft, etc.).

Waste tissues can be used for the production of tissue components in the absence of contraindications, for research activities, or disposed of as medical waste.

Conclusion

An attempt has been made in this article to systematize some of the terms and definitions used by the professionals of tissue banks in the course of their work. We have tried to be guided by the terms and definitions currently prevailing in the legal field, specifying them in relation to the source of tissue collection.

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