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## SCIENTIFIC BACKGROUND OF THE STATE AND PROBLEMS OF DEVELOPMENT OF INTERNATIONAL INSTITUTIONAL PRINCIPLES FROM THE QUESTIONS OF DEVELOPMENT OF MECHANISMS OF PUBLIC ADMINISTRATION BY TRANSPLANTOLOGY

**Abstract.** Transplantation is proven to be the most important method of treatment that is used when other methods are ineffective. Accordingly, the state, which cares for its citizens, is obliged to create mechanisms of state administration of transplantology, a basis for the normal functioning of social relations, including those related to transplantation. The state through the authorities must ensure the right to a healthy life, as well as guarantee the observance of the rights to protect human dignity. It is determined that modern medical science in the developed countries of the world is gaining tremendous growth in development, and all because of the fact that the health issue is particularly acute in society. Legislation is an important link in building and regulating social relations, but it is only part of a mechanism that functions in society. The basic institutional foundations for the development of mechanisms of state administration of transplantology in the European community are defined. Diedden concluded that it was the state's ac-

tions to ensure such patient rights as a free choice of doctor; receiving medical aid; timely and adequate awareness; consent or refusal of the patient from treatment; the attitude of the doctor to the medical and personal information entrusted to him as confidential; patient's right to a decent death; on spiritual or moral support or on its deviations. The opinion is based on the fact that when developing the mechanisms of state administration of transplantology in the European community, much attention is being paid to informing the population. Information – positive or negative – plays an important role in the public to the donation of organs. When planning such information and ways of its dissemination, the assistance of professionals – experts in communication – is needed. Government support is needed in all countries involved in transplantology. We believe that an indicator of the efficiency of public administration in the field of transplantation of European countries is that the most important principles of organization of the transplant service are considered by them to be the perfect training of the erudite, knowledgeable specialists, the mandatory development of research training programs, the inclusion of the fundamentals of donor and transplantation in the lawyer training program, observance of the principles of international cooperation, formation of the school of national transplantology.

**Keywords:** public administration in the field of transplantation, principles of international co-operation, European community, patient's refusal of treatment.

## **НАУКОВЕ ОБҐРУНТУВАННЯ СТАНУ ТА ПРОБЛЕМ РОЗВИТКУ МІЖНАРОДНИХ ІНСТИТУЦІОНАЛЬНИХ ЗАСАД З ПИТАНЬ РОЗРОБКИ МЕХАНІЗМІВ ДЕРЖАВНОГО УПРАВЛІННЯ ТРАНСПЛАНТОЛОГІЄЮ**

**Анотація.** Доведено, що трансплантологія є надважливим методом лікування, який застосовується тоді, коли інші методи неефективні. Відповідно, держава, яка дбає про своїх громадян, зобов'язана створити механізми державного управління трансплантологією, базу для нормального функціонування суспільних відносин, у тому числі тих, що стосуються трансплантації. Держава через органи влади має забезпечувати право на здорове життя, а також гарантувати додержання прав із захисту людської гідності. Визначено, що сучасна медична наука в розвинутих країнах світу набирає колосальних обертів у розвитку, а все тому, що в суспільстві особливо гостро стоїть питання охорони здоров'я. Законодавство є важливою ланкою в побудові та врегулюванні суспільних відносин, але це лише частина механізму, який функціонує в суспільстві. Визначено основні інституціональні засади розробки механізмів державного управління трансплантологією у європейському співтоваристві. Визначено, що саме держава своїми діями має забезпечити такі права пацієнта: вільний вибір лікаря; отримання лікарської допомоги; вчасна та адекватна інформованість; згода чи відмова пацієнта від лікування; ставлення лікаря до медичної та особистої інформації, що довірена йому, як до конфіденційної; право пацієнта на гідну смерть; на духовну чи моральну підтримку або на її відхилення. Обґрунтовано думку, що при роз-

робці механізмів державного управління трансплантологією у європейській спільноті велика увага привертається інформуванню населення. Інформація — позитивна чи негативна — грає важливу роль у ставленні громадськості до донорства органів. При плануванні варіантів такої інформації і шляхів її розповсюдження необхідна допомога професіоналів — експертів по комунікації. Підкреслено, що країнам, які зайнялися трансплантологією, необхідна підтримка уряду. Показником ефективності державного управління в галузі трансплантології європейських країн є і те, що найважливішими принципами організації служби трансплантації вони вважають бездоганну професійну підготовку ерудованих, обізнаних спеціалістів, обов'язковий розвиток програм навчання наукових досліджень, включення основ донорства та трансплантації у програму навчання юристів, дотримання принципів міжнародної кооперації, формування школи національної трансплантології.

**Ключові слова:** державне управління в галузі трансплантології, принципи міжнародної кооперації, європейське співтовариство, відмова пацієнта від лікування.

## **НАУЧНОЕ ОБОСНОВАНИЕ СОСТОЯНИЯ И ПРОБЛЕМ РАЗВИТИЯ МЕЖДУНАРОДНЫХ ИНСТИТУЦИОНАЛЬНЫХ ОСНОВ ПО РАЗРАБОТКЕ МЕХАНИЗМОВ ГОСУДАРСТВЕННОГО УПРАВЛЕНИЯ ТРАНСПЛАНТОЛОГИЕЙ**

**Аннотация.** Доказано, что трансплантология является важнейшим методом лечения, который применяется тогда, когда другие методы неэффективны. Соответственно, государство, которое заботится о своих гражданах, обязано создать механизмы государственного управления трансплантологией, базу для нормального функционирования общественных отношений, в том числе касающихся трансплантации. Государство через органы власти должна обеспечивать право на здоровую жизнь, а также гарантировать соблюдение прав по защите человеческого достоинства. Определено, что современная медицинская наука в развитых странах мира набирает колоссальные обороты в развитии, а все потому, что в обществе особенно остро стоит вопрос охраны здоровья. Законодательство является важным звеном в построении и урегулировании общественных отношений, но это лишь часть механизма, который функционирует в обществе. Определены основные институциональные основы разработки механизмов государственного управления трансплантологией в европейском сообществе. Пришли к выводу, что именно государство своими действиями должно обеспечить такие права пациента как свободный выбор врача; получения врачебной помощи; своевременная и адекватная информированность; согласие или отказ пациента от лечения; отношение врача к медицинской и личной информации, доверенное ему, как к конфиденциальной; право пациента на достойную смерть; на духовную или моральную поддержку или на ее отклонение. Обосновано мнение о том, что при разработке механизмов государственного управления трансплантологией в европейском сообществе большое внимание отводится информированию населения. Ин-

формация — положительная или отрицательная — играет важную роль относительно мнения общественности к донорству органов. При планировании вариантов такой информации и путей ее распространения необходима помощь профессионалов — экспертов по коммуникации. Подчеркнуто, что государством, которые занялись трансплантологией, необходима поддержка правительства. Показателем эффективности государственного управления в области трансплантологии европейских стран является и то, что важнейшими принципами организации службы трансплантации они считают безупречную профессиональную подготовку эрудированных, знающих специалистов, обязательное развитие программ обучения научных исследований, включение основ донорства и трансплантации в программу обучения юристов, соблюдение принципов международной кооперации, формирование школы национальной трансплантологии.

**Ключевые слова:** государственное управление в области трансплантологии, принципы международной кооперации, европейское сообщество, отказ пациента от лечения.

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**Problem statement.** The urgent need of the European countries in the field of healthcare is an introduction of new technologies for improvement and development of the industry. Organ transplantation is one of these current and important tendencies in improving the delivery of health services, a new step in modern health care and a huge step in health care for people. This is clearly demonstrated by the fact that in the world a large number of people living with transplanted organs. More than a million transplant operations were done in the world at the end of the second millennium.

**Analysis of recent researches and publications.** Specialists from all over the world are focusing more and more on finding ways to improve the health system. However, we cannot fully analyse the work of scientists because of the lack of a thorough comprehensive study on the development of international institutional foundations on the

development of mechanisms for the management of transplantology in the European countries.

The organs transplantation control was preceded by the invention of the vascular suture by A. Carrel (1902), the discovery of the blood groups by K. Landsteiner (1900), A. Decastello and A. Sturli (1902). The mentioned scientific discoveries have become the impetus for the emergence of qualitatively new relations that were in need of regulation.

**The purpose of the research** is to reveal the peculiarities of the state and problems of the development of international institutional foundations on the development of mechanisms for public administration of transplantology.

**Presentation of the main material.** It is impossible to ensure proper protection of life and health of citizens without proper state administration in matters concerning organ and tissue

transplantation. In order to prevent all kinds of abuses in organ transplantation procedures and to regulate procedures and processes involving transplantology. State governance in the European countries is carried out in such a way that the development of transplantology management mechanisms. It is based on the basic principles that define guarantees and ensure the protection of public relations in the field of transplantation. We consider the main international institutional principles that the European community is guided in developing mechanisms for state control of transplantology. We can distinguish in 5 stages their formation and development:

#### Stage I: 1981–1987

At this stage, the Lisbon Declaration on Patient Rights was adopted. It has become one of the first international institutional foundations that guided the state through transplant management. According to it, management mechanisms were developed that were aimed at regulating the actions of doctors, namely, to fulfil their obligations in the interests of the patient. At the same time, they should act in conscience, taking into account the legal, ethical and practical norms of the country where they practice. At this stage, state regulation is carried out within the framework of the Lisbon Declaration, which aims to support the fundamental rights and freedoms that must be owned by patients. By analysing the aforementioned and fundamental principles of this declaration, which in the future became international principles for the development of mechanisms for the management of transplantology in the European community, we can con-

clude that it is the State itself to ensure the patient's rights such as: free choice of physician; receiving medical aid; timely and adequate awareness; consent or refusal of the patient from treatment; the attitude of the physician to the medical and personal information that is entrusted to him as confidential; right of the patient to a decent death; and on spiritual or moral support or on its rejection [1].

#### Stage II: 1987–1991

This stage of development is characterized by the presence of not only the Lisbon Declaration, but also the adoption of guidelines for transplantation. In the 1987, the 40<sup>th</sup> Session of the World Health Assembly, having been concerned about the trafficking of human organs for profit, launched an initiative focused on the preparation of the first WHO guidelines on transplantation, which was approved by the Assembly in 1991 in resolution WHA44.25 [2]. Accordingly, the development of mechanisms for state governance in the field of organ transplantation was carried out on the basis of both documents.

#### Stage III: 1991–1997

The third stage of the formation and development of international institutional foundations is marked by the Convention on Human Rights and Biomedicine of 1997 [3]. The Chapters VI and VII available therefor determine the actions of States concerning transplantation issues. After analysing it, we can highlight the aspects in which countries are required to create appropriate mechanisms for managing transplantology. Namely, the creation of such mechanisms requires the followings:

(a) Provision of state guarantees in cases where organs and tissues for their

transplantation are withdrawn from living donors. Such actions are allowed only for the purpose of treatment of the patient and under the condition that a suitable organ cannot be obtained from the corpse and it is recognized that it is not possible to conduct alternative treatment with comparable efficacy;

(b) Obtaining a clearly expressed and specific agreement on the donation. Therefore, the state must provide mechanisms for obtaining such consent either in writing or at the appropriate official instance;

(c) Ensuring the rules prohibiting the removal of any organs or tissue from people who are not able to give an agreement on the donation;

(d) Ensuring that the state complies with the law in exceptional cases. Such cases include the removal of regenerative tissues from people who are not able to consent to this. When permission for such seizure is to be carried out strict supervision of the observance of special conditions, indicated as mandatory for execution in such cases; and

(e) Compliance with the conditions for the execution of appropriate procedures, in cases where the withdrawn parts of the human body for medical interventions are stored and used for purposes other than those for which they were withdrawn.

In particular, it is noted that transplantation is not allowed, in the case of another method of treatment. Transplantation is allowed only if there is no other way that would have yielded a similar result. Thus, according to the Convention, the countries had to regulate and ensure the inadmissibility of receiving material remuneration. Ana-

tomical parts cannot be bought or sold, and they just cannot lead to financial benefits for the person they have been deleted or to third parties, whether natural or legal person, such as, for example, hospital. In addition, in accordance with this regulation, which, in our opinion does not stop the person from whom the organ or the tissue was taken, the State had to regulate the question of obtaining compensation, which, although not part of remuneration, however, compensates for this man it costs or loss of income (for example, as a result of hospitalization).

#### Stage IV: 1997–2002

In order to develop transplantology, as well as to improve existing provisions, an additional protocol was adopted to the Convention on Human Rights and Biomedicine. It should be noted that the provisions of this Additional Protocol apply not to all types of organs and tissues. Thus, new provisions on tissues apply to blood-forming germ cells. However, the application of this Protocol does not apply to reproductive organs and tissues, embryonic organs, blood and blood derivatives. States should ensure that the organs and tissues, if necessary, are distributed exclusively to patients, as indicated in the official letter of expectation. It was also the responsibility of the countries to ensure compliance with the conditions for the removal of organ or tissue from living donors, which is possible only after obtaining from him an informed and explicit consent for this. This person has the right to withdraw his consent. Regarding the deceased persons acting as donors, a rule should be provided that the anatomical parts cannot be removed from the deceased

person, if he/she is not recognized dead in accordance with the law. Doctors involved in witnesses' deaths are not allowed to participate directly in the removal of anatomical parts in a deceased person and in any subsequent transplantation procedures. The anatomical parts cannot be removed from the deceased persons until consent is given in accordance with the law or the permit for such removal is not received. Accordingly, such removal was prohibited in the case of an existing objection to the deceased in the life of the removal of organs. In the course of medical intervention, the removal of anatomical parts to the body of the deceased person should be treated with respect and take all reasonable measures to preserve the immutable appearance of the body of the deceased person. As we see, both the Convention and the Protocol contain provisions for the prohibition of the use of the human body and its anatomical parts in order to enrich and not hinder payments that do not materially benefit, in particular:

- Compensations for loss of earnings and other legal expenses of living donors caused by removal of organs or related to medical examination is allowed;

- Payment of compensation for legal fees for legal medical or related services incurred due to transplantation is allowed;

- Payments of compensations are allowed in case of unforeseen losses incurred by a living person as a result of removal of organs.

Almost the most important task for the countries was to ensure the inadmissibility of trade in organs and tissues [4].

#### Stage V: 2002–2010

The guidelines that were approved by the Assembly in 1991 have had a major impact on the code of conduct and practice in this profession, on public policy throughout the world for almost two decades. But, following the consultation process that took several years, the World Health Assembly adopted on the resolution WHA63.22 on May 21, 2010, on the basis of which it approved an updated version of the WHO Guidelines and identified progress towards optimizing donor practices and transplant practices. Accordingly, the main institutional framework for developing mechanisms for the management of transplantology in the European community should be based on:

- Adherence to the Guidelines for the Transplantation of Human Anatomical Parts and to ensure, where appropriate, their compliance with their own policies, laws and legislation on donation and transplantation;

- Promoting systems for disinterested, on a voluntary basis and free donation and increasing awareness and explaining to the public the benefits of the voluntary free software anatomical body parts from deceased and living donors;

- Preventing the pursuit of material gain in the conclusion of body parts transactions, organ transplantation and transplant tourism, including by encouraging health professionals to notify the relevant authorities when they become aware of such practices, in accordance with national capacity and legislation;

- Promoting a system of transparent, equitable distribution of organs, cells and tissues based on clinical cri-

teria and ethical standards, as well as equitable access to transplantation services in accordance with national capacities, which is the basis for community support of voluntary donation;

- Enhancing the safety and efficiency of donor and transplantation, contributing to the use of international best practices;

- Strengthening national and multinational bodies and/or capacity to oversee, organize and coordinate donation and transplantation, with particular emphasis on maximizing donation from deceased donors and protecting the health and well-being of living donors through appropriate health and long-term care services;

- Collaborating on data collection, including adverse events and reactions, on practice, safety, quality, efficacy, epidemiology and ethical aspects of donation and transplantation; and

- Encouraging the implementation of globally harmonized labelling systems for cells, tissues and human organs as such to facilitate the national and international tracking of human material for transplantation [5].

In addition to the main international principles, the modern state policy of highly developed countries for the development of mechanisms of state administration of transplantology is based on the principles of improving and attracting innovative technologies in transplantology. Scientists have developed a 3D printer capable of producing organs, tissues and bones that can theoretically be implanted in the human body. We can agree with the opinion of the researchers that this technology requires ‘further development’, however, the logical conclusion of the develop-

ment of 3D-bio-printing should be the creation of complete organs, bones and tissues, which will significantly reduce the waiting time for transplants for those who need it, and even allow to replace healthy human organs for their improved version. But today and in the near future, tens of thousands of people who are waiting for organ transplants can only hope that they will be next in the transplant lists and that the operation will be successful [6]. Now, a new perspective is opened before humanity: it is possible to ‘print’ on the printer any human body, to create from it an engineering structure enriched with stem cells of the patient, and to get the perfect prosthesis. In any case, such human organs as the liver, kidneys, heart and lungs have not yet been able to grow any regenerative surgeon. However, countries such as the United States, Sweden, Spain and Israel already have access to the bio-printing so-called ‘simple organs’ at the level of clinical trials and special programs. The American government is constantly investing in similar programs, except Wake Forest, which collaborates with the Pentagon, in order to reproduce the work of the liver, heart and lungs. Massachusetts Institute of Technology also receives significant amounts [7] for it. From the foregoing, we can conclude that the health of the nation is so relevant for the modern developed countries, that, in addition to providing citizens with qualifying medical assistance. The countries take on permanent participation in innovative projects aimed at improving the provision of medical services and health care in general.

**Conclusions.** We have been improved the scientific substantiation



of the state and problems of the development of international institutional foundations on the development of mechanisms of state control of transplantology by distinguishing the 5 stages of their formation too. Moreover, we can emphasize that each of the stages of development brought new opportunities and guarantees the development of transplantology in the world. The result of such development of each country has already depended on the coherent and effective management within the countries themselves.

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