

Legal and social aspects of patient rights' ensuring in order to access quality and blood component safety: international experience and necessity for its implementation in Ukraine

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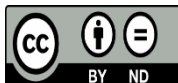


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ABSTRACT

The article raises the issue of patient rights' ensuring to access high-quality and blood component safety, both, as in Ukraine as in other countries. The importance of effective national blood service creation in each state in order to affirm and ensure human rights in health care is emphasized. The best international experience in this field is analyzed in the work. In accordance with the international law principles the main directions of its implementation in Ukraine are outlined. In particular, the need to create an education system, aimed at promoting donation, was emphasized in the article. The creation of an electronic system for blood donation and its components, training of donor recruitment specialists, ensuring the key bioethical principle of equality of patients in matters of blood donation and its elements, the development of a modern system for determining the quality and safety of donor blood and its components and etc. are offered in the issue.



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1. INTRODUCTION

In particular, the creation of the blood service functioning in Ukraine and the state of patient right ensuring in order to provide the blood component availability and quality have always caused and is still continuing to cause much debates. Blood service is known to be a branch of health care [1]. Moreover, health care, in its turn, is a general responsibility of the state [2]. The problem of the national blood service reforming received a new impetus in the research of Ukrainian and foreign scientists after 2014, when active hostilities began in the east of our country. Thus, a well-known researcher of medical and pharmaceutical law, notes in his substantive work on the analysis of the implementation of national legislation to European standards "...existing legislation declarativeness on blood donation and its components, ignoring the requirements of legislation on non-compliance Ukraine Association Agreement with the EU..." [4]. Emphasizes that the current legislation on blood donation "complicates a clear understanding of the concepts and may lead to incorrect understanding of the laws and regulations of Ukraine" [5]. Note that the structure of the blood service needs "immediate improvement, which will provide the introduction of state policy improvement in the field of free voluntary donation; the improvement of normative, the legal acts on the blood service issues, taking into account the international treaties ratified by Ukraine; the improvement of the motivation system of the population for free donation and encouragement of the organizers of the donor movement." [6] Blood donation has always been under the scrutiny of the state, because its importance for the health of the nation and the security of the gene pool is beyond doubt. The first blood bank in the Soviet Union was established in 1930, when donations became widespread as a result of proper state propaganda, Thus, the first Ukrainian blood transfusion institute was established in Kharkiv during this period. Such measures, as well as the strategic work carried out by the state, proved to be critically useful during the Second World War, when the developed system of donation and delivery of blood services was crucial for attracting more than 5.5 million people. The army received more than 1.5 million canned bloods. The population's attitude, who acted as the donor, nevertheless that they, themselves, suffered greatly from hunger and exhaustion from the war, allowed to consolidate as legally as morally and ethically with the highest humanism and patriotism.

The pace of blood service development set in the 1930s was further developed in the 1960s. It became the greatest achievements in medicine at that time and it was connected with the areas of haematology and transplantation. Unfortunately, in the last years of the Soviet Union existence, any clear steps, taken by the state in order to develop donations and the effective existence of blood services have been stopped. Unfortunately, it should be noted that, for many years this sad legacy was real and remained its influence to this day in our country. Therefore, the issue of legislative regulation and reform of the blood service, the timeliness of the legislator's response to changes in the political and economic life of the state is extremely important. Considering the state-chosen European integration vector of development, this is especially relevant currently. After all, Article 428 of the Association Agreement with the EU defines one of Ukraine's responsibilities as the approximation of legislation and practice to the principles of the EU Acquis, in particular in the field of blood service [3]. Thus, the study of international experience in the reform and sustainable development of blood services is very important and promising. The purpose of the article is to study the international experience of legal and practical patient rights to access high-quality and safe blood components, as well as to identify promising opportunities to apply the positive aspects in improving the efficiency of the blood service in Ukraine.

2. Materials and methods of research

To achieve this goal, the following methods were used: the comparative law in order to clarify the state of implementation of international norms in national law, analysis and synthesis in order to systematize the information obtained and deceive the most optimal ways to use it), comparative-historical method for

clarifying the legal evolution of the state of ensuring the rights of patients to the availability of blood components in different countries. The prognostic method was used during the development of the author's proposals to improve the regulatory framework for the functioning of the blood service.

3. Results

Spain

The donation system of the blood service organizing and functioning in Spain is considered one of the best in the world and has its own term "Spanish model". Considering our analysis, the leading positions of Spanish medicine are achieved due to a combination of factors, including a clear and understandable legal framework, which not only clearly defines the legal status of participants in this process, but also allows the national blood service to function effectively; powerful public education work to promote donation and increase the status of donors in society. In our opinion, a positive factor in the development of the blood donation system in Spain is the positive attitude of the Catholic Church, which position in the countries is very influential. The Spanish model of the blood service organization system belongs to the mixed type, when there is a combination of options for accumulation and meeting the needs of consumers in donor blood, both, as independently by doctors as in special centers. This model allows 17 regional centers to function effectively in the country, each of which has an autonomous status and management. At the same time, the current legislation, the Law on Blood Donation (2005), in particular, regulates the order of clear systemic interaction of all centers, the main purpose of which is to ensure 100 percent of the population's need for blood components. According to official data, Spain is the undisputed leader in the main indicators that characterize the quality of the relevant model of blood service. The Ministry of Health and Social Welfare is directly responsible for the general regulation of the blood service in Spain. [8] Scientific and methodological guidance is provided by the Scientific Committee on Blood Safety, which includes transfusion specialists from various medical institutions. Functionally, the Spanish blood service system works in the following way. Direct blood collection in the country is carried out by territorial blood transfusion centers, where it undergoes appropriate processing and testing. Blood is delivered to the centers by specialized vehicles. It is also the responsibility of the centers to transport the material to the hospitals.

According to information sources, every day more than 30 medical institutions apply to the centers for the required amount of blood. It is believed that thanks to the introduction of the centralization component in the activities of regional centers, consumers have the opportunity to use the highest quality blood, including through the unification of the necessary measures to EU standards and requirements [9]. These measures have allowed the Spanish model of blood service to have a very high rating on such key international criteria as the quality of care, patient safety and satisfaction, compliance with national and European industry legislation [10].

The United Kingdom

Since 2005, the National Blood and Transplant Service have been providing organizational and methodological guidance to the blood service in the country. According to the Statute [11], the powers of this organization include reliable and effective provision of blood components and anatomical materials. One of the main service features is a powerful information work on the promotion of donation and establishing stable relations with regular donors. Measures taken by the UK blood services can significantly reduce inefficient use of blood, namely, and reduce the percentage of write-offs of components due to the expiration date. The blood service of the United Kingdom belongs to the regional model, which is quite understandable, considering the federal structure of the state. The Transfusion Centers of England, Wales, Northern Ireland and Scotland deal with the blood component supply to the population of the concerned

regions. At the same time, there is a system of national control, which is provided by the National Blood and Transplant Service. It ensures direct work with regular donors in the following way, described further in the article. The donor receives an invitation letter, stating the last date of blood donation and indicating the place and time of the next blood draw in the relevant district. Blood collection events are usually held on church premises, which also have a positive impact on the promotion of donations in the country. All necessary medical equipment is delivered to the appropriate place by special transport. Each donor has the opportunity to reserve the time of blood donation in advance, which is quite a convenient moment, because usually at such events there are queues of people willing to donate blood. According to one of the main principles of the functioning of the blood service in the UK is the comfort of the donor, raising his awareness and satisfaction with the donor function [12]. A positive step in the functioning of the country's blood service is the construction of a powerful quality control system, which led to the creation of an archive of samples in which positive reactions to certain markers were recorded in the relevant test system. According to English scientists Lee D.A. and Howell D.R., such an archive is a model for learning from research, development and quality and safety of transfusion activities [13]. In Germany, blood services are provided by four types of organizations: German Blood Transfusion Services of the German Red Cross, State and Municipal Blood Transfusion Services, Commercial Blood and Plasmapheresis Centers of the plasma fractionation industry [14]. The most powerful organization that receives and distributes blood in the country is the Blood Service of the German Red Cross (das Deutsche Rote Kreuz, DRK). This organization provides 70 percent of patients' blood needs. One of the features of the work of Red Cross blood bank specialists is creativity in finding and attracting new ones and support of regular donors. Such measures include drawing prizes, during promotions, awarding, depending on the number of donations, donors with the sign "Honorary Needle". The possibility of donating blood is provided not only for residents of large places, where donation is carried out in stationary premises, but also for representatives of rural areas, for which mobile blood transfusion stations operate.

The main task of legislation, which governs the donation procedure, is the Transfusion Act (TFG) [15]. The law clearly regulates all problematic issues related to transfusion manipulation. In particular, the aspects of donor selection, consent to appropriate intervention, the procedure for maintaining documentation, protection of personal data and many other issues are regulated, while the norms are very carefully and clearly spelled out. Evidence of respect for a potential donor is the procedure of bar coding of the donor of his blood, which similar to the United States. Even if the donor has already donated blood, he must put an appropriate bar code on the blood tank, which allows or, conversely, prohibits the use of blood in the future for donor function. If a person came as member of a company, for example, or according to the event, held in a a company, what is also common in Germany, or because of the reasons of reluctance to disclose any personal moments such as risky sex, drug use, etc. may donate blood, but at the same time determine that he does not consent to the use of own blood for transfusion. All this testifies to the respect for donation and donors by the state.

USA

The function of gathering and distributing blood in the United States is directly entrusted to the relevant blood banks. Each bank must be licensed by the State Department of Health and registered with the Food and Drug Administration (FDA) [16]. It is also necessary to have accreditation from the American Blood Bank Association [17]. In the United States Blood donation gains increased attention and support not only from the church, but also from private businesses. Each blood donation campaign, carried out by the relevant blood bank, is carried out jointly with representatives of local businesses such as cafes, shops, transport companies, entertainment centers, etc. All of this mentioned above allows you to turn a routine action into a bright show with raffles, gifts, discounts, contests and something like this. The possibility of

donating blood on a paid basis is allowed by American law. Donors enjoy this right in some states, but the in the country principle attitude to donation is different as an important as necessary duty of the citizen. This is facilitated by strong social advertising of donation at the federal and regional levels. There are separate car parks for donors, they are members of the respective clubs "Golden Club", "Gallon" and so on. All this, of course, increases the social significance of donation and has a positive effect on the reputation of the donor, which, given the mentality of Americans, is very important.

4. CONCLUSIONS

The key to the effective functioning of the blood service in Ukraine and the fulfillment of its main goal of providing the population with the necessary amount of safe and qualitative blood and its components is a combination of many legal, economic and social factors. Presently, the urgent need for the state is to fulfill its obligations in order to implement European legislation on blood donation. The adoption of a separate legislative act, which will define the functional system of the blood service of Ukraine, is reviewed as an urgent purpose of the new "Verkhovna Rada". It should be noted that such steps have already been taken by a team of prominent scientists and practitioners, and a very clear and professional draft law "On the National Blood Service" has been proposed [18]. Undoubtedly, it is necessary for the principle of patients' equality, regardless of their status and even places of imprisonment, must be applied in ensuring the right to qualitative and affordable blood and its components [19]. It is also important for ensuring this right the active state participation in creating an electronic system of donors' list, recipients and blood banks. Moreover, it is necessary to create an effective modern system for determining the quality and safety of blood and its components. Donor advocacy needs to be enshrined at the state level, and strategic steps are needed to attract new and retain permanent donors. The importance and humanity of donation understanding should be formed in the children from preschool. Real steps are needed to be systematically involved by private businesses in donations, the formation of social responsibility and a positive image in society. A separate step should be done in the specialists' training. They are as follows: potential donors' recruiters, specialists, familiar with legislation industry, but there is must also be elements of management, marketing, advertising and PR activities. We believe that a systematic combination of such legal, economic and social measures will lead to the emergence in the country of an effective, adequate to the challenges of today's national blood service.

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