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Legal Treatment of Blood and Blood Components in Croatia

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Abstract

Every person has a right to health care and the possibility of achieving the highest possible level of health, in accordance with the provisions of the Health Protection and the Law on Compulsory Health Insurance. Every person is obliged to take care of their health. No one may endanger the health of others. Each person is required to provide emergency first aid to the injured or sick person and allow her access to urgent medical assistance.

The Republic of Croatia in the realization of social care for the health of their populations throughout its area provides facilities for the general population to effective, high-quality and safe blood products.

Keywords: Blood; Blood components; Health; Croatia

Nomenclature: NN = Narodne novine = National newspaper

1. Introduction

Health, as well as socio-economic categories, includes in itself the interests of individuals and the interests of society [1]. The relationship of the individual and society towards health history is changing. The nearby village of past health, its protection and improvement were considered individual care and private interests of the individual. Today, however, about the health of almost all over the world speaking as an important public interest, a significant factor of economic and social security and the essential components of economic and social wellbeing. The right to health is programmed as one of the fundamental human rights. This evolution of understanding and treatment of health is a reflection of changed social and economic relations in the modern world [2]. Therefore, here it must be emphasized that in every country health legislation reflects social conditions, general legislation and current health policy and also provide guidance for the organization and management of health services [3]. On the other hand the state of public health and health care directly affected by many other laws except those in the field of health.

The craniovertebral venous system consists of cranial veins and veins of the vertebral column [4]. These veins are interconnected with no valves, allowing blood to flow freely in both directions. The veins of the brain, dural venous sinuses, veins and diploic emissary veins belong it cranial veins. The veins of the vertebral column consist of external and internal vertebral venous plexus and of basivertebral veins. The vertebral veins, posterior intercostals veins, veins lumbar and lateral sacral veins drain blood directly from craniovertebral venous system in azygos vein or in the superior and inferior vena cava.

The craniovertebral venous system with other venous systems are forming numerous anastomosis, which in pathological conditions represent a collateral pathway for blood to the heart and allow the direct spread of neoplasms of the thoracic, abdominal and pelvic cavity in the area of the cranium and spine. In addition, the significance of cranial veins and veins of the upper part of the respiratory system are part of the selective brain cooling mechanism which is particulary important in condition of hyperthermia.

Blood is a liquid tissue that runs in a closed circulatory system of the body. Blood is essential to maintain the normal function of all organs and cells in the human body. The main function of blood is to supply the tissues with oxygen and nutrients. The human body is a between 4.5 and 5.5 liters.

Given that the health of the population is one of the most important tasks of each State, the Republic of Croatia passed a series of laws in the field of health. Law on blood and blood products is just one of them and it can be said that one of higher quality.

According to the Law on blood and blood components [5], the blood is blood collected from blood donors in the anticoagulant solution for the processing of blood components for transfusion or for further processing, and blood component is any therapeutic composition for transfusion made from human blood or blood components.

The Republic of Croatia their rights, obligations, tasks and objectives in the area of supply of the population effective, high-quality and safe blood products is realized:

- Planning needs for treatment of patients with drugs that are produced from human blood,

- Promoting the principles of self-sufficiency in the supply of the population with blood products through voluntary unpaid blood,

- Ensuring conditions for raising public awareness on the need and purpose of collecting blood medicinal products prepared from blood,

- By providing funds on the entire Croatian territory for harmonizing collection and blood testing and production, storage and distribution of blood components with the achievements of scientific and technological development,

- Establishing and ensuring the development of health information systems in the field of transfusion medicine in the Republic of Croatia,

- Ensuring the development of scientific activities in the field of transfusion medicine,

- Ensuring conditions for the education of health professionals in the field of transfusion medicine.

2. Availability of Blood Components

In order to ensure the availability of blood products for all health institutions network of transfusion services is determined by the required number of authorized medical institutions for Croatian area or district (regional) governments. Network transfusion services is determined by the basic health care network in accordance with the Law on health care [7].

Planning, data collection and testing of blood and the production, storage, distribution and issuing of blood products must carry a health institution or the health institution which is to perform certain of these activities given the approval of the Minister of Health in accordance with the provisions of the Law on blood and blood products .

Authorized healthcare institution in which the operator producing blood products must ensure the responsible person - doctor specialist transfusion medicine with at least five years of experience in the field of specialty and who is responsible for the collection, testing, processing, storage, distribution and issuing blood components in accordance with the law of blood and blood components. The responsible person is an employee of the Croatian Institute for Transfusion Medicine and duties of the responsible person of the blood establishment made on the basis of the agreement concluded between the Croatian Institute for Transfusion Medicine and the autorized health institution.

3. Testing of Blood

Blood establishments licensed to carry out the blood testing must test each collected unit of blood or blood components. The method and test conditions shall be prescribed by ordinance of the minister responsible for health, at least for:

- ABO and Rh D blood type,

and the following blood transmitted diseases:

- HIV1 / 2, hepatitis B, hepatitis C, and syphilis.

4. Ensuring the Quality of Blood and Blood Products

Autorized health institutions are required to establish a quality assurance system in performing transfusion service. More detailed standards for the organization of the quality assurance system conforming to internationally recognized standards in the field of transfusion medicine and scientific and technological development, prescribed by the minister responsible for health.

To ensure the quality of blood and blood components all persons involved in the collection and testing of blood and the production, storage and distribution of blood products must be adequately professionally trained, with the obligation of continuous professional training in accordance with a separate law.

Promotion and organization of blood donations and blood components in the Republic of Croatia are based on the principles of voluntariness, gratuitousness, anonymity and solidarity. These principles mean that the blood establishment collecting donated blood, for her not to pay any compensation, voluntary donors are anonymous and give blood in solidarity with those in need.

To take the blood or blood component is forbidden to give the service fee.

For a given blood or blood component donor must not receive remuneration.

Providers of blood and blood components may be an adult person for whom a medical doctor determined the lack of medical reasons that could cause damage to the health providers or patients. Exceptionally, for autologous transfusion, donor blood or blood components do not have to be an adult.

A person who approaches giving blood or blood components must be notified of possible reactions during blood collection, the extent of blood testing and personal data protection.

Before each donation of blood or blood component medical doctor is obliged to examine the person granting access. A medical doctor who performs the examination of the person giving access to the responsible person of the blood establishment.

Before each donation of blood or blood components that person access to benefits must give consent for the donation of blood or blood components. The consent shall be given in writing and must be the expression of the free will of the service, based on the relevant information on the purpose of giving you the usual risks.

Croatian Institute for Transfusion Medicine keeps the register of blood donors. The register separately stated data on persons who temporarily or permanently should not be blood donors.

Register of blood donors must be part of the national system for transfusion. The register must be available to all health institutions, which collect blood.

Promotion of blood donations and blood components in the Croatian territory conducted by the Croatian Institute for Transfusion Medicine and the Croatian Red Cross. Promotional activities should be continued and consistent with needs for sufficient quantities of blood and blood products throughout the Croatian territory throughout the full year.

5. The System of Quality of Blood and Blood Products

The responsible person in the authorized healthcare institution shall establish a system of quality blood and blood components [6]. To ensure the quality of blood and blood components responsibility of all persons involved in the working processes of authorized healthcare institutions. The director of the health institution provides a systematic approach to quality and the implementation and maintenance of quality systems. The quality system of blood and blood products includes quality management, quality assurance, continuous quality improvement, personnel, premises and equipment, documentation, collection, testing and processing, storage, distribution, quality control, blood component recall, and external and internal auditing, contract management, non-conformance, errors and self.

The responsible person shall introduce a quality system that ensures that all critical processes are specified in appropriate instructions and are performed in accordance with standards and specifications. The director or a person authorized shall review the system at regular intervals to verify its effectiveness and introduce corrective measures if deemed necessary.

Rooms in authorized healthcare institutions, as well as places for collection of blood outside the blood establishment shall be adapted and maintained to suit the activities to be performed in them. They shall enable the work to proceed in a logical sequence, so that the risk of errors, and shall allow for effective cleaning and maintenance to the risk of contamination was minimal.

At authorized healthcare institutions, as well as the place for the collection of blood outside the blood establishment there should be some room for a confidential discussion and for assessing the suitability of individuals to be donors. This area must be separated from all the rooms in which processing is performed. Blood collection shall be carried out in a space that is airy, clean, comfortable and designed for the safe withdrawal of blood from donors. The space must be properly equipped for the donors experiencing adverse reactions or injuries from events associated with blood donation. The area must be organized so as to ensure the safety of both donors and personnel as well as to avoid errors in the collection procedure.

The quality system of the blood establishment shall ensure that the requirements for the storage and distribution of blood and blood components intended for the production of drugs in the blood is in compliance with the Law on blood and blood components and regulations issued pursuant to that act. Procedures for storage and distribution shall be validated to ensure blood component quality during the entire storage period and to exclude mix-ups of blood components. All transportation and storage actions, including receipt and distribution, shall be defined by written procedures and specifications. Autologous blood and blood components, as well as blood components collected and prepared for specific purposes shall be stored separately.

6. Collection of Blood

Autorized health institutions should establish and maintain procedures for safe donor identification, medical examination and an interview with the service and assess the suitability of the service. These procedures must be carried out before each blood donation. The donor interview shall be conducted in such a way as to ensure confidentiality. The donor suitability records and final assessment shall be signed by a medical doctor designated by the responsible person.

The blood collection procedure shall be designed to provide positive identification and verification and secure record of service, in order to clearly establish a link between the donor blood / blood components and blood samples taken. Systems sterile bag for the collection of blood and blood components and their processing shall be obtained from approved suppliers that meet the documented requirements and specifications and must be CE marked. The serial number of the blood bag shall be traceable for each blood component. Blood collection procedures shall be such that the risk of microbial contamination. During blood donation, blood samples are taken for laboratory testing service. Samples are transported and stored in a manner that guarantees the preservation of the quality of the test sample. For the labeling of records, blood bags and laboratory samples should be used identical donation numbers. Procedures that have minimal risk of identification error and mix.

After collection, the blood bags taken / blood component be handled in a way that maintains the quality of the storage and transport temperature appropriate to further processing requirements.

Authorized healthcare institution must have documentation to ensure that each unit of withdrawn blood / blood component can be linked to the collection and processing system into which it was collected and / or processed.

All equipment and technical devices shall be used in accordance with validated procedures.

Processing of blood components shall be carried out using appropriate and validated procedures including measures to avoid the risk of contamination and microbial growth in the prepared blood components.

In all phases of the bags in which the blood / blood component should be labeled with relevant information for their identification. In the absence of a validated computerized system for status control, the labeling shall clearly distinguish between blood and blood components are released for use by those who are not.

7. Monitoring Adverse Events

The system of traceability and labeling of each blood component produced from blood donors to patients and vice versa throughout the country is a set of procedures and measures that can be unmistakably identify each individual blood donors, a dose, produced blood components and patients. The system of traceability and labeling of blood components should be compatible with international systems of traceability and labeling in order to ensure traceability of blood products at the international level.

The Ministry is obliged to establish a single national system for reporting adverse and unexpected events and reactions associated with:

- Collection and testing of blood and the production, storage and distribution of blood products, which could affect their efficiency, quality and safety,

- The application of blood products, in case of doubt on their effectiveness, quality and safety.

The system documentation, classification and assessment of severity and unexpected adverse events and reactions shall allow international exchange of data.

Any serious adverse event and serious adverse reaction authorized healthcare institution shall immediately notify in writing the Croatian Institute for Transfusion Medicine and the Ministry responsible for health. Blood establishments are required to establish an effective and proven system of withdrawal from the market of blood products that caused or may cause serious adverse event or serious adverse reaction.

8. Export and Import of Blood and Blood Components

Blood and blood components may not be exported from the Croatian.

The Minister may, exceptionally, in case of natural disasters and other emergencies, as well as in cases where there is an urgent, medically justified need, to approve the export of blood and blood components. In this case, it must be ensured in accordance with the testing of blood and blood components.

Blood and blood products may not be imported into the Community.

The Minister may, exceptionally, in case of natural disasters and other emergencies as well as in cases where there is an urgent, medically justified need, to approve the import of blood and blood components. Imported blood and blood components must comply with the conditions prescribed by the blood and blood components and testing shall be provided in accordance with the same law.

9. Protection of Data

Medical information on the service levels are confidential and must be protected from unauthorized access.

Personal data on providers of professional secrets. Personal data is stored and communicated in accordance with special regulations governing the protection of professional secrecy and protection of personal data.

10. Conclusion

The Republic of Croatia measures of economic and social policy creates the conditions for the implementation of health care, as well as the conditions for the protection, preservation and improvement of population health and harmonize the functioning and development in all areas of health care in order to ensure the implementation of health care population. Republic of Croatia is indeed water quality health care for its citizens, as evidenced by the quality Law on Blood and Blood Products for which one can still say that it is one of the better legislation in the field of health.

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