

**28 Annex - Consumer and health protection**

**220. SAFE BLOOD STRATEGY**

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GOVERNMENT OF REPUBLIC OF MONTENEGRO  
MINISTRY OF HEALTH

SAFE BLOOD STRATEGY

**April, 2006**

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## INTRODUCTION

Improvement of health protection quality is one of the leading challenges for most of the health systems and especially for public health sector. Transfusion activity has always had special place in health protection system. Because of medicine's texture made from human's blood from which depends safety of transfusion treatment, EU recommended Directive that do not represent just demand of the profession but moral and ethic imperative. There are few medicine departments that passed as many changes as transfusion did. Regarding to its importance and extraordinary development WHO CoE EU, special attention is given to improvement, safety and quality of transfusion treatments by their legislative body.

Regarding to Directive EU blood and blood components providing as medicine that originates from humans represents national interest. Modern and sophisticated transfusion system is based on collaboration of experts with different profiles of science, technology and public health. The biggest blood donor, patient and healthcare workers safeties are permanent challenges for each precipitator in process of transfusion activity.

Besides risks of the transfusion treatments are dwindling, this section is permanently facing many challenges and unknown risks. This is necessity to induct quality control system that will ensure coherent production accordant respecting standards that will mistakes brought to minimum and make modern standard in transfusion. Improving quality forms which main goals are to decrease mistakes, increase patient security, upgrade the service and decrease expenses, are solutions which are obligations and challenges.

WHO and CoE, through law regulations, are insisting more and more on quality improving in transfusiology with main object in getting patient and whole public confidence in transfusion treatments.

Main concept of providing enough amount of safe blood on principles of voluntary anonymous and free donating from its own potential represents base of transfusion .

Good organization of transfusion service is based on ballast of security, provides good quality cure via transfusion that will be accessible to each citizen. Implementation of control quality system in health system of Montenegro is one of the particular determinants of health system and priority of this goal is safe blood.

Goal of providing this Strategy is conducting of modern system of safe blood in Montenegro. Ministry of Health of the Republic of Montenegro recognizing base and importance of problem of safe blood decided that providing blood as cure for its citizen's make as priority of health politics and at the same time national priority.

In that matter it has been established Republic Commission for Blood Transfusion in 2003. according to article 15 of The Law of State Administration (Official Gazette, no 38/2003) as professional advise body in Ministry of Health consists of all representatives that are involved in this process attempting to systematically come up with and realize Program of safe blood.

In purpose of realization of that activity it is formed Working group, in this field, for creating the Low on providing blood with mission of making draft Low on providing blood based on EU Directive 2002/98.

The Commission consist of Ministry of Health representatives, Health Fond, Republic Red Cross, Ministry of education and science, medical doctors specialists of transfusion, clinic medical doctors who are applying blood and representatives from voluntary blood donors.

The main goals of this Commission are:

- Involvement in drafting the Low on providing blood;
- Applying professional consultative services in shaping politic and strategy providing blood, blood components, blood derivative and blood medicine;
- Organizational proposal of transfusion department on Republic level in purpose of involving standards in providing safe blood process for medical treatments also for blood reserve in emergent situations;
- Planed and permanent work on bringing up popularize blood donating;
- Planes per year recommendation about blood supplies , blood components, blood derivates and medicines from blood providing.

Ministry of Health of the Republic of Montenegro is in charge of work of this Commission.

## 2. ANALYSIS OF EXISTING SITUATION

According to census number of citizens of the Republic of Montenegro is 620.145 (Monstat) and number of refugees is 31.217. Population between 18 - 65 years old is 60 %. A citizens older then 65 years old is making 12, 1%. There are 38% rural and 62% are urban citizens.

There is 30 public and 269 private institutions that includes pharmacies in Montenegro's health system. Despite of existence of a large number of private health institutions, public sector is dominating. Public health institutions are organized on primary, secondary and tertiary level.

### 2.1. ORGANIZATION OF TRANSFUZIOLOGY SERVICE IN MONTENEGRO

Blood transfusion services are organized within public health institutions on secondary level and cover necessities of whole population. All of them are doing their work through nine transfusion local unites in hospitals. Eight of cabinets are for blood transfusion (less capacity with limited work) within General and Specialized Hospitals and Centers for blood transfusion within Clinic Center in Podgorica. Centers for blood transfusion in Clinic Center are the biggest and well provided unites and it is being referent institution for transfusion for Montenegro.

Units for transfusion are situated in organizational and financial competence of General Hospitals and Special Hospitals for Traumatology and Orthopedic in Risan. Different level of organization and equipped of transfusion cabinets, working conditions in it, unequaled volume and complication of work are main labels of existing unites for transfusion in Montenegro.

On Montenegro's territory yearly is collected around 14 000 units of blood (80 % from family donation and 20 % from voluntary blood donations). From total number, Center for transfusion in Clinic Center in Podgorica, yearly treats around a half from a whole number of units of blood, while the rest number is divided on eight cabinets.

### ORGANISATION AND STRUCTURE OF TRANSUSIOLOGY SERVICE

- Center for Blood Transfusion CC Podgorica.....1
- Cabinets for Blood Transfusion in general hospitals .....7
- Cabinet for Blood Transfusion in Special Hospital Risan.....1

### 2.2 WAY OF FINANCING

Base of financing system in health sector is represented by The Law on Health Insurance. With this law it is considered contribution that is refunded by employees and other insured person's categories. Fond for Health insurance is obligated for managing health insurance scheme, financing public health institutions and financing rights of insured persons. Whole budget for financing of all rights from health insurance is 6.5% GDP or 165 € per capita. Way of financing health services in transfusion domain is:

- Services for blood transfusion are financed through means of payment dedicated to hospitals by Republic Fond for Health Insurance.
- There are no resources meant for transfusion activity from budget or any other resource.
- Staff, equipment, reagents and expenditures are financed by Fond for Health Insurance through means of payment dedicated to hospitals.

### 2.3 LEGISLATION

There is no Law for blood transfusion in Republic of Montenegro. Regarding that transfusion services are being practiced according to Former Republic of Yugoslavia's regulations ~ Completion of regulation about Service for blood transfusion-1995:

- Law on medicines production and market - Official Gazette SRY no18/93,
- Bylaw on conditions for doing health services in health institutions and other kinds of health services - conditions in the way of cadres- Official Gazette SRY no 99/92
- Regulation for blood reserves collecting - Official Gazette SRY no 36/93
- Regulation for conditions for collecting, production and refinement human blood, its ingredients and derivates- Official Gazette SRY no 36/94
- Expertly, methodologically and doctrinal work instruction in blood transfusion service. Official Gazette SRY 36/93
- Law on citizens protection of infection diseases that are destroying whole country - Official Gazette SRY no 51/84 and 63/90
- Decision for health institutions network plan - Official Gazette SRY no 50/92

Within institutional reform which is first phase in healthcare reform Republic of Montenegro adopted new laws which is making a new frame for functioning healthcare system. Those are:

- The Law on Health Care, Official Gazette RMN no 39/04
- The Law on Health Insurance, Official Gazette RMN no 39/04
- The Law on Medicines, Official Gazette RMN no 80/04
- The Law on Medical Aids, Official Gazette RMN no 79/04
- The Law on Citizen Protection of Infection Diseases, Official Gazette RMN no 32/05

With new law on transfusion, or law on safe blood, we would provide necessary legislative for transfusion services.

### 2.3 PRESENT SITUATION IN BLOOD TRANSFUZIOLOGY SERVICES

#### A) SPACE

Existing space that is used for transfusion in Republic of Montenegro is not equal in demanded technology also in demanded standards. Transfusion services in Republic of Montenegro are situated in inadequate space within hospitals they belong to. Standards in space for doing services are not good in size, technique solutions and location. Some cabinets are located in basements or barracks.

#### B) EQUIPMENT

Existing equipment in blood transfusion cabinets is old (15-30 years older), what makes trouble in everyday work and it enables establishing set of standards in work process as well as establishing new methods. The existing equipment is very old, most of it is exceeded and it could not be serviced by manufactories any more. Beside that, there are many lacks in basic equipment in lot's of Cabinets, and result is inadequate usage of blood and blood components meaning inadequate transfusion treatment.

#### C) STAFF

There are 1139 employed medical doctors in healthcare system in Republic of Montenegro and there of:

- 12 medical doctors specialists in transfusiology
- 37 transfusion technicians with V degree level of professional education
- 7 medical technicians general course and laboratory technician
- 1 referent for VD blood (voluntary blood donors)

Most of cadre in transfusion sector in Republic of Montenegro regarding to existing service organization, especially among technicians, is being in inadequate used. That means that in Blood Transfusion Center, where is work amount and complication the biggest, staff is in to much in use, while in some services there are surplus of cadre.

Specialization in transfusiology is not attractive (very difficult and responsible job, low payment, work is not possible in private practice, overloaded work hours because of existing only one transfusiologist in most of the services, etc) and medical doctors do not show interest in this medicine area.

In pedagogic and motivational work and recruitment voluntary blood donators (it is very important area in providing safe blood) in Republic of Montenegro works only one person, referent for voluntary donating, who is going to go in retirement next year.

Beside that, huge numbers of medicine transfusion technicians with V degree level of professional education enabled for work in blood transfusion are also almost in retirement. D) SERVICES IN TRANSFUSION UNITES

*- Amount and difficultness in transfusion procedures in cabinets of Republic of Montenegro are very different because of provided mentioned services.*

**Procedures that are presently enrolled are:**

- Blood collection and production - work with donors, ABO/Rh screening, testing on blood - transmitting diseases (HIV, HBC, HCV and Syphilis), preparation blood components, work on the field.
- Immune-serology production of blood samples for income and outcome patients - BG ABO/Rh, DAT,IAT.
- Blood testing of income and outcome patients on infective diseases.
- Interaction - blood preparation for patients
- Blood and blood components issue
- Rh pregnancy prevention
- Irregular antibodies identification
- Issuing blood groups for IDs

E) MODERN TRANSFUSIOLOGY TREATMENTS are practiced through chemotherapy principles, which means make up just for blood patient needs using adequate blood components or derivates. There are only 2% of indications for using whole blood in clinic practice.

F) BLOOD COMPONENTS PREPARATION in transfusion services

- Center for blood transfusion- Clinic Center Podgorica - 98% blood units
  - Deplasmated and concentrated erythrocytes
  - Washed Erythrocytes
  - SSP
  - CP
  - ST
- General Hospital BAR
  - Deplasmated Erythrocytes
  - SSP
- General Hospital NIKSIC
  - Deplasmated Erythrocytes
  - SSP
- In other Blood Transfusion Services - Kotor, Risan, Cetinje, Bijelo Polje, Berane and Pljevlja blood is mostly used as whole blood or according to necessity erythrocyte and plasma are divided by spontaneous sedimentation
- In threading by blood in Republic of Montenegro is being in used at least 46% of the whole blood

f) NUMBER OF BLOOD DONORS

Number of population that is involved in donating is 14 000 or 2,13 %. Structure of blood donors is: family donors is 80% and voluntary 20%.

According to WHO and EU for having enough amounts of blood for necessities of its citizens for everyday treatments, urgent cases and extremely situation, it is necessary donating percent have to be 4-5% of population.

INSTITUTION	POPULATION	NO.OF DONORS	%	DAILY
CTBCC	201 382	5300	2,63	20



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BAR	68 150	1 197	1,75	5
KOTOR	66 236	1 103	1,66	4
RISAN*		343		
NIKSIC	88 884	1 786	2,00	7
CETINJE	33 886	465	1,37	2
BUELOPOLJE	70 249	1 188	1,69	5
BERANE	94 598	1 291	1,36	5
PLJEVLJA	45 223	620	1,37	2

\*Blood Transfusion Cabinet – Risan is taking blood for Special Orthopedic Hospital necessities from aimed blood donors.

### 2.4. EXISTING ORGANIZATION LACK:

- Chopped Blood Transfusion Services up,
- There is no coordination among services on national level,
- Decoresponding of legislative,
- Non existing aimed instruments for financing transfusion activity,
- Small number of blood donators that does not cover population needs,
- Inconvenient structure of blood donators (80% - family donators)
- Non existing mobile unites for work on the field.

### 2.5. WORKING PROBLEMS:

- Small number of blood donators that does not cover population needs;
- Inconvenient structure of blood donators (80% - family donators);
- Inconvenient facilities for blood transfusion;
- Old and inconvenient equipment (15-30 years and more);
- Non existing process for blood dividing into blood components – irrationalness ;
- Inconvenience of adequate transfusion treatments through using directional chemotherapy in most of the hospitals;
- Inconvenient way of creating of documentaries and labeling blood units;
- Non existence of standards in clinic blood and blood components use;
- Inconvenient way of storage of infective materials;

### 2.6. CONSEQUENCES

- Uncoordinated size and quality of work in transfusion unites;
- Non existence of standards in blood and blood components collecting, producing and processing;
- Non existent quality system and quality control during the work;
- Non existence of equality among the citizens in accessible and efficient blood components and chemotherapy
- Inconvenient overloading of existing cadre;
- Non rational and economical inefficiency.

## CONCLUSION

Based on analyzed condition in transfusion sector in the Republic of Montenegro it could be concluded that existing organization, working conditions and functioning of this activity have big importance for health and health system, should be promoted according to modern demanding of profession and healthcare safety.

Existing problems that represents existing system of making blood storage shows it is inconvenient, unsafe and inefficient.

Existing transfusion organization in Republic of Montenegro presents barrier for establishing EU standards (Directive EU 2002/98) resulting with consequences such as impossibility to provide enough amounts of the safe blood for necessities of all citizens, rational usage of blood and blood components, adequate clinic usage of the same and financial security of this healthcare system.

## 3. EU DIRECTIVES AND RECOMMENDATIONS

### FOR SETTING QUALITY AND SAFETY STANDARDS IN BLOOD TRANSFUSION SYSTEM

According to the EU Directives, supply of blood and blood components, as a remedy of human origin, constitutes a national interest and comes within the competence of the Ministry of Health, i.e. the State.

## EU DIRECTIVES

The EU Parliament and the Council of Europe's transfusion medicine expert team passed basic Directives and Recommendations on the role of the Ministry of Health, i.e. the State, in the field of blood transfusion.

The objective of passing Directives is the supply of the safe blood for the purposes of a country's population, based on the principles of voluntary unpaid blood donations, self-sufficiency in the provision of blood and blood components, and protection of blood donors and recipients, which is governed by the following official documents:

- Responsibility of the Authorities within the Health System in the Field of Blood Transfusion – Recommendation (88) 4;
- Setting Standards of Quality and Safety for the Collection, Testing, Processing, Storage and Distribution of Human Blood and Blood Components – Recommendation 2002/98;
- Protection of Donors' and Recipients' Health in the Field of Blood Transfusion – Recommendation (95) 14;
- Hospitals and Clinician's Role in the Optimal Use of Blood and Blood Components – Recommendation (2002) 4;
- The Introduction of Pathogen Inactivation Procedures for Blood Components – Recommendation (2003) 11;
- Guide to the Preparation, Use and Quality Assurance of Blood Components – Recommendation (95) 15.

By the EU Directives 2002/98, it has been decided that the recommendations of the EU experts, which were adopted by European countries as national standards, should take a legal form and be transformed into one single Law on Blood Transfusion, i.e. Law on the Provision of Safe Blood and Blood Components for the purposes of their citizens. The enactment of the aforesaid Law constitutes one of the European integration entrance requirements.

With a view to preparing for international integration, Stability Pact, World Health Organization and the Council of Europe initiated the »Safe Blood« Project, in order that the countries of the Balkans may become involved in the process of standardization and reaching compliance with European norms in this field.

## 4. »SAFE BLOOD« PROJECT

Based on the Dubrovnik Declaration (2001), the implementation of the programmes of the Stability Pact for South-East Europe started with the support of the World Health Organization. For the purpose of accomplishing the objectives of the Dubrovnik Charter, seven projects have started in the area of the protection of health of vulnerable population, improvement in the approach and promotion of regional cooperation among the countries-signatories of the Declaration.

- »Safe Blood« Project is one of the projects that started in November 2004, when the Montenegrin Ministry of Health placed its signature in agreement to access the Project. This Project has been implemented in the organization and under the patronage of the SP, WHO and CoE, in cooperation with the health ministries of the

above mentioned countries. Current activities on the Project in Montenegro have not been funded by any donors, in difference to other countries where considerable donor funds have been engaged in the transfusion service capacity building.

The »Safe Blood« Project objectives are as follows:

1. accomplishing self-sufficiency in the provision of safe blood and blood components through:
  - increase in voluntary unpaid blood donation,
  - introduction of legal regulations prescribed by the EU Directives,
  - establishing the system of quality and quality control in accordance with the EU recommendations, (introduction of the prescribed EU standards to apply to the whole process of the transfusion-related work – including the manner of record-keeping, development and setting of clinical interface, hemovigilance).
2. Regional Equality in Blood Quality and Safety as a Requirement for Future Integration, EU Accession and International Cooperation.

Within the scope of the Project activities, »Report on the Blood Provision Policy, Transfusion Service Organization and Accessibility« has been written. In addition, the »Report on Quality Control in Transfusiology in Montenegro« has been developed. There have also been two working meetings of the West Balkan countries where experiences and current situations in respect of the legal framework, manner of the provision of blood, blood donation, transfusiological service organization, manner of financing and clinical cooperation, have been presented.

The »Safe Blood« has been identified as a priority area of the Strategy of Fighting HIV/AIDS in Montenegro with a view to providing sufficient quantity of safe blood intended for the treatment of patients. This Strategy was adopted by the Government of Montenegro and certain funds have been allocated by the Global Fund based on competition.

The above mentioned activities constituted the bases for developing the Strategy.

### 1. STRATEGY OBJECTIVES

The purpose of developing the Strategy of Safe Blood is the provision of sufficient quantity of safe blood for the needs of citizens using own potential, in accordance with the EU Directives.

The aforesaid objective shall be accomplished through:

1. Increase in the level of voluntary blood donation (VBD) up to the level of self-sufficiency by developing and implementing a sustainable National programme, and
2. Foundation of a public institution of blood transfusion of Montenegro, as an independent entity founded pursuant to the Law on Transfusion, whereby the roles and duties of all stakeholders in this system will be defined.

Provision of safe (secure) blood implies a standardised product intended for the needs of daily treatment of patients, as well as sufficient quantity of blood reserves intended for the cases of emergency and special circumstances. The accomplishment of the aforesaid objective enables international cooperation in this field, which constitutes one of the requirements for the European integration.

The primary objective may be achieved through the accomplishment of special goals set out in the EU Recommendations on the introduction of standards and EU Directives in the blood transfusion system.

### 4.1 SPECIAL GOALS

1. Development and implementation of a national programme with regard to blood transfusion comprising own standards, recommendations and guidelines for all segments of basic transfusion (motivation, recruitment and keeping of voluntary unpaid blood donors from low-risk population groups, collection, testing, processing, storage and distribution of blood and blood components);
2. Developing national policy related to clinical blood transfusion,

3. Establishing the quality control system in transfusiological work,
4. Setting functional and coordinated organization of blood transfusion service,
5. Considering the optimal manner of funding the Blood Transfusion Institute,
6. Upgrade of infrastructure necessary for improving safety of blood and remedies derived from blood,
7. Preparing a programme of constant education and training for the staff in transfusion service,
8. Establishing a modern, integrated information system.

#### 4.1.1. Development and Implementation of National Programme with Regard to Blood Transfusion Comprising National Standards, Recommendations and Guidelines for All Segments of Basic Transfusion

##### 1. Motivation, Recruitment and Keeping of Voluntary Unpaid Blood Donors from Low-Risk Population Groups

This specific goal of paramount importance for the provision of blood as a medicine of human origin, requires development and implementation of sustainable National Programme, through diverse approach involving many branches and wider social awareness.

This entails:

- conduct of educational, motivating and advertising activities on disseminating the information about the significance of voluntary blood donation/donors (VBD),
- recruitment of VBD from low-risk population groups, and
- keeping regular VBD.

Basic activities pertain to:

- education of the whole population,
- education of volunteers,
- long-running national campaign on the importance and culture of voluntary blood donation.

The above activities are implemented through the conduct of educational lectures and seminars for all groups of population, especially the young, through preparation and distribution of promotional material, as well as through media promotion of VBD (videos, interviews, posters, billboards, leaflets, intended for target groups of population and distributed in accordance with the schedule).

The stakeholders are:

- Institute of Blood Transfusion,
- Red Cross of Montenegro,
- Institute of Public Health,
- Health and education institutions and media network.

Successful implementation of such National Programme requires continuity in conduct over a long period of time.

##### 2. Blood Collection

It implies the preparation and implementation of the Action Programme of Blood Collection in Montenegro.

The Programme should achieve:

- provision of coordination of the activities of blood collection on the whole territory of Montenegro,
- gradual substitution of family blood donors with voluntary donors from low-risk groups by forming mobile teams for field work,
- increase in the percentage of collected blood from 2.13% to 4%, as recommended by WHO,
- increase in the safety of collected blood units,
- preparation of the Programme of Introducing Donor Plasmapheresis in Order to Produce Blood Derivatives.

Within the scope of the above mentioned activities, the following step would be the preparation of the programme of care for voluntary blood donors as health associates, which entails the awareness of their health condition and provision of support in case of arising health problems.

### 3. Blood Testing

With a view to ensuring the safety of blood, all collected units are to undergo compulsory testing. Within the National Strategy, it is necessary to formulate the National Programme of Blood Testing with a standard protocol.

At the same time, protocols for separate activities, testing, selection and evaluation of screening tests, should also be established.

The requirements that must necessarily be met for the purpose of adequate testing are:

- well educated staff,
- availability of equipment and reagents,
- compulsory use of certified tests.

Within the scope of Blood Testing Programme, it is necessary to set reference laboratories with precisely defined responsibilities for tackling all unclear results. It is also necessary to establish quality cooperation with the epidemiological service for monitoring and analysis of results obtained, as well as to form a VBD computer database that must not be widely accessible.

The standards also impose formation of an ethical committee that should inform VBD of the results of testing the blood for presence of markers of infectious diseases transmitted by blood.

### 4. Processing, Storage and Distribution of Blood

In order to achieve this goal, it is necessary to establish and organize a coordinated blood transfusion service at the national level with a prepared Programme of Processing, Storage and Distribution of Blood/Blood Components, whereby the following would be accomplished:

- the provision of adequate quantity of safe blood including the definition of standards for preparation, storage and distribution of blood/blood components,
- creating conditions (equipment, working conditions and vehicles) for storage, distribution and transport, including the preparation of written instructions on these activities, i.e. drafting Standard Operating Procedures (SOP),
- increase in the safety of prepared blood, i.e. component,
- deciding on the institution to be responsible for processing, storage and distribution of blood,
- drafting Programme of the Manner and Dynamics of Blood Storage and Distribution.

#### 4.1.2. Developing National Policy on Clinical Transfusion

Transfusion of blood/components in the area of clinical transfusiology implies quality control, maintenance and improvement in accordance with the recommendations of the World Health Organization, which is to be accomplished through:

- rational use of blood,
- drafting a guide as to rational use of blood,
- ensuring availability of blood/components,
- formation of hospital transfusion committees assigned with medical control, monitoring the quality of clinical transfusion in hospitals and developing quality standards and indicators required for introducing the system of control, maintenance and improvement of clinical transfusiological practice.

#### 4.1.3. Establishing Quality Management System

For the purpose of providing sufficient quantity of high-quality blood/components with maximum efficiency and minimum risk for the donor and the patient, transfusiological service must have established quality management system. This system is compulsory for the EU Member States, in accordance with the Council of Europe's Directive 2002/98/EEC establishing the quality and safety standards for testing, processing, storage and distribution of blood and blood components.

The Directive prescribes formation of a competent regulatory body that should supervise the system of quality on regular basis and issue licences for work to transfusiological institutions. The system entails compliance with the principles of good manufacturing practice as to pharmaceuticals used in medicine, as well as the introduction of ISO 9001:2000 standard.

The quality system requires:

- organizational structure with clearly defined responsibilities and authority of all functions and relations among the functions;
- predetermined and provided required resources as to the staff, equipment and space;
- implementation of all operating procedures in accordance with the principles of good manufacturing practice, brought into line with appropriate regulations;
- monitoring, measuring and improving the quality of goods and services;
- documentation relating to the quality system;
- implementation of the system;
- licencing of transfusiological institutions.

#### 4.1.4. Establishing Nationally Coordinated Blood Transfusion Service

The provision of sufficient quantity of safe blood and blood components requires a well structured and organized blood transfusion service, since poor organization leads to inefficient and irrational use of already scarce blood reserves, which contributes to the increase in blood transfusion expenses of the state budget.

According to the WHO recommendations and EU Directives, the governments of Member States should promote and support centralised organization and management of blood transfusion service, introduction of modern technologies, application of uniform equipment, reagents, tests and substitutes for blood, as well as an integrated information system for the whole service.

The EU 2002/98/EC Directive defines two types of institutions within the national blood transfusion service:

- institutions handling VBD and transfusiological procedures relating to the collection, testing, processing, storage, distribution, transport and rational use of blood and blood components;
- institutions oriented towards the activities relating to the patients, i.e. to hospital blood transfusion service – blood bank.

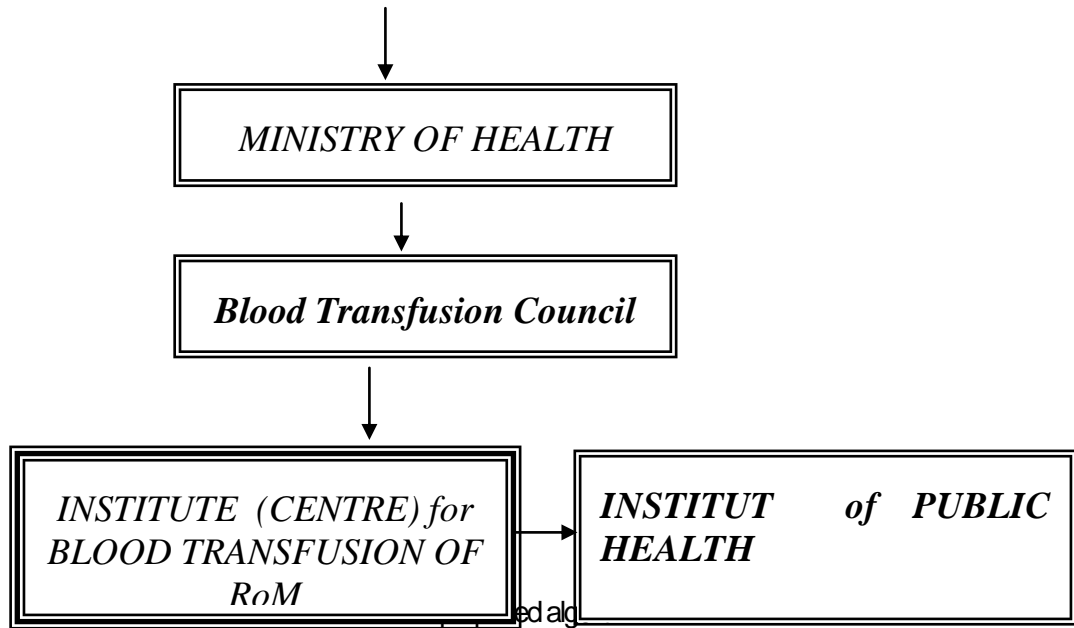
Implementation of the Directive enables:

1. introduction of quality control and consistent procedures;
2. optimal use of resources;
3. better understanding of the costs of management and procedures of the national system of blood reserves – cost-effectiveness.

Considering the number of operations and the total number of 14,000 collected units per year, (approx. 21, or 22 units per 1,000 citizens; in the EU, there are 40-50 units per 1,000 citizens on the average), it is advisable that the functions of blood provision merge into one national body responsible for blood transfusion, by establishing the Institute of Blood Transfusion and improving the hospital patient-oriented function, including the clinical practice in the field of transfusion, with the current standards of practice applied within the EU.

Organisation – proposed model:

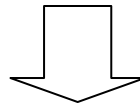
*GOVERNMENT OF THE  
REPUBLIC OF*



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*Ministry of Health*

*Developing Policy*





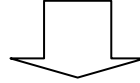


*Delegating Authority*

*Government Body - Council*

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Managing Functions





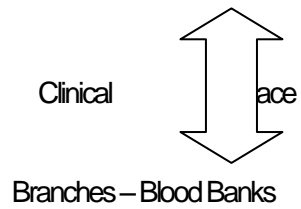
*Authority Delegation*

*INSTITUTE - Centre for Blood Transfusion*

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*Operative Functions*

*Producer and Supplier*



Provision of Services

### Tasks:

#### MINISTRY OF HEALTH

- To establish the system of auditing and licensing
- To provide for the compliance of the system with legislation and related regulations

#### NATIONAL BODY – COUNCIL OF BLOOD TRANSFUSION

- Under the jurisdiction of the Ministry of Health and within the responsibility of MoH
- Coordination of staff education and training
- Reference centre for reagents, equipment, procedures, problems and questions
- Coordination of public relations for the purpose of increasing awareness and knowledge

#### INSTITUTE (CENTRE) FOR BLOOD TRANSFUSION – OPERATIVE SERVICE

- Located in Podgorica, bound up with the Clinical Centre and University
- Serves as a department of supplying blood reserves

This Centre should be responsible for:

- Donation monitoring and collection of blood and plasma,
- Processing of collected blood and plasma,
- Testing of collected units,
- Control of quality, provision of quality and release of processed units – component specification,
- Storage,
- Related logistics and distribution of weekly supplies for work, quality, safe and efficient blood components to hospitals,
- Support to hospital committees of blood transfusion in the form of providing expert knowledge, clinical advice on the application of component therapy and alternatives, coordinating evaluation of hospitals in the region and collection of regional information on the appropriate use of blood and incidence and types of posttransfusion side effects.

The plan is to establish an available regional storage, i.e. distribution centre, in one of the hospitals in the north of Montenegro, so as to avoid the problems relating to transport during the winter months.

In addition to the above mentioned, tasks of the future Centre are the following:

- Provision of community interface including public and potential donors by way of establishing, stimulating and coordinating programmes oriented towards raising public awareness, strengthening motivation and cooperation with the Red Cross,
- Provision of clinical interface with hospitals and clinics by way of delivering clinical consultation services oriented towards adequate use of blood components and alternatives – clinical advice,
- Provision of support for hospital transfusions – blood banks, in collection and patient-oriented functions – immunohematology and compatibility testing.

The Institute (Centre) should be located in the space of adequate size and layout of rooms, furnished in accordance with the Good Manufacturing Practice criteria (GMP).

The seat of the Institute would be in Podgorica, whereas the regional centre for storage and distribution would be located in the North of the country.

Considering the level and structure of blood donors in Montenegro (80% family blood donors), the proposed model of transfusiological service organization, consistent with the principles of the European Union, requires certain period of time in order to be fully implemented. For this reason, it is necessary to come up with an interim solution that would basically retain the existing units within the health institutions that would continue to perform the same duties, but under the supervision of Montenegrin Institute of Blood Transfusion, the foundation of which will follow the enactment of the Law.

### 5. Manner of Funding the New Blood Transfusion Organization

The work/operation of national safe blood centres constitutes public interest and, by the rule, is financed from the Government budget. The new organization and functions of the future institution that is to assume the functions of the national centre for blood transfusion, in accordance with projected solutions and practice of West European countries, should be financed from the following two sources: Budgetary resources funds and compulsory health insurance funds. Accordingly, the Institute of Blood Transfusion of the Republic of Montenegro will be financed from the funds of the Ministry of Health, i.e. the Budget, for the activities of public interest in the area of transfusiology, and from the funds of the Republic Health Insurance Fund, for the activities related directly to the patient.

### 6. Upgrade of Infrastructure Necessary for Improving the Safety of Blood and Blood Components

The quality of goods and services relating to transfusion directly depends on the conditions under which the activities are being performed. Each institution must define, provide and maintain the infrastructure necessary for meeting the quality standard requirements. In those terms, the required standard would be an appropriate infrastructure that encompasses:

- buildings, working space and related equipment,
- processing equipment ( hardware and software),
- services of providing support ( in relation to transport and communications).

For the purpose of supplying space for the work/operation of Montenegrin Blood Transfusion Institute/Centre, it is necessary to start the activities regarding the elaboration of a project, designation of a location, construction and furnishing of the Institute/Centre in Podgorica. Activities on the preparation and introduction of new organization will include the construction of annexes to, or reconstruction of transfusiological units in common hospitals and the special hospital. The implementation of this Programme must involve local communities.

In respect of the equipment for the work of transfusiological service, the attempt will be made at having unified equipment (due to the advantages in servicing and standardization of transfusiological procedures), which is provided by adopting a uniform furnishing plan.

### 7. Preparation of the Programme of Constant Education and Training for the Blood Transfusion Staff

Particularity and sensitivity of the duties of transfusiological service require qualified staff relating to education, training, knowledge and experience.

For this reason, special programmes of constant education, training and freshening up of the acquired knowledge of staff will be developed for all segments of transfusiological work.

### 8. Establishing Modern Integrated Information System

Information system constitutes an important component of the safe blood strategy in order that efficiency in work and long-term safety for donors and patients may be achieved.

In this area, the information system should cover all segments of the transfusiological service working process, starting with the selection of donors, registration, tracking of a blood unit from the donor to the end user, through to the provision of quality and financial management.

Accomplishing the projected goals will be conducted in stages, in accordance with the schedule contingent on the provision of financial resources for each single activity, and the list of defined priorities. The ultimate goals of the strategy are expected to be accomplished by the end of 2010.

Priority activities are as follows:

1. Enactment of the Law on Blood Transfusion – June, 2006
2. Foundation of the Institute of/Centre for Blood Transfusion, with local units, following the enactment of the Law,
3. Construction, or reconstruction, of the facilities for operation of the Institute and transfusiological units, and provision of full equipment – June, 2007
4. Assuming the blood units' testing at the national level – June, 2007