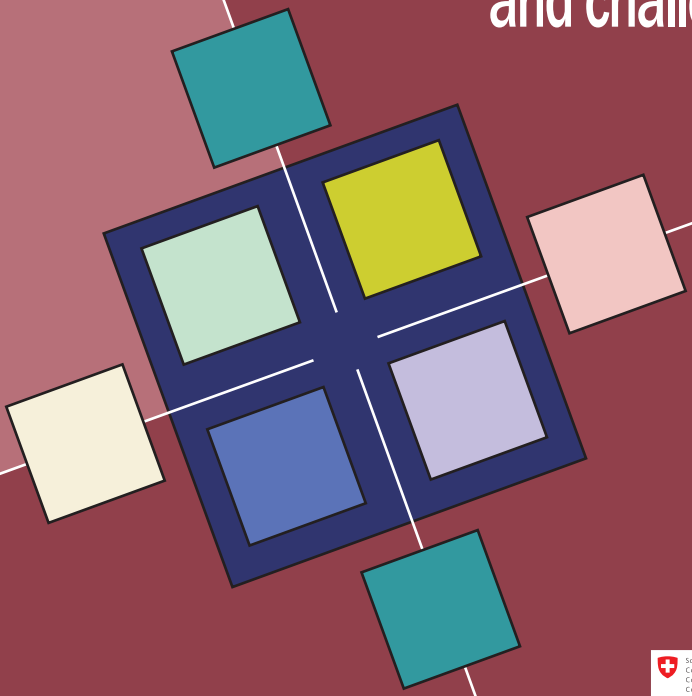
SOUTH-EASTERN EUROPE HEALTH NETWORK

Blood services in south-eastern Europe

Current status and challenges



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Blood services in south-eastern Europe

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Keywords

BLOOD TRANSFUSION - standards
QUALITY CONTROL
SAFETY MANAGEMENT - organization and administration
EUROPE, EASTERN
EUROPE, SOUTHERN

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Contents

Acknowledgements

This book has been compiled on the basis of contributions of the SEE country project managers and their teams: Dr Irena Seferi (Albania), Dr Dragan Sarenac (Bosnia and Herzegovina), Professor Andrey Andreev (Bulgaria), Dr Dorotea Sarlija (Croatia), Dr Larisa Catrinici (Republic of Moldova), Dr Florentina Vladareanu (Romania), Dr Snezana Draskovic (Serbia), Dr Gordana Rasovic (Montenegro), and Dr Kocho Dimitrovski (The former Yugoslav Republic of Macedonia).

The regional analysis, based on the data provided in the framework of the project, has been performed with the contribution of: Dr Lenka Walterová, Dept of haematology, Liberec Hospital, Czech Republic; Dr Ole Berseus, Dept of Transfusion Medicine, University Hospital Örebro, Sweden; and Dr Alina Dobrota, regional SEE blood project manager, Constanta, Romania.

The financial support of the Swiss Agency for Development and Cooperation towards the printing of this publication is gratefully acknowledged.

Special thanks for their dedication and support to Dr Maria Haralanova, Regional Adviser, Public Health Services and Dr Dora Mircheva Dimitrova, Technical Officer, Public Health, Division of Country Health Systems, WHO Regional Office for Europe; and Dr Alexander Berlin, Honorary Director of the European Commission.

Appreciation is due to Lisa Copple, Quality of Health Systems Programme Assistant, for her significant help along the way.

Editor: Dr Valentina Hafner

Chapter 1

THE BLOOD SAFETY PROJECT

Summary

The countries of south-eastern Europe (SEE) have experienced important changes in the past fifteen years. New social, political and economic challenges appeared with the fall of totalitarian regimes in the region and the dissolution of USSR and Yugoslavia. The move from centralised to market based economies affected the health system in its entirety, leaving populations increasingly exposed to health threats.

Recognizing the need to support the region, the European Community initiated in 1999 the Stability Pact aimed to sustain the development of a comprehensive, long-term conflict prevention strategy.

The Stability Pact is based on experiences and lessons learned from worldwide international crisis management. Governments across the region are increasingly concerned with ensuring the physical wellbeing and better health of their populations. This focus on health reflects political commitment embodied in a cooperation process launched in 2001 at the First South-East European Health Ministerial Forum. The SEE countries themselves established the South-Eastern Europe Health Network and their representatives met in Dubrovnik to sign an unprecedented political commitment to improve the health in the region. This came to be known as the Dubrovnik Pledge.

The major outcome of the Dubrovnik Pledge was the identification of and subsequent project development along seven agreed health priorities (including blood safety), to be implemented in each SEE country at approximately the same time, and integrated within a regional approach.

In November 2005, the 2nd Health Ministers' Forum, in its Skopje pledge, reiterated the commitment to continue cooperation in the priority areas agreed in 2001, to further consolidate the SEE health network at regional level, and to assume full responsibility for regional cooperation on health and health related issues.

The blood safety project aims to increase quality and regional self-sufficiency in the provision of safe blood and blood products., and it is led by Romania.

The project comprises two components. Component 1 aims to strengthen mutual trust and acceptability of the quality of blood in the region through reinforcement of national blood safety policies according to international requirements and ensuring self sufficiency in safe blood. Component 2 aims to increase the transnational availability of safe blood and blood components for medical emergencies and special circumstances. Only the first component has been developed to date, kindly supported by the Government of Slovenia, Switzerland, the Council of Europe and the WHO Regional Office for Europe.

Introduction

In the last 15 years the SEE region has suffered large scale changes that were associated with the loss of many lives, population movements, civil unrest and in some territories armed conflict. Whole ethnic groups faced discrimination and violence.

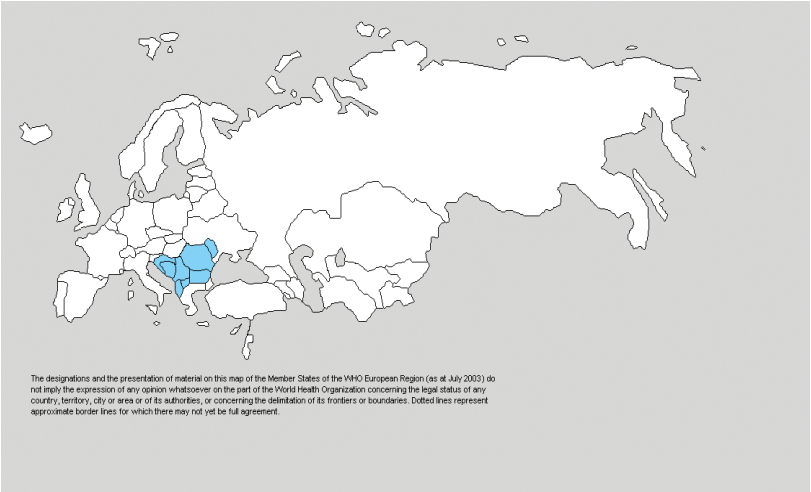
This was recognized by the European Union (EU) and in a position statement adopted in April 1999 the formation of the Stability Pact was envisaged. The aim of this Stability Pact is to help ensure cooperation among its participants towards comprehensive measures for long-term stabilisation, security, democratisation, economic reconstruction and development of the region, and to establish durable, good neighbourly relations among and between them and with the international community.

This initiative was transformed into reality on 10 June 1999 in Cologne, Germany, through the adoption by the international community of the Stability Pact for South Eastern Europe. In the founding document, more than 40 partner countries and organisations undertook to support the countries of south-eastern Europe "in their efforts to foster peace, democracy, respect for human rights and economic prosperity in order to achieve stability in the whole region". The Pact was reaffirmed during a summit meeting in Sarajevo on 30 July 1999. Subsequently, the Initiative for Social Cohesion was launched in 2000, addressing the daily lives of people in SEE: social dialogue, social protection, housing policy and employment policy.

Countries of south-eastern Europe have invested significant efforts in the pursuit of wide-ranging reforms of their health sectors, addressing issues of financing, organisation and management of health services. These reforms came in response to the inadequacies of the health systems inherited from the communist era, the pressures arising from political and economic transition, a collapse in the funding available for health care and, to different degrees, to the effects of conflicts and economic sanctions. While the countries have followed different trajectories, their overall aims in the health sector have often been very similar, and there is much that could be learned from comparing and contrasting their experience in the process of reform so far. By doing so, it is possible to distinguish common challenges for the future as well as areas where reform efforts need to intensify in some countries of the region more than in others.

The increasing concern to ensure the physical wellbeing and better health of their populations, and the focus on health, reflect political commitment embodied in a cooperation process launched in 2001 in Dubrovnik at the First South-East European Health Ministers Forum. The Dubrovnik Pledge was signed by the Ministers of Health of Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Romania, The former Yugoslav Republic of Macedonia and by the Federal Secretary for Labour, Health and Social welfare of Yugoslavia. The Republic of Moldova joined in June 2001.

Seven Regional Projects, budgeted at over Euro 8 million, including one on blood safety, were designed and initiated to implement the political commitments of the pledge. The governments of Belgium, France, Greece, Hungary, Italy, Norway, Slovenia, Sweden and Switzerland supported the projects both technically and financially. Council of Europe and the WHO Regional Office for Europe have become partners in supporting and coordinating the projects.



Stability Pact countries are coloured in blue for a general position of the SEE health network.

Blood safety

The European region hosts a wide variety of blood transfusion services at different levels of development, finances and support. Increasing cross border movement, the HIV/AIDS epidemic, and inequalities in terms of quality standards and safety requirements in blood services/health services are continuous challenges for the quality and safety of the blood reserve. The falling trends in blood donation in many countries (due to lack of education and awareness), and the ageing European population raise additional concerns with regard to availability and access to transfusion therapy.

The cost/benefit challenge in terms of blood safety and hospital economics is becoming more and more acute, especially in countries with limited resources, as a reflection of the existing burden of disease and the necessity of intervention.

Action is required to address shortfalls and imbalances in national blood supplies within the health systems framework. Emphasis is given to the whole blood service configuration (national coordination, sustainability and adequate resources). Voluntary non-remunerated blood donation remains a recognized cornerstone in the process.

Shared experiences, information exchange, cooperation and partnership are considered essential mechanisms for progress in the field.

The quality of blood and increasing self sufficiency in the provision of safe blood and blood products have been priorities of the World Health Organisation and the Council of Europe for more than a decade.

The European Union has acquired competency in public health with the Maastricht Treaty of 1992, which was enhanced in 1999 by the Amsterdam Treaty, article 152 which is specifically directed to public health. The need for high standards of quality and safety of organs and substances of human origin, blood and blood derivatives was mentioned there for the first time. Based on Article 152 of the Treaty, the European Parliament and the Council adopted Directive 2002/98/EC, which amends Directive 2001/83/EC.

Directive 2002/98/EC, setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, was issued on 27 January 2003 and represents a foundation for further legislation in the field. The following documents, binding for member states, include "daughter directives": 2004/33/EC on technical requirements, 2005/61/EC on traceability and reporting of serious adverse events and reactions and 2005/62/2005 dealing with quality systems.

Designed in respect of public health principles, EU directives aim to set a comparable level of blood services safety in all member states, supported by a community quality system providing for regional self sufficiency. These must be transposed into national legislation and implemented in daily practice in the blood services of EU and candidate countries and represent a challenge to be met through enhanced cooperation, communication and shared experiences at national and international level.

The Council of Europe promotes the principles of voluntary non-remunerated blood donation, European self-sufficiency in blood and blood components and protection of donors and recipients. Several recommendations were issued in this field (the most recent are listed below).

- R (2001)4 on the prevention of vCJD transmission by transfusion
- R (2002)11 on the hospital's and clinician's role in the optimal use of blood
- R (2003)11 on introduction of pathogen inactivation procedures for blood components
- R (2004)19/2004 on criteria for authorisation of organ transplantation facilities
- R (2004)8 on autologous cord blood banks
- R (2004)18 on teaching transfusion medicine to nurses.

The most widely known and used is Recommendation (95) 15 on the preparation, use and quality assurance of blood components. This 'quality guide' is updated annually and is thus very flexible, reacting to all the developments and changes in the field. It is a most valuable tool in the hands of professionals in the field – its importance is shown by the fact that it has been translated into many national languages not only within the EU but in SEE countries as well.

World Health Organization emphasised the importance of an integrated approach to blood safety as early as 1975 (WHA28.72). A blood safety programme was subsequently established to develop and promote strategies for blood safety on global, regional and national levels through advocacy and provision of technical support to WHO Member

States. A number of World Health Assembly (WHA) resolutions, recommendations, guidelines, and other supportive documents have been issued to strengthen national blood services as a first line intervention in the prevention of HIV/AIDS nosocomial transmission and in the provision of safe and quality health care. The main WHA and Executive board resolutions in the field are listed below:

- 1975 – WHA28.72: national blood services based on voluntary unpaid blood donors;
- 1987 – EB79.R1: national blood policies;
- 1995 – WHA48.27: international collaboration;
- 2000 – WHA53.14: HIV/AIDS confronting the epidemic – blood safety priority and World Health Day 7 April;
- 2002 – WHA 55.13: quality of care: patient safety;
- 2003 and 2004: blood safety on agenda in regional committees; and
- 2005 – WHA 55.13: World Blood Donor Day annual global event.

The WHO integrated strategy for blood safety is aimed to support capacity building in blood transfusion at country level through advocacy, technical assistance, training and documentation, highlighting to Member States the need to strengthen and support the development of well-organized and sustainable blood transfusion services. The WHO aide memoire for national blood programmes briefly presents key issues of the integrated strategy to strengthen safety and adequacy of the blood supply:

- establishment of a nationally coordinated well organized blood transfusion service;
- collection of blood from voluntary non-remunerated donors from low risk populations;
- appropriate testing, processing, storage and distribution of blood and blood components;
- reduction of unnecessary transfusions through the effective clinical use of blood, including use of alternatives to transfusion; and
- quality systems covering every step of the blood chain, from recruitment and selection of safe donors to administration and monitoring outcomes of blood transfusion to the patient in need.

Having the background of this body of European legislation, WHO and CoE recommendations, guides and manuals and on the basis of previous international initiatives and experiences, the SEE blood safety project was launched as one of the projects stemming from the Dubrovnik Pledge.

WORLD HEALTH ORGANIZATION

Blood Safety

AIDE-MEMOIRE

for National Blood Programmes

A well-organized blood transfusion service (BTS), with quality systems in all areas, is a prerequisite for the safe and effective use of blood and blood products.

The HIV/AIDS pandemic has focused particular attention on the importance of preventing transfusion-transmitted infections (TTIs). Between 5% and 10% of HIV infections worldwide are transmitted through the transfusion of contaminated blood and blood products. Many more recipients of blood products are infected by hepatitis B and C viruses, syphilis and other infectious agents, such as Chagas disease.

The global burden of disease due to unsafe blood transfusion can be eliminated or substantially reduced through an integrated strategy for blood safety which includes:

- Establishment of a nationally-coordinated blood transfusion service
- Collection of blood only from voluntary non-remunerated blood donors from low-risk populations
- Testing of all donated blood, including screening for transfusion-transmissible infections, blood grouping and compatibility testing
- Reduction in unnecessary transfusions through the effective clinical use of blood, including the use of simple alternatives to transfusion (crystalloids and colloids), wherever possible.

Words of advice

- **Secure government commitment and support for the national blood programme**
- **Establish a blood transfusion service as a separate unit with responsibility and authority, an adequate budget, a management team and trained staff**
- **Educate, motivate, recruit and retain voluntary non-remunerated blood donors from low-risk populations**
- **Ensure good laboratory practice in screening for transfusion-transmissible infections, blood grouping, compatibility testing, blood component production and the storage and transportation of blood products**
- **Reduce unnecessary transfusions through the effective clinical use of blood, including alternatives to transfusion**
- **Establish a quality system for the BTS**
- **Train all BTS and clinical staff to ensure the provision of safe blood and its effective clinical use**

Checklist

Blood transfusion service

- ❑ Government commitment and support
- ❑ National blood policy/plan
- ❑ Legislation/regulation
- ❑ Organization with responsibility and authority for the BTS
- ❑ BTS management committee
- ❑ BTS medical director
- ❑ BTS quality manager
- ❑ Specialist BTS advisory groups
- ❑ Trained BTS administrative and technical staff
- ❑ Adequate budget
- ❑ National quality system

Blood donors

- ❑ National blood donor programme officer
- ❑ Blood donor unit
- ❑ Blood donor recruitment officer
- ❑ Standard operating procedures
- ❑ Training of staff in blood donor unit
- ❑ Low-risk donor populations
- ❑ Educational materials
- ❑ Register of voluntary non-remunerated blood donors
- ❑ Donor selection, deferral, care and confidentiality
- ❑ Donor notification and referral
- ❑ Monitoring of TTIs

Testing of donated blood

- ❑ Technical officer
- ❑ Screening strategies and protocols
- ❑ Training of laboratory technical staff
- ❑ Screening of all donated blood for TTIs
- ❑ Blood grouping and compatibility testing
- ❑ Good laboratory practice, including standard operating procedures (SOPs)
- ❑ Continuity in testing
- ❑ Effective blood cold chain

Clinical use of blood

- ❑ National policy and guidelines on the clinical use of blood
- ❑ Training of clinicians and BTS staff
- ❑ Prevention, early diagnosis and treatment
- ❑ Alternatives to transfusion (crystalloids and colloids)
- ❑ Effective clinical use of blood
- ❑ Monitoring and evaluation

 WHO/BCT/02.03. Printed July 2002

Key elements

Establish a blood transfusion service

It is the responsibility of governments to ensure a safe and adequate supply of blood. This responsibility may be delegated to a non-profit non-governmental organization, but the BTS should be developed within the framework of the country's health care infrastructure.

The BTS requires government commitment and support and recognition as a separate unit with an adequate budget, management team and trained staff.

Important activities in establishing a blood transfusion service include:

- Formalization of government commitment and support
- Development of a national blood policy and plan
- Development of necessary legislation/regulation for the BTS
- Formation of an organization with responsibility and authority for the BTS
- Formation of a BTS management committee
- Appointment of a medical director
- Appointment of a quality manager
- Appointment, when necessary, of specialist BTS advisory groups
- Appointment and training of staff experienced in each key aspect of the BTS
- Development and implementation of a budgeting and finance system to ensure a sustainable blood programme through cost recovery and/or annual budget allocation
- Establishment of national quality system, including guidelines, standard operating procedures, accurate records, monitoring and evaluation.

Educate, motivate, recruit and retain low-risk blood donors

High priority should be given to the elimination of family/replacement and paid blood donor systems, which are associated with a significantly higher prevalence of TTIs.

Voluntary non-remunerated blood donors from low-risk populations who give blood regularly are the foundation of a safe and adequate blood supply.

Important activities include:

- Appointment of an officer responsible for the national blood donor programme
- Establishment of a BTS unit responsible for donor education, motivation, recruitment and retention
- Appointment of a designated blood donor recruitment officer
- Preparation of SOPs in accordance with BTS guidelines
- Training of staff in the blood donor unit
- Identification of donor populations at low risk for TTIs
- Development of educational materials
- Establishment of a register of voluntary non-remunerated blood donors
- Assurance of safe blood collection procedures, including donor selection and deferral, donor care and confidentiality
- Donor notification and referral for counselling
- Monitoring of TTIs in the donor population.

Test all donated blood

The BTS should develop and maintain a national strategy for the testing of all donated blood and blood products, using the most appropriate and effective tests, and for good laboratory practice.

Important activities include:

- Appointment of a designated technical officer
- Development of protocols for the testing, selection and evaluation of appropriate screening assays to be used at each site
- Training of BTS laboratory technical staff
- Screening of all donated blood for TTIs, including HIV, hepatitis viruses, syphilis and other infectious agents, such as Chagas disease
- Blood grouping and compatibility testing
- Good laboratory practice, with effective documentation, including standard operating procedures
- Procurement, supply, central storage and distribution of reagents and materials to ensure continuity in testing at all sites
- Maintenance of an effective blood cold chain for the storage and transportation of blood and blood products.

Reduce unnecessary transfusions by effective clinical use of blood

Blood transfusion has the potential for acute or delayed complications and the transmission of infection. The risks associated with transfusion can be reduced by minimizing unnecessary transfusions through the effective clinical use of blood and blood products and the appropriate use of simple alternatives to transfusion which are safer and more cost-effective.

Important activities include:

- Development of a national policy and guidelines on the clinical use of blood
- Training in the clinical use of blood for all clinicians involved in the transfusion process and for BTS staff
- Commitment to the prevention, early diagnosis and treatment of conditions that could result in the need for transfusion (obstetrical complications, trauma and other causes of anaemia)
- Availability of intravenous replacement fluids (crystalloids and colloids) for the correction of hypovolaemia
- Availability of pharmaceuticals and devices to minimize the need for blood
- Effective clinical use of blood and blood products in accordance with national guidelines
- Monitoring and evaluation of the clinical use of blood.

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SEE Blood safety project

With the structures of blood transfusion service being disrupted in some countries of SEE due to political and socio-economic difficulties, the need for support and mutual collaboration in the region has become increasingly clear. National authorities have started to recognize the importance of blood safety in the public health area and to express their commitment to supporting development in the field of transfusion medicine.

The project "Blood Safety – Increasing regional self-sufficiency in safer blood and blood components" was developed as a follow-up to the Dubrovnik Pledge when blood safety was recognized as one of the 7 priority interventions required at regional level.

"We will meet the health needs of vulnerable populations in SEE, mobilizing human and financial resources to the extent possible to increase the quality of and regional self-sufficiency in the provision of safe blood and blood components".

After the 8th meeting of the SEE Health Network held in June, 2004 in Ohrid (The former Yugoslav Republic of Macedonia), a pre-inception meeting for this project – a two day seminar on governance principles for blood transfusion service – was held in Bucharest, Romania, October 2004, with the support of the Irish Blood Transfusion Service. Its objectives were to:

- strengthen the understanding of stewardship with focus on governance principles involving major stakeholders in the national blood service;
- support the restructuring process of the blood transfusion system according to EU, CoE and WHO recommendations;
- introduce an operational framework as a meaningful tool for benchmarking, assessment, planning, implementation, evaluation and progress monitoring; and
- develop preliminary action plans for participating countries.

The meeting was attended by senior managers from blood transfusion services and representatives of ministries of health from all eight countries in the SEE Stability Pact as well as representatives of WHO, the Council of Europe, the European Commission, the Finnish Red Cross Blood Transfusion Service and the Irish Blood Transfusion Service.

The blood project, in which Romania took the lead, has been formulated with the long-term aim to increase the transnational availability of safe blood for emergencies and special circumstances, to build up regional self-sufficiency and to achieve mutual trust in the acceptability of the quality of blood in south-eastern Europe. The issue of regional self-sufficiency of the blood supply as compared to national level has also been considered, especially in the light of the small populations in most of the Stability Pact countries.

The project structure was confirmed by the 9th Meeting of SEE Health Network held in Chisinau, Republic of Moldova in November 2004, and signed by all national health coordinators from SEE countries, the WHO Regional Office for Europe and the Council of Europe.

The project is organised and managed by the following bodies: project steering committee, executive committee, regional project office and regional project manager, and national project coordinators. The WHO Regional Office for Europe provides the secretariat.

The project comprises two components.

Component one (focused on the harmonization of national blood safety policies/ strategies, to ensure the basis for further technical developments)

Strengthening mutual trust and acceptability of the quality of blood in the region

Objectives:

a) The development of national policies on blood safety in accordance with EU directives and international recommendations in the field.

b) Increasing the availability of blood and blood components through sustainable promotion of voluntary non-remunerated blood donations.

Component two (focused on some specific technical issues)

Increasing trans-national availability of safe blood for medical emergencies and special circumstances, as well as availability of rare blood group donations

Objectives:

a) Building a regional network of institutions and professionals able to respond to both national and regional needs.

b) Establishing a regional information system (E-network) for a rapid identification of blood availability.

c) Setting up mechanisms for rapid transportation of blood and blood components.

This report addresses Component one, which was supported by Switzerland, the WHO Regional Office for Europe and the Council of Europe with the contribution of Slovenia and Croatia.

Component one of the project, 'The development of national blood safety policies in accordance with EC directives and international recommendations' was launched in June 2005 by the 1st Regional Meeting of Project Managers held in Ljubljana, Slovenia. It built on the agreement which emerged from the previous meeting (Bucharest 2004) on the need for a legislative framework for the blood services in the respective countries in order to establish proper governance, regulatory, financial and ethical frameworks.

The development of national blood policies in participating countries is considered one of its main achievements. The team spirit enhanced during the implementation process and the development of common operational tools contributed to setting up a professional network among SEE countries to promote sharing of information and expertise. Identification of common solutions to comparable challenges and strengthened cooperation have increased confidence in existing capacities and their potential as driving forces for change.

In the European context, the SEE health network is a regional development uniting countries that have undergone similar changes during the last 15 years, at different paces that have been generated by local conditions. The continuation of the SEE blood safety project with component 2 is considered essential to consolidate the existing achievements and maintain the political recognition and professional commitment to this public health priority, towards effective, reliable and sustainable blood services.

Chapter two

BLOOD SAFETY POLICIES

Summary

A general overview of blood transfusion services was recognised as a prerequisite for further decisions in the process of reform, and this was undertaken in all participant countries according to a commonly agreed reporting structure. The present report focuses on dedicated national policies and regulatory frameworks.

Blood services in all the countries concerned are fragmented and often hospital based. Blood establishments as producers of components are usually combined with blood bank services within one hospital department. This results in substantial differences in levels of development within one country and a lack of coordination of activities with an inevitable impact on the adequacy and sustainability of the blood supply.

Existing legal and regulatory frameworks aim for harmonisation with European legislation, Council of Europe and WHO recommendations concerning blood transfusion. Currently however, these are in different states of revision/planning/implementation. National blood policies are not in place, but expected to be developed as one of key outcomes of this project.

Financial support of the service comes from different sources and generally is not adequate. This results in inadequate infrastructure (facilities, equipment) of the service and difficulties in performing regular activities (shortages in consumables, staff etc.).

Quality and safety of the whole process require increased attention throughout the region, with vast differences reported at intercountry and inter-institutional level. Thus, each step of the blood transfusion chain needs to be addressed:

- education, recruitment and retention of safe blood donors
- quality of testing, processing, storage and distribution of blood and blood components
- appropriate clinical use of blood and transfusion outcome monitoring.

Inadequacies in blood transfusion services (BS) are to be addressed by reforming the system through restructuring into nationally coordinated services on the basis of legislative and regulatory frameworks integrated within the health systems perspective, and supported by the respective governments.

Introduction

This report describes blood safety policies and legislation currently in place in south-eastern Europe. The countries involved are Albania, Bosnia and Herzegovina, Bulgaria, Croatia, the Republic of Moldova, Romania, Serbia and Montenegro and The former Yugoslav Republic of Macedonia.

The report briefly covers the background of the countries concerned – their recent history, and the importance of the Stability Pact for further development of the region; and their health service infrastructure, more specifically as regards the sustainability

and safety of the blood supply. It covers the Stability Pact framework and its importance for the development of BS in the respective countries.

European Union (EU) legislation and World Health Organisation (WHO) and Council of Europe (CoE) recommendations and guidelines concerning the quality and safety of the blood supply are touched upon with reference to the widely available publications on this subject.

The methodology of data collection is described and findings discussed. The validity of data relies on national reporting. An overall description of the blood policies, the structure and functioning of services, the availability of donors and the supply of blood and its components within the region is presented in the context of current legislation. The relation between perceived clinical needs and actual demand for blood and blood components is considered. The need to create national blood programmes and restructure services is discussed, as well as possibilities of increased cooperation within the region.

The final section summarises achievements in the field since the launch of the project and presents recommendations for further step-wise progress.

Methodology

Component one of the project, 'The development of national blood safety policies in accordance with EC directives and international recommendations' was launched in June 2005 by the 1st Regional Meeting of Project Managers held in Ljubljana, Slovenia. It built on the agreement which emerged from the previous meeting (Bucharest 2004) on the need for a legislative framework for the blood services in the respective countries in order to establish proper governance, regulatory, financial and ethical frameworks.

The objectives of this first meeting were to actually launch the project and:

- to create team spirit and enhance common trust;
- to introduce a managerial approach to project implementation towards delivery of planned outputs on both national and sub regional levels;
- to agree on a detailed structure of national reports to be prepared as a basis for transversal analysis of blood policies, services and availability; and
- to identify major steps for collaboration and outline the timetable for national and subregional action.

A common structure for national reports has been developed and agreed upon, to be used for the baseline assessment of national blood services. This approach was chosen with the aim of ensuring maximum uniformity in the reporting process. The country project managers undertook the responsibility for preparing national reports in close consultation with the regional project manager.

Several difficulties have been encountered in the process of data collection. Disparities among different sources of data were found, affirming the need for consolidated national data registers. This was, however, to be expected, as a majority of the countries have only recently emerged from a period of large scale political changes followed by drastic demographic changes due to refugee influxes as well as internal or external displacements. This had to be taken into the consideration when analysing the reports.

The reports were structured around key elements, addressing the status of blood policies, services and availability in the respective countries.

The health systems approach has been chosen, with an introductory section comprising general information and demographic data of the country, political and structural considerations.

- The stewardship component contained information on existing legal and regulatory frameworks concerning BS and their compatibility with EU legislation, WHO and CoE recommendations and data on regulatory bodies and agencies.
- The financing component briefly detailed the various funding mechanisms of the BS.
- The resource generation component covered the structure of the BS, technical facilities, equipment and staff.
- The service delivery components compiled information on blood collection, quality management from national policies to daily practice at institutional level, and blood supply and demand, including the extent of computerisation and implementation of IT systems.

The reporters were asked to cover any outstanding issues and draw conclusions from their data.

Progress towards the objectives was monitored and reported during the subsequent meeting held in October 2005 in Zagreb, Croatia, where national reports were presented and analysed and a brief regional overview was presented. Next steps were agreed upon and an outline of project achievements to date was delivered during the Skopje Ministerial Forum (November 2005).

Results

Overview

National reports provided a data base to be built upon in the respective countries. This revealed the degree of difference between the eight SEE member states, as well as common features within the aim to achieve quality, safe blood transfusion. It also provided a benchmarking opportunity and has elucidated the main issues that require immediate attention.

This report gives an overview of the data presented by the national project managers within their national reports. Not surprisingly there are gaps in the uniformity of the data. The quantity and quality of information varies since often the data were either not available or thought to be insufficiently reliable.

On the other hand, it shows clearly the need for reform in BS in order to obtain a safe, sustainable, cost effective and highly functional system.

General country parameters

All eight project countries are republics with a recent history of political changes – the executive power lies with president/prime minister and Council of Ministers, the legislative function is assumed by the parliament and the judicial function by Supreme or Constitutional Courts.

Two of the eight SEE countries had a particular administrative and political structure: Bosnia and Herzegovina and Serbia and Montenegro. This lead to differences inside the country, and from one region to another.

Bosnia and Herzegovina consists of three entities, ethnically different and almost autonomously administered, as follows:

- Federation of Bosnia and Herzegovina – 10 cantons, each with its own legislative and executive institutions;
- Republic of Srpska;
- District of Brcko – an independently administered area of 493 km^2, population 85 000, with only one hospital and one hospital-based blood service.

At the time of the analysis, Serbia and Montenegro comprised two independently administered entities: Serbia and Montenegro.

SEE region – geographic and demographic characteristics

- total surface: 636 698 km^2
- population: 55 681 386 inhabitants
- density: 83.69 people/sq km
- distribution: urban: 55% and rural: 45%
- age: teenagers and blood donation age (15–64 y.): ~ 69%, with > 65 y.:~ 12.8%.

Basic demographic parameters of all eight countries are summarized in Table 1.

Table 1. Demographic indicators of SEE Region

COUNTRY	Size (Sq km)	Population	Density People /sq km	Rural %	Urban %	Gender		Age (%)	
						Female %	Male %	20–64y	>65y
Albania	28 648	3 126 153	109.12	55.5	44.5	50.20	49.80	53.56	7.52
Bosnia and Herzegovina	51 209	3 828 397	76.15	~56.0	43.9	51.15	48.85	62.79	12.16
Bulgaria	111 000	7 845 841	70.68	30.6	69.4	51.40	48.60	NA	17.00
Croatia	56 542	4 437 460	78.48	42.0	58.0	52.00	48.00	median age: 39.97 y	
Republic of Moldova	33 800	3 606 800	106.71	58.6	41.4	52.00	48.00	~62.50	~13.60
Romania	238 500	21 673 328	90.87	46.7	53.3	51.20	48.80	61.30	14.50
Serbia	77 474	7 498 000	96.78	48.42	51.58	NA	NA	NA	NA
Montenegro	13 812	620 145	44.89	38.0	62.0	50.20	49.80	~67.20	12.10
The former Yugoslav Republic of Macedonia	25 713	2 045 262	79.54	40.5	59.5	50.05	49.95	~68.70	10.80

(source: www.who.int and national reports)

There are considerable variations in size and population distribution (urban vs. rural), while the gender structure, density of population and percentage of persons eligible for donation (age 20–64 y) are comparable.

The economies of the countries show very large differences as well, with an over tenfold variation in the GDP per capita, the highest being in Croatia and the lowest in the Republic of Moldova. The total health expenditures mirror this fact as well. The percentage of the health budget dedicated to transfusion services was not available in most of the reporting countries.

Health systems perspective

The development and organization of the blood service is strictly linked to the health care system status in every country. The process of evaluation and the emerging lines of action need to be seen within the health systems framework to ensure implementation and viability of change.

Stewardship

Legal and Regulatory Framework

The Ministry of Health (MoH) is ultimately responsible for BS in all SEE countries. Respective governments, though the MoH, are involved in the elaboration and approval of laws, policies, strategies and action plans in the field of blood services

and transfusion medicine. In Serbia and Montenegro and in Bosnia and Herzegovina these responsibilities are with the MoH of each respective entity (Serbia, Montenegro, Federation of Bosnia and Herzegovina, Srpska Republic).

Once developed, the draft laws – primary and secondary legislation – are submitted for endorsement to the Parliament. Responsibility for implementation of the legal provisions belongs to the MoH.

In most countries, groups of professionals in the field are appointed as members of an advisory body of the MoH. Their influence in the decision-making process varies, but generally is not very extensive.

The process of restructuring BS has been proposed, planned or started in all the SEE countries. Seven of eight countries declared that no national blood policy is in place or in the elaboration process.

Bulgaria and Serbia have a national strategy for blood safety and availability.

All the countries have annual plans for blood collection, based on historical estimation.

Legal Documents

Two of the eight countries – Romania and Bulgaria – have already endorsed the laws on blood transfusion that transpose the Directive 2002/98/EC. Secondary legislation is in the process of elaboration.

Croatia and Serbia have drawn up the draft of the new Law on blood transfusion, for endorsement during 2006.

In Bosnia and Herzegovina development of a new Law on transfusion medicine is foreseen.

Other countries identified different stages of dedicated legislation, ranging from the absence of a well defined law on BS to an existing law which require major revisions for compliance with modern quality and safety requirements. Generally, the absence of one comprehensive law on blood transfusion led to dispersion of articles related to transfusion to other laws, such as that on public health protection.

In the absence of national legislation/regulations, WHO and CoE materials have been translated into national languages in most of the countries and adopted these as national guidelines used in daily practice.

All countries express their political commitment to move further in the field of transposition of European Legislation into national legal frameworks.

Regulatory bodies/agencies

Processes of authorization, accreditation and licensing of BS are not yet implemented or mandatory in most of the countries.

Bulgaria and Romania, which recently endorsed updated laws calling for accreditation and licensing of BS, are developing these processes.

In Croatia, where blood and blood products are considered drugs, the Agency for Medicinal Products and Medical Devices is responsible for licensing BS since 2004.

Accreditation for laboratory tests performance falls under the Agency for Accreditation (established in 2005).

Routine and regular inspections of BS are not in place as yet, but are considered and in the process of development.

Internal auditing, organized at institutional level, has been reported by all the countries. The current system of inspections and audits is described as variable in frequency and thoroughness in different institutions.

Advisory bodies, as reported by countries:

- Experts' Commission of the MoH – Albania (not yet functional), Bosnia and Herzegovina (planned), Bulgaria, Croatia, The former Yugoslav Republic of Macedonia, Republic of Moldova, Romania – functional, Serbia and Montenegro (not yet functional).
- National consultative body for voluntary blood donation (Bulgaria, Romania – planned).
- Commission on haemovigilance (Republic of Moldova – functional, Serbia – non-functional, Bulgaria and Romania – planned).

Financing

Funding of the health service is provided through different sources. Primary responsibility lies with the state budget and/or public health insurance funds. Health insurance is generally mandatory for both employers and employees. A relatively small portion of financing comes from private sources – out of pocket payments, sponsorship, etc. At present, private health insurance is not prevalent in any of SEE countries.

Financing of the blood service varies between the countries, sources depending on the organization of the system:

- health insurance funds, allocated through the hospital budget, where BS is hospital-based;
- health insurance funds reimbursing the hospitals with the amount charged by an independent blood establishment – fee for service;
- state budget, through the MoH budget, where the blood establishment is an independent institution, subordinate to the MoH;
- combined – sponsorship, external sources, state budget, health insurance funds; and
- MoH budget for promotion activities and the health insurance fund may concurrently fund the blood service.

Table 2. Economic indicators of SEE region

COUNTRY	Gross Domestic Product (GDP) US$ per capita 2003	Total Health Expenditure as% of GDP (WHO estimates)		UNDP Human Development Index (HDI) 2003	PPP US$ per capita (WHO estimates)	
		2003	2004		2003	2004
Albania	1933	6.5	6.6	0.780	366	409
Bosnia and Herzegovina	1684	9.5	9.3	0.786	327	359
Bulgaria	2539	7.5	7.7	0.808	573	635
Croatia	6479	7.8	7.9	0.841	838	897
Republic of Moldova	463	6.7	7.5	0.671	166	202
Romania	2619	6.1	5.7	0.792	540	566
Serbia	2528	9.6	10.1	0.780 (2001)	373	431
Montenegro	NA				NA	NA
The former Yugoslav Republic of Macedonia	2277	7.1	7	0.797	389	411

(source: www.who.int and national reports)

Comparing the available data regarding the evolution of financing mechanisms for the BS during the last 3–5 years, different tendencies are noted regardless of the fact that all the Ministries of Health have acknowledged transfusion as a priority in the public health field:

- no substantial change of allotted funds (The former Yugoslav Republic of Macedonia, Bulgaria);
- slight increase of allotted funding (Albania, Republic of Moldova); and
- decrease of allotted funding (Romania).

The percentage of funds dedicated to the various types of expenditure was reported by 5/8 countries, and varies extensively, e.g. the percentage of funds spent on:

- staff expenditure varies from 15.2% (Albania) to 47.32% (Bulgaria)
- equipment expenditure varies from 0.69% (Bulgaria) to 53.7% (Republic of Moldova)
- running costs vary from 26.8% (Republic of Moldova) to 84.8% (Albania).

Services

Health care is mainly provided by public institutions. Private health care institutions do exist, but the degree of private sector development varies from one country to another depending on its historical, social and political background.

Blood services are public in the whole region. In some cases, private blood services are specifically prohibited by law (e.g. Bulgaria).

Organization and structure

The structure of the BS differs throughout the region, with three different organizational schemes being reported:

1. all institutions involved in BS activities are hospital-based (Albania, Montenegro);
2. combination of hospital-based BS and independent BS (Bosnia and Herzegovina, Bulgaria, Croatia, Republic of Moldova, Serbia, The former Yugoslav Republic of Macedonia); and
3. the majority of BS are independent, the hospital-based BS being a minority (Romania).

Seven countries have a national institute which is generally on a higher level of expertise than the rest of BS in the respective country and as a rule sets the pace for progress in the field. It is in most cases closely linked to the MoH and has the responsibility of coordinating the implementation of specific legislation. It usually takes the role of reference BS in the country. Legally and financially however, the hospital-based BS are subordinate to the respective hospitals rather than to the national institute.

In Montenegro, the BS of Podgorica hospital has to some extent taken over the function of the national institute (as a reference centre).

The number of BS, mostly hospital-based, is very high which implies low numbers of yearly donations. These services usually cover the whole range of activities of both blood establishment and blood bank (donations, processing, testing and storage of blood and blood components as well as pre-transfusion testing and release of blood components to the hospitals).

Numbers of BS and their structure is summarized in Table 3.

Table 3. Structure of blood transfusion services

COUNTRY	National/ regional institute	Blood establishment	Blood banks	Mixed activities	Comments
Albania	Yes-NBTC	-	-	31(NBTC=independent +30 hospital-based)	-
BIH-Srpska	-	-	-	10 (hospital-based)	1 Reference institution
BIH-F BiH	Yes-TMI	-	1	16 (TMI +15 hospital-based)	-
BIH-Brcko	-	-	-	1	-
Bulgaria	Yes-NCHT	-	56	28 (NCHT +4 RCHT +23 hospital-based)	
Croatia	Yes-CITM	-	13	21 (CITM +20 hospital-based)	1 Reference institution
Republic of Moldova	Yes-NBTC	3 (1 national +2 regional)	23	23 (hospital-based)	-
Romania	Yes-NITH	42 (41 independent +1 hospital-based, military)	330	3 (hospital-based)	1 Reference institution
Serbia **Montenegro**	Yes-NBTI/2 RBTI -	3 (1 national +2 regional) - -	70 -	44 (hospital-based) 10 (hospital-based)	- 1 Reference institution
The former Yugoslav Republic of Macedonia	Yes-NITM	1(NITM)	1	23 (hospital-based)	-

(source: national reports)

Blood donors: education, promotion, retention

Healthy individuals can donate between 18 to 65 years of age. There is a predominance of urban populations, notably males aged 30 to 40 years.

The number of donations per year varies from 3.6/100 inhabitants, approximating many European countries (Croatia), to as low as 0.5/100 inhabitants (Albania). The average number of donations reported per 100 inhabitants is 2.1, suggesting that self-sufficiency is not yet achieved at regional level (Table 4).

Table 4. Annual collections 2004

COUNTRY	Collection figures for whole blood/ aphaeresis procedures	Donation figures/100 population
Albania	16 078/0 units	0.5
Bosnia and Herzegovina		1.8
Srpska	23 390/0 units	
F BIH	42 655/0 units	
Brcko	2 697/0 units	
Bulgaria	152 813/349 units	1.9
Croatia	156 705/1.581 units	3.6
Republic of Moldova	28 289 7kg/965 9 kg	1.7
Romania	352 539/886 units	1.7
Serbia and	232 174/5158 units	3.1
Montenegro	14 280/0 units	2.1
The former Yugoslav Republic of Macedonia	54 758/170 units	2.7

(source: national reports)

All countries recognize that voluntary, non-remunerated blood donation is a prerequisite for safer blood donation, but as the current priority is the sufficiency of the blood supply, this goal has not yet been reached.

The reported situation with respect to blood donor population is as follows (Table 5):

- voluntary paid donors are still present in the region, in different percentages;
- voluntary 'remunerated' donors receive 1–2 days of holiday ensured by law in some countries, free admission to health care services, food tickets etc.;
- non-remunerated donors receive a meal at the donation site, small tokens and reimbursement of travel expenses; and
- replacement donors (i.e. family and directed donations): a large population of replacement donors corresponds to the high percentage of first time donors in some countries, with a proportional increase of related risks posed to safety.

Table 5. Types of donations according to donor reimbursement

COUNTRY	Paid %	Remunerated/ non-remunerated %	First time donor %	Regular/repeat donor %	Replacement donor %
Albania	23.8%	-	76.2%	23.8%	~ 71.5%
Bosnia and Herzegovina					
Srpska	-	all/-	22.83%	77.17%	69.72%
F BIH	-	NA	35.51%	64.49%	53.32%
Brcko	-	NA	15%	82%	18%
Bulgaria	4.1%	-/31.2%	21.73%	78.27%	64.7%
Croatia	-	-/all	9.90%	90.10%	-
Republic of Moldova	0.3%	NA	30%	70% (10+60)	96%
Romania	-	79%/21%	20%	70%	10%
Serbia and	-	-/all	21.2%	78.8%	19.4%
Montenegro	-	NA	NA	NA	80%
The former Yugoslav Republic of Macedonia	-	-/all	18%	82%(50+32)	6%

(source: national reports)

Blood transfusion services promote blood donation as part of their activities at institutional level, involving the medical personnel and sometimes the local Red Cross organization and other NGOs. Generally, no trained staff solely allocated to this task are available.

A separate budget for donor promotion is provided to a very few countries (Bosnia and Herzegovina, Croatia, Serbia, and The former Yugoslav Republic of Macedonia). Usually it is used in collaboration with Red Cross/Red Crescent national society for the organization of mobile collection sessions. External financial support has been given to the organization of some campaigns.

Public media generally supports the blood donation campaigns. Civil society, clinicians, patients groups, and local authorities have a minor role, except in few particularly local settings.

Blood donation, processing, testing, quality systems, blood supply vs. demand

Blood donation is largely organized on comparable general rules, based in CoE and WHO recommendations. Donor selection usually complies with European rules and regulations except for the fact that a standardized written questionnaire and proper informed consent are not always present.

Processing

Blood collection is generally made as standard, obtaining whole blood. Some countries perform aphaeresis procedures (for platelets and plasma) in limited numbers.

Whole blood is further processed into blood components in percentages varying from one country to another; with substantial differences both inter-institutionally and intercountry. Still some regions within the country have a rather large proportion of whole blood used as such without further processing.

Whole blood processing follows national regulations or international guidelines; however the procedures are not uniform at national and regional level, depending on the equipment available, local standard operating procedures and specific hospital requests. Processing activity, with a national average percentage, is illustrated in Table 6.

Table 6. Processing of whole blood

COUNTRY	% of processed whole blood units	Discarded units (%)
Albania	73.80	14.6
Bosnia and Herzegovina		
Srpska	66.26	7
F BIH	63.93	5.68
Brcko	63.00	7
Bulgaria	96.00	4.79
Croatia	97.49	9.04
Republic of Moldova	100.00	NA
Romania	61.00	5.28
Serbia and	83.88	NA
Montenegro	~ 60.00	2.4
The former Yugoslav Republic of Macedonia	91.30	4.39

(source: national reports)

Some institutions do not have the equipment available for rapid plasma freezing so some plasma stays either liquid or frozen as low category (not fresh frozen plasma). Cryoprecipitate is produced in all countries except Bulgaria, where corresponding blood derivatives are available, meeting the demand.

Blood components are produced only for national use, most countries facing insufficiency of blood collection versus perceived needs. Export/import of whole blood and blood components is either prohibited or restricted by law, MoH authorization being necessary for performing this activity in special circumstances.

Plasma fractionation with a full range of products (including coagulation factors concentrates, anti-thrombin and i.v. immunoglobulin) is not available in SEE countries. Croatia, Bulgaria, Serbia and the Republic of Moldova produce albumin and i.m. immunoglobulin in local facilities. Plasma derivates are imported for national needs depending on the available resources. This issue of using national

plasma for external contract fractionation, developing a regional fractionation plant or other solution, is yet to be addressed and is not part of this project.

Testing

All SEE countries have national requirements regarding mandatory tests for blood borne pathogens and blood grouping, to be performed on all collected blood in compliance with minimal requirements stated in the EU Directive. Additional tests have been kept in use by some countries (i.e. liver enzyme test ALT etc).

Serum samples are kept for different lengths of time for subsequent additional or retroactive testing as needed (Table 7).

Table 7. Mandatory testing of donations

COUNTRY	ABO	Rh(D)	Kell	antiHIV	HBsAg	antiHCV	Syphilis	HTLV	ALT	sample archiving
Albania	+	+	Regular donor	+	+	+	+	-	+	+
Bosnia&Herzegovina	+	+	D neg	+	+	+	+	-	-	-
Bulgaria	+	+	Special cases	+	+	+	+	-	-	-
Croatia	+	+	+/-	+	+	+	+	-	-	+/-
Moldova	+	+	D neg /+	+	+	+	+	-	+	+
Romania	+	+	+	+	+	+	+	+	+	+
Serbia and	+	+	NA	+	+	+	+	-	-	NA
Montenegro	+	+	NA	+	+	+	+	-	-	NA
The former Yugoslav Republic of Macedonia	+	+	-	+	+	+	+	-	-	NA

(source: national reports)

The prevalence of transfusion transmitted infections (TTI) is high in the donor population in comparison with EC countries (Table 8), but the data must be interpreted with caution as some institutions have no way of confirming repeatedly reactive samples, while others only provided information on TTI prevalence in first time donors.

Table 8. Prevalence of TTI in donor population

COUNTRY	HIV%	HBV%	HCV%	SYPH%	HTLV%
Albania	0.01	3.02	0.13	0	-
Bosnia and Herzegovina*					
Srpska	0.038	0.504	0.389	0.179	-
Federation BH	0.030	0.973	0.316	0.145	-
Brcko	0	1.85	0.950	0.037	-
Bulgaria**	0.0039	2.12	0.38	0.06	-
Croatia***	0.003	0.022	0.021	0.012	-
Republic of Moldova	0.025	5.8	3.0	2.6	-
Romania	0.010	0.32	0.045	0.40	0.001
Serbia and Montenegro	0.0095 0.001	0.25 0.30	0.21 0.30	NA 0.13	- -
The former Yugoslav Republic of Macedonia	0.00	1.32	0.53	0.39	-

* No confirmation tests performed
** Data for first time donors
*** Confirmed positive

(source: national reports)

Quality systems

Currently none of the countries has a quality management system implemented at national level. There are examples of functioning quality systems at institutional level in selected cases, namely in some large institutions (national institutes).

The quality issue has been considered by professionals and stakeholders and unanimously recognized as essential, however 6/8 countries do not have a quality policy approved and in effect. Bulgaria and the Republic of Moldova have already elaborated the national quality policy and the document is approved.

Elements of the quality system have been implemented at institutional level, and are most often represented by basic documentation (standard operating procedures, standard donors' files, maintenance records, regular activity reports).

Internal audits and inspections are mentioned by a few countries, but they are neither regularly organized in all institutions of the respective country nor following EU standards and international recommendations.

All the blood transfusion systems have used WHO documents and the CoE Guide as referral standards in the absence of national ones. Few countries have adopted the CoE Guide as national guideline. The lack of national coordination led to the absence of uniformity in their application and heterogeneity at regional level.

Demand vs. supply

It is generally estimated that hospital demands are higher than the real need. Improvements are necessary in the clinical use of blood by limiting overuse and introducing good clinical practice. A tool for this rationalization – the hospital transfusion committees – is either nonexistent or non-functional. Some national laws have for years had mandatory provisions related to the appointment and responsibilities of these committees, but these were not translated into practice.

Requests for blood components are made on special forms, nationally or locally set up, containing data on patient identification, diagnosis and transfusion indication. The responsibility for transfusion therapy indication and monitoring is with the attending physician.

Traceability of blood components is partially ensured at institutional level, based mostly on hand written documents. The lack of IT systems makes it very difficult to follow the distributed units.

Haemovigilance as a national and functional system does not yet exist in any of the SEE countries. Elements have been implemented at institutional level. The example of Croatia, as a member of the European haemovigilance network, is to be mentioned, where punctual data has been reported annually since 2004 on a voluntary basis.

The process of introducing haemovigilance at national level is only just beginning in some of the countries, while in others is not yet prepared.

Resources

Facilities, equipment and staff

Facilities

Buildings are generally reported to be inadequate for the activities of modern blood services. In some cases special funds from either internal or external sources have been provided to modernize some of them.

The high number of existing BS calls for rethinking of the network on a national scale for a cost effective and feasible intervention.

Equipment

Very little basic equipment for donations, processing, testing and storage of blood and blood components is reported as adequate and periodically maintained.

The exceptions, to a certain extent, are the automatic analyzers (where available), e.g. for testing of markers of transfusion transmitted infections, which are in many cases periodically calibrated and maintained by the manufacturer.

All other equipment is generally repaired only on demand. There is usually a substantial gap in the structure, amount and type of equipment between national institutes and smaller, dispersed hospital-based BS.

There is no national Information Technology (IT) system for the BS functioning in any of the project countries. National databases of donors do not exist. Communication between BS is either in writing, by telephone and/or fax. Computer systems are in place in some institutions, but generally on a local level only and covering only part of the BS activities. Traceability is considered possible mainly at institutional level.

Staff

As the organization is fragmented, most services (with the exception of major and/or national institutions) report inadequate numbers of competent staff. Skill levels are often low, training is inappropriate, and poor salaries do not attract highly qualified staff.

Transfusion medicine is not generally recognized as a medical specialty in Albania, the Republic of Moldova and Romania, which do not currently have a specific residential postgraduate training.

Other countries recognize a specialization in transfusion medicine. Three years training is finalized in most cases by a board examination resulting in a dedicated diploma. In some countries, training in the field of haemostasis and coagulation is an integral part of the specialty.

Training of nurses and laboratory technicians is present at different levels of specialization.

Continuous education programmes developed for regular training of different categories of personnel are in place either on a national basis or locally.

Discussion

Blood policies

It was shown in the previous section that successful completion of the present blood safety project would significantly contribute to strengthening safe and sustainable blood supply for the eight SEE countries.

Even though blood safety was declared one of the priorities for action at the ministerial level and in the Dubrovnik Pledge, not all countries have yet undertaken subsequent concrete steps to restructure their BS.

Provision of an adequate supply of safe blood periodically draws extensive public attention, but almost always it is in connection with some adverse events or incidents, immediately followed by a short period of focus on the actual needs of the blood service. Unfortunately, it seldom results in sustained support, and the safe blood supply competes for public attention and resources from limited budgets with other areas of interest such as cancer, TB, mental health disorders, cardiovascular disease etc.

A framework for blood policies has been formulated at the European Union level and a number of guidelines and recommendations have been issued by WHO and other relevant international bodies as a defined reference standard. These call for formally agreed blood policies in all SEE countries.

Reorganization of the blood service

Establishment of nationally coordinated BS is the cornerstone of further development. At present, blood services are fragmented into many dispersed facilities which are financially dependent on different entities (hospitals or MoH in most cases). It cannot be expected that these services will receive priority in all the respective organisations.

Common policies and strategies for collection, processing and testing are being adopted with great difficulty under these conditions. Also, it is inevitable that major differences occur in the services, largely dependent on the immediate financial situation of the institution/hospital, where the service is situated as well as on local conditions (buildings, equipment, and staff).

In most instances, hospitals are reluctant to relinquish jurisdiction of the blood service, fearing a loss of the blood source for their institution in the context of a recognized blood supply inadequacy in the whole area.

Cost containment is difficult to achieve when each individual blood service processes and tests relatively small numbers of donations. The requirements for facilities and equipment and the demand for professional staff are to a certain extent independent of the numbers of collected units of blood. The expected cost of putting in place proper quality systems is far too high for small services where only a few thousand or even hundred donations are collected annually. The same constraints apply to standardisation of processing, which is inevitably endangered where small numbers of processed units are concerned.

All these facts call for reorganization of blood services into a nationally coordinated system under the umbrella of a competent national authority. This authority should be designated as a key player in the stepwise reform of blood services and implementation of the requirements of European Union legislation into daily practice. These should be applied not only in the central institutions of the country but throughout the whole system of transfusion services within a nationally coordinated approach. This has to be supported by introduction of legislative measures corresponding to relevant European directives and recommendations.

Reforming the service cannot be done rapidly but must take into consideration the existing services and conditions of work to avoid endangering the current blood supply. Stepwise progress is to be planned, supported by the adoption of a national policy and strategy for blood safety. Centralisation of testing and processing of collected blood is the goal in the first phase.

Blood collection must recognize the needs of donors, therefore mobile collections and/or various collection sites are to be considered as a viable solution, provided compliance with recognised norms of quality and safety is in place during the process (selection, collection, storage, transportation of collected blood units).

Quality management systems are to be put in place with a clear designation of licensing, auditing and inspection procedures as part of the constant monitoring of compliance to quality standards and requirements at organizational level. Extensive support is needed for the implementation of quality systems in the blood service at local level.

Funding of the system must be adequate to provide for the basic needs of this extensive reorganization process. The cost effectiveness of a reorganized blood service is to be expected in the long run.

Blood availability

The percentage of donors in different SEE countries differs widely, as does the structure of donor populations. The model of altruistic blood donation has been adopted for short periods when a feeling of national cohesion prevailed, but in the long run this has been retained only in a fraction of donations. A voluntary, non-remunerated, regular donor population is the goal of any blood service aiming to supply safe blood and blood components.

Replacement donations, either as family or directed donations, have been recognized as carrying a higher infection risk for the recipient when compared to non-remunerated regular donors. In some cases, replacement donations are actually hidden paid donations (some form of payment being made by the relatives or the recipient him/herself).

Paid donation, especially in countries with a high rate of unemployment and poverty, can be perceived as one of the ways to cover the cost of living. Even though paid donors are inevitable in some settings at least at present, efforts should be made to lower their numbers in favour of a non-remunerated blood donor population.

This should be done by staff especially trained for the task, through education and information of the public and motivation of the target population of low-risk potential donors. The programme must contain not only education and motivation of first time donors, but also concentrate on donor retention through satisfaction and donor care as well as social recognition of the gift of blood in the community. Special funds must be allocated for these activities. The International federation of of Red Cross and Red Crescent societies can be of substantial help as can other NGOs.

The World Blood Donor Day event, which became an annual celebration in 2005 (resolution WHA 58.13) is expected to increase awareness on the importance of and need for voluntary non remunerated blood donation and further enhance the momentum of promotion and education activities in the field.

Blood demand

Self sufficiency is a target for BS. While the number of donations should be rising, balance must be kept with the clinical use of blood, blood components and products as well.

Unnecessary transfusions are still performed at many institutions. Blood may be used as volume replacement instead of other solutions due to the comparatively low or no cost of the transfused unit. In addition, simple blood alternatives, even when largely available, are not used properly.

It is the responsibility of well-functioning blood services to monitor the use of and develop mechanisms for rational use of blood. Guidelines endorsed by local transfusion committees in the institutions administering blood and blood components are one of the tools for implementing good clinical practice in blood transfusion.

Good communication between the blood service and the clinical users, as well the preventive component of primary health care (pregnancy follow up, anaemia screening etc.), are essential.

Effective haemovigilance systems need to be supported as part of the reporting and learning culture and of the continuous process to strengthen patient safety and improve the quality of care.

The whole process is to be seen and implemented within the health systems framework and the health care level of development in each of the concerned countries using the regional perspective of common challenges, shared experiences and collaborative action.

Conclusions and recommendations

The outcomes of Component one of the blood project can be summarized in the following recommendations targeting primarily the ministries of health of the respective countries as well as the professionals in the field of blood transfusion.

Rationalisation of blood transfusion services

The currently fragmented, mainly hospital-based blood services under the legal and financial responsibility of various entities must be reformed, with the support of a proper legal and regulatory framework, into a nationally coordinated service. This should ensure an adequate supply of blood and blood components of comparable quality and safety on both local and national levels. Development of mutual trust in this respect (harmonized, accepted and implemented quality and safety standards for the blood supply) in the whole region will support and enhance the transnational availability of safe blood and blood components for emergencies.

To effectuate the existing political commitment of the government, the reform must cover all levels throughout the country, and include technical and practical issues of blood transfusion practice. Responsibilities of both blood establishments and blood banks should be clearly stated in accordance with European Union Directive 2002/98/EC, WHO and CoE dedicated recommendations. Requirements should be introduced in a step-wise manner into daily practice on the basis of newly adopted national legislation transposing the directives.

Changes should be coordinated by a single body with both legal and financial responsibility for the service. Mechanisms for licensing and accreditation, including regular inspections and audits, need to be introduced.

Adequate financial coverage of the system must be guaranteed after careful analysis of the running and projected costs. A short term financial burden is to be expected, while the system should attain increased cost-efficiency after rationalisation of the services.

Emphasis on quality and safety

The safety of both donors and recipients is of utmost importance. Blood transfusion services, in collaboration with other organisations, should concentrate on the education, promotion, recruitment and retention of voluntary, non remunerated donors from low risk populations, with the aim to reach an adequate percentage of quality donors.

Donor care and counselling is to be developed. The entire blood transfusion chain must become safer and more reliable, resulting in better products and services provided to donors and to recipients.

Quality systems should be introduced into donor selection, collection, processing, testing, storage of blood and blood components as well as to pre-transfusion testing, release and administration.

The need to ensure traceability of each unit of blood from donor to recipient and back again, as well as reliable national registers and databases, requires appropriate supportive IT/computerisation of the blood services.

Principles of haemovigilance on local, national and international levels are expected to result in safer transfusion practice in the long term.

Strengthening infrastructure and staff expertise

With a nationally coordinated system, a needs assessment of blood services infrastructure – buildings and equipment – can be elaborated and steps taken towards replacement. Bulk purchases of quality reagents and consumables after a transparent and careful decision-making process are yet another step towards cost containment while retaining or increasing quality.

Adequate expertise of staff is a prerequisite for a well-functioning system. Educational programmes with regular training and proficiency testing must be introduced for all categories of staff.

Standardized and postgraduate training resulting in a transfusion speciality diploma/specialisation for medical doctors, biochemists, biologists, pharmacists and other professionals in the field is to be introduced.

Laboratory technicians, operators and nurses should receive regular updated information and training after an initial specialised training programme in the field.

Accurate assessments of blood needs

Evidence-based principles in medical decision-making should be introduced to the clinical use of blood. This may prevent the administration of blood and blood components in situations which could be resolved through other simple alternatives.

The importance of the prevention component with respect to reducing blood transfusion needs should be fully acknowledged at both primary health care level and in hospital services.

Up-to-date guidelines for the clinical use of blood should be available to all clinicians and adherence to them monitored.

Realistic assessments of actual blood needs are possible only if based on such practices.

Communication and collaboration

There is a need for joint efforts and extensive collaboration to ensure that blood and blood products are safe, accessible, and available at reasonable cost, used appropriately and provided within a sustainable health care system. This requires an informative and constructive exchange of success stories and lessons learned between the various stakeholders involved, and a collaborative teamwork approach.

A solid national blood service network needs to be developed, enhancing communication between professionals inside and outside the blood service, facilitating the information flow and providing immediate feedback and evidence for decision making according to requirements and needs.

The SEE blood service regional network needs to be further consolidated to assist in the process of change, increasing availability and equitable access to a quality and safe blood supply. This collaborative exercise has already proven its value by increasing mutual understanding and confidence between participant countries as well as providing a platform for constructive communication and commonalities of action towards increasing regional self-sufficiency in safer blood and blood components.

Chapter three

QUALITY REVIEW OF BLOOD SERVICES

Summary

Given the importance of quality management systems in strengthening the safety and availability of the blood supply at regional and national level, a baseline review of the existing quality status of blood services in each of the south-eastern Europe (SEE) countries has been performed. The exercise was completed country by country using the WHO "Quality Status Report for individual blood transfusion services" as operational tool. The present report presents a compilation and analysis of data as provided by the national and regional counterparts (national quality assessment reports).

Undertaken almost 1 year after the national assessment of blood services, it provides an opportunity to monitor implementation of Component One of the Blood Safety Project, "The development of blood safety national policies in accordance with the EC Directives and the international recommendations" developed under the Stability Pact – Social Cohesion initiative.

The development and implementation of quality management systems reflect the fragmented organization of the blood services in the SEE countries, as well as the weak coordination mechanisms functioning at national level. A dedicated legal framework is in the process of development or updating in all the countries, aiming towards harmonization with the international recommendations for quality and safety as well as EU requirements. The endorsement and implementation of current provisions vary greatly among the participant countries, mostly depending on the organization, resources and financing of their blood services.

Quality elements are already in place but due to the lack of nationally coordinated guidance, most of the work is performed locally at institutional level and on a generally accepted individual basis. The status of quality systems as reported shows little progress compared to what was already described one year earlier in the previous report mentioned above.

According to the national reports there is an ongoing process to develop appropriate documentation of work at the level of individual blood centres, or even departments, with particular emphasis on main dedicated institutions. Variation in practices is often recorded, particularly in the case of hospital-based blood centres, in line with the quality approach in place in the respective facility. National haemovigilance systems have not been developed, and further progress is related to both a common taxonomy and recognition of basic requirements that need to be established.

The elaboration and endorsement of a national blood policy with a set of quality indicators in accordance with the EU Directives, Council of Europe and WHO recommendations, should be given the highest priority in all the countries lacking such a document, followed by a timetable for its implementation.

The existing initiatives on quality management training for the blood services initiated within the overall framework of WHO Quality Management Training should be further enhanced to foster information exchange between participating countries as well as strengthen the blood service quality network in the region.

Introduction

The present report provides a review of the current status of quality systems implementation in the blood services of the SEE countries: Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Montenegro, the Republic of Moldova, Romania, Serbia and The former Yugoslav Republic of Macedonia.

General information on the number and type of blood service units functioning at national level in participating countries, blood collection figures (2004) as well as percentages of replacement and paid donations within the blood supply is summarized in the table below.

COUNTRY	National/ regional BEs	No. of BEs	No. of hospital BBs	No. of collected WB units (2004)	% of replacement and paid donations in the blood supply
Albania	1 NBTC	-	30 (4 under NBTC)	16 078	36% replacement donations 60% paid donations
Bosnia and Herzegovina					
Federation.BiH	1	15	1	42 655	70% replacement donations
Republic.Srpska		10	-	23 390	53% replacement donations
District.Brcko		1	-	2 697	18% replacement donations
Bulgaria	1 NCHT 4 RBCs	23 (hospital-based)	56	152 813	64% replacement donations 3,7% paid donations
Croatia	1 CITM 4 RBCs	19 (hospital-based)	14	156 705	All donors voluntary non- remunerated
Montenegro	-	10 (hospital-based)	-	14 280	20% replacement donations
Republic of Moldova	1 NBTC 2 RBCs	-	23	62 265	75% replacement donations 1.5% paid donations
Romania	1 NITHB	41 standalone + 4 hospital based	330	364 491	10% replacement donations
Serbia	1 NBTC 2 RBCs	3	70	232 174	20% replacement donations
The former Yugoslav Rep. of Macedonia	1 NITM	21 (hospital-based)	3	54 758	6% replacement donations

The previous section on "Blood safety policies" summarizes the status of quality management systems (QMS) in the blood services, considering all participating countries at the time of reporting, as follows:

- None of the SEE countries had a nationally implemented and/or coordinated QMS.
- Only two countries had a national quality policy.
- Separate elements of the quality system were implemented locally.
- Where internal audits and inspections have been mentioned, these were not organized on a regular basis.
- WHO documents, guidelines and toolkits, and the Council of Europe (CoE) quality guide and recommendations are being used as referral standards. The dedicated European directives provide a model for the regulatory framework.

Given the importance of quality in strengthening the safety and availability of the blood supply at national and regional level, it was decided to further investigate the current quality status and existing quality system elements.

The QMS constitutes a structure which guarantees that all the quality parameters are continuously updated, accounted for, measured, compiled and acted upon. The dedicated EU directives provide elements for the development of supportive regulatory frameworks.

The latest edition of the CoE "Guide to the preparation, use and quality assurance of blood components" includes a special chapter on quality system (QS) for blood establishments, based on the principles of good practice and quality management, as described in the EU GMP guidelines and ISO 9000-series standards.

In 2002, WHO developed the Quality Management Project for Blood Transfusion Services, targeted to build capacity in quality management through comprehensive training, monitoring and follow-up. This comprehensive programme has the quality management course as one of its core elements, with a dedicated training toolkit. Building a "quality culture" is an essential requirement for understanding basic principles of quality systems and appropriate management mechanisms. The Aide-Memoire "Quality Systems for Blood Safety" provides key elements and a checklist for the development and implementation of functional quality systems in the blood services.

WORLD HEALTH ORGANIZATION

Quality Systems for Blood Safety

AIDE-MEMOIRE

for National Blood Programmes

Blood transfusion is a key part of modern health care. It is the responsibility of the national blood programme to provide an adequate supply of blood for all patients requiring transfusion and to ensure the quality of blood and blood products for clinical use. All products must be safe, clinically effective and of appropriate and consistent quality.

The strategies for achieving this are:

- A well-organized, nationally-coordinated blood transfusion service (BTS)
- Blood collected from regular, voluntary non-remunerated blood donors from low-risk populations
- Testing of all donated blood, including screening for transfusion-transmissible infections, blood grouping and compatibility testing
- Appropriate clinical use of blood.

Every blood transfusion service should develop an effective quality system to ensure the implementation of these strategies. The quality system should cover all aspects of its activities and ensure traceability, from the recruitment and selection of blood donors to the transfusion of blood and blood products to patients. It should also reflect the structure, needs and capabilities of the BTS, as well as the needs of the hospitals and patients that it serves.

Key elements of quality systems include:

- Organizational management
- Standards
- Documentation
- Training
- Assessment.

Management commitment and support are essential for the development, implementation and monitoring of a national quality system in order to ensure continuous quality improvement. All staff should understand the importance of quality and the consequences of failure in the quality system.

Words of advice

- **Secure the commitment and support of management at all levels**
- **Identify the need for quality in the national blood policy**
- **Develop a national quality policy and plan**
- **Secure adequate resources**
- **Designate a national quality manager with overall responsibility for the implementation of quality systems in BTSs at all levels**
- **Develop a quality section, with appropriate staffing and expertise, in each blood centre and hospital blood bank**
- **Provide training in quality for all BTS staff and other health care professionals involved in blood transfusion**
- **Assess the effectiveness of the quality system continually**

Checklist

Prerequisites

- ❑ Nationally-coordinated BTS
- ❑ Management commitment and support
- ❑ Integration of quality in the national blood policy
- ❑ National quality policy and plan
- ❑ National quality manager
- ❑ Adequate resources

Organizational management

- ❑ Clearly defined organizational structure
- ❑ Quality manager in each blood centre and hospital blood bank
- ❑ Quality section in each blood centre and hospital blood bank
- ❑ Culture of quality
- ❑ Commitment and support of all staff
- ❑ Identification of processes and procedures and their critical control points

Standards for quality systems

- ❑ Regulatory or legislative framework
- ❑ Appropriate national or international standards
- ❑ Standards relevant to BTSs

Documentation

- ❑ Appropriate, comprehensive documents, including a quality manual and standard operating procedures (SOPs)
- ❑ Complete, accurate records
- ❑ System for controlling documents

Training

- ❑ Training policy and plan
- ❑ Training of all BTS staff in quality and quality systems
- ❑ Training of other health care professionals involved in blood transfusion
- ❑ Evaluation of training and its impact

Assessment

- ❑ Validation
- ❑ Ongoing data collection and analysis
- ❑ Haemovigilance
- ❑ Regular review of all activities
- ❑ Internal and external audits
- ❑ Error management, corrective and preventive action
- ❑ External quality assessment schemes

Key elements

Requirements for quality systems in blood transfusion

It is the responsibility of governments to ensure that the blood and blood products provided for clinical use by the national blood programme are safe, adequate to meet demand, effective and produced consistently to the appropriate standards.

To achieve this, the blood transfusion service must develop an effective quality system. This should provide a framework within which BTS activities are established, performed in a quality-focused way and continuously monitored to improve outcomes.

The establishment of a quality system will ensure the collection of adequate supplies of blood from regular, voluntary non-remunerated donors, the testing of all blood before use and the appropriate clinical use of blood.

Prerequisites for developing a quality system within the national blood programme include:

- Nationally-coordinated blood transfusion service
- Commitment and support of management at all levels
- Recognition of the importance of quality in the national blood policy
- National quality policy and quality plan detailing the strategy, mechanism and resources for their implementation
- Designation of a national quality manager with the necessary responsibility and authority for the development, implementation and monitoring of the quality system
- Provision of appropriate, adequate and sustainable resources to support the development and maintenance of the quality system.

Organizational management

Central to an effective quality system is commitment and support from management at all levels, including:

- Clearly defined organizational structure that defines accountability, authority and responsibility
- Designation of a quality manager, with the necessary skills and expertise, in each blood centre and hospital blood bank
- Formation of a quality section or identified work area in each blood centre and hospital blood bank from which quality activities can be coordinated
- Development of a culture of quality through a management focus on building quality into all activities
- Motivation of staff to ensure their commitment and support for the quality system
- Identification of specific processes and procedures and their critical control points.

Standards for quality systems

Relevant and appropriate standards are required to provide the framework for the development of the quality system:

- The existence of any relevant national legislation or regulations must be acknowledged and incorporated into the framework for quality
- Standards may be national or international: e.g. International Organization for Standardization (ISO) and Good Manufacturing Practice (GMP)
- The standards adopted must be relevant to the BTS and its activities.

Documentation

An effective and accurate documentation system that ensures traceability of all BTS activities is the foundation of good quality management.

Important activities include:

- Development of a quality manual: a document describing the quality system, including the organization's quality policy, standards and procedures
- Production and use of appropriate, comprehensive documents for all activities, including standard operating procedures, forms, labels and any other documents required
- Generation and maintenance of complete and accurate records
- Development of a system to manage the issue, use and retrieval of documents.

Training

Comprehensive, appropriate and effective training is required for all BTS staff and other health care professionals involved in blood transfusion.

Important activities include:

- Training policy and plan
- Training for all BTS staff in general principles of quality, the quality system, documentation and the use of quality monitoring tools
- Training programmes for other health care professionals involved in blood transfusion
- Clear understanding of the role of the individual in the quality system and the consequences of quality failures
- Ongoing monitoring and evaluation of training and its impact.

Assessment

Ensuring quality is a continual process. Ongoing assessment of the effectiveness of the quality system is essential through:

- Validation of all processes, procedures, equipment and reagents
- Ongoing collection and analysis of data generated from key activities and their use in quality improvement
- Establishment of haemovigilance through a system of monitoring, reporting and investigation of adverse incidents related to all blood transfusion activities
- Regular review of all activities to assess the overall effectiveness of the quality system and ensure continuous improvement
- Programme of regular internal and external audits of the quality system
- Reporting and analysis of errors with effective corrective and preventive action
- Active participation in appropriate external quality assessment schemes to improve laboratory performance.

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Methodology

The research methodology has been commonly agreed by all participant countries. Data were collected using the WHO questionnaire for "Quality Status Report for individual BTSs", which is part of the WHO quality management training toolkit. The validity of the data presented relies on the reporting from the respective country.

The questionnaire was translated into the respective national languages and distributed to all blood establishments (BE) and to at least some of the blood banks (BB) in participating countries. Completed questionnaires were collected at country level by the country project manager. Then data were amassed and analyzed to provide a better picture of the national quality system status in the blood service. The national reports were subsequently compiled into a brief regional overview.

Results and discussion

The national reports, although using the same operational tool for data collection, have provided differentiated feedback.

- Some countries provided both the questionnaire with centralized data and general comments based on an analysis of the given data.
- Some reports focused only on information related to the national BE, with some limited general information covering the remainder of the institutions involved in transfusion activities.
- Only one national report gave specific information on the blood banks.
- For one participating country, the national report consisted only of a compiled questionnaire, which led to difficult interpretation of some of the data provided.
- In some cases, it is possible that unclear translation of the questionnaire into the national language or use of the English version generated inadequate answers.

The existing heterogeneity in the organization of blood services at national level was reflected in the answers received. Constant contacts with the national project managers were required for further clarification with all national counterparts. Collected data were compiled for the 9 SEE countries to provide an overview of the status and the work undertaken in the field of quality systems as applied to national blood services.

1. Quality systems

In all the SEE countries there is progressive work towards developing and implementing a national quality system for the blood service (BS), supported by an adequate regulatory framework.

In the absence of a coordinated plan for the elaboration and implementation of a national quality system, and to ensure a consistent level of quality and harmonized documentation throughout the country, protocols and guidelines are in most cases developed and introduced locally without a quality policy and vision.

1.1. Quality framework

1.1.1. Quality policies/ coordination

In most of the participant countries a **national quality policy** has not yet been elaborated or implemented. In the absence of a national plan and appropriate coordination mechanisms, the different elements of a quality system are being introduced in a sequence that follows the local needs as perceived.

Only Bulgaria and the Republic of Moldova indicated in their report that a national quality policy has been endorsed by law, and that a quality manual is under development.

- According to legal requirements, since 2005 all BEs within the Bulgarian blood service must undergo an individual accreditation process. In the national report the major quality elements are well described for the national blood centre (NBC) and the four regional blood centres (RgBC), but very little information is given regarding the 23 hospital-based transfusion facilities.
- The blood service of the Republic of Moldova has the legislative background introducing quality management system requirements, but information on the current situation in the peripheral collection facilities is very scarce.

In Albania, Bosnia and Herzegovina (BIH), Croatia, Montenegro, Romania, Serbia and The former Yugoslav Republic of Macedonia there is no national quality policy yet in place.

- At institutional level, some BEs have taken the initiative of working on a quality policy and/or a quality manual. This is reported in 30% to 50% of the BEs in Croatia, Romania and Serbia.
- In Croatia two BEs have been certified according to ISO 9001:2000. In Serbia, the Novi Sad Transfusion Institute has been certified for quality management systems.

Two **dedicated institutions** have been set up in BIH: the Agency for health care quality and accreditation (AKAZ) of the Federation of BIH (FBIH) and the Agency for accreditation and quality improvement (AAQI) of Rep. Srpska (RS). The dedicated institutions recently created are expected to work towards the development of national quality policies and related standards, as well as technical support

to their implementation. AKAZ standards are already being piloted in several hospitals in FBIH.

It is important to note that even in the countries where the regulatory framework is in place, there is a clear need for national coordination towards the elaboration and implementation of a national quality system.

1.1.2. Quality manual/ standards & procedures

A **quality manual** as such does not exist in any of the SEE countries. Work is underway to develop its required elements. The documents related to organizational structure and managerial mechanisms of the quality approach will be part of the quality manual and some have been included in the previous section for a better overview of existing coordination mechanisms.

Elements of the quality system related to organization and personnel, such as a documented and authorized **organizational structure** and organigram, are generally in place in all of the 9 countries and within most of their respective major institutions. In general, institutions organized as independent BEs have their organizational structure documented and authorized by the director or in some cases by the Ministry of Health. This type of documentation is missing for most of the hospital-based BSs, particularly those functioning as hospital departments (considered as part of the hospital organization). As regards the above-mentioned documents, the national reports indicate that these are in place at:

- all National Blood Centres (NBC)/ RBCs in Bulgaria, all BEs in Romania and the Republic of Moldova
- around 50-60% of the BEs in Croatia and Serbia
- only a few in Bosnia and Herzegovina
- only the NBC in Albania and The former Yugoslav Republic of Macedonia
- none of the 10 BEs (all hospital-based) in Montenegro

The **quality manager** function, with a specific person appointed without any overlapping with other tasks, is filled only at NBC level and in some other major BEs. In most BEs the lack of specialized medical staff necessitates the delegation of multiple tasks, such as directorship and quality manager, to the same person. The director is considered in all cases to be responsible for the quality of work.

Job descriptions are in place to varying degrees among the SEE countries, covering all the departments (Bulgaria, the Republic of Moldova, Romania) or only the main departments of the BE.

Standard operating procedures (SOP) are locally developed at institutional level. Generally they are in place for all the processes or at least for the main steps (testing for transfusion transmissible infections (TTI), blood grouping, processing etc) in 30-50% of the BEs.

- Bulgaria has already endorsed 127 SOPs and the general procedures in use in all five main blood centres (NBC + 4 RgBC), as part of the future quality manual.

- Serbia has introduced 11 national SOPs, 5 draft versions are being finalized and an additional 5 are under preparation, as part of the work towards a quality manual.
- In Romania general SOPs for testing of donated blood grouping and quality control of blood components are mandatory and used by all BEs.
- In the Republic of Moldova the elaboration of SOPs is part of the process now started to implement a national quality system.
- For Albania and The former Yugoslav Republic of Macedonia the NBCs have SOPs, but these are lacking at the level of other blood centres.
- In Montenegro, where all hospital-based transfusion services are depending on the hospital organization, in most of the cases there are no written procedures.

A system of revision and documents control has been set up only in some centers, conducted annually and/or if changes are introduced.

The bottom-up approach to setting quality systems has been initiated in many of the participant countries, however the absence of a regulatory framework led to random selection of quality elements and uncoordinated process of their development. Thus executive documentation, such as SOPs, protocols, and guidelines are often elaborated and used locally, while the required comprehensive managerial approach and related documentation are missing.

1.1.3. Quality assessment/ monitoring

The processes, organized at institutional, local, national or regional levels, provide an accurate measure of quality implementation and are part of the continuous improvement cycle. In the light of reported data, discussion will focus on accreditation, auditing policies and handling of errors.

There is no uniform approach to **licensing and accreditation** of blood transfusion institutions in the selected countries. Accreditation of blood services became mandatory by law in Bulgaria, and is performed by a specialized body of the Ministry of Health (accreditation committee). In Croatia, the National Accreditation Agency certifies the blood borne pathogens laboratory (testing procedures).

Other countries report licensing procedures in place (i.e. State Sanitary Inspection in Romania, Ministry of Health in The former Yugoslav Republic of Macedonia), subject to yearly inspection, which are more related to safety and hygiene requirements.

Auditing is not yet a general policy and neither a national, documented audit schedule or trained auditors are usually available. According to the new blood law, auditing of blood services should start in Bulgaria in 2007 on a yearly basis.

Some of the countries reported the existence of audit policies developed and applied locally, at institutional level.

- BIH: 39% of BEs (11 out of 28) have an internal audit policy, but only half of them also have a documented auditing schedule.
- Croatia: 35% of BEs have an internal audit policy, but only 5 of them have a documented schedule for the process and trained auditors.
- Serbia: 60% of BEs have an internal audit policy, but only half of these have a documented auditing schedule.
- The Republic of Moldova and Romania: reported internal auditing processes for all BTCs.
- Montenegro: reported random auditing process, on a yearly basis, with the support of the Institute of National Health Management.
- Albania and The former Yugoslav Republic of Macedonia: only the NBC has a documented schedule for internal audits, but no policy.

The number of **auditors** trained and certified in the specifics of the blood service is very low or non-existent in the SEE countries. Internal audits are performed by the quality manager, the person responsible for quality assurance or ultimately the manager of the BE. Self inspection is performed in all countries and all blood services without supportive documentation and as part of the routine work of the department managers.

Bulgaria and Romania have mandatory provisions for regular inspections undertaken by appointed institutions, but report that the inspection system is not yet functional. Both Bulgarian and Romanian blood services were subject to several external audits in conjunction with their integration into the European Union.

External audits of blood services were conducted in 2005 in BIH (two hospital-based BEs), in the Republic of Moldova, and in Serbia (8 BEs) and in 2000 in The former Yugoslav Republic of Macedonia. Correction processes for identified non-conformities were reported in all cases.

A documented national strategy for **errors reporting** and handling is in place in the Republic of Moldova. Albania and Montenegro indicate no national or institutional polices for error reporting and investigation. Variations are linked to the institutional level in the other SEE countries as follows: 4% of BEs in BIH, around half of blood services in Croatia (national data collected by the NBC), Romania and Serbia, and at national institute level only in The former Yugoslav Republic of Macedonia. Attention is given mostly to adverse events related to blood transfusion therapy.

The processes of **quality assessment and monitoring** do not appear to be systematically performed and adequately regulated. Important progress has been recorded in Bulgaria, Republic of Moldova and Romania, but the updated comprehensive legislative support requires effective mechanisms for implementation. The restructuring of blood services in all SEE countries is a prerequisite for operational quality management systems.

1.2. Qualification of personnel

A comprehensive national training strategy in the transfusion field must consider all the medical, para-medical and non-medical categories involved in these activities, including staff working in the clinical services.

Currently, national training policies for blood safety have been developed in the Republic of Moldova (national programme for 2002-2006) and in Bulgaria (legal specification). These target staff of the blood service (doctors and nurses) and clinicians. In Romania the national training policy and programme are in the process of elaboration, being a mandatory requirement of the updated blood law. In The former Yugoslav Republic of Macedonia, a national policy and programme for training in the field have been prepared by the national transfusion institute.

Local training schemes have been developed in all SEE countries, some of which are part of the continuous education programme. Increased attention has recently been given to training programmes for nurses and laboratory technicians, all personnel being trained in standard operating procedures.

- Bulgaria, Croatia, Romania and Serbia have reported local training schemes for all blood transfusion service staff coordinated by the national blood institution in the country.
- BIH and The former Yugoslav Republic of Macedonia have locally organized training courses for medical staff and laboratory technicians.
- Albania reports local training sessions for blood service staff organized by the NBC.

Health professionals are licensed by the national professional bodies of their countries at regular intervals (i.e. 2 years in Bulgaria, 5 years in Romania, 6 years in Croatia) and they must undergo continuous education or a refresher course on a yearly basis. The duration of post graduate training in transfusion medicine varies according to country, and is not a recognised speciality in Albania, the Republic of Moldova or Romania.

In all SEE countries efforts are undertaken to cover training needs through local initiatives but using different curricula, structures and levels of information. Only part of the training sessions are followed by outcome assessment and only some of the institutions keep records of these training sessions.. Capacity building in quality management is required to consolidate a common understanding of quality principles and requirements, and facilitate the necessary cultural change for successful implementation. Strengthening and harmonization of training schemes require increased attention

The initiation of training schemes in quality management for blood services is expected to enhance the development of nationally adapted curricula using the WHO training toolkit as a reference. It is important to mention that selected representatives from participating countries have attended WHO training sessions on quality management for the blood service, contributing to the initiation of the quality approach at their wok place. Local curricula based on these experiences are in the process of development in Bulgaria, Croatia and Romania. Such initiatives should boost the local capacity and understanding of quality concepts and requirements, and contribute to the implementation process.

1.3. Infrastructure and supplies

1.3.1. Premises and health worker safety

The status and adequacy of premises varies between and within the countries, as already mentioned in the previous report. The safety requirements, as part of the quality process, related to work conditions, processes and personnel are considered at health system level.

A safety policy and general procedures are set by mandatory regulations in Bulgaria, the Republic of Moldova and Romania, covering the transfusion field. According to these regulations, a person responsible for ensuring safety at the workplace must be appointed and trained. Also, procedures for work related injuries and waste disposal are in place at the BEs. Often the managerial level bears this additional responsibility.

Albania and Montenegro do not have written procedures in place, but internal rules for health worker safety as well as biological waste disposal have been set up. In The former Yugoslav Republic of Macedonia, SOPs for waste disposal are in place only for the NBC.

For the rest of the SEE countries, the safety issue has been treated differently according to local decision:

- BIH: out of 28 respondent BEs, 13 have a safety policy and/or specific SOPs in place.
- Serbia: out of 39 respondent BEs, 28 have a safety policy, and 26 report dedicated SOPs.
- Croatia: out of 27 respondent BTCs, 23 have a safety policy, and 25 report related SOPs.

For the national or local health authorities, the issue of waste disposal constitutes a very important challenge, as it refers to both potentially infectious waste and plastics included in medical devices, i.e. blood bags (polyvinyl and DEHP softened plastics). The difficulties encountered by some BEs in dealing with disposals according to universal safety rules are underlined in the national reports from BIH and Montenegro.

Some of the SEE countries already have in place regular training programmes on safety at work, mostly at local level. Albania, Montenegro, and The former Yugoslav Republic of Macedonia have not yet introduced or organized specific training on safety.

1.3.2. Equipment

The status and availability of equipment are again varied between and within countries. Modern equipment responding to quality and safety requirements has been provided primarily through various external support programmes, usually to the main blood service institutions. The average age of equipment in use varies from 2 to 30 years, which actually also reflects the accuracy/quality of performance.

Critical blood service equipment is reported to be in place in all SEE countries excepting Albania and The former Yugoslav Republic of Macedonia. For BIH, Bulgaria, Romania and Montenegro, identification and listing are performed once a year on a

national basis, while in Croatia, the Republic of Moldova, and Serbia this exercise is performed locally.

Validation of new equipment is regulated by

- specific documented policy at national level in: Bulgaria and the Republic of Moldova; and at local level in BIH and Croatia.
- specific validation procedures in Albania, Romania, and Serbia.
- no documented policy and/or procedure in Montenegro and The former Yugoslav Republic of Macedonia.

Calibration of all critical equipment is performed according to

- national provisions including maintenance schedule in Bulgaria and the Republic of Moldova.
- local documented policy or procedures in Croatia, Romania, Serbia and BIH (over 50% of blood institutions).

Calibration is usually ensured by service contractors, also in charge of maintenance and repair of the respective equipment. Regular servicing and maintenance is performed in all countries for TTI testing equipment, following a documented frequency of 6 months. For other critical items, Albania, BIH, Montenegro and The former Yugoslav Republic of Macedonia report irregular maintenance of equipment due to a lack of regulated procedures but in some cases also worn-out equipment.

The refrigerators in use are of different categories and capacities, including in some cases ordinary domestic cooling systems. Temperature monitoring is part of routine procedures in all SEE countries, being performed automatically and visually (1 to 6 times daily) and registered. Refrigerators are connected to emergency generators in total or in part according to the size of the institution.

All NBCs are connected to emergency generators and have emergency procedures in place.

1.3.3. Supplies

The acquisition procedure for critical items is different among the SEE countries, depending on the national/local organization and specific legislation. The process is seldom centralized, ordering being under the direct control of either the NBC or BE/ hospital as follows:

- Centralized acquisition process for critical items (reagents, test kits, blood bags) for the blood transfusion service in the country in Albania, Bulgaria, the Republic of Moldova, and Romania.
- Individual purchase process, either by the BE itself or by the hospital-based service through the hospital acquisition department. In the latter situation, the transfusion unit very often has no control over the quality of the purchased items.

Documented procedures for inspection of critical supplies are in place in most of the countries. The minimum stock level of critical supplies is monitored and ensured

using various mechanisms. A minimum stock value is estimated based on the needs assessment performed by the individual BEs, and consolidated at national level in Albania, Bulgaria, and Romania. In the cases where an independent BE cooperates with hospital-based transfusion units, the estimation of shared/required minimum stock requirements and documented procedures is generally in place (for the majority of institutions).

Most of the reports indicate that thanks to appropriate monitoring, delivery and use, there was no exhaustion of critical supplies during the last 12 months. An emergency stock of critical items is ensured at national level in some of the countries (i.e. Bulgaria, Romania). The particular situation of Montenegro needs to be mentioned, where for the last year purchase of key items has been performed on a three month basis due to financial constraints,.

The risks of depletion of particular supplies have been encountered only in cases where acquisition is made by the individual institutions, as reported:

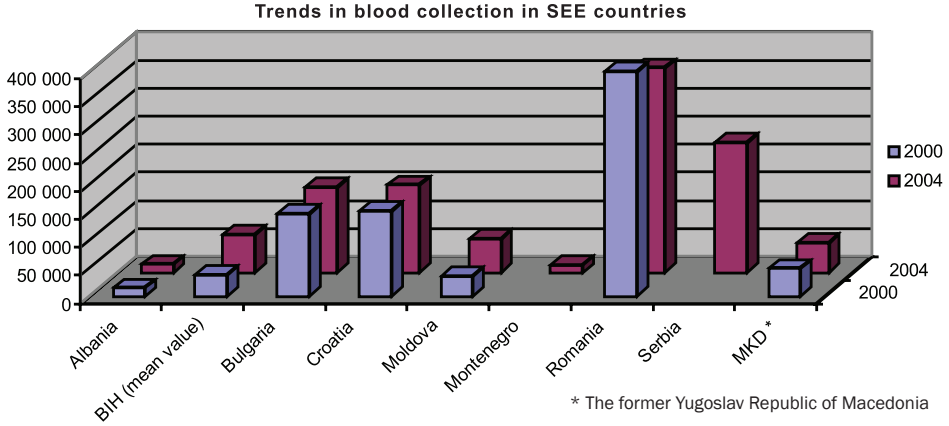
- BIH = 1-3 occasions occurring in 19 out of 28 BEs.
- Serbia = 17 occasions occurring in 7 out of 41 BEs
- The former Yugoslav Republic of Macedonia = 2-3 occasions

Expiry of the storage time for test kits/reagents is reported only in isolated cases by some countries, therefore the risk of discarding test kits/reagents because of outdating is not considered a problem. With regard to the storage conditions for critical items, i.e. temperature, these are monitored and recorded in all SEE countries either manually or automatically depending on the equipment available.

2. The Vein to Vein chain

2.1 Blood donation

The **blood donor pool and the trends** in blood donation over the last years indicate the need for development and implementation of dedicated and appropriately funded national blood donor programmes.



* The former Yugoslav Republic of Macedonia

It is known that both the quality and the availability of the blood supply depend on the quality of the donor, therefore appropriate education, and information as well as adequate procedures for selection, collection and storage of collected blood prior and after processing are all important factors.

A **national programme for blood donation** has been reported for Bulgaria and the Republic of Moldova (part of the health programme 2007-2011). Such a programme is stipulated in the new Romanian blood law, as well as the constitution of a dedicated advisory committee at ministerial level.

In terms of organization, at the NBC/RgBC level there is usually an identified department for blood **donor management**. In the case of smaller BEs or hospital-based blood banks, information is rather insufficient, but it is very seldom that either dedicated department or staff are specifically assigned and respectively trained. The overall situation in the SEE countries appears as follows:

- BIH reports a separate donor management department for 4 large BEs and an appointed person responsible for the remaining BEs. The former Yugoslav Republic of Macedonia has a separate department for donor management only in the NBC.
- The Republic of Moldova reports the existence of a separate donor management department. Bulgaria reports a separate donor management department for the NBC/ RgBCs. The same applies to Albania and Romania.
- In Croatia and Serbia, almost half of existing BEs have reported a separate donor management department.
- Montenegro reports no separate donor management department. All 10 BEs are hospital- based and the working medical staff is involved in several activities, including donor management.

In Bulgaria and Romania information material for donors and about donations is nationally standardized. In addition, various materials are developed during dedicated promotion campaigns. Specific campaigns were organised during the last two years in Bulgaria, Croatia, Romania and Serbia, with promising results. For the rest of the SEE countries most informative donor materials are provided on a local basis and mainly focused on information for and motivation/recruitment of donors. SOPs on donor recruitment and retention are sometimes locally prepared and material on donor counseling is only very rarely reported.

Collaboration with the national Red Cross societies in the field of safe donor promotion and recruitment is an important driving force of the process in BIH, Bulgaria, Croatia, Montenegro, Serbia, and The former Yugoslav Republic of Macedonia, and has recently been reactivated in Albania. In the Republic of Moldova and Romania efforts are undertaken to stimulate involvement of the national Red Cross in this field. The role of blood donor associations has to be mentioned in Albania, BIH, Croatia, Romania and Serbia.

The annual world blood donor day event is being celebrated in all participant countries with the aim of bringing together all stakeholders involved and further sustain the level of awareness and recognition of safe blood donors.

The donor selection process appears to be standardized in all SEE countries. The self deferral questionnaire for blood donors is part of the process, however its format and use are subject to local variations.

- Standardized self deferral questionnaires are used on a national scale in Bulgaria, the Republic of Moldova, Romania, and in most of BEs (>90%) in Croatia.
- Self deferral questionnaires are used locally in Albania, BIH, Serbia and The former Yugoslav Republic of Macedonia.
- No self deferral questionnaire is reported used in Montenegro.

The selection criteria, developed with reference to the CoE guide and WHO recommendations are generally included in the national regulations.

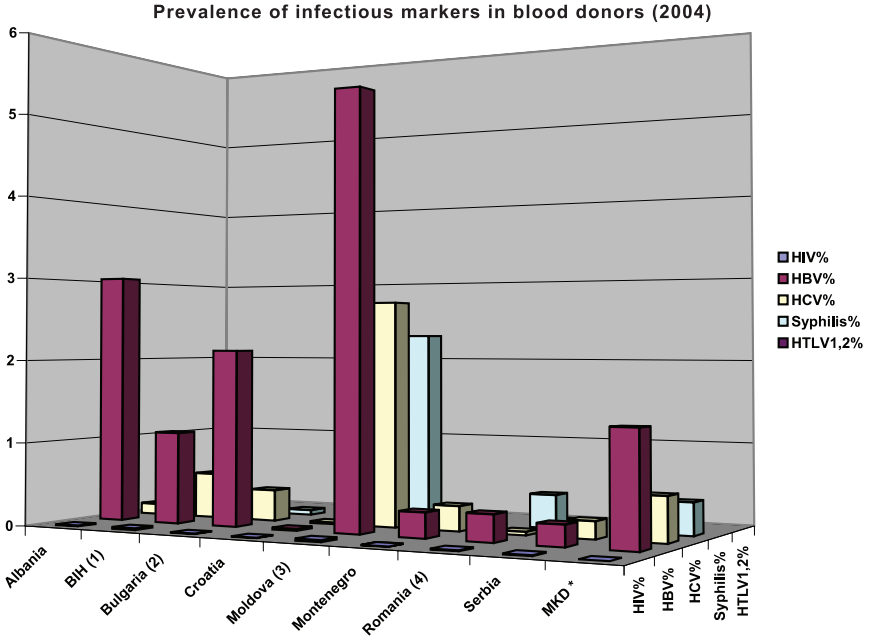
Blood donor registers exist only at institutional or local level, most of them paper-based and often handwritten. No national donor registers are currently in place except in Bulgaria, where this has been included as a mandatory requirement in the new blood law. Even in Bulgaria the national register is paper-based, using data as reported by the blood services and compiled at national level. It is to be mentioned that both in Croatia and Serbia a few of the BEs report no donor register.

National regulations for blood donation and collection seem to be place in all SEE countries. The identification systems in use vary largely according to the national organization of the blood service, the institutional structure and level of computerization. Blood donations are identified using a bar coding system in Bulgaria, and locally in BIH (only the Transfusion Medicine Institute of Federation BIH), in Croatia (6 BEs), and Romania (3 BEs). Different numeric identification systems are used in other countries, with the name of the donor almost always present on the collected blood unit or related preparations. The possibility of overlapping numbers from previous years' donations does exist in some of these circumstances, leading to difficult investigation procedures in case of delayed transfusion related events.

The need for harmonized and nationally supportive information technologies is essential to maintain the required level of safety and traceability of donors, donations, related samples and components as well as their final destination/outcome. Bulgaria, the Republic of Moldova, Romania and Serbia report planning for the implementation of a computerized system which should include the national donor register.

2.2. Blood testing

All SEE countries have national regulations regarding mandatory tests for TTI and for blood grouping (ABO-D) on all donated blood units. The regulations are in full compliance with the minimal requirements stated in the EU Directive (HIV, HCV, HBV, Syphilis, ABO grouping, RhD grouping and antibody screening).



(1) mean value given for BIH (no comfirmatory testing)

(2) figures for 1st time donors given for Bulgaria

(3) figures for replacement donors given for Republic of Moldova

(4) HTLV testing performed only in Romania

* The former Yugoslav Republic of Macedonia

SOPs on testing are reported for the majority of BEs and in several countries these are based on national models. There is a great variation in the procedures for validation and use of internal or external controls, both between the different countries and also within the same national blood transfusion service. In Romania, where purchase of TTI reagents is centralized (annual tender), all reagents are distributed in the territory together with a set of control samples and procedures.

In all countries test kits and reagents must be certified (CE mark) and in most cases the only controls are those supplied by the manufacturer with the respective test kit.

The procedures for blood group serology are less regulated but in general show the same picture. Only registered commercial reagents or test kits are used for blood grouping, with the positive and negative controls very often prepared in house or locally by the NBC/RgBC.

Records of invalid test runs are kept as based on local decision. Results from an invalid run would be accepted only in case of emergency and when no another option is available.

Expired reagents would be used only in special conditions, such as an emergency, or lack of valid kits, as reported by 20 out of 41 BEs in Croatia and 1 out of 21 BEs in Serbia. Albania and The former Yugoslav Republic of Macedonia did report isolated cases when expired serum was used for Rh grouping. Under no circumstances would the expired reagents or test kits be used in Bulgaria, Romania, BIH, the Republic of Moldova and Montenegro.

External quality assessment schemes for TTI are organized at national level in Romania, Croatia and Bulgaria, and locally in BIH (1 BE) and Serbia (1 BE). External quality assessment schemes for blood group serology are reported to take place at national level in Bulgaria and Croatia, and locally in BIH (1 BE) and Serbia (1 BE).

Registers with laboratory results and quality controls are usually computerized, laboratories being some of the first locations in the blood service to benefit from information technologies.

2.3. Blood processing

Almost all collected blood is processed into components according to national and local requirements and capacities. Documented specifications and guidelines for blood processing are reported to be in place in all SEE countries. SOPs for production are in use in most of the centres, as well as formal procedures for quarantine and release of blood components.

- Processing of blood components is performed according to nationally standardized SOPs in Romania and Bulgaria following national specifications for each component and complying with EU standards.

- Albania (NBC), the Republic of Moldova and The former Yugoslav Republic of Macedonia (NBC) have also reported the implementation of specifications and SOPs for blood component processing.

- For BIH, Croatia and Serbia most of the BEs have introduced documented specifications and SOPs for whole blood processing.

Compliance to standards should be continuously monitored to ensure the accuracy of the process and the suitability for the purpose of the expected outcome.

- Monitoring of the quality of blood processing is nationally implemented by law or national programme only in Bulgaria and the Republic of Moldova.

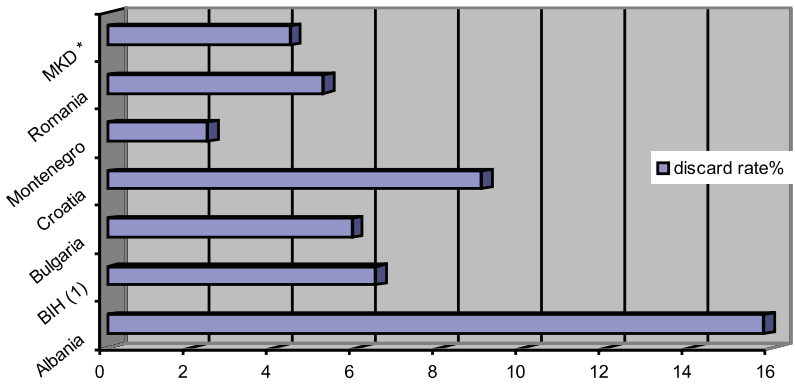
- Romania has implemented quality control of blood components; currently bacteriological control is performed in all the BEs, but haematological control is available mainly in the regional BEs.
- The former Yugoslav Republic of Macedonia reports a quality system in place for the processing of blood components at the NBC.
- In Croatia and Serbia most of BEs perform, record and monitor a quality control programme for the production of blood components.
- Albania and Montenegro have not yet introduced this element of the quality system.

Formal written procedures for quarantine/release have been developed and nationally implemented in Bulgaria and the Republic of Moldova, and locally in Croatia, Serbia, BIH, Romania, The former Yugoslav Republic of Macedonia and Albania, with differences between the BEs in the same country. A system of blood stock control is in place at institutional level (with the exception of Albania and Montenegro).

The discard rate (from 2.4% in Montenegro to 15.8% in Albania) is documented in all countries, and has infectious markers as one of the main causes for discard. National data on discarded blood components were not available for Serbia (discard monitored at institutional level) and the Republic of Moldova.

Discarded blood units out of total collection figures

Rate of discarded blood units, as% of annual collection (2004)



(1) Mean value presented for BIH (Rep. Srpska 6.67%, Fed. BIH 5.68%, Brcko dist. 7%)

* The former Yugoslav Republic of Macedonia

Most of the SEE countries have not yet achieved self-sufficiency in blood components, and hospital requests often appear to be only partially covered.

2.4. Blood use – the clinical interface

Communication between the blood service and the hospital user (clinical site) is mainly based on written and oral requests. The issue of blood and cross matching is reported to be regulated in all countries (with the exception of Montenegro). Dedicated SOPs and pre-transfusion protocols are in place in all institutions concerned in Bulgaria, and the Republic of Moldova, and in most of these in BIH, Croatia, Romania and Serbia.

Standardized blood request forms are used on a national scale in Bulgaria and the Republic of Moldova, and in the rest of the countries at institutional level, subject to local variations. It is to be mentioned that due to lack of reinforcement mechanisms, the use (and degree of completion when used) of standard reporting forms – even when issued by the national methodological institution (i.e. in Albania, The former Yugoslav Republic of Macedonia) – remains subject to local policies.

Documented blood ordering schedules are in place and use in all SEE countries except Montenegro, with confined variations. Monitoring of turn around time for blood units used, where in place, has higher priority in hospital settings when compared to blood services, as illustrated in Croatia (10% of BEs, and >40% of hospital blood banks).

National guidelines for the clinical use of blood and blood components have been developed in Bulgaria, and partially developed in Serbia (6 guidelines for specific conditions and components). WHO and CoE dedicated documents are used as technical reference in Albania, BIH, the Republic of Moldova, and Montenegro, and have been translated into the national languages of Romania and The former Yugoslav Republic of Macedonia.

Even when available, the application of clinical guidelines is limited, leading to improper use of blood components and often to abuse of fresh frozen plasma during therapeutic procedures. This explains the various volumes of components requested for the same pathology and the satisfactory management of all medical conditions even when the overall hospital request for blood components is partly covered. Alternatives to transfusion are available in all SEE countries. None of the participating countries could provide data on monitoring the coverage of clinical requests for blood and blood components and subsequent estimation of real needs. The general perception is that hospital requests exceed actual requirements.

Hospital transfusion committees are expected to play a key role in the improvement of clinical performance. Such structures already exist on a national scale in Bulgaria, the Republic of Moldova and Romania, in most hospitals in Croatia and locally in BIH (3), Serbia and The former Yugoslav Republic of Macedonia (2), however their level of operation has been very limited to date. There are no hospital transfusion committees in Albania and Montenegro.

The formation of hospital transfusion committees is part of the national haemovigilance system. Such a system is not yet functional on a national basis in any of the participating countries, however legal provisions have been developed in Bulgaria, Croatia, the Republic of Moldova and Romania in the process of transcription of EU requirements.

Haemovigilance elements are already place in all SEE countries and these are expected to converge at national level once the appropriate regulatory support and infrastructure are in place.

Traceability of blood units is reported by all countries with local limitations generated by lack of information technologies and identification procedures, which raises particular challenges when compared to current requirements. Traceability is mostly ensured by BE documentation, as in many countries standardization of data registered at hospital level is weak.

Reporting of adverse or unexpected events is usually limited to severe reactions, according to the regulations in place. When these occur, they are reported following the local structure, to the national transfusion institution, then to the Ministry of Health and dedicated agencies for investigation (i.e. Agency for medicinal products and medical devices in Croatia, Legal Medicine Institute in Romania, or National Haemovigilance Committee in the Republic of Moldova). Reporting protocols are seldom in place for average incidents (more often reported orally than in written form, and directly to the issuing blood service). No details have been provided on the outcomes of the investigations beyond provision of information to the hospital and the issuing institution.

3. Communication and IT technologies

A comprehensive IT system supporting a national network of blood services does not appear to exist in the SEE countries. With a few exceptions, computers are used in the daily routine at NBC level using integrated software produced locally or internationally. In the RgBCs and some larger BEs computers are mainly used with local applications for registration of donors, deferrals, monitoring of blood collection and sometimes stock control.

The reported situation per country is as follows:

- Bulgaria: The 5 main BEs are fully computerized, with an integrated system connecting the NBC and the 4 RgBCs. Measures have been initiated to supply computers also to the hospital-based blood banks.

- BIH: There are important differences between the three entities, with computers for donor database and collection figures in Rep. Srpska (2) and Brcko district (1), and full computerization and ISBT 128 barcode in the Transfusion Medicine Institute of the Federation BIH, where also half of the blood centres report computer applications in use.

- Croatia: The NBC is fully computerized and local IT applications are being gradually introduced in 8 BEs and 9 BBs. Existing computers are not interlinked and variations in the structure of reporting have been recorded.

- Montenegro reports no computers used in the blood transfusion service.
- The Republic of Moldova: The very few existing computers are not linked and all documentation is kept manually.
- Romania: Computerization has been partially introduced in a few centres; however neither computer units nor centres are interlinked. Development of a national IT system with external support has been initiated.
- Serbia: computers are in place in the main BEs and work is in progress towards the development of a national IT network.
- The former Yugoslav Republic of Macedonia: The national institute is computerized with full package dedicated software for blood transfusion. There are only 6 centres without computers; where these are in place they are not interlinked and are used mainly for donor registration and secretariat.

Appropriate attention needs to be given to supportive information technologies in the blood services of SEE countries to secure full traceability of donated units of blood and resulting components along the vein to vein chain. The current identification procedures in place as well as the limited network communication between departments and blood services raises important challenges in terms of donor and patient safety, being subject to both manual transcription and delayed feedback.

Conclusions and recommendations

The development and implementation of quality management systems reflect the fragmented organization of the blood services, as well as the weak coordination mechanisms functioning at national level. A dedicated legal framework is in the process of development or updating in all the countries, aiming towards harmonization with the international recommendations for quality and safety and EU requirements. The endorsement and implementation of current provisions vary greatly among the participant countries, mostly depending on the organization (i.e. centralized, independent or hospital-based blood centres), resources and financing of their blood services.

The quality status review illustrates the high level of awareness in all SEE countries as to the importance and need for implementation of quality systems in the blood services. Performed less than one year after the initial assessment, it allows a certain degree of comparison with regard to the regional progress in the quality work in this interval. In general the same picture is being described particularly for the regulatory initiatives. The elaboration of a national quality policy has not yet been finalized, started or even planned in most of the SEE countries.

Professional competence in transfusion medicine is being developed and consolidated in all SEE countries. A dedicated expert advisory body to the Ministry of Health bringing together various stakeholders has been appointed in most of the countries. However it has

no decision-making function and its direct impact has so far been limited to planning the reorganization of the blood service. Thus the status of quality systems as reported shows very little progress compared to what was described one year earlier in the previous report.

Quality elements are already in place but due to the lack of nationally coordinated guidance, most of the work is performed locally at institutional level and on a generally accepted individual basis. On the local level, the national quality assessment reports indicate ongoing work in the documentation of existing processes and procedures, with particular emphasis on national and regional institutions. The example of a hospital-based quality management approach, involving a quality management committee, in BIH deserves to be mentioned. Similarly in Croatia, the recently constituted society of laboratory technicians held a meeting focused on EU quality systems and quality audits. However at national level no significant progress has been made in this area

Variation in practice is recorded in the case of hospital-based blood centres due to the need to complement the quality approach in place in the respective facility. This sometimes leads to divergence in the documentation work, which may be expected to slow down or impede the national harmonization process and increase the need for both human and financial resources.

The lack of a nationally coordinated blood transfusion service is a huge obstacle for harmonized quality standards and the formation of a harmonized quality management system on a national basis. The wide ranging organization both at regional and national levels, the inter-country and inter-institutional differences in resources (infrastructure, medical personnel and equipment) and funding generate the recorded variation in both quality status and immediate capacity for change.

Low efficiency in the oversight of quality work at national level increases the pre-existing heterogeneity. This effect is further enhanced by the absence of a common information system where data could be collected, compiled, compared and exchanged. The implementation of a computerized information technology system at national level is expected to follow closely the existing or planned reorganization of the blood service.

National haemovigilance systems have not been developed, and further progress is related to both a common taxonomy and recognition of basic requirements that need to be established. At institutional level, the same variation in approaches applies, related to the local organization of the services. Even so, it is to be noted that two SEE countries have been participating in the European haemovigilance network: Croatia as a member and Romania as observer.

The current work needs to be supported by appropriate regulatory mechanisms. National blood policies have been consolidated in all participating countries (at least in their draft stage in some cases) in 2006. Together with a national blood programme with full legal, regulatory and financial support, these are absolute prerequisites for a functional quality management system in compliance with EU, CoE and WHO recommendations.

Highest priority should be given to the endorsement of the national blood policy accompanied by a set of quality indicators in all the countries lacking such a document. A national policy on quality would be the next logical step, and act as starting point for the elaboration of a subsequently structured plan for implementation. Reform of the blood transfusion services supported by an updated legal and regulatory framework and a proper strategy and plan adapted to national resources, priorities and needs, remains a pre-condition for effective implementation of quality management systems.

This process could be enhanced by strengthening local capacity in quality management systems for the blood service through the organization of more formal training programmes using a consistent curriculum adapted at national level. The existing initiatives on quality management training for the blood services initiated within the overall framework of WHO Quality Management Training should be further enhanced by striving for the institutionalization of dedicated national curricula. At SEE regional level, this could foster information exchange and shared experiences between participating countries as well as stimulate and activate the blood service quality network in the region.

The value of sustained cooperation, networking and information exchange needs to be fully recognized, as does its contribution to the development of coordinated and effective strategies for action, fostering national and regional harmonization.

Emerging regional strategic considerations for strengthened quality, safety and availability of the blood supply

The Dubrovnik Pledge and later the Skopje Pledge, signed in November 2005 during the Second Ministerial Forum held in Skopje, The former Yugoslav Republic of Macedonia, by all the SEE government representatives, confirmed the unanimous political commitment to regional cooperation in the field of public health and consolidated the SEE Health Network alliance, assuming responsibility for project development in the thematically identified area.

The implementation of Component 1 of the SEE blood safety project brought significant benefits as recognized by all participant countries:

- Increased political awareness of blood safety and self sufficiency.
- Clarification of existing gaps and priorities of action for blood service reform.
- Enhanced work on new or updated blood legislation in conformity with EU requirements.
- Development/ completion/ update of dedicated national blood policies/ strategies.

- Increased concern and action towards implementation of a systemic quality approach.

The results of the regional analysis have been examined from the health system perspective. The commonly identified challenges have accordingly been grouped along the 4 functions of the health system, for a comprehensive approach.

Stewardship:

There is a lack of a comprehensive, updated, legal and regulatory framework to support appropriate organisation and coordinated functioning of the blood service at national level. The identification/ creation of a national, competent authority for the blood service is an important part of the process.

Financing:

There is often inadequate financing for the blood service due to its heterogeneity and various contributing mechanisms to BS funds. A dedicated budget for the blood service must be based on appropriate estimation of real needs and a defined cost containment policy.

Resources (non-monetary):

The lack of appropriate infrastructure (in most of the cases in terms of inappropriate buildings and outdated equipment), as well as the unevenly distributed and limited number of skilled staff are linked to the random distribution of blood services activities, with degrees of complexity not always related to actual collection capacities and local needs.

Services:

The disparate quality services are a result of the above, the lack of quality management systems, and inappropriate IT support and inefficient haemovigilance (when in place), impacting directly on the quality, safety, availability and access to transfusion therapy when needed.

In response to these challenges, several premises for strategic directions have been defined.

1: There is a need to fully recognize the importance of quality and safety of blood services within the health systems framework.

2: The official adoption of modern blood policies, supported by appropriate allocation and efficient use of funds and resources, is a prerequisite for efficient service delivery. As previously noted, national blood policies have been drafted/ updated as a result of work undertaken and coordinated through the SEE network.

3: Attaining self-sufficiency and a quality, safe blood supply requires a comprehensive approach including:

- Education of the general population of all ages in healthy lifestyles and voluntary, non-remunerated blood donation as a recognised cornerstone for blood safety and availability.

- Prevention and early diagnosis of pathologies requiring blood therapy, with particular emphasis given to primary health care services and increased availability of information to patients, clinicians and the public at large.

- Appropriate use of blood and blood components and products at the clinical site (including availability and use of alternatives whenever feasible).

- Quality management along the whole blood transfusion chain, supported by the appropriate regulatory mechanisms and resources.

Progress achieved and changing epidemiological trends and social patterns (including expanding cross border movement) need to be regularly analyzed, recognizing successes and failures, and responding efficiently to identified gaps.

A strong and functional European professional network is needed to support concerted action, communication and information exchange to strengthen the quality and safety of blood services and contribute to the overall improvement of the quality of care and patient wellbeing.

Chapter 4

COUNTRY PROFILES

Albania

1. General info on the country:

Size			28 648	Sq km
Population			3 126 153	
Median age			28.9 years	
PPP US$ per capita (WHO estimates)	2003:	366	2004:	409
Total health expenditure as% of GDP :	2003:	6.5%	2004:	6.6%

2. Political and structural considerations

Political level with responsibility for blood policy legislation

- The blood service (BS), created in 1951, is under Government responsibility through the Ministry of Health.
- The BS is funded from the state budget with an annual allocation based on the previous year's expenditure (0.85% of total health budget in 2004).

3. Legal and regulatory framework

Legal documents regulating the functioning of the BS and related areas

- The law on "Blood transfusion service, control of blood and blood components" has been in force since 1995 and requires revision and updating.
- Several guidelines and regulations covering different steps of the vein-to-vein chain issued in 1999 (testing) and 2000 (selection of donors, collection and processing, storage and transportation), are in the process of revision and updating

Regulatory bodies/agencies

- The Ministry of Health constitutes the competent authority through the Sanitary Inspectorate.
- The National Transfusion committee, expert advisory body to the Ministry of Health, is not functional.

4. Organization and structure of the blood transfusion system

- The BS consists of the National Blood Transfusion Centre (NBTC) with 4 subsidiary blood banks in Tirana and 26 peripheral hospital based blood establishments at district level.
- The NBTC is under the direct managerial responsibility of the Ministry of Health, while the NBTC director and Hospital Service director have in-line managerial responsibilities with respect to related blood services.
- There is no licensing or accreditation system available for the BS.

5. Dedicated human resources

- A total of 33 transfusion medicine specialists are working in the BS (42.4% in Tirana and the rest in district hospital blood banks) with a ratio of 1 doctor to 2 technicians.
- There is no national curriculum for training in transfusion medicine either at postgraduate or undergraduate level. Practical courses in the field are organized periodically by the NBTC.
- A dedicated budget for training and continuous education has not been identified.

6. Quality management

- There is no national quality policy and programme for the BS.
- Documentation is partially developed at local level, according to institutional priorities.

- Internal audits are performed at NBTC level and partially in some of the other blood establishments and blood banks.

7. Blood donation and collection

a) Donor selection process

- Documentation provided to donors includes HIV/AIDS information sheet and explanations of blood donation.
- A donor self deferral questionnaire has been developed by the NBTC, and is regularly used in Tirana, randomly at district level.
- Donor selection criteria are nationally regulated and comply with international recommendations and EU dedicated directive specifications.
- Donors and donations are manually registered at the local blood establishment. The identification system uses the identification letter of the blood bank and the number of donation beginning with 'one' on yearly basis.

b) Blood testing requirements

- Testing of all donated units is mandatory for
  - TTI: hepatitis B (HbsAg), HIV (anti-HIV), hepatitis C (anti-HCV) and syphilis
  - blood group antigens ABO-D and irregular antibodies for 1st time donors
  - Rh phenoytype, Kell, Duffy Kidd and Lewis antigens for regular donors.
- The table below indicates prevalence of infectious markers in the donor population.

	2001	2002	2003	2004
HBsAg	2.45	3.72	2.84	3.02
Anti-HIV	0.01	0.01	0.02	0.01
Anti-HCV	0.24	0.32	0.17	0.13
Syphilis	0.02	0.03	0.02	0

c) Blood collection

- 0.5% donations in the general population, and high reliance on paid and replacement donations.
- 16 078 units of whole blood were collected in 2004, with a slight increase compared to 12 093 units in 2002.
- The 2004 blood supply was provided by:
  - voluntary non-remunerated donations: 4.4%
  - replacement donations: 36%

- paid donations: 60%
- 1st time donors 40% and paid regular donors 60%.

- Since 2001 there has been a steady increase in replacement donations, while the number of voluntary non-remunerated donations show a marginal increase.

8. Blood supply and demand

a) Supply of blood, blood components and plasma derived products:

- The current blood supply is insufficient, however neither monitoring of clinical request coverage nor an estimation of actual needs is available.
- The table below indicates trends in annual processing of collected blood (percentages are calculated against annual collection figure).

	2002	2003	2004
Annual collection figure	12.093	13.399	16.078
Plasma (fresh frozen plasma + cryo-poor plasma)	9488 73.3%*	10351 77.25%	11881 73.8%
Cryoprecipitate	3118 25.7%	3086 23.1%	2016 12.5%
Platelet concentrate	139 1.1%	239 1.7%	296 1.8%
Factor VIII (imported)	About 1 500 000 units/year		

- The percentage of discarded units has increased from 6.4% (2003) to 15.8% (2004), mainly due to prevalence of infectious agents.

b) Clinical management

- The national guidelines on the clinical use of blood components and products are in preparation, using WHO dedicated manuals. The CoE guide has been translated into the local language and is used at institutional level.
- Prescription and administration of blood components are under the responsibility of the physician, and should follow standardized request procedures and transfusion protocols.
- Hospital transfusion committees have not been established and there is no haemovigilance system in place.

9. Promotion of voluntary non-remunerated blood donation

- At the time of reporting, there was no strategy for promotion of voluntary non remunerated blood donation and no national programme addressing this issue.

- The issue has been considered as one of the key directions for action in the national strategy for the BS, prepared and adopted end 2005.
- NBTC has reactivated collaboration with the local Red Cross Society in the field of promotion of and education in voluntary non-remunerated blood.
- The new national strategy for safe blood transfusion 2005-2010 and emerging blood policy are expected to enhance the reform of the BS, development of the national blood programme and the implementation of changes required for a safe and adequate blood supply.

Bosnia and Herzegovina

1. General info on the country:

Size			51 209	Sq km
Population			3 828 397	
Median age			38.4 years	
PPP US$ per capita (WHO estimates)	2003 :	327	2004 :	359
Total health expenditure as% of GDP :	2003 :	9.5%	2004 :	9.3%

2. Political and structural considerations

Political level with responsibility for blood policy legislation

Republic of Srpska (RS)

- The blood service (BS) is under Government responsibility, through the Ministry of Health and Social Welfare.
- Financing of BS is included within contracting of hosting health institutions with the Health Insurance Fund. There is no separate budget for the BS.

Federation of Bosnia and Herzegovina (FBIH)

- Health care has divided jurisdiction between canton and federal authorities, organized at cantonal level, and coordinated at federal

level, through the respective Ministries of Health. Responsibility for blood legislation lies at federal level.

- Financial responsibility for the BS lies at both federal and cantonal level. Funding of BS comes from the Health Insurance Fund within contracting arrangements of hosting hospital. Financing of the Transfusion Medicine Institute of FBIH is provided partly from federal budget and partly from own income sources. There is no specifically dedicated budget for the BS.

Brcko District (BD)

- The BS is under Government responsibility through the Department of Health and other Services. The parliamentary assembly of BD is responsible for blood policy and legislation.
- The blood transfusion service is funded from the hosting hospital budget. BS requirements are evaluated on a yearly basis and included under a specific code in the calculations of the hospital budget.

3. Legal and regulatory framework

Legal documents regulating the functioning of the BS and related areas

- There is no national blood programme or blood policy in place in any of the three entities of Bosnia and Herzegovina. Work has been initiated to revise and update the current legal documents regulating the BS in compliance with international recommendations and EU dedicated directives.
- The current law 'Regulation for use of human blood, its components and derivatives' was issued in 1989 and remains in force in all three entities. Efforts have been undertaken to revise and update this legislation.
- Additional law and acts on health protection, prevention of infectious diseases and health insurance have been issued in recent years, comprising also partial regulations applied to blood services.

Regulatory bodies/agencies

- Ministry/Department of Health constitute the competent authority.
- Licensing or accreditation of BS is not yet in place.

Republic of Srpska

- There are two regulatory agencies: the Drug agency (drugs including blood products) and Agency for accreditation and quality Improvement (accreditation of health care institutions).

Federation of Bosnia and Herzegovina

- The Department of Drugs within MoH FBIH (imported blood products) and the Agency for health care quality and accreditation of FBIH are the regulatory bodies.

Brcko District

- The controlling body lies in the Inspections Division, within the Department for Public Safety.

4. Organization and structure of the blood transfusion system

Republic of Srpska

- There are 10 BS, with each clinical centre and general hospital having their own transfusion service, and all performing complete blood chain activities.

Federation of Bosnia and Herzegovina

- The 17 BS are represented by the Transfusion Medicine Institute (TMI) of FBIH (stand-alone BS institution) and 16 BS as part of hospitals or clinical centres.
- With the exception of one, all existing BS perform complete blood chain activities.

Brcko District

- The BS consists of one hospital transfusion department performing complete blood chain activities.

5. Dedicated human resources

- The number of qualified staff varies according to the centre, and follows the decentralized organization of the services.
- A specific budget for continuous education and training of staff is not identified.

Republic of Srpska

- Physicians have an unrestricted licence approved by the Medical Chamber.
- There are 13 board certified specialists in transfusion medicine, 5 undergoing postgraduate training, and 74 nursing staff.

Federation of Bosnia and Herzegovina

- Physicians are licensed by the Medical Chamber, while licensing of nursing staff is required in some cantons only.
- There are 26 board certified specialists in transfusion medicine, 2 undergoing postgraduate training, and 133 nursing staff.

District of Brcko

- Physicians have an unrestricted licence approved by the Medical Chamber.
- There are 2 board certified specialists in transfusion medicine, and 6 nursing staff specifically trained.

6. Quality management

- There is no quality policy developed at federal or entity level, however ongoing work on quality systems is being done locally.
- All BS are subject to self inspection performed by managerial staff at various levels.

Republic of Srpska

- Two hospitals have initiated implementation of quality standards, including their transfusion departments (Doboj & Gradiska).

Federation of Bosnia and Herzegovina

- AKAZ is the responsible agency for development of quality policy and standards.
- Quality policy group established in TMI FBIH Sarajevo, and sector for organization and advance of quality established in Clinical centre Tuzla.
- Two hospitals have initiated implementation of quality standards, including their transfusion departments (Travnik & Nova Bila).
- Two BS (TMI BIH and Clinical Hospital Mostar) undergo periodic external quality control.

7. Blood donation

a) Donor selection process

- Documentation provided to donors is produced locally, with an entity specific donor card in RS and BD, and subject to canton variation in FBIH.
- Donor selection criteria are regulated according to international recommendations (CoE guide and EU requirements).
- Donors and donations are registered locally in manual or computerized registers depending on the availability of computers.

b) Blood testing requirements

- Testing of all donated blood units is mandatory for hepatitis B (HbsAg), HIV (anti-HIV), hepatitis C (anti-HCV), and syphilis. Confirmation of positive results for transfusion transmitted infections is only performed in FBIH (TMI and CH Mostar).
- The table below shows compiled prevalence of infectious markers in blood donations for 2004, in all three entities.

Blood testing	HBsAg	Anti-HCV	Anti-HIV1,2	Syphilis
FBiH	0.973% (415)	0.316% (135)	0.03% (13)	0.145% (62)
RS	0.504% (118)	0.389% (91)	0.038% (9)	0.179% (42)
BD	1.85% (50)	0.95% (26)	0	0.037% (1)
TOTAL	**0.849% (583)**	**0.366% (252)**	**0.032% (22)**	**0.154% (105)**

- Testing of all donated blood units is mandatory for ABO blood groups and RhD antigen. Antibody screening is performed only in some BS.

c) Blood collection

Republic of Srpska

- 23 390 units of whole blood were collected during 2004 (84.19% at fixed collection sites).
- The donor population consists primarily of family replacement donors (69.72%), with 22.83% 1st time donors.
- Overall collection figure is declining, with consistent reduction in blood donation recorded in Banja Luka over the last years.

Federation of Bosnia and Herzegovina

- 42 655 units of whole blood were collected during 2004 (69.62% at fixed collection sites).
- The donor population varies according to site with voluntary non remunerated blood donations 20% (Bugono, Nova Bila), 60% (Sarajevo, Zenica, Tuzla) and 70% (CH Mostar).
- Overall family donations represent 53,32%, with 35.1% 1st time donors. Blood collection figure shows positive trends.

District of Brcko

- 2697 units of whole blood were collected during 2004 (77% at fixed collection site).
- The donor population consists of 82% voluntary non-remunerated donors and 18% family replacement donors, with 15%. 1st time donations.
- Participation of voluntary non-remunerated blood donors appears to be slowly increasing.

8. Blood supply and demand

a) Supply of blood, blood components and plasma derived products (produced and/or imported):

- Existing technical capacities for blood component preparation vary widely in FBIH and RS.
- The table (next page) provides a comparative overview of blood components produced in the three entities in 2004.

	Whole Blood	Red Blood Cells	Fresh Frozen Plasma	Platelets	Cryo precipitate
FBIH	26.99% (11 513)	63.93% (27 268)	52.44% (22 370)	10.05% (4 288)	5.84% (2 492)
RS	33.36% (7 802)	66.26% (15 498)	34.68% (8 111)	2.17% (506)	6.43% (1504)
BD	39.01% (1052)	63% (1699)	32.11% (866)	9.86% (266)	19.99% (539)
Total	**29.63% (20 367)**	**64.68% (44 465)**	**45.60% (31 347)**	**7.36% (5 060)**	**6.60% (4 535)**

- The current clinical demand for blood and blood components appears to be covered.

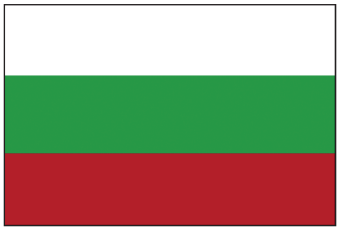
b) Clinical management

- At present there are no guidelines on the clinical use of blood adopted at entity or federal level. Some hospitals use local guidance on the use of blood components as well as references to existing international recommendations.
- There are no haemovigilance system or standardized reporting forms in place, however the reporting process of serious adverse events related to transfusion is in place.
- One hospital transfusion committee has been established in the University Clinical centre of Sarajevo.

9. Promotion of voluntary non remunerated blood donation

- There is no national blood donor programme in Bosnia and Herzegovina. Current legal provisions stipulate donor incentives such as days off work and sometimes free health care services.
- Promotion activities are undertaken in all three entities in collaboration with local Red Cross societies and blood donor associations at different degrees according to resources available. Blood donation propaganda is generally undertaken on a voluntary basis by the staff of the BS.
- No dedicated trained staff or specific budget for promotion activities exists, with the exception of FBIH where blood donor promotion is financed from federal and cantonal level. Accordingly, a special service for donor promotion has been established in TMI Sarajevo, and donation coordinators are in place in Tuzla and Mostar. In BD, a local committee has been appointed to work on the programme for voluntary blood donation.
- The celebration of Blood donor day and now of World Blood donor day is used as a good opportunity to raise awareness and further enhance safe blood donation

Bulgaria



1. General info on the country:

Size			111 000	Sq km
Population			7 845 841	
Median age			40.8	years
PPP US$ per capita (WHO estimates)	2003 :	573	2004 :	635
Total health expenditure as% of GDP	2003 :	7.5%	2004 :	7.7%

2. Political and structural considerations

Political level with responsibility for blood policy legislation

- The national blood service (BS) is under Government responsibility through the Ministry of Health.
- The BS is funded mainly from the republican budget through the Ministry of Health (0.74% of total expenditure for health care, 2003), with no substantial increase in allotted funds in the last 3 years.

3. Legal and regulatory framework

Legal documents regulating the functioning of the BS and related areas

- The law on blood, blood donation and blood transfusion dated 2003 provides the legislative framework for the BS. The law and its additional acts and regulations have been developed in compliance with EU requirements and WHO recommendations.
- The Blood safety strategy 2005-2010 defines blood safety as a strategic priority for national health care policy and sets the foundation for national blood policy development.

Regulatory bodies/agencies

- The Ministry of Health constitutes the competent authority, with its control functions implemented through authorized officials and the Bulgarian Drug Agency.
- The National Drug Agency and the Expert accreditation committee of the Ministry of Health have regulatory functions, the first being involved in inspections and investigations, the latter in the accreditation process.
- A National consultative committee for the stimulation of voluntary, non-remunerated blood donation is foreseen in the national programme.

4. Organization and structure of the blood transfusion system

- The BS consists of:
  - 5 independent bodies (financed by the Ministry of Health for their specific activities): 1 National Centre of Haematology and Transfusiology (NCHT) acting as methodological body at national level, 4 Regional Centres of Haematology and Transfusiology (RCHT - Plovdiv, Varna, Pleven, Stara Zagora),
  - 23 departments of transfusion haematology in multi-profile hospitals,
  - 56 hospital transfusion facilities (storage, distribution and patient testing).
- A national accreditation scheme for blood institutions is being introduced with the new legal framework.

5. Dedicated human resources

- There are 212 physicians working in the national BS (of which 78 have postgraduate studies in transfusion medicine), 246 nurses and

177 laboratory technicians (total staff number 785). These are mostly concentrated in the 5 main facilities (national and regional centres).

- All personnel involved in blood collection, testing, processing and storage must undergo mandatory training every two years.

6. Quality management

- A national quality policy was adopted end 2005, and the Medical Standard for transfusion haematology which entered into force in 2006 specifies quality management requirements.
- Quality monitoring, quality control and self inspection are carried out, although not at full volume, in the 5 major centres. Annual audits to be performed by the Bulgarian Drug Agency are planned for 2007.

7. Blood donation

a) Donor selection process

- Documentation provided to donors is nationally standardized and includes pre-donation educational material, a donor self-deferral questionnaire and written consent.
- Donor selection criteria are included in the Medical standard of Transfusion haematology, applied nationally and in compliance with EU requirements, CoE and WHO recommendations.
- Donors and donations are registered in computerized registers at the national and regional centres and compiled at central level in the national donor register.

b) Blood testing requirements

- Testing of all donated units is mandatory for hepatitis B (HbsAg), HIV (anti-HIV), hepatitis C (anti-HCV) and syphilis. TTI testing of donated blood has been carried out since July 2001 only in NCHT and the 4 RCTH, all reagents being centrally supplied.
- The following table illustrates the prevalence of blood borne infections in 1st time donors as compared to the general population (2005).

TTI Marker	1st time donors	Population at large
HBs Ag	1,15%	Approximately 5%
Anti HIV	0.0039%	0.0052%
Anti HCV	0.11%	Approximately 1%
Syphilis	0.11%	Data not available

- All blood units are tested for blood groups ABO, RhD and irregular antibodies. Testing is centralized at the NBC and RBCs' level.

c) Blood collection

- 153 337 units of whole blood and 836 apheresis platelet concentrates were collected in 2005 indicating a gradually positive trend (as compared to 142 951 whole blood units collected in 2002).
- The blood supply for 2005 relied heavily on replacement donations (68%), with 79% regular donors and 21% 1st time donors.
- Since 2002 there has been an increase in the number of replacement donations while the number of voluntary non-remunerated blood donations remains constant.

8. Blood supply and demand

a) Supply of blood, blood components and plasma derived products (produced and/or imported during 2005):

- 97.34% of total collection figure was fractionated into components, providing red cell concentrates (149 115 units), single donor platelet concentrates (22 498 units), apheresis platelet concentrates (836 units) and fresh frozen plasma for transfusion (16 681 litres).
- Out of the total collection figure, 11 136 litres of plasma were fractionated into 20% albumin solution and immunoglobulins. Highly purified coagulation products are imported (F VIII 1.1 U/inh, F IX 400 000 U, small amounts of fibrinogen and recombinant F VIIa).
- All emergency requests are covered but no figures on total demand versus supply are available.

b) Clinical management

- National guidelines on the clinical use of blood have been available since 1996. New guidelines have been included in the Medical standard of transfusion haematology.
- All prescriptions of blood components for transfusion are done by the responsible physician and ordered on a nationally standardized request form.
- Hospital transfusion committees are in place in all major hospitals, under the responsibility of a specialist in transfusion medicine. Transfusion practices undergo revision every three months and

compiled annual reports must be submitted to the NCHT. The degree of compliance and comprehensiveness of provided data varies.

- The new law has introduced haemovigilance as a mandatory system with uniform reporting of adverse transfusion events.

9. Promotion of voluntary non-remunerated blood donation

- The promotion of voluntary non-remunerated blood donation is included in the current legislation for the BS.
- The national blood donor programme foresees an appointed National Consultative Committee for the stimulation of voluntary, non-remunerated blood donation. The committee is planned to have a broad representation covering policy makers, BS, educational sector, media and NGOs.
- No specific funds for promotional work are currently available.
- There are ongoing dedicated training programmes for BS staff and a sustained collaboration with the local Red Cross in promotion and communication techniques.
- The promotion programme “Safe Blood” involves clinicians, patient groups, the Red Cross and Red Crescent Societies, Blood Donors’ associations and other NGOs including civil society.

Croatia

1. General info on the country:

Size			56 542	Sq km
Population			4 437 460	
Median age			39.97 years	
PPP US$ per capita (WHO estimates)	2003:	838	2004:	897
Total health expenditure as% of GDP:	2003:	7.8%	2004:	7.9%

2. Political level with responsibility for blood policy legislation

- The BS is under Government responsibility through the Ministry of Health.
- As part of the public health system, BSs are funded directly or via the hospital budget from the Croatian Institute for Health Insurance. Additional funds are collected on a fee for service basis. Only the Croatian Institute for Transfusion Medicine (CITM) is financially independent.

3. Legal and regulatory framework

Legal documents regulating the functioning of the blood service and related areas

- Various laws and additional acts issued during the last 10 years (i.e. health care law 2003; law on drugs and medical products 2003, Regulation on blood and blood components 1999 etc) regulate the functioning of BS.
- The new law on 'blood and blood component supply' follows EU requirements and international recommendations in the field, and was submitted to Parliament end 2005.
- The national blood policy has recently been drafted and the reorganization of the blood service already proposed in 1998 and 2002.

Regulatory bodies/agencies

- Ministry of Health constitutes the competent authority, with an advisory board of experts in transfusion medicine (also specified in the current law).
- The Agency for Medicinal Products and Medical Devices (AMPMD since 2004) is responsible for licensing of BS.
- Agency of Accreditation (established beginning 2005) responsible for accreditation of testing laboratories.

4. Organization and structure of the blood transfusion system

- The BS consists of 34 blood centres with 1 independent reference centre (CITM) reporting directly to the Ministry of Health, and 33 transfusion departments/blood banks. Full range of blood chain activities is performed in 20/34 BSs.
- There is one national plasma fractionation centre that manufactures albumin and immuno-globulins only (Institute of Immunology).

5. Dedicated human resources

- There is a large workforce of employees with a limited number of subspecialties, due to increased dispersion of the BS.
- Physicians are certified by the Medical Chamber every 6 years. Most technicians have been trained in transfusion medicine at the CITM.

6. Quality management

- The GMP system for medical products is a mandatory system for all blood establishments. To date, CITM has been licensed by AMPMD and two blood centres have been certified according to ISO 9001:2000.
- National standards and operating procedures for work were issued in 1995, and complemented with the updated editions of the CoE quality guide.
- CITM has initiated systematic quality controls, as well as a voluntary proficiency testing programme for blood group serology and infectious markers.
- Internal audits are partially functioning and annual external audits (Agency of Accreditation) are planned for 2007.

7. Blood donation

a) Donor selection process

- Documentation provided to donors is subject to local variation.
- Donor selection criteria are nationally regulated and follow EU requirements and international recommendations.
- Donors and donations are locally registered in manual or computerized databases. There is no national donor register or common database.
- All donors are voluntary and non remunerated.

b) Blood testing requirements

- Testing of all donated units is mandatory for hepatitis B (HbsAg), HIV (Anti-HIV), hepatitis C (Anti-HCV) and syphilis. Confirmation of repeatedly reactive tests is performed in CITM for the whole country.
- The following table provides an overview of prevalence of infectious markers in the donor population (2004).

Total number donations tested: 155,454	HBsAg %	Anti-HCV %	Anti HIV1,2 %	TPHA/VDRL %
Repeated reactive	0.105	0.178	0.077	0.071
Confirmed positive	0.022	0.021	0.003	0.012
Number of new donors tested: 15,514	HBsAg %	Anti-HCV %	Anti HIV1,2 %	TPHA/VDRL %
Repeated reactive	0.174	0.045	0.006	0.013

- Testing of all donated units is mandatory for blood groups ABO, RhD and screening for irregular antibodies.

c) Blood collection

- 156 705 units of whole blood (3.6 units/100 inhabitants), and 1581 aphaeresis donations (1491 platelet concentrates and 90 plasma units) were collected in 2004.
- The collection rate has remained stable during the last 3 years, with 34.78% collected at fixed sites (2004).
- All donors are voluntary non-remunerated. 1st time donors accounted for 10% of the total collection figure.

8. Blood supply and demand

a) Supply of blood, blood components and plasma derived products (produced and/or imported during 2004):

- All collected blood is separated into components and distributed to hospitals. The existing numbers of donations (> 3.6/100 inhabitants) meet the need of red cell concentrates.
- Plasma is collected also through aphaeresis procedures for fractionation purposes, subject to external contracting.
- The following blood products were used in 2003:
  - Albumin: 98g/million inhabitants
  - i.v. Gamma globulin 332 kg/million inhabitants
  - Factor VIII 1.96 I.U./inhabitant

- The real clinical needs have never been estimated, all hospital requests concerning emergency procedures being covered.

b) Clinical management

- WHO guidelines for the clinical use of blood and several related national recommendations have been introduced through the Croatian Society for Haematology and Transfusion Medicine.
- All prescriptions of blood components for transfusion are done by the responsible physician and ordered on a locally produced request form.
- A mandatory system for reporting adverse transfusion events is in place, regulated by various acts (1999 and 2005), with reporting of all reactions to the AMPMD and serious events to the MoH. A parallel voluntary reporting system through CITM proved more successful, with data on adverse transfusion reactions collected and compiled since 1999. The register for transfusion reactions is hosted by the transfusion service of the Clinical hospital Rebro in Zagreb.
- Most hospitals have a Transfusion Committee and activities tend to improve on a yearly basis.
- Croatia is member of the European Haemovigilance Network.

9. Promotion of voluntary non-remunerated blood donation

- The promotion of voluntary non-remunerated blood donation is included in the current legislation (Law on Croatian Red Cross and Health care Law), with specific funding.
- The Croatian Red Cross and the blood services bear the responsibility for blood donor propaganda and education.
- There is no official national blood donor programme. Promotion/ collection targets are set as based upon estimated requests incoming from hospitals, collected at CITM level and further planned and coordinated in collaboration with the local Red Cross representative.
- Specific training is available and currently there are several trained promotion coordinators (i.e. 2 at Red Cross state level and 40 at regional and local level). The 2 coordinators at CITM level account for 60% of hospital requests in Zagreb.

Montenegro

1. General info on the country:

Size		13 812 Sq km,
Population		620 145
Age structure	0-14 years	20.7%
	15-64 years	67.2%
	> 65 years	12.1%

2. Political and structural considerations

Political level with responsibility for blood policy legislation

- The BS is under Government responsibility through the Ministry of Health.
- The BS is financed from the Health Insurance Fund, as part of the hospital/clinic budget to which the service belongs.

3. Legal and regulatory framework

Legal documents regulating the functioning of the blood service and related areas

- The current law regulating the functioning of the BS dates from 1989. A new legal framework is under development, observing modern quality and safety requirements for the BS.

Regulatory bodies/agencies

- Currently there are no official regulatory bodies but provisions for these are included in the upcoming law on blood transfusion.
- The National Commission for blood transfusion (multidisciplinary) has been appointed as advisory body at MoH level since 2004.

4. Organization and structure of the blood transfusion system

- The BS consists of 10 transfusion services, all hospital based, with the Centre for Blood Transfusion of the Clinical Centre of Montenegro (national reference centre) and 9 units for blood transfusion in various hospitals.
- There is no national coordination of BS and these are under the organizational and financial responsibility of their hosting hospital. The opening of a BS is licensed by the MoH.
- All units appear to perform full range of the blood chain activities, and provide the blood supply for hosting hospitals.

5. Dedicated human resources

- A total of 12 transfusion medicine specialists are working in the BS, all trained at the medical university in Belgrade (3 year training), with a 1 to 3.6 ratio when reported to dedicated trained technical staff.
- There is no dedicated strategy or budget for training and continuous education of staff in the blood service.

6. Quality management

- There is no national or institutional quality policy. Quality work is mainly related to local routine procedures.
- Documentation on blood donors, donations and testing exists at institutional level and is kept for 30 years.

- Self inspection and internal audits are reported. External audits are done by the Republican fund for health care on a yearly basis.

7. Blood donation

a) Donor selection process

- Documentation provided to donors is used on a national basis, and is included in the voluntary blood donors' booklet.
- Donor selection criteria are nationally regulated by the 1989 legal provisions. The self deferral questionnaire is under development
- Donors and donations are registered in local manual registers. There is no national donor register.

b) Blood testing requirements

- Testing of all donated units is mandatory for hepatitis B (HbsAg), HIV (Anti-HIV), hepatitis C (Anti-HCV) and syphilis, with all testing locally performed. The TTI prevalence in donors' population (2004) is compiled in the following table

	HBV	HCV	HIV	Syphilis
% TTI prevalence in blood donors	0.3	0.3	0.001	0.13

- Testing of all donated units is mandatory for blood groups ABO, RhD and screening for irregular antibodies.

c) Blood collection

- 14 280 units of whole blood were collected in 2004, mainly at fixed collection sites (90%). The collection figure has been stable over the last 5 years.
- The blood supply is based upon family replacement donations (80%).

8. Blood supply and demand

a) Supply of blood, blood components and plasma derived products:

- Collected blood is separated into components around 50%, with production of red cell concentrates (7680 units), platelet concentrates

(2397 units), cryoprecipitate (457 units) and fresh frozen plasma for transfusion (7680 units) – 2004 data.

- About 60% of total requests are covered (full coverage of emergency requests), but there are no figures on real clinical need.
- The 2004 ratio production/demand was 14200/24000 units, with 2.4% discard rate of unused blood.

b) Clinical management

- There are no national guidelines on clinical use of blood components. The guidelines/recommendations from WHO and CoE are used together with national textbooks in clinical transfusion medicine.
- Prescription and administration of blood components lie with the responsible physician. The nurse performing the transfusion is equally responsible for the technical part.
- Adverse events must be reported to the BTC of Montenegro, according to established protocols.
- There is no system of haemovigilance in place, and there are no hospital transfusion committees.

9. Promotion of voluntary non-remunerated blood donation

- A national blood donation programme is being developed in collaboration with the Red Cross (RC) on a yearly basis; however, this is not specifically budgeted.
- Promotion activities are undertaken by volunteers within the RC, while in the BS, this responsibility lies with the transfusion medicine physician.

Republic of Moldova

1. General info on the country:

Size			33 800	Sq km
Population			3 606 800	
Median age			32.3	years
PPP US$ per capita (WHO estimates)	2003:	166	2004:	202
Total health expenditure as% of GDP:	2003:	6.7%	2004:	7.5%

2. Political and structural considerations

Political level with responsibility for blood policy legislation

- The BS is under Government responsibility, through the Ministry of Health and Social Protection (MoH).
- Funding of the BS comes from the state budget, as part of the total health expenditure (5.6% in 2004), through MoH. Figures are based upon annually estimated needs, and have recorded a slight increase in the last 3 years.

3. Legal and regulatory framework

Legal documents regulating the functioning of the blood service and related areas

- The law regulating blood donation dates from 1993 and is in the process of revision. It is complemented by additional acts, altogether with the national programme for development of the blood service.
- The national programme for development of the blood service is updated on a 5 year basis (2002-2006, 2007-2011) to better respond to national quality and safety needs.
- The CoE guide has been translated in the local language and is used as national technical reference.

Regulatory bodies/agencies

- The MoH acts as competent authority for the BS.
- The National centre for preventive medicine and the National drug agency have regulatory functions for health institutions, their role in relation to the BS to be further elaborated within the new law.
- Appointed commissions with supervision and advisory functions:
  - Inter-department commission – monitors the development of the national blood programme.
  - National haemovigilance committee – expert advisory group.

4. Organization and structure of the blood transfusion system

- The BS consists of the National Blood Transfusion Centre (NBTC), 2 regional blood centres, 21 hospital blood transfusion sections and 23 hospital blood transfusion cabinets.
- The national BS is organized according to four levels of complexity:
  - Level 1: the NBTC, with supervisory and methodological functions for the network, reporting to MoH.
  - Level 2: the regional BCs (North and South), performing the full range of blood chain activities at regional level, reporting to level 1 and MoH.
  - Levels 3 and 4: the hospital based transfusion sections and transfusion cabinets respectively, reporting to hosting institution, and methodologically to levels 2 and 1. Activities performed are limited to blood collection and/or patient related activities.

- The BS institutions are accredited by the National council for evaluation and accreditation of health services.

5. Dedicated human resources

- A total of 36 physicians are working in the BS, with 27 transfusion medicine specialists, with an average ratio of 1 doctor for 5 nurses/ technicians.
- Training in transfusion medicine is organized by the state medical university, as well as for technical staff. Practical courses in the field are organized periodically by the NBTC.

6. Quality management

- A national quality policy and plan have been formulated and work is progressing towards the development of a 5 year implementation programme for quality management systems in the BS.
- The national centre for Preventive Medicine is responsible for planned inspection procedures of the BS.
- The State laboratory for the control of blood components, diagnostics and products is responsible for product quality control .

7. Blood donation

a) Donor selection process

- Documentation provided to donors is standardized on a national basis, including the self deferral questionnaire.
- Donor selection criteria are nationally regulated and follow the CoE guide.
- Donors and donations are recorded in local registers, with efforts undertaken towards data centralization at national level.

b) Blood testing requirements

- Testing of all donated units is mandatory for hepatitis B (HbsAg), HIV (Anti-HIV), hepatitis C (Anti-HCV) and syphilis. The following table indicates the prevalence of TTI in blood donors for 2004.

	HBsAg	Anti-HCV	Anti-HIV	Syphilis
% TTI prevalence in blood donors	5,8	3,0	Total positive results 0,28 Confirmed positive 0,025	2,6

- Testing of all donated units is mandatory for blood groups ABO, RhD and Kell, and screening for antibodies.
- Testing is centralized basis, in 3 locations: NBTC and 2 RgBCs Samples are archived for 12 months.

c) Blood collection

- 28 289.7 kg is the total collected blood volume for 2004. The collection figures indicate a constant increase during the last 4 years.
- Blood collection is mainly performed on fixed sites (78.4%).
- The blood supply is almost exclusively based upon family replacement donations (96%), with 30% of 1st time donors in 2004.

8. Blood supply and demand

a) Supply of blood, blood components and plasma derived products:

- Almost all collected blood is fractionated into components: red cell concentrate, fresh frozen plasma, platelet concentrate and cryoprecipitate.
- Raw plasma is used for local fractionation purposes with production of albumin solutions, immunoglobulins and fibrin glue.
- It is to be noted that 157 auto-transfusion procedures have been reported, with no details on the type, number and outcome of collected units.
- Needs for blood and blood components are estimated on a yearly basis, using previous years' average consumption figures.

b) Clinical management

- There are national guidelines on the clinical use of blood components distributed to all hospitals.
- Prescription and administration of blood components are under the responsibility of the attending physician. Transfusion protocols must be approved and attached to the medical chart of the patient.

- According to mandatory haemovigilance requirements, all major hospitals have transfusion committees to review their clinical use of blood and blood components. Adverse events are reported for investigation to the National Haemovigilance Committee.

9. Promotion of voluntary non-remunerated blood donation

- The national blood donor programme is included in the national programme for the development of the blood service.
- The issue of pro-donation education and promotion seems to benefit from increased attention, with no dedicated funding at this point in time.
- Staff responsible with promotion activities has received training on site .
- Promotion campaigns have been organized with the support of various stakeholders, involving clinicians, patient groups, Red Cross society, blood donor associations, however with limited efficiency.
- The national programme 2007-2011 will include specific measures concerning education, promotion and retention of voluntary non remunerated blood donation.

Romania

1. General info on the country:

Size			238 500	Sq km
Population			21 673 328	
Median age			36.6	years
PPP US$ per capita (WHO estimates)	2003:	540	2004:	566
Total health expenditure as% of GDP :	2003:	6.1%	2004:	5.7%

2. Political and structural considerations

Political level with responsibility for blood policy legislation

- The BS is under the Government through the Ministry of Health, which has haematology and transfusion safety as one of the national priority health programmes.
- The national BS is financed completely from the state budget. Financing of the BS network is done through the National Institute for Blood Transfusion (NIBT).
- There has been a slight decrease in allotted funds, measured as percentage of the total health cost, during last 2 years.

3. Legal and regulatory framework

Legal documents regulating the functioning of the blood service and related areas

- The current law regulating the blood service was adopted end 2005, and follows EU dedicated requirements and WHO recommendations. It is complemented by additional orders and acts covering various aspects of the BS.

Regulatory bodies/agencies

- Ministry of Health constitutes the competent authority.
- The State Sanitary Inspectorate is in charge with periodic licensing of BSs.
- The National Blood Transfusion Committee acts as expert advisory body to the Ministry of Health.

4. Organization and structure of the blood transfusion system

- The BTS consists of the
  - National Institute of Blood Transfusion (NIBT - former Institute of Transfusion Haematology), reference and coordination of the network,
  - 8 regional blood centres coordinating the subsidiary 33 blood establishments,
  - 4 hospital blood centres in Bucharest, and
  - 330 hospital based blood banks.
- All blood establishments and blood banks have a license to function issued by the Ministry of Health, and are subject to annual inspection by the State Sanitary Inspectorate.

5. Dedicated human resources

- A total of 124 physicians, 99 biologists/chemists and 662 nurses are working in the BS. 85% of dedicated institutions report insufficient personnel.
- Physicians are licensed by the College of Physicians, and nurses by the national Order of Nurses.
- There is no national curriculum for training in transfusion medicine either at postgraduate or undergraduate level. The speciality as such existed

only for a short period of time (2000-2003). Practical courses in the field are organized periodically by the NIBT for all categories of personnel.

6. Quality management

- There is no national quality policy but the current regulations foresee a mandatory quality management system for all blood establishments and blood banks. A national quality manual is in process.
- The CoE guide has been translated into the local language and is being used as technical reference.
- Internal audits are only partially functioning. External quality assessment schemes have been initiated on testing for transfusion transmissible infections.
- The WHO quality management training toolkit has been translated into the local language and there are plans for its inclusion in the continuous education schemes.

7. Blood donation

a) Donor selection process

- Documentation provided to donors is nationally standardized and includes pre-donation education material and donor self-deferral questionnaire.
- Donor selection criteria are nationally regulated and revised according to the EU requirements.
- Donors and donations are registered locally in manual or computerized registers. There is no national donor register or uniform information technology system in place.

b) Blood testing requirements

- Testing of all donated units is mandatory for hepatitis B and C, HIV, HTLV I/II and syphilis. At present, all primary testing is performed locally, confirmation of positive results being centralized.
- The following table presents trends and prevalence of TTI markers in blood donors, 2000 to 2004

	TTI MARKERS							
	ANTI-HIV-1+2(*)		ANTI-HTLV-I/II(**)		ANTI-HCV		HBsAg	
	FTBD (%)	RBD (%)	FTBD (%)	RBD (%)	FTBD (%)	RBD (%)	FTBD (%)	RBD (%)
2000	0.040	0.0026	0.073	0.0111	1.33	0.030	5.30	0.067
2001	0.045	0.0026	0.089	0.0019	1.30	0.029	4.95	0.083
2002	0.020	0.0007	0.061	0.0001	1.27	0.027	5.11	0.075
2003	0.032	0.0040	0.043	0.0002	1.17	0.010	5.70	0.071
2004	0.038	0.0022	0.046	0.0002	1.21	0.010	5.40	0.073

Abbreviations:

FTBD: First Time Blood Donors

RBD: Repeat Blood Donations

Observations:

(*) - Only one case of HIV-2 has been confirmed in a FTBD.

(**) - Only HTLV-I but no HTLV-II has been confirmed.

- Testing of all donated units is mandatory for blood groups ABO, RhD and screening for irregular antibodies.

c) Blood collection

- 352 539 units of whole blood were collected in 2004. Collection trends indicate a slow increase as compared to 2003.
- 70% of the blood supply comes from fixed site collection.
- In 2004 the donor population consisted of 70-74% regular donations and about 20% 1st time donors.

7. Blood supply and demand

a) Supply of blood, blood components and plasma derived products (produced and/or imported during 2004):

- Collected blood is fractionated about 62%, and the following table indicates the availability of blood components in 2004.

Blood and components	Produced	Ordered	Delivered
Whole blood	140 896	566 844	349 864 62% fractionation into components
Red cells concentrate	211 643		
Fresh frozen plasma	193 197	313 072	190 081
Platelet concentrates	58 741	94 239	58 727
Cryoprecipitate	16 887	41 626	18 246

- Highly purified coagulation products are imported.
- Even at a 60% coverage of the requests for blood components, the actual clinical needs appear to be met. No figures on the real clinical demand/need are available.

b) Clinical management

- The existing practices are based on the translation of the WHO Clinical Use of Blood manual into the local language and its distribution in the network.
- Prescription and administration of blood components lie with the responsible physician according to where the procedure takes place.
- Adverse event reporting is regulated and mandatory within 48 hours of its occurrence, following a specific protocol.
- The hospital blood transfusion committees are stipulated by law, however their degree of functionality is limited. The new blood law draws specific provisions with respect to national haemovigilance systems.

9. Promotion of voluntary non-remunerated blood donation

- Promotion of voluntary non-remunerated blood donation is included in the current legislation of the blood service. In addition, one of the major objectives of the national blood programme is promotion and recruitment of voluntary non remunerated blood donors.
- No specific funds for promotion work are currently available, and there is no specifically trained staff in the network.
- The Foundation for Non-remunerated Blood Donors is working together with the BS on promotion and education activities. Several successful motivation/recruiting campaigns have been organized during the last 3 years.
- Efforts have been undertaken to reactivate collaboration with the local RC society and increase involvement of the civil society.

Serbia

1. General info on the country:

Size	77 474 Sq km
Population	7 498 000
Median age	40.4 years

2. Political level with responsibility for blood policy legislation

- The BS is under the Government through the Ministry of Health.
- MoH provides 0.5% from state budget for promotion of voluntary blood donation. The BS as part of the public health system is funded, directly or via the hospital budget, from the Health Insurance Fund.

3. Legal and regulatory framework

Legal documents regulating the functioning of the blood service and related areas

- Laws and regulations related to various aspects of BS have been collected in the code book on regulations for effective blood transfusion (includes new Act on health care and protection and new Act on

blood transfusion, 2006). Compliance with EU dedicated directives is observed in the framework of these new legal provisions.

- The national strategy for Serbian blood services was adopted in 2005 and foresees clear restructuring of the network by 2010.

Regulatory bodies/agencies

- There is no independent regulatory body for the BS, but this is foreseen in the both the national strategy and the new law.
- The National Agency for Medical Drugs is in charge of the registration and quality of medical devices (blood bags, reagents etc.) used in the BS, as well as the implementation of the national plasma programme.
- The National Haemovigilance Committee was founded 1996, but is still not functional.

4. Organization and structure of the blood transfusion system

- The BS is decentralized and is currently organized in three levels:
  - 3 Blood -transfusion institutes: 1 national and 2 regional, within university centres.
  - 44 Blood transfusion centres within various health care facilities (hospitals, health care centres, clinical centre).
  - 70 Blood transfusion departments/laboratories within hospitals, clinics and institutes.
- The plasma fractionation centre is located in the national Blood Transfusion Institute.
- The blood transfusion institutes and centres perform the full range of activities related to the blood chain, while the blood transfusion departments/laboratories are in charge of patient services only.
- The project for the reorganization of the Serbian blood service financed by the European Agency for Reconstruction was started in 2003.

5. Dedicated human resources

- A total of 194 physicians (of which 166 are transfusion medicine specialists) and 730 medical technicians and nurses are working in the BS.
- There is a 3 year national curriculum in transfusion medicine (medical university Belgrade) for training of medical doctors, and a one year dedicated training for technicians.
- A new act on health chambers foresees periodic licensing for physicians.

6. Quality management

- There is no national quality management system. In accordance with the defined national strategy, quality management systems will be implemented in all BS.
- Certified quality management system exists in Novi Sad transfusion Institute. The Blood transfusion institute of Serbia and the Regional transfusion Institute Nis are in the process of implementing quality systems under direct supervision of the national transfusion committee.
- Internal audits are partially functioning and annual external audits will be mandatory in the legal framework planned for 2007.

7. Blood donation

a) Donor selection process

- Documentation provided to donors is not nationally standardized.
- Donor selection criteria are nationally regulated and currently being revised for compliance with modern quality and safety requirements.
- Donors and donations are locally registered in manual or computerized registers. A national computerized information system for the BTS has been approved and implementation initiated.

b) Blood testing requirements

- Testing of all donated units is mandatory for hepatitis B and C, HIV, and syphilis. Testing is decentralized and currently performed at 47 centres. Plasma for fractionation is in addition tested for hepatitis-C virus by PCR-technique.

- The following table indicates prevalence of TTI markers in blood donor population in 2004.

	HBsAg	Anti-HCV	Anti-HIV
% TTI prevalence in blood donors	0.25	0.21	0.009

- Testing of all donated units is mandatory for blood groups ABO, RhD and screening for irregular antibodies.

c) Blood collection

- 232 174 units of whole blood and 5158 aphaeresis units (852 platelet concentrates and 4306 plasma donations) were collected in 2004.
- Mobile collection plays an important role, providing about 47.67% of the whole blood supply.
- All donors are voluntary non-remunerated, of which replacement donors comprise 19.4%. The 1st time donors accounted for 21.2% of all donations in 2004.
- There is no national donor register. A unified information system has been foreseen for implementation second half 2006.

7. Blood supply and demand

a) Supply of blood, blood components and plasma derived products:

- The following blood and blood components were produced and delivered in 2004:
  - Whole blood (27 073 units)
  - Red cell concentrates (194 755 units)
  - Fresh frozen plasma for transfusion (137 282 units)
  - Platelet concentrates (10 658 units plus 852 aphaeresis concentrates)
  - Cryoprecipitate (26 000 doses)
- All clinical needs for blood components are covered but there are no figures on total demand versus supply.

- Requirements for plasma derivatives are satisfied through local fractionation programme (albumin and immune globulins, 20% of request) and importation of products (e.g. 4 million I.U. of FVIII imported annually). In 2004, 13 000 litres of raw plasma were fractionated within the country.

b) Clinical management

- A number of national guidelines for clinical protocols and specific disease management are available. The guidelines are introduced through the National Transfusion Committee and distributed to all hospitals.
- All prescriptions of blood components for transfusion are done by the responsible physician and ordered on a nationally standardized request form. On the clinical side there is a standardized transfusion protocol and documentation routines.
- There is no haemovigilance system at national level, although related procedures are being carried out in large clinical centres. Hospital Transfusion Committees are being established. These already exist in some major health care institutions using transfusion therapies.

9. Promotion of voluntary non-remunerated blood donation

- The national BS strategy implies sustained activities for motivation, education and recruitment of voluntary non remunerated blood donors.
- Specific funding is dedicated at government level for the promotion of voluntary non remunerated blood donation, accounting for about 1% of the total health budget of the MoH.
- The BS and the Red Cross are in charge of these promotion and education activities. Several campaigns have been organized since 2003, such as 'Let life win', and 'Your 5 minutes-someone's whole life', under the auspices of the National Office of the President, MoH, RC, EAR and the three blood transfusion institutes.
- Efforts are being undertaken to bring together the various stakeholders involved, with media support, in promotion and education activities.

The former Yugoslav Republic of Macedonia

1. General info on the country:

Size			25 713	Sq km,
Population			2 045 262	
Median age			34,1	years
PPP US$ per capita (WHO estimates)	2003:	389	2004:	411
Total health expenditure as% of GDP :	2003:	7.1%	2004:	7.0%

2. Political and structural considerations

Political level with responsibility for blood policy legislation

- The BS is under Government responsibility, through the Ministry of Health.
- Financing of the BS is related to its organizational setting:
  - The National Institute for Transfusion Medicine (NITM) is funded from 3 different sources:
    - Health Insurance Fund (HIF) directly – personnel costs
    - State budget – promotion activities
    - Fee for service basis – back charge to hospitals
  - Hospital transfusion departments are financed from the hospital budget

- 1.15% of total health budget is estimated to be used for the BS, with no substantial change in the last 3-5 years.

3. Legal and regulatory framework

Legal documents regulating the functioning of the blood service and related areas

- The functioning of BS is regulated by various laws (specific articles) and additional acts from 1991 to 2004, including the Health Care law. The regulatory provisions of the 1989 blood law are being revised, towards the elaboration of a modern legal framework observing EU dedicated directives.
- A national plan and a national programme for the organization and improvement of blood donation are elaborated on a yearly basis.

Regulatory bodies/agencies

- Currently there are no official regulatory bodies or agencies.
- The National Commission for blood transfusion (advisory body to the MoH) is in charge of the development and updating of the National blood policy

4. Organization and structure of the blood transfusion system

- The BTS consists of one independent centre (NITM), 20 hospital based transfusion departments and 4 health care centre transfusion units. Out of the total of 25 BSs, 19 perform full range of blood chain activities.
- NITM has only an advisory/reference role at national level; all other BS are incorporated into the structure, hierarchy and budget of their hosting hospitals.
- Licensing and accreditation of BS are carried out only at their opening by the MoH, and not seen as a continuous, regular process.

5. Dedicated human resources

- A total of 81 transfusion medicine specialists are working in the BS (3 years postgraduate training), with a reported ratio of about 1.8 technical staff per doctor.

- Licensing applies only to physicians and is granted by the Macedonian Medical Chamber.
- 11 BS have reported that existing personnel is not sufficient.

6. Quality management

- There is no national or institutional quality policy. Quality work is fragmented and mainly relating to local routine procedures.
- Existing documentation covers primarily donors and donations (testing, processing, distribution cross match), and it is kept for a duration of 10 years.
- Quality monitoring and regular quality control are missing. Inspections are performed by MoH inspectors once a year, targeting mainly sanitary aspects.
- Internal audits do not function as systematic regular procedures, but are performed occasionally. The latest external audit took place in the year 2000.

7. Blood donation

a) Donor selection process

- Pro donation education materials produced by the local Red Cross Society are available and used on a national basis.
- Documentation provided to donors includes the self deferral questionnaire in 83% of BSs, and its format is subject to local variation.
- Donor selection criteria are regulated on a national basis, and require updating in line with latest EU requirements. About 24% BSs have no evidence of donor deferrals.
- Donors and donations are registered in local manual registers and there is no national donor register available.

b) Blood testing requirements

- Testing of all donated units is mandatory for hepatitis B (HbsAg), HIV (Anti-HIV), hepatitis C (Anti-HCV) and syphilis. Confirmation of positive tests is performed by the NITM. Donors with confirmed positive results are referred to the Clinic for infective diseases as patients.

- The table below indicates prevalence of TTI in blood donors (2004)

TTI	Screening test positive	Confirmation test positive
HBV	1,51%	1,32%
HCV	0,73%	0,53%
HIV	0,03%	0%
syphilis	0,39%	

- Testing of all donated units is mandatory for blood groups ABO, RhD and screening for irregular antibodies. About 80% of testing is performed locally.

c) Blood collection

- 54 758 units of whole blood and 170 aphaeresis platelet concentrates were collected in 2004 (slow but steady increase in total collection figures since 2001).
- The donor population consists of 82% regular/repeat donors, and 18% of 1st time donors.

8. Blood supply and demand

a) Supply of blood, blood components and plasma derived products:

- In the absence of national standards regarding the quality and safety of the blood components, the 1998 CoE guide (translated in local language) is used as reference at institutional level.
- Estimated values indicate 77% coverage of surgery requests and 84% coverage of internal medicine requests. No figures with respect to the real clinical need are currently available.

b) Clinical management

- There are no national or local guidelines on the clinical use of blood. The WHO dedicated manual has been translated into the local language and distributed to the specialists (reported degree of use around 68%).
- Prescription of blood components lies with the responsible physician. Administration of blood falls under the responsibility of the technician, after the compatibility check has been signed by the transfusion specialist.

- There is no national haemovigilance system in place. Standard forms for reporting of adverse events/reaction to blood transfusion are available, however these are not always recognized and/or reported accordingly.
- Only two hospitals have a transfusion committee (Skopje and Struga).

9. Promotion of voluntary non-remunerated blood donation

- The national blood donor programme is being developed on a yearly basis, with the Red Cross organization as the main partner.
- A specific budget is dedicated for the organization and improvement of voluntary non remunerated blood donation provided directly to the Red Cross.
- Three BS have specially trained staff for promotion activities (NITM, Veles, Prilep). In the remaining BS, promotion activities are undertaken by the transfusion medicine specialists.
- Even though the local Red Cross (RC) organization has staff in charge of promotion activities, these have not undergone dedicated training.
- Patient groups (Life spark- malignant diseases; and Hemolog-haemophilia) and associations of blood donors support on a random basis the BS and RC promotion activities.
- The NITM campaigns, such as 'Blood for everybody during summer'; 'Humanity on exam'; and 'Police and humanity' had good results within the targeted groups, encouraging further campaign planning and development.

ANNEXES

1. Dubrovnik Pledge
2. Skopje Pledge
3. National Reports Structure
4. Quality Assessment Questionnaire
5. Glossary
6. Country Managers

Annex 1

The Dubrovnik Pledge

Meeting the Health Needs of Vulnerable Populations in South East Europe

We the Ministers of Health of South East Europe (SEE), gathered here today at the Health Ministers' Forum for Regional Health Development Action in South East Europe recognize the damaging effects on health of recent wars, continuing unrest and conflict, as well as the economic hardships faced by the populations of SEE during their countries' transition to market economies. We accept the challenge to play a key role in strengthening the fundamental human rights of our societies and of vulnerable populations and individuals within them to effective health care, social wellbeing and human development, in line with the principles of the World Health Organization and the Council of Europe.

Focus on specific strategies

We, the Ministers of Health of: Albania; Bosnia and Herzegovina; Bulgaria; Croatia; Romania and the former Yugoslav Republic of Macedonia; and the Federal Secretary for Labour, Health and Social Welfare of Yugoslavia commit ourselves through government action to the following goals.

WE WILL WORK IN PARTNERSHIP with relevant national and international bodies and organizations: to ensure equity, health gain and a better quality of life and health care (including reduced inequalities in its infrastructure and balanced primary and secondary services and public health interventions for the populations of SEE); and to collaborate on issues of common concern, including the harmonization of policies, legislation and information systems, institutional capacity building and networking to build an infrastructure to pursue regional goals and future European integration.

WE WILL MEET THE HEALTH NEEDS OF VULNERABLE POPULATIONS IN SEE, mobilizing human and financial resources to the extent possible to:

- increase citizens' access to appropriate, affordable and high-quality health care services;
- intensify social cohesion by strengthening community mental health services;
- increase the quality of and regional self-sufficiency in the provision of safe blood and blood products;
- develop integrated emergency health care services that are offered free of charge to the user;
- strengthen the surveillance and control of communicable diseases;
- strengthen institutional capacity and intersectoral collaboration for access to affordable and safe food products; and
- establish regional networks and systems for the collection and exchange of social and health information.

Plea to international stakeholders

The Health Ministers' Forum for Regional Health Development Action in South East Europe recognizes the need for assistance from international stakeholders to achieve the goals of this Pledge.

WE LOOK TO the Council of Europe and the World Health Organization for strategic guidance in developing mechanisms to coordinate partnership with national and international agencies in the fulfilment of this Pledge and request their support in organizing a first meeting to monitor and evaluate the progress achieved by such partnership.

WE ASK THAT the international community assist, within the framework of the Stability Pact for South East Europe, by providing resources to support the implementation of the above-mentioned urgent action areas for health reconstruction and development. In so doing, we commit ourselves to transparency and dedication in the implementation and reporting of all project activities and their results.

WE REQUEST that the World Health Organization Regional Office for Europe and the Council of Europe report to their governing bodies about this Pledge and the progress achieved towards its goals.

SIGNATORIES

Albania	**Romania**
Ms Ruki Kondaj Secretary General of the Ministry of Health for The Minister of Health of Albania	Dr Daniela Bartos Minister of Health of Romania
Bosnia and Herzegovina	**The former Yugoslav Republic of Macedonia**
Dr Zelko Misanovic Minister of Health of the Federation of Bosnia and Herzegovina Dr Milorad Balaban Minister of Health of the Republika Srpska	Professor Petar Milosevski Minister of Health of the former Yugoslav Republic of Macedonia
Bulgaria	**Yugoslavia**
Dr Bojidar Finkov Minister of Health of Bulgaria	Dr Miodrag Kovac Federal Secretary for Labour, Health and Social Welfare of Yugoslavia
Croatia	**For the Secretariat of the Meeting**
Dr Ana Stavljenic Rukavina Minister of Health of Croatia	Mrs Gabriella Battaini-Dragoni Director General for Social Cohesion Council of Europe Dr Marc Danzon Regional Director for Europe World Health Organization

Dubrovnik, 2 September 2001

Annex 2

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

CEB
COUNCIL OF EUROPE DEVELOPMENT BANK

WORLD HEALTH ORGANIZATION
EUROPE

Second Health Ministers' Forum
With the special participation of ministers of finance

Health and Economic Development in South-Eastern Europe in the 21st Century
Skopje, The former Yugoslav Republic of Macedonia, 25–26 November 2005

EUR/05/5056095
15 November 2005
54634
Original English

The Skopje Pledge

STABILITY PACT
FOR SOUTH EASTERN EUROPE

SOUTH-EASTERN EUROPE HEALTH NETWORK

We, the Ministers of Health of Albania, Bosnia and Herzegovina, Bulgaria, Croatia, the Republic of Moldova, Romania, Serbia and Montenegro, and The former Yugoslav Republic of Macedonia, have gathered for the Second Health Ministers' Forum for health and economic development in South-eastern Europe in Skopje, The former Yugoslav Republic of Macedonia on 25 and 26 November 2005 with the purpose of discussing progress achieved towards the goals of the Dubrovnik Pledge.

Current situation

We acknowledge the importance of the role of the South-eastern Europe (SEE) Health Network - in partnership with the World Health Organization (WHO) Regional Office for Europe and the Council of Europe, supported by the Council of Europe Development Bank and in the framework of the Social Cohesion Initiative of the Stability Pact – in meeting the challenges related to the health needs of vulnerable populations in the SEE region.

We:

- recognize that health, as an integral determinant of social cohesion, and an investment and a major factor in development, is essential to lasting peace, stability and economic progress;
- recognize that regional cooperation in the field of health is a vital part of the European Union (EU) integration process;
- recognize that health and the health systems in the SEE region are facing important challenges;
- recognize that there is a need to continue to develop, strengthen and support work being carried out in this area in general and, in particular, to improve the access of vulnerable populations in society to the health services of the region;
- recognize that there is a need to promote the exchange of experiences within the area of health systems and health system reform, at international, regional and national levels;
- express our gratitude for the support received from international and bilateral institutions and governments, and particularly the important analytical and policy development work of the Council of Europe, the Council of Europe Development Bank and the WHO Regional Office for Europe.

Looking forward

Having reviewed the concerted action taken over the last five years in health development as a bridge to reconciliation, peace and development, we accept the challenge of reforming the health systems in the region and thus contributing to its economic development in the twenty-first century.

WE UNANIMOUSLY AGREE:

- to continue to cooperate beyond 2005 on the initiative: "Health development action for south-eastern Europe: the South-Eastern Europe Health Network" (hereinafter referred to as the SEE Health Network);
- to further consolidate the SEE Health Network alliance at regional level, according to its agreed Statutes, which form an integral part of this Pledge (Annex);

- to assume full responsibility for regional cooperation on health and health-related projects;
- to continue regional cooperation and concerted efforts to improve the health systems of the countries in the SEE region in order to secure universal access to high-quality public health services for the populations of the region, based on sustainable financing;
- to confirm our commitment to implement action in the thematic areas identified in the Dubrovnik Pledge and, in doing so, to develop and apply the common criteria and procedures outlined in the Statutes;
- to demonstrate the economic potential of health as a means to increase productivity and decrease public expenditure on illness: a healthy population works better and produces more;
- to strengthen regional collaboration and coordination on preparedness planning for emerging priorities and to put this forward as a priority for action within the SEE Health Network;
- to advocate that national governments should put health higher on the political agenda and ensure that health is reflected in the policies and strategies of other sectors;
- to empower health professionals to ensure a sustainable long-term improvement in public health.

WE COMMIT OURSELVES to transparency and dedication in the implementation and reporting of all project activities and their results.

Plea to international stakeholders

The Second Health Ministers' Forum on Health and Economic Development in South-Eastern Europe recognizes the need for assistance from international stakeholders to achieve the goals of this Pledge.

WE LOOK TO the Council of Europe and the WHO Regional Office for Europe for strategic guidance in further consolidating regional cooperation through concerted action to improve the health systems in the region and provide its populations with universal access to high quality health services. We also request their support in the further implementation of action related to the thematic areas outlined in the Dubrovnik Pledge and in fulfilling the commitments of this Pledge.

WE ASK THAT the international community assist by providing resources to support the implementation of urgent action for health and economic development in the above-mentioned areas. In doing so, we commit ourselves to transparency and dedication in the implementation and reporting of all project activities and their results, in accordance with the Statutes of the SEE Health Network.

WE REQUEST THAT the WHO Regional Office for Europe and the Council of Europe report to their governing bodies on this Pledge and the progress achieved towards its goals.

SIGNATORIES

Ministers of Health of the SEE Member States

ALBANIA
Dr Maksim Cikuli
Minister of Health

BOSNIA AND HERZEGOVINA
Mr Zlatko Horvat
Secretary, Ministry of Civil Affairs

BULGARIA
Professor Radoslav Gaydarski
Minister of Health

CROATIA
Professor Neven Ljubicic
Minister of Health and Social Welfare

REPUBLIC OF MOLDOVA
Professor Ion Ababii
Minister of Health and Social Protection

ROMANIA
Mr Vasile Leca, Charge d'Affaires a.i., Embassy of Romania to The former Yugoslav Republic of Macedonia

SERBIA and MONTENEGRO
Professor Miodrag Pavlicic
Minister of Health of the Republic of Montenegro

THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA
Professor Vladimir Dimov
Minister of Health

Witnessed in the presence of:

Partner States

BELGIUM
Ms Leen Meulenbergs
Advisor, Ministry of Health

GREECE
Dr Pavlos Theodorakis, SEE National Health Coordinator, Ministry of Health and Social Solidarity

NORWAY
Mr Wegard Harsvik
State Secretary, Ministry of Health and Care Services

SLOVENIA
H.E. Mr Marjan Siftar, Ambassador of Slovenia to The former Yugoslav Republic of Macedonia

SWITZERLAND
Mr Romain Darbellay,
Deputy Chief of Mission, Embassy of Switzerland to The former Yugoslav Republic of Macedonia

Partner Organizations

Council of Europe
Mr Alexander Vladychenko
Director General, Directorate General III-Social Cohesion

Council of Europe Development Bank
Mr Krzysztof Ners
Vice-Governor

Social Cohesion Initiative of the Stability Pact for South Eastern Europe
Mr Laurent Guye, Director of Working Table II-Economy

WHO Regional Office for Europe
Dr Marc Danzon
Regional Director for Europe

Skopje, The former Yugoslav Republic of Macedonia, 26 November 2005

Annex 3

National reports on blood policies, services and availability

1. General info on the country:

- Size, urban/rural, population (age and gender structure)
- GDP, HDI, health expenditure (% GDP)
- Health system perspective: describe the health system in general, private/public services, funding processes (state budget, health insurance fund, other sources), where/how the blood service lies

2. Political and structural considerations

Political level with responsibility for blood policy legislation

Decision-making level for the implementation of legislation (according to national setup, e.g. Ministry, national structure – e.g. national institute, regional centre etc)

- Legal responsibilities
- Financial responsibilities

Funding of the blood service:

Describe mechanism of financing (i.e. state budget, health insurance fund etc.)

- % of total health budget
- % of budget dedicated to staff, equipment and running costs
- evolution during last 3-5 years

3. Legal and regulatory framework

3.1. National blood policy and plan

- if a national policy and plan is in place, what is the needs assessment process that has been used

3.2. Legal documents regulating the functioning of the blood service and related areas – attach documents (English version where available is preferred); describe in a concise manner the content

- area regulated
- current/planned revision process, if any
- gaps identified – are/will these be addressed

- ☐ internal regulations to be quoted as well

3.3 Compatibility of existing national legislation with the EU directives and WHO and CoE recommendations for quality and safety of blood and blood components

- ☐ A comparative table indicating the correspondence/differences between the EU texts would facilitate their transposition at the appropriate time
- ☐ Implementation of WHO and CoE recommendations (grouped according to WHO key issues listed in the aide-memoir for national blood programmes)

3.4. Regulatory bodies/agencies

- ☐ Competent authority: independent regulatory body
- ☐ National agencies/institutions with regulatory functions
- ☐ Advisory bodies (national commission for blood transfusion, national commission for haemovigilance, etc – indicate if functional)
- ☐ Indicate if mentioned in current law or considered legislation

4. Organization and structure of the blood transfusion 'system'

- ☐ Number and type of blood institutions
- ☐ Licensing and/or accreditation of blood institutions (and who provides this service)
- ☐ Hierarchical structure of the service at national level
- ☐ Functions of existing blood institutions
- ☐ Relationship between blood establishments and blood banks
- ☐ Staffing issues: number, category of staff, training programme, adequacy, licensing

5. Quality management

- ☐ Quality policies: national, local or institutional levels
- ☐ Quality systems: describe the existing systems if any, availability and actual use
- ☐ Documentation: top management levels (e.g. quality manual) and executive levels (operational documents), record maintenance
- ☐ Inspection services and procedures: quality monitoring, quality control, self inspection
- ☐ Auditing systems: internal and external audit

6. Technical facilities

a) **Structural: location**/setting – indication of the structure with respect to buildings and facilities

b) **Technical: equipment** available

	Availability	Type	Age	Validation/ calibration
blood collection				
testing				
processing				
storage				
transportation				

- ☐ Maintenance procedures/programmes in place
- ☐ Indication of the recognized gaps/perceived needs in equipment availability

c) **Communication and information** technology equipment

- ☐ Communication systems between departments and centres
- ☐ Computer availability and use (register, traceability, info exchange between laboratories or institutions etc.)
- ☐ IT maintenance

7. Blood donation

a) Donor selection process

- ☐ Documentation provided to donors: type, use and uniformity (national scale)
- ☐ Donor identification (identification number, bar code etc.)
- ☐ Donor selection criteria (including age and donation intervals), whole blood and aphaeresis donors
- ☐ Questionnaire
- ☐ Medical examination carried out before donation
- ☐ Structure of donor deferrals, where available

b) Blood testing requirements

- Tests required and protocols
  - Transfusion transmissible infections (indicate prevalence of blood borne infections in the donor population and if available in the population at large)
  - Blood group serology
  - Biochemistry
- Location of testing (local, central etc)
- Archiving of samples (duration)

c) Blood collection

- Relative share of blood collection at fixed sites mobile and fixed blood collection
- Annual collection figure (latest available), including aphaeresis
- Evolution during the last 3-5 years

d) Structure of the donor population

- Overall trends in blood donation
- Type of blood donors: unpaid/family/paid, (non) remunerated, regular donor, repeat donor, first time donor
- Age, sex, rural/urban/regional distribution
- National registry of donors

8. Blood supply and demand

a) Supply of blood, blood components and plasma derived products (produced and/or imported):

- Type: components and products (annual figure and percentage of separation into components)
- Quantity: annual production figure/annual request
- Requirements (quality and safety standards related to the validated blood unit)
- Coverage of clinical request and where possible evaluation of real needs
- Possibility to import and export/exchange of blood and blood and blood components including requirements

b) Discarded blood and blood components/products

- Quantity (% out of total annual collection figure), if possible, provide trends for the last 3-5 years
- Cause: % per cause of discard
- Disposal process (including existing regulations)

c) Clinical management

- ☐ Guidelines availability and type of guidelines (international, national, local)
- ☐ Standardised request forms
- ☐ Responsibility of prescription/ordering/administration
- ☐ Pre transfusion protocols (i.e. compatibility testing)
- ☐ Availability of emergency procedures
- ☐ Communication blood service – clinical site
- ☐ Haemovigilance elements, including traceability and reporting schemes (adverse reactions)
- ☐ Hospital transfusion committees

9. Promotion of voluntary non-remunerated blood donation

- ☐ Legal and ethical provisions – if specifications related to donor promotion are quoted in any law or other legal document
- ☐ National blood donor programme
- ☐ Budget for donor promotion and its use
- ☐ Available trained staff
- ☐ Involvement of stakeholders
  - Clinicians
  - Patient groups
  - Red Cross and Red Crescent Societies, Associations of Blood Donors, other NGOs
  - Civil society
- ☐ Effectiveness of previous campaigns if the case

10. Outstanding issues

11. Conclusions

Annex 4

Quality Status Report for Individual BTSs

Background Information

1. Name of centre _____
2. Address of centre _____
3. Approximate number of units collected annually _____
4. Component preparation

Component	Prepared (Yes/No)	%prepared by single whole blood donation	%prepared by apheresis
Packed cells			
Fresh frozen plasma			
Cryoprecipitate			
Platelet concentrates			

5. What percentage of donations come from voluntary, non-remunerated blood donors? ☐

Quality Systems — Yes / No

1. Is the organizational structure defined and documented? ☐ ☐
2. Is the document authorized (signed) by the head of the centre? ☐ ☐
3. Is there a chart (organigram) that shows the organizational structure with authority, responsibility and accountability? (If yes, please attach a copy) ☐ ☐
4. Do all staff have a job description that specifies tasks, authority, all departments? ☐ ☐
   responsibilities and accountability? If no, in some departments? ☐ ☐
   State which _____
5. When are job descriptions reviewed?

Regularly?	When tasks change?	Rarely?

6. Is there a specific person appointed as the quality manager/ officer? ☐ ☐
   If yes, give the name of the person _____
7. What proportion of time does the person devote to this function?

100%	50-100%	<50%

8. Does the centre have a documented quality policy? ☐ ☐
9. Is there a quality manual available? ☐ ☐
   If yes, is this a current edition? ☐ ☐
10. Are there written procedures (SOPs)? all departments? ☐ ☐
    If no, in some departments? ☐ ☐
    State which _____
11. Is there a plan for regular review of documents? ☐ ☐
    If yes, when was the last review and how many documents were reviewed? _____
12. Are quality system documents controlled? ☐ ☐

Training

	Yes	No
13. Is there a training policy or strategy?		
14. Is there a system for assessing training needs for all staff?		

15. Staff training (please tick the appropriate box if applicable)

Type of staff	Training programmes	Curriculum developed	Training material	Technical training	Management training	On-going education
Medical personnel						
Blood donor motivators						
Blood donor counsellors						
Donor clinic staff						
Lab technicians						
Prescribers of blood						
Others (specify)						

	Yes	No
16. Is there a system for assessing the outcomes of the training programmes?		
17. Are staff trained to SOPs to ensure competency?		

18. When were staff last trained to ensure competency?

Type of staff	Last trained
Medical personnel	
Blood donor motivators	
Blood donor counsellors	
Donor clinic staff	
Lab technicians	
Prescribers of blood	
Others (specify)	

	Yes	No
19. Are records maintained of all training in the centre?		

Stock Control (Consumables)

	Yes	No
20. Does the centre have direct control over ordering?		
21. Is there a system of stock control?		
22. Has a minimum stock level been determined for each critical item?		
23. Are there documented procedures for the inspection of all critical supplies which are received? If yes, give a few examples _____		
24. Is stock maintained under the correct conditions? E.g. refrigerators		
25. Are those conditions monitored? E.g. temperature monitoring		
26. On approximately how many occasions in the last 12 months has your BTS run out of a critical item?		
27. Are there procedures in place for such occasions?		
28. Approximately how many kits or reagents were discarded in the last 12 months due to expiry?		

Quality Audits

	Yes	No
29. Is there a general policy on quality audits?		
30. Is there a documented audit schedule?		
31. Does the centre have trained auditors?		
32. Does the centre have authorized auditors?		

33. Last quality audits done

	Date of last audit	By whom
Internal		
External		

34. Non-conformances identified during the last audit

No. identified	No. not closed by due date

Equipment Yes No

35. Has all critical equipment been identified and documented? ☐ ☐
If yes, please provide a copy of the list

36. Is there a documented policy for validating new critical equipment? ☐ ☐

37. Is there a documented policy for calibration of all critical equipment? ☐ ☐

38. Are the methods for calibration documented? All equipment ☐ ☐
If no, some equipment ☐ ☐

State which _____

39. Do the methods include the frequency of calibration? ☐ ☐

40. Is there a maintenance schedule for all critical equipment? All equipment ☐ ☐
If no, some equipment ☐ ☐

State which _____

41. Are records kept of calibrations? ☐ ☐
Do these include when the calibration was done? ☐ ☐
Who did the calibration? ☐ ☐
What the result was? ☐ ☐

42. Are records kept of maintenance and repair? ☐ ☐

43. Is there a system to ensure that equipment is calibrated and maintained within the specified time period? ☐ ☐

44. How many pieces of equipment are currently not in use due to breakdown? ☐

45. Are refrigerators and freezers:
Alarmed? ☐ ☐
Connected to an emergency generator? ☐ ☐
Monitored? ☐ ☐

46. How often are the temperatures of refrigerators and freezers checked? ☐

47. How is the information from the check recorded? _____

Safety

48. Is there a documented policy on safety procedures at your centre? ☐ ☐

49. Is there a person responsible for ensuring safe work practices? ☐ ☐

50. Are there standard procedures (SOPs) covering the following safety issues:
Work related injuries? ☐ ☐
Waste disposal? ☐ ☐

51. Is there a specific area in training that ensures staff are aware of their responsibility regarding cleanliness and tidiness? ☐ ☐

Errors

52. Is there a documented policy or strategy for error reporting and handling? ☐ ☐

53. Does the policy include how to:
report errors? ☐ ☐
investigate errors? ☐ ☐
resolve errors? ☐ ☐

54. In the last 12 months:

	>20	20	10	<10	unknown
Errors reported					
Errors solved					

Blood Donor Clinic

	Yes	No
55. Is there an identified separate department responsible for blood donor management?	☐	☐

56. Are the following documents available for:

	SOPs		Information material	
	yes	no	yes	no
donor education?				
donor motivation?				
donor recruitment?				
donor retention?				
donor counselling?				

57. Is there a questionnaire used for donor selection?	☐	☐
58. Is epidemiological data used to target low-risk groups for blood donation?	☐	☐
59. Is there a blood donor register?	☐	☐
60. Does the register clearly differentiate between active and deferred blood donors?	☐	☐
61. Is data from donor selection activities monitored, analyzed and acted on?	☐	☐
62. Is data received from the laboratory regarding positive results monitored, analyzed and used?	☐	☐

Laboratory testing

63. Is there a documented policy or strategy for tests done on donated blood?	☐	☐
64. Are there standard procedures (SOPs) for:		
HIV testing?	☐	☐
HBsAg testing?	☐	☐
HCV testing?	☐	☐
Syphilis screening?	☐	☐
ABO grouping?	☐	☐
Rh grouping?	☐	☐
Antibody screening?	☐	☐
65. Control used on testing for transfusion-transmissible infections:		
Internal quality controls (IQC)?	☐	☐
Controls graphed?	☐	☐
Validation of test runs based on kit controls?	☐	☐
Validation of test runs based on IQC?	☐	☐
66. Are records maintained of invalid test runs?	☐	☐
67. Is there a documented system for ensuring the accuracy of data entry/transcription?	☐	☐

68. What control are used in blood group serology? _____

_____

69. How frequently are the blood group serology controls used? ☐

70. Which of the following are recorded about tests done:

date of test?	☐	☐
person performing test?	☐	☐
name, batch no., and expiry date of reagents/kit used?	☐	☐
results of calculations?	☐	☐
whether the test run was valid?	☐	☐

any other? _____

71. Are there any circumstances under which you would accept results from invalid runs? ☐ ☐

Briefly describe the circumstances and how you would control this? _____

_____

_____

Laboratory testing contd. Yes No

72. Are there any circumstances under which you would use expired reagents or test kits? ☐ ☐
Briefly describe the circumstances and how you would control this? _____

_____

_____

73. Does the testing laboratory participate in an external quality assessment scheme (EQAS) for:
TTI testing? ☐ ☐
Blood group serology? ☐ ☐
Please state the names of the schemes and the tests covered: _____

_____

Processing of blood products

74. Are there documented specifications for each product made? ☐ ☐
75. Are there standard procedures (SOPs) for the production of each product? ☐ ☐
76. Are there records of quality monitoring of production? ☐ ☐
77. Is the data from quality monitoring analyzed on a continuing basis? ☐ ☐
78. Are there formal written quarantine/release procedures? ☐ ☐
79. Is there a system of blood stock control? ☐ ☐
80. Percentage of expired products:

Blood group	**Whole blood**	**Packed cells**	FFP	Platelet concentrates
O RhD pos				
A RhD pos				
B RhD pos				
AB RhD pos				
O RhD neg				
A RhD neg				
B RhD neg				
AB RhD neg				

Clinical Interface Yes No

81. Are there standard procedures (SOPs) for:
Cross matching? ☐ ☐
Issue of blood and blood products? ☐ ☐
Managing adverse transfusion reactions? ☐ ☐
Investigating post transfusion infections? ☐ ☐
82. Is there a system for monitoring turn-around time? ☐ ☐
83. Are there guidelines for the clinical use of blood? ☐ ☐
84. Is there a system for auditing the guidelines? ☐ ☐
85. Is there a standard blood request form? ☐ ☐
If yes, please provide a copy.
86. How many of the hospitals to whom you provide blood have hospital transfusion committees? ☐
87. Is there a documented blood order schedule for surgical cases? ☐ ☐
88. Are there established criteria for monitoring the activities of the cross match laboratory? ☐ ☐
89. What is the cross matched to transfused ratio? ☐ ☐
90. Has the laboratory ever had to carry out a formal look-back? ☐ ☐
If yes, how successful were you in tracing all the applicable records? _____

91 Are alternatives to human blood available? Please give the products used _____

Annex 5

Glossary (compiled definitions WHO, CoE, EC)

Advocacy: The actions of a person who has been given the power by a consumer to speak on her or his behalf, who represents the concerns and interests of the consumer as directed by the consumer, and provides training and support to enable consumers to better represent themselves.

Accreditation: A cyclical quality improvement process whereby an organization, programme, or individual is assessed against a set of standards to determine if this organization, programme or individual meets or exceeds standard criteria.

Audit: Systematic, independent and documented examination to determine whether activities comply with a planned and agreed quality system. Systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled – ISO 9000 (2000).

Audit programme: Systematic, independent and documented examination to determine whether activities and related results comply with a planned and agreed quality system.

Benchmarking: The study of a competitor's product or business practices in order to improve the performance of one's own company.

Blood establishment: Any structure or body responsible for any aspect of the collection and testing of human blood or blood components, and their processing, storage and distribution.

Blood bank: Hospital unit which stores, distributes and performs compatibility tests on blood and blood components for use the hospital, including hospital based transfusion activities.

Calibration: The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard.

Civil society: Political, social and cultural collectives that exist between the level of the individual and the level of state which lie beyond the control of the state and are safeguarded by the rule of law e.g. civil, religious and professional associations and trade unions.

Clinical interface: The relationship between the producers and users of blood and blood products.

Compliance: A product or a service that is meeting predetermined standards (required standards).

Consistency: Doing the same thing time after time, which makes the outcome more predictable and allows for reduced variation in products and processes.

Continuous quality improvement: The ongoing improvement process at the centre of all quality systems: plan, do, check and act, as encapsulated in the Deming Cycle.

Corrective action: Action taken to eliminate the cause of a detected nonconformity or other undesirable situation – ISO 9000 (2000).

Deming cycle: The plan-do check-act cycle.

Document control: Formal control of the issue, use and review of authorized documents within the quality system.

Documentation: Written policies, instructions and records involved in providing a product or services; information and its support medium.

Effectiveness: Measure of the extent to which planned activities are realized and planned results achieved.

Efficiency: Relationship between the result achieved and the resources used – ISO 9000 (2000).

Error: An incident where the quality system has failed.

Evaluation: The process describing measurement of the value or worth of a programme or service.

External quality assessment (EQA): The external assessment of performance using samples of known but undisclosed content, and comparison with the performance of other laboratories. An external quality assessment scheme is required for regular monitoring and evaluation of performance, organized at national, or regional level.

External quality assessment scheme (EQAS): A recognized scheme for organizing EQA. This can be a local scheme or organized at national, regional or international levels.

Good manufacturing practices: The part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate for their intended use and legal requirements.

Haemovigilance: Organized surveillance procedures related to monitoring, reporting, investigation and follow up of adverse incidents/near misses related to all blood transfusion activities.

Indicator: Information gathered directly or indirectly at the critical control points in a process or procedure.

Infrastructure: System of permanent facilities and equipment of an organization – ISO 9000 (2000).

Inspection: Conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging.

Internal quality assessment (IQA): The assessment of a laboratory's overall quality system by the process of halving a sample, analysing each half in the same manner and comparing the results.

Management system: System to establish policy and objectives and to achieve those objectives.

Monitoring: The continuous measurement and observation of the performance of a service or programme to see that it is proceeding according to the proposed plans and objectives.

National blood authority: The highest policy formulation and decision making body under the national health authority for issues pertaining to blood services in the country. All major stakeholders in the blood transfusion process are usually represented in this authority.

National blood policy: a statement of intent by the national health authority that defines the organizational, financial and legal measures that will be taken to ensure the quality, safety, availability and accessibility of blood transfusion within the country.

National blood programme: The government programme with overall responsibility for planning, implementation and monitoring of all activities related to blood transfusion throughout the country. Responsibility of the implementation of the blood programme may be fully or partially delegated to a governmental or non-governmental organization designated as the national blood service.

National blood service: the organization with statutory national responsibility for the provision of blood for transfusion and liaison with clinical services for the appropriate use of blood for patient care. The national blood service coordinates all activities concerned with blood donor recruitment and collection, testing, processing, storage and distribution of blood and blood products, clinical use of blood and surveillance of adverse transfusion events. Activities are carried out within a network of national/ regional blood centres and hospital blood banks.

Organizational structure: Orderly arrangement of responsibilities, authorities and relationships between people – ISO 9000 (2000).

Performance indicators: Statistical data and measures of clinical, social, vocational and economic outcomes.

Prevalence: The percentage of the population suffering from a disorder at a given point in time or during a given time.

Prevention: Intervention that occur before the initial onset of a disorder. Preventive interventions can be targeted universally at the general population, and selectively at population subgroups or individuals whose risk of being subject to transfusion therapy is increased. Changes to risk and protective factors generally require long term sustained efforts across multiple efforts sectors of the community at large and government.

Procedure: Specific activity that forms the basic unit of a process. Specified way to carry out an activity or a process – ISO 9000 (2000).

Quality: Totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs. Ability of a set of inherent characteristics of a product, system or process to fulfil requirements of customers and other interested parties – ISO 9000 (2000).

Quality evaluation: Systematic examination of the extent to which an entity is capable of fulfilling specified requirements. Progression in the principles of a quality system from inspection, quality control, quality assurance, total quality management.

Quality improvement process: A process that measures performance, identifies opportunities for improvement in the delivery of care and services, and includes actions and follows up.

Quality management system: System to establish a quality policy and quality objectives and to achieve those objectives.

Quality manager: The appointed, responsible and authorized individual within a organization with the responsibility for developing and managing the quality system.

Quality manual: Document specifying the quality management system of an organization – ISO 9000 (2000).

Quality plan: Document specifying the quality management system elements and the resources to be applied in a specific case – ISO 9000 (2000).

Quality policy: Overall intentions and direction of an organization related to quality as expressed by top management – ISO 9000 (2000).

Quality system: Organizational structure, processes, procedures and resources needed to implement quality requirements.

Record: Document stating results achieved or providing evidence of activities performed – ISO 9000 (2000).

Resources: Elements that are put into the mental health service. E.g. facilities, staff (human resources), medication and vehicles.

Serious adverse event: Any untoward occurrence associated with the collecting, testing, processing, storage and distribution of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients, or results in prolonged hospitalization or morbidity.

Stakeholders: Individuals or groups who have an interest in the policy issues or decisions. They comprise a wide range of groups, with various degrees of organization, resources and influence, however involved in the process in a direct or indirect manner, including decision making level, medical profession, carers, producers and consumers.

Standard operating procedure: Written instructions for the performance of a specific procedure.

Traceability: Ability to trace the history, application or location of that which is under consideration – ISO 9000 (2000).

Validation: That part of a QA system that evaluates in advance the steps involved in operational procedures or product preparation to ensure quality, effectiveness and reliability (GMP). Confirmation and provision of objective evidence that the requirements for a specific intended use or application have been fulfilled – ISO 9000 (2000)sp.

Voluntary non-remunerated blood donor: A person in good health with a good medical history who gives blood/plasma for therapeutic use voluntarily and freely without receiving any form of payment in return.

Work environment: Set of conditions under which a person operates – ISO 9000 (2000).

Annex 6

List of project managers

REGIONAL PROJECT MANAGER

Dr Alina Mirella Dobrota

Director

Regional Blood Transfusion Centre

Constanta, Romania

NATIONAL PROJECT MANAGERS

Albania

Dr Irena Seferi

Director

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Republic of Moldova

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Romania

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