

South-eastern Europe Health Network



Current status and future strategies in Safe
Blood and Blood Components Transnational
Availability for Medical Emergencies and Special
Circumstances, in South Eastern Europe



SEE Regional Health Development Centre for Blood Safety

**Current status and future strategies in safe
blood and blood components' transnational
availability for medical emergencies and special
circumstances, in south-eastern Europe**



**World Health
Organization**

REGIONAL OFFICE FOR **Europe**

ABSTRACT

The present analysis is focused specifically on the response of blood services to internal or external emergency situations in south-eastern European (SEE) countries, using data provided by national, multidisciplinary teams, within the context of the SEE Health Network (SEEHN) and blood safety project activities. Blood services cover the demands for blood components and products for transfusion therapy, which are essential to keep patients alive. Therefore, specific preparedness action plans for external and internal emergencies pertaining to the coordinated operability of blood services should be part of the local, regional and national contingency plans.

Keywords

Blood transfusion

Safety management

Europe, eastern

Europe, southern

Address requests about publications of the WHO Regional Office for Europe to:

Publications

WHO Regional Office for Europe

Scherfigsvej 8

DK-2100 Copenhagen Ø, Denmark

Alternatively, complete an online request form for documentation, health information, or for permission to quote or translate, on the Regional Office web site (<http://www.euro.who.int/pubrequest>).

© World Health Organization 2011

All rights reserved. The Regional Office for Europe of the World Health Organization welcomes requests for permission to reproduce or translate its publications, in part or in full.

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either express or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use. The views expressed by authors, editors, or expert groups do not necessarily represent the decisions or the stated policy of the World Health Organization.

CONTENTS

Acknowledgments	iii	Part 2: Report of the first training of trainers in increasing transnational availability of safe blood and blood components for medical emergencies and special circumstances	32
Part 1: Current status and future strategies in safe blood and blood components' transnational availability for medical emergencies and special circumstances, in south-eastern Europe	4	Background	33
Summary	5	Introduction	34
Introduction	6	Presentations and national reports	35
Development of the SEE blood safety project	6	European Commission (EC) legal framework and WHO recommendations and guidelines for blood and patient safety	35
The SEE Regional Health Development Centre for Blood Safety	8	CoE/EDQM recommendations and guidelines for safe blood components, products and services	35
Regional overview of the capacity of BS to respond to emergencies and special circumstances	8	Blood donor management and prospective evaluation of blood needs	36
Methodology	9	Voluntary, non-remunerated blood donation: ethical and social features in emergency situations and special circumstances	37
Results	10	Emergency operation plans for blood transfusion in special circumstances	37
General information	10	Principles of mass casualty incidents (MCI) and hospital preparedness plans	38
Health-care services	11	Romanian approach to MCI management – a case-study	38
Blood supply management in special circumstances	15	Best practice protocols for clinical safety in disaster situations	39
Discussion	24	Maintaining an adequate blood supply in case of a pandemic	40
Health-care services/Blood services	24	West Nile virus outbreak management in Romania in 2010 – a case-study	40
Blood supply management in special circumstances	25	Transfusion medicine education in medical emergencies: the European School of Transfusion Medicine (ESTM) experience	41
Case-studies	26	Quick alerts and monitoring systems for transfusion medicine in emergencies	42
Conclusions and recommendations	26	Slovenian experience on blood service response in emergencies	42
Organization of BS	27	National reports	43
Legal or regulatory provisions for BS emergency response should be implemented	27	Development of a 'Moodle' electronic platform for e-learning and information exchange	48
Quality Management Systems	27	Conclusions and recommendations	49
Donors, blood donations and availability of blood supplies	27	Issues identified and targets proposed	49
National information system	28	Emerging recommendations	49
Blood supply management in special circumstances	28	Annex 1 Questionnaire for data collection and glossary	51
Communication	29	Annex 2 Programme of work	57
References	30	Annex 3 List of Participants	59

Acknowledgments

This publication draws from contributions from the SEE country project managers and their multidisciplinary teams: Dr Irena Seferi (Albania), Dr Dragan Sarenac (Bosnia and Herzegovina), Professor Andrei Andreev (Bulgaria), Dr Dorotea Sarlija (Croatia), Dr Gordana Rasovic (Montenegro), Dr Svetlana Cebotari (Republic of Moldova), Dr Laura Pacurariu (Romania), Dr Snežana Jovanovic Srzentic (Serbia), and Dr Risto Dukovski (the former Yugoslav Republic of Macedonia).

The regional analysis of the compiled dedicated reports provided by participant countries was performed by Dr Fatima Nascimento.

Particular thanks go to Dr Gilles Follea for his support in drafting the meeting report presented in the second part of the publication, and to Marie Emmanuelle Behr Gross for her insight during the publication development.

The financial support from the Government of Slovenia and from the Council of Europe / European Directorate for the Quality of Medicines and HealthCare to develop the background work and to print this publication is gratefully acknowledged.

Special thanks for their dedication and support go to Dr Maria Ruseva, Regional Adviser Public Health Services, Dora Mircheva Dimitrova, Technical Officer, Public Health, Division of Health Systems and Public Health, from the World Health Organization (WHO) Regional Office for Europe; and to Dr Alexandre Berlin, Honorary Director of the European Commission.

The technical editing of this publication has been done by Dr Olivia Ligia Burta, head of the South-eastern Europe (SEE) Regional Health Development Centre for Blood Safety in Oradea, Romania and Dr Valentina Hafner, Programme Manager Health Care Quality, Division of Health Systems and Public Health, WHO Regional Office for Europe.

Part 1:

**Current status and future strategies
in safe blood and blood components'
transnational availability for
medical emergencies and special
circumstances, in south-eastern
Europe**

Summary

Blood services (BSs) have been experiencing, during the last ten years, major structural reforms across Europe, in the continuous search for ensuring adequate, safe and cost-efficient performance and blood supplies that respond to national and sometimes cross-border needs. The rapid development of existing and new testing and processing technologies has increased public expectations in terms of safety and quality of medicinal products for transfusion therapy. Novel clinical technologies have allowed for better treatment of conditions requiring blood transfusion, but have also generated new demands for blood components and products, integrated in more complex treatment schemes for other pathologies. These issues have led to increased pressure on the economics and capacity of delivery of BSs.

While literature quotes various generic figures for a self-sufficient blood supply, this is ultimately translated into the BS capacity to cover national needs in blood and blood components for transfusion. These needs are variable, and correspond to the national morbidity patterns, the existing level of health-care capacities, and the structure and distribution of the population. The BSs also have to respond to the additional challenges generated by emergencies and special circumstances, when these occur.

Emergency requests in response to traffic injuries, accidents, or other unpredictable situations of a higher magnitude, such as natural disasters or mass casualties, require a predictable and planned degree of flexible arrangements, allowing for an immediate response from BSs.

The ability to respond to special circumstances demands appropriate coordination of various activities, good communication plans, and the involvement of different technical and medical staff who are trained to operate in a context requiring particular skills, often deployed in an unusual set-up. Contingencies related to operating equipment breakdown or a disruption of disposable medical devices also have to be considered in particular circumstances.

Despite the fact that BS are not front-line services in emergency situations, their capacity to cover the demands for blood components and products for transfusion therapy is essential to keep patients alive. Therefore, specific preparedness action plans for external and internal emergencies pertaining to the coordinated operability of blood services should be part of the local, regional and national contingency plans.

The present analysis is focused specifically on the response of BS to internal or external emergency situations in south-eastern European (SEE) countries, using data provided by national, multidisciplinary teams, within the context of the SEE Health Network (SEEHN) and blood safety project activities.

The SEE countries have different levels of development concerning emergencies or special circumstances, which is perhaps a reflection of the status of health-service development and the implementation of quality management systems.

Although all SEE countries have the capacity to respond to emergency situations, as presented in the case-studies, many countries reported various degrees of inadequacy, reflected by incomplete documentation, coordination, and revision of emergency plans, and an absence of education and team training through appropriate drills, and effective communication.

Recommendations addressing the improvement of the services are presented as concluding remarks of the analysis.

Introduction

Blood transfusion is a life-saving therapy and often a relatively common procedure in emergency medicine. In order to ensure safety and a quality outcome, blood supplies and patient blood management should follow updated regulatory requirements and draw from the best available evidence. National guidelines for the use of blood and blood components in emergency situations are of great importance in order to avoid poor control and inconsistencies in the administration of these blood components and products. Appropriate management of trauma patients includes the rapid recognition of potential bleeding sources and the implementation of measures to minimize blood loss and restore tissue perfusion. Massive transfusion protocols, used for the treatment of uncontrolled haemorrhage, especially in emergency situations, improve patients' outcome and simplify and standardize transfusion practices [1]. In Europe, a Task Force for Advanced Bleeding Care in Trauma, with experts coming from surgery, anaesthesia, emergency medicine, intensive care medicine and haematology/transfusion medicine, formulated specific recommendations for the management of trauma patients, including the use of blood components and derivatives [2].

The role of blood transfusion services is crucial in human and natural disasters, which simultaneously affect a high number of the population that represent both the potential blood donors and the potential recipients. Preparedness plans [3, 4] assist BS to react immediately in a consistent and coordinated manner, independent of the situation, for example, a disaster with a high request for blood components or an epidemic/pandemic situation where the number of blood donors available is greatly affected. It is therefore advisable that countries have contingency plans and that institutions have preparedness plans to face uncommon circumstances.

Development of the SEE blood safety project

The SEEHN was established in 2001. It is a political and institutional forum set up by the governments of Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Montenegro, the Republic of Moldova, Romania, Serbia and the former Yugoslav Republic of Macedonia to promote peace, rec-

onciliation and health in the region. The WHO Regional Office for Europe lends technical support to the SEEHN's various health projects, and supplied its secretariat, along with the Council of Europe, from 2001 to 2009. On 1 January 2010, the SEEHN took over ownership of the regional cooperation for health and development under the auspices of the Regional Cooperation Council (RCC) and the SEE Regional Cooperation Process. The SEEHN proved to be of crucial importance in the development of the public health sectors in the participant countries, and achieved major political and technical results based on enhanced partnership, sharing of experiences and cross-fertilization of ideas.

Blood safety is one of the key priorities that require immediate action to ensure public health strengthening as identified by the SEEHN, and formally endorsed by the National Health Authorities of the participating countries.

The project "*Blood safety – increasing regional self-sufficiency in safer blood and blood components*" aims to increase quality and regional self-sufficiency in the provision of safe blood and blood products and is being implemented as a follow-up to the commitment of the south-eastern European Ministers of Health (Dubrovnik Pledge) in the framework of the Stability Pact Initiative for Social Cohesion. This commitment was reiterated by the Second Health Ministers Forum in 2005 (Skopje Pledge). The project (led by Romania), was supported by the Government of Slovenia, Switzerland, the Council of Europe, the WHO Regional Office for Europe, and the nine participating countries. During the period 2005-2009, two project components were developed and implemented with successful outcomes, as described below.

Component One of the project, "*Strengthening mutual trust and acceptability of the quality of blood in the SEE region*", was completed successfully in 2006, achieving a health-system-based assessment of national blood services and the subsequent development/reinforcement of national blood safety policies in participant countries. This was a major step forward in the process of regional harmonization, promoting common principles and internationally agreed policies and practices in the field of blood safety, and reinforcing mutual trust on the quality of blood supplies in the region.

Component Two of the project, “Increasing transnational availability of safe blood and blood components for medical emergencies and special circumstances”, was launched in April 2008, in Ljubljana, with the financial support of the Government of Slovenia.

The main purposes of this component were to develop a common framework for national programmes on voluntary, non-remunerated blood donation (VNRBD); to achieve self-sufficiency in safe blood; to strengthen the knowledge, implementation and use of Quality Management Systems (QMS); and to set up an information system on stock management and availability for special circumstances, as presented in Figure 1.

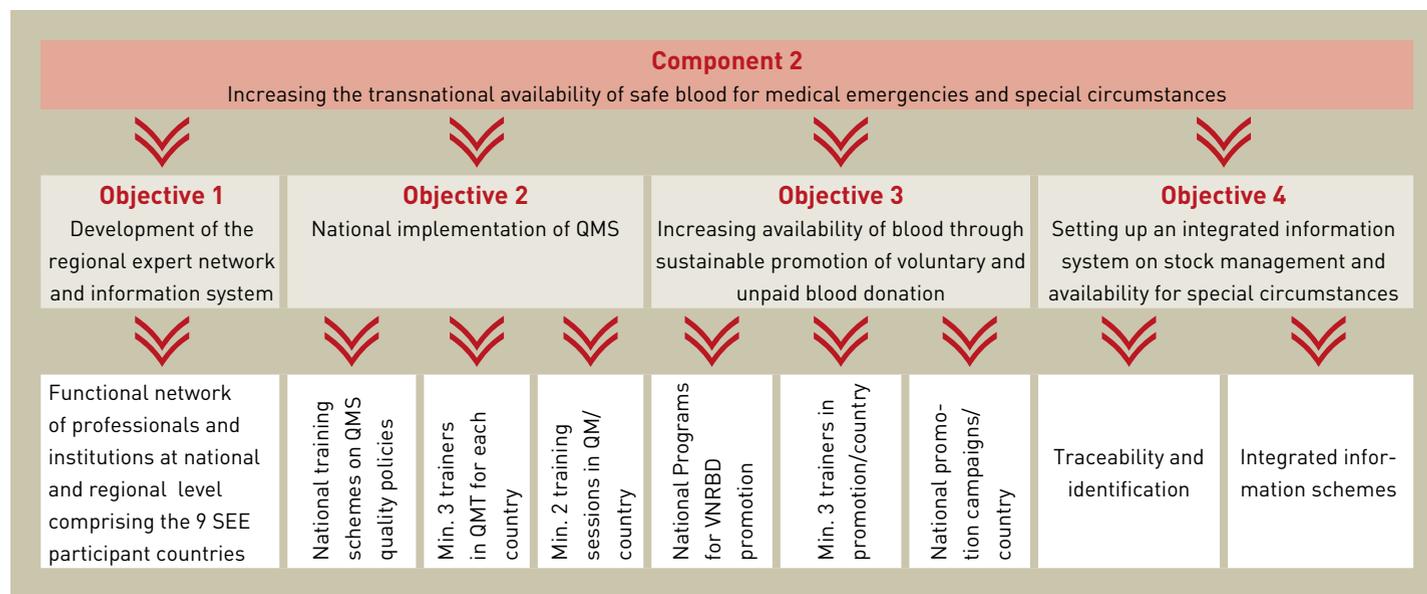
Once Component Two was partially completed in 2009, the relevance of the remaining objectives led to an extension of the timeframe for two more years (Addendum to Component Two), to reinforce the regional capacity of the response of blood services to emergencies and special circumstances [5].

The SEE Regional Health Development Centre for Blood Safety

The Memorandum of Understanding on the Future of the SEEHN signed in April 2009 reinforced the goal of the SEEHN to improve, on a sustainable basis, the health of the SEE population through regional cooperation. Subsequently, the Regional Health Development Centres (RHDCs) were established in June 2011, in Sofia, to act as coordinators of the respective technical networks.

The RHDC for Blood Safety was opened in 2011, and is hosted by the Regional Blood Transfusion Centre Oradea, Romania. Its overall goal is to contribute towards increasing quality and regional self-sufficiency in the provision of safe blood and blood products. This is expected to be reached through the exchange of knowledge and good practices in strengthening the BS through the established network. Capacity building exercises will be developed in close cooperation with health authorities, to support strengthening safety and availability of blood supplies, meet clinical needs and ensure patient safety.

Figure 1 – Component Two - Objectives



The RHDC initiated its work in June 2011, with a multidisciplinary training of trainers dedicated to blood supply management in emergencies and special circumstances. This first capacity building exercise started a dedicated review of the emergency response abilities of the blood service in the nine SEE participant countries. Based on this initial experience, a dedicated curriculum is under development, fostering integration of health and social services. At the training, a dedicated electronic platform was set up to enhance communication and information exchange within and beyond the professional blood safety network.

Regional overview of the capacity of BS to respond to emergencies and special circumstances

The regional analysis that follows has been developed using the national reviews and the questionnaire developed during the meeting mentioned above and briefly describes the capacity of the BS to face emergencies or other special circumstances in the SEE countries. A report of the meeting is presented in the second part of this document.

Methodology

The analysis was based on data provided by the national project managers and their multidisciplinary teams. National data was collected using a questionnaire developed for the purpose.

The questionnaire was drafted through a consultation process and was successfully piloted as background structure for the SEE country presentations in the June event in Oradea. The questionnaire format was subsequently finalized with the contribution of all participants during the meeting in Oradea. A glossary covering the key terminology used was added to ensure a common understanding during the data collection process (Annex 1).

The completed questionnaire and the national report were complemented by national case- studies, illustrating in practical terms the modalities and speed of addressing emergency situations in the field.

Data provided was not always complete, reflecting the diverse organizational set-ups and the local capacity of multidisciplinary data management.

This analysis should be seen as the first of its type with a subregional/regional perspective.

Results

The compiled analysis of questionnaires, national reports and case-studies reveals different levels of development in countries that have moved out from a totalitarian regime, some of them having had major changes, either in population or in borders.

Some of the reports provided incomplete information, which can be justified by the difficulty to collect data outside the structures of the BS and related to a specific year.

General information

The SEE countries have a cumulative number of about 53 701 628 inhabitants, distributed as presented in Table 1. Regardless of the differences in gender population among the nine SEE countries, there is an overall predominance of females, which corresponds to 51.1% of the SEE region population.

About 65% of the population is in the age group from 15(18) to 64 years old, identifying a great theoretical potential to increase the number of blood donors. However, the mean and median ages of the population in SEE countries are very different, ranging respectively from 28.6/29.9 in Albania to 41.5/45 in Bulgaria.

Table 1- Demographic data

Country	No. of inhabitants	Gender %		Distribution			Age	
		male	female	0-15(18)	15(18)-64	>64	mean	median
Albania	3 195 000	50.9	49.1	27.0	65.0	8.0	28.6	29.9
Bosnia & Herzegovina	3 860 171	48.83	51.17					
FBIH	2 424 992	48.9	51.1	17.9*	67.2*	13.96	38.44**	
RS	1 435 179	48.6	51.33	18.4	62.03	19.52	40.8	
Bulgaria	7 364 570	48.7	51.29	13.19	68.3	18.49	41.5	45
Croatia	4 290 612	48.0	52.0	15.1	68.1	16.8		41.4
Republic of Moldova	3 560 400	48.1	51.9	17.8	66.7	15.5	36.3	
Montenegro	626 048	51.0	49.0	20.60	66.60	11.9	35.9	
Romania	21 431 298	48.68	51.31	20.75	64.34	14.9	39.6	38.76
Serbia	7 320 807	48.6	51.3		61.83		41	41
The former Yugoslav Republic of Macedonia	2 052 722	50.12	49.88				37.2	

* Age groups from 0–14 and 15–64

** Mean age only from Brcko District

FBIH = Federation of Bosnia and Herzegovina

RS = Republika Srpska

Health-care services/Blood transfusion services

Organization and financing

All SEE countries and federations have public BS, under the direct responsibility of the Ministry of Health. While national policies for the BS are common, the way the BS are organized shows a degree of diversity.

Most of the countries are in the full process of restructuring their blood services towards national coordination, and to comply with European Union (EU) requirements, WHO and Council of Europe (CoE) recommendations and guidelines. BSs are essentially part of the public sector and non-profit services, although Croatia has one private hospital blood bank.

The majority of SEE countries present a mixed system. BSs are independent (separate from hospitals as a service), however, a certain number of hospital-based BSs perform all or part of the activities of the blood establishments (Albania, Bosnia and Herzegovina, Bulgaria, Croatia, the Republic of Moldova and Serbia).

Montenegro is the only country with a very high number of totally hospital-based BS. The new structure, approved by the Government, consists of an Institute of Transfusion Medicine (NITM) coordinating the network, and eight regional branches located in hospitals. The restructuring process is under development.

Romania and the former Yugoslav Republic of Macedonia are the only countries where the blood establishments have an individual structure: the National Blood Transfusion Institute (BTI) in Romania, and the National Institute of Transfusion Medicine in the former Yugoslav Republic of Macedonia, that lead, organize, and technically and financially coordinate all activities of the BS. In Romania, the exception is the military blood transfusion centre, which is financially dependent on the Ministry of Defence. In the former Yugoslav Republic of Macedonia, the 19 transfusion medicine hospital units are also, since December 2010, under the organizational and financial management of the National Institute of Transfusion Medicine.

The SEE countries have different regulations over where blood transfusions can be performed. Whereas in some countries, blood transfusion is performed in almost all types of health-care facilities, in others, blood component transfusion is permitted only in hospital settings. The vast majority is carried out in public institutions.

Governments are generally responsible for the BS. Economic support is provided directly or indirectly through the Ministry of Health or Health Insurance Funds respectively, as for other public health-care services. Only a small portion of financing comes from private sources. Ambulance services are financed by Health Insurance Funds, usually under contract. When in place, the prices of blood components are national and usually approved by the Ministry of Health, and in the majority of cases are based on the costs incurred to obtain the blood components in each country.

Table 2 presents, in a very basic format, the public/private split in relation to BS, as reported by participant countries.

The reimbursement for blood components is essentially performed by the Government, directly or indirectly, through a budget from the Ministry of Health or through Health Insurance Funds paying blood components units. For this reason, the majority of countries issue blood components to hospitals free of charge, others are reimbursed according to contracts, or charge only for the blood components that exceed the annual contractual agreement. In some countries, only the blood components issued to private services are paid for.

Blood donors/donations and annual demands

The reported numbers of blood donors are difficult to compare due to a lack of national centralized information technology (IT) and a lack of a common definition of an "active donor". For example, two participant countries consider an "active donor" a donor that has given blood more than twice during one year, while other countries consider an "active donor" to be a donor who has given blood at least once during one year.

The consolidation of voluntary, non-remunerated blood donation is still in progress in three countries (Albania, Bosnia and Herzegovina, and

Table 2 – Organization of health care and the blood transfusion service (BTS)

Countries	Blood Establishments/Blood Centres			Health-care Facilities*			Hospitals Performing Transfusion Therapy		
	Public	Private	Others	Public	Private	Others	Public	Private	Others
Albania	31			38			31	9	
Bosnia & Herzegovina	28						31	2	2 PPP**
Bulgaria	29			502	213		469	213	
Croatia	13	1		66	60		46	3	
Republic of Moldova	23			78	11	6	55	9	6
Montenegro	9			30	109		10	2	
Romania	42						227	21	
Serbia	47			89	NA		44	NA	
The former Yugoslav Republic of Macedonia	23			137	6	96 Specialist + PHC***	53	5	

* Health-care facilities where blood transfusion could be administered in emergency situations

** PPP = Public-private partnership

*** PHC = Primary Health Care

the Republic of Moldova). These countries have a large base of family replacement blood donors, all of them usually first-time donors. Paid donation is still reported by one country (Albania), although not for first-time donors. These donors give blood at least twice a year. Table 3 presents the estimated number of blood donors and donations in the SEE countries.

The average number of blood donations in all of the SEE countries is about 23/1000 inhabitants. Numbers are increasing but still do not prove to be enough to ensure self-sufficiency of the region.

It is important to note that there are great differences among the SEE countries: whereas Croatia has a level of donation of 41 units/1000 inhabitants, Albania has only 7.5 units/1000 inhabitants. The use of blood components, specifically red blood cells, is ultimately dependent on the

number of units collected, and countries generally report covering their basic needs. Nevertheless, emergencies or special circumstances could eventually be solved through intercountry cooperation and support.

The percentage of O Rh negative donors in almost all of the countries is between 4.2% and 6%, which should usually be enough to face emergency situations. However, one country (Romania) has only 2.7% O Rh negative donors and this percentage might prove insufficient in an emergency situation.

The number of blood components used or issued is difficult to obtain in some countries, namely in those where the centralization of activities is in progress or where the information technology is not implemented.

Table 3 - Estimated number of blood donors/donations

Country	Active donors	Blood Donations	Index (%)	Prevalence
				O Rh neg (%)
Albania	20 018	24 092	7.5	4.34
Bosnia & Herzegovina		76 486	19.8	
FBIH and BD		48 733		
RS		27 753		6.2
Bulgaria	119 110	162 658	22.1	4.7
Croatia	92 000	177 355	41.3	6.0
Republic of Moldova	61 331	72 486	20.3	4.2
Montenegro	11 000	15 325	24.5	
Romania	480 150	400 285	18.7	2.72
Serbia	159 000	247 775	33.8	5.7
The former Yugoslav Republic of Macedonia	NA	56 846	27.6	

FBIH = Federation of Bosnia and Herzegovina

BD = Brcko District

RS = Republika Srpska

The figures presented in Table 4 illustrate the gaps in national data, and correspond in some countries to the blood components transfused and, in others, to the blood components issued. It should be noted the substantial difference between these two categories: blood components transfused are the ones actually used, while blood components issued might include a certain percentage of discard or return.

Data diversity makes intercountry comparison difficult from this point of view. However, it is important to point out that, in line with data received, the use of Fresh Frozen Plasma (FFP) compared with the use of Red Blood Cells (RBC) is very high in most of the SEE countries. This direction might require further exploration in terms of economics and patient safety, to identify if there are some indications in relation to volume replacement therapy, where pharmaceutical formulations (non-blood) should be available.

Blood supply management in special circumstances

A national, multisectoral emergency-management legal framework, including blood supply management

A well-structured plan covering the different sectors in play during an emergency situation is of critical importance. A legal and/or regulatory dedicated framework is required for the development of intersectoral actions that are usually involved in emergency management and response.

Regulatory frameworks covering national, multisectoral emergency management in the SEE countries present a wide variability, from minor provisions to more complex legal requirements.

Table 4 – Blood components used/issued

Country	RBC	Platelets Re-covered	Platelets adult dose	Platelet Apheresis	FFP	Cryo	Whole Blood (WB)	Others	Total
Albania *	13 087	1 812	0	0	13 251	192	0	0	28 342
Bosnia & Herzegovina	data not available for the country								
FBIH+BD	1 719#	75#	0	0	395#	21#	0	0	15 312##
RS	22 486	1 673	0	0	15 810	682	0	0	40 651
Bulgaria	181 466	0	3 745	2 075	92 656	0	1 654	0	281 596
Croatia**	data not available								
Republic of Moldova	38 844	9 081	0	0	58 737	12 998	0	0	119 660
Montenegro	12 321	333	501	0	9 111	0	1 765	0	24 031
Romania	286 766	53 759	0	0	189 526	0	81 373	0	611 424
Serbia	data not available for the country, only data from three main BTSs								
**BTI Serbia	61 694	49 962	0	1 600	46 963	6 504	2 058	0	168 781
**BTI Vojvodina	35 593	21 072	0	396	26 136	184	3	0	83 384
**BTI Nis	22 450	10 220	70	127	14 500	2 396	0	13	49 776
The former Yugoslav Republic of Macedonia	24 794	14 119	0	0	25 346	5 458	502	0	70 169

* only Tirana

issued by Brcko District (BD) only

issued by BD plus Institute for Transfusion Medicine in FBIH

** number of blood components issued

FBIH = Federation of Bosnia and Herzegovina

RS = Republika Srpska

Albania and Montenegro have legal and regulatory provisions regarding emergencies, but these do not include blood supply management. In Romania, the organization of emergency medical services is regulated by ministerial orders. The remaining countries have in place or in progress legal and regulatory provisions that include the management of blood supplies in emergencies.

A national, multisectoral committee, empowered to manage emergency situations, exists in six countries: Albania, Bulgaria, Croatia, the Republic of Moldova, Romania, and the former Yugoslav Republic of Macedonia. In Romania and the Republic of Moldova, a representative from the BS is part of the committee. The other countries do not report having any committee to deal with emergency situations with respect to planning and monitoring the collection and use of blood components.

Availability of emergency medical services in normal circumstances

In normal circumstances, emergency services are available through both public and private services, except in Bosnia and Herzegovina where emergency services are exclusively in public hospitals.

Pre-hospital emergency care can be provided in health-care facilities outside hospitals in all Member States except Bosnia and Herzegovina, where this care can be provided only in public hospitals, in mobile units or in ambulances transporting patients to hospitals. All countries have ambulances with basic life support and/or mobile intensive-care units. There are a greater number of these ambulances in the public sector. In addition to ambulances, helicopters are used to transport emergency patients in Bosnia and Herzegovina and in Romania (which has dedicated helicopters for this purpose).

What appears to be some uniformity in emergency medical services (EMS) (Table 5) actually corresponds to a great diversification of organizations, ranging from the almost non-existence of structured services to highly differentiated services.

According to reported data, Romania has very well-structured emergency medical services organized at a national level, with emergency committees operational at national, county and local levels, a General Inspectorate for Emergency situations, professionals dedicated to

emergency services, operational centres and an Action Command. The emergency medical services are organized at a pre-hospital level, with mobile services for emergency, resuscitation and extrication and in-hospital emergency care, organized around eight regions.

Serbia also has well-structured emergency medical service networks, with emergency care divided by different levels of care services, according to the degree of emergency, including ambulance services with life support or intensive-care units. However, it is not clear how the different levels of care services are articulated.

Croatia is currently restructuring its emergency medical service supported by the Bank for Reconstruction and Development, with the objective of improving the efficiency and outcomes of the system. As part of its restructuring efforts, the Croatian National Institute of Emergency Medicine, 21 County Institutes of Emergency Medicine and county-level call centres are being set up. The Emergency Medicine Network was formally established in February.

In Montenegro, the emergency care out of hospitals is only based on mobile intensive care units. In Bosnia and Herzegovina, only the public sector has the possibility to deal with emergencies. Emergencies are only treated in hospitals, and only one hospital has an emergency centre. The Republic of Moldova and Romania have emergency medical services in private hospitals as well.

The majority of countries did not provide information about the organization of emergency medical services, only information about the number or existence of such services.

Availability of critical medical laboratory equipment and supplies used for diagnosis and treatment

All countries have inventory lists of critical equipment and material for laboratory diagnosis and treatment for emergency situations under normal circumstances. A national inventory list exists for the majority of countries and is generally included in the emergency/contingency plans. Such inventory lists exist at a regional/local level in Bosnia and Herzegovina and Albania.

Table 5 – Availability of EMS in normal circumstances

Country	Availability of EMS									
	Public					Private				
	Out of hospital	In hospital	Ambulance services			Out of hospital	In hospital	Ambulance services		
			Type A	Type B	Type C			Type A	Type B	Type C
Albania	Yes	Yes	Yes	Yes	Yes	NA	NA	Yes	Yes	
Bosnia & Herzegovina	No	Yes	Yes	Yes	Yes	No	No	No	No	No
Bulgaria	Yes	Yes	Yes	Yes	Yes	Yes		Yes	No	Yes
Croatia	Yes	Yes	Yes	Yes	Yes	NA	NA	Yes	No	No
Republic of Moldova	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Montenegro	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	No
Romania	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Serbia	Yes	Yes	Yes	Yes	Yes	NA	NA	NA	NA	NA
The former Yugoslav Republic of Macedonia	Yes	Yes	Yes	Yes	Yes			Yes		

NA = data not available

Type A = medical transport

Type B = basic life support

Type C = mobile ICU

Each country has a strategic stock of blood components. The stock (number of units per blood group, as well as type of blood components) is defined based on the prevalence of blood groups in the population and the use of blood component units for five days. The number and the type of blood components, as well as the need for specific blood groups, differs from one country to another. Only Albania reported that the blood components stock (based on three to five days use) is usually insufficient to cover emergency situations, due to the frequent lack of supplies. A provision of O Rh negative red blood cells is part of this strategic stock. The strategic stock also includes medical devices for blood collection, processing and testing.

Usually, the renewal/discard of the strategic stocks of blood components is based on the related shelf life. Medical devices have a great variability of renewal, depending on the type of material, ranging from two months to one year. In terms of equipment renewal, this is very variable and not all countries refer to it but, according to informal reporting, it is done according to the maintenance plans.

Training in medical emergency management

A general overview of training in medical emergency management, including transfusion medicine training, is presented in Table 6.

Table 6 – Training curriculum in transfusion and emergency medicine, by health care professional category

Training Curriculum	Transfusion Medicine					Emergency Medicine				
	Para medical	Medical	Post graduate	Continuous	e-learning	Para medical	Medical	Post graduate	Continuous	e-learning
Albania	no	yes	no	yes	no	no	yes	yes	yes	no
Bosnia & Herzegovina	no	yes	yes	yes	no	yes	yes	yes	yes	no
Bulgaria	yes	yes	yes	yes	no	yes	yes	yes	yes	yes
Croatia	yes	yes	yes	yes	no	yes	yes	yes	yes	in progress
Republic of Moldova	yes	yes	yes	yes	no	yes	yes	yes	yes	no
Montenegro	Training in Emergency Medicine including Transfusion Medicine does not exist									
Romania	no	yes	no	yes	on going	yes	yes	yes	yes	on going
Serbia	no	yes	yes	yes	no	no	yes	yes	yes	no
The former Yugoslav Republic of Macedonia	no	yes	yes	yes	no	no	yes	introduc- tion	yes	no

Medical training curricula, postgraduate specialization and/or continuous medical education in blood transfusion and in emergency medicine exist, or are being developed in almost all countries. The Member States in the SEE region have transfusion medicine as a postgraduate specialization (6).

Three countries (Bulgaria, Croatia, and the Republic of Moldova) include education in transfusion medicine in their paramedical training curriculum; and five countries (Bosnia and Herzegovina, Bulgaria, Croatia, the former Yugoslav Republic of Macedonia, and Romania) have a diploma in emergency medicine.

Croatia and Romania have e-learning platforms that are under development.

Quality management

Countries have started to implement quality systems, but none of them has a quality management system implemented at national level, except

Bulgaria, where all the blood transfusion centres (BTCs) are quality accredited by specialized commissions of the Ministry of Health.

Albania, Croatia, the Republic of Moldova, Serbia and the former Yugoslav Republic of Macedonia have good manufacturing practices (GMP) in use in one or more BTCs. Croatia and Serbia are the only two countries that have two BTCs certified by ISO standards.

Both the Federation of Bosnia and Herzegovina and Republika Srpska in Bosnia and Herzegovina have implemented the quality system approach with the goal of achieving ISO certification. International standards are being used in the absence of national ones.

National standards for the performance of emergency departments exist in Bulgaria, the Republic of Moldova, Romania, and Serbia, and are partially implemented or in progress in Albania, Croatia, and the former Yugoslav Republic of Macedonia.

Table 7 – Emergency documentation

Documentation:* <i>see legend</i>	1	2	3	4	5	6	7	8
Albania	no	no	no	no	no	no	no	no
Bosnia & Herzegovina	no	no	partially	yes	yes	no	partially	partially
Bulgaria	yes	no	yes	yes	yes	yes		yes
Croatia	yes	in progress	yes	yes	yes	yes	no	yes
Republic of Moldova	yes		yes	yes	yes	yes		yes
Montenegro	in progress							
Romania	yes	no	yes	yes	yes	yes	yes	yes
Serbia	yes	yes	yes	yes	yes	yes	yes	yes
The former Yugoslav Republic of Macedonia	yes	yes	yes	yes	yes	yes	yes	yes

*1 = Crisis preparedness plan for EMS (out of hospital and in hospital)

2 = Risk assessment and preparedness information system

3 = Contingency plans for medical treatment in disasters

4 = Written triage system (standards and protocols)

5 = Procedures for patients without identification system

6 = Haemo-vigilance/emergency reporting systems

7 = Biosecurity protocols

Montenegro does not have quality systems implemented, but has a national emergency response plan in preparation.

Documentation

The documents existing in the SEE countries on emergency management are compiled in Table 7.

8 = Quality and safety monitoring reports

From the nine reporting countries, only the former Yugoslav Republic of Macedonia and Serbia reported to have all the documentation in place. In Romania, some emergency units/ services are already certified by ISO standards, while others are still in process. Two countries (Albania and

Montenegro) did not provide information about the existence of documentation on quality management linked to emergencies.

Data processing

Full data processing is virtually non-existent in the SEE countries, due to the lack of a single national information system or integrated information systems that could merge the existing different systems used at a national level (Table 8).

Table 8 – National data processing

National data processing:	Blood donor register	Available blood Supplies	Clinical demand/ use of blood	Blood activities software	Hospital & pre-hospital activities software	Integration stress support systems
Albania	no	no	manual	no	no	no
Bosnia & Herzegovina	no	no	no	no	no	no
Bulgaria	no	no weekly report	no national form available	no	no	no
Croatia	in progress	yes CITM	yes	in progress	in progress	foreseen
Moldova	yes	yes	yes	yes	yes	
Montenegro	no	partially local	partially local	no	no	no
Romania	no	yes	yes	yes in BTCs	yes	yes
Serbia	in 3 main BTCs	no	no integrated	no integrated	no	no
The former Yugoslav Republic of Macedonia	In progress	not yet	not yet	only Skopje	not completely	under development

CITM = Croatian Institute for Transfusion Medicine

Moldova is the only country with a national IT system, which is a computer network connecting all blood collecting points and medical institutions that use blood products. This system allows efficient management of information regarding all the activities of the BS and the use of blood components.

Croatia has new, national transfusion software under development.

The Albanian information system provides available data from the national blood donor register and blood supplies, and has a devoted software covering blood service activities for the Tirana region only.

Bosnia and Herzegovina, Serbia, Bulgaria, Romania and the former Yugoslav Republic of Macedonia have local and/or regional software in the BTCs, but interconnections between BTCs do not exist, which hampers the national processing of existing data.

Montenegro did not provide information regarding the existence of an information system.

Risk communication

All countries have means of risk communication in place, either to the public or to the partners/ stakeholders.

In some countries, there are dedicated structures or personnel for the task. For example, in Croatia, the Ministry of Health and Social Welfare is responsible for risk communication to the public/media, while the Crisis Management Committee communicates with partners. In Albania and Serbia, information to the public/media is provided by a person specially appointed by each health-care institution for the task.

National and international support mechanisms foreseen for emergency management

All SEE countries, except Bosnia and Herzegovina, have national support mechanisms foreseen for emergency management, in various forms.

The former Yugoslav Republic of Macedonia plans to implement the national e-learning platform.

Romania plans to complete the development of the White Plan and Red Plans for emergency situations

Four countries have also foreseen international support.

- ◆ Albania counts on WHO and the Red Cross Society support, as well as other nongovernmental organizations (NGOs) and neighbouring countries, depending on the characteristics of the emergency situation.
- ◆ Montenegro considers the development of the national emergency response plan to include international support mechanisms through agreements and cooperation projects, but does not refer to any specific entity.
- ◆ In Croatia, the development of the Emergency Medical Services and Investment Planning Project continue, supported by the Ministry of Health and Social Welfare and the World Bank.
- ◆ Romania has foreseen international support for the accurate diagnosis of emergent transmissible infectious diseases.

National experience

The most common medical emergency situation affecting the blood services in all SEE countries, during the last five years, has been multiple traumas due to traffic accidents. The countries have had, during the same period of time, other kinds of emergency situations that occasionally affect the blood stocks, for example, firearms and edged weapons' injuries, and workplace accidents in Bosnia and Herzegovina; a train derailment in Montenegro; and explosions and earthquakes in Albania.

Situations related to infectious threats, such as epidemics in Albania (hepatitis A), in the former Yugoslav Republic of Macedonia (morbili virus and swine flu), in Romania (West Nile virus), and in Serbia (swine flu) did not have high impact on blood supplies. The same limited impact was generated by floods in Albania, the former Yugoslav Republic of

Macedonia and Montenegro. Countries faced these situations without major problems.

It is, however, important to stress that Albania, Croatia and Serbia, mentioned a seasonal shortage of blood stocks and of O Rh negative red cells in particular.

Only Romania has experienced one epidemic over the last 12 months: the country was affected by West Nile virus infection. Decisions were taken based on risk assessment, and blood collection was suspended in regions where cases with neural invasive disease were identified, and blood components were quarantined for two weeks. The impact of the pandemic on the blood supplies was negligible.

General perception of how the BS operate/would operate in emergency situations under the current conditions

So far, the transfusion services have been able to respond to their emergency situations, regardless of the need to improve the current conditions. In general, SEE countries feel rather comfortable with the capacity of emergency response, except Montenegro that refers to inadequate conditions, and Albania that reports inadequate blood supply and proper logistics. These countries, and the Republic of Moldova, consider that their respective capacities will soon increase for a better coordinated response to emergency situations. Romania stresses the possible shortage of blood supplies if facing big disasters and the need for back-up storage equipment.

The general perception of the current capabilities of the BS to respond to emergencies is summarized in the Table 9.

Table 9 – General perception of current conditions

Albania	The national organization is a strong point. Weak points are insufficient blood supply and a lack of proper logistics for operation in special circumstances.
Bosnia & Herzegovina	There is a satisfactory response to emergencies (and five days' worth of stock).
Bulgaria	There is a good response due to the implementation of different degrees of cooperation and responsibilities.
Croatia	Current capabilities to respond are very good and better than before.
Republic of Moldova	Restructuring is in progress with the support of the Government and uniformity of the blood system in the country will allow for a better response in the future.
Montenegro	The BS is operating under great pressure and in inadequate conditions. However, restructuring action to implement a national service, staff education and training is in place.
Romania	The response will be better with an increase in blood supply and back-up equipment to face emergency situations that have a large need for blood components.
Serbia	Well-performing response for emergencies.
The former Yugoslav Republic of Macedonia	Better capabilities, due to the excellent cooperation of the stakeholders. There should be an increase in disposable medical devices.

To illustrate the ability to face emergency situations or special circumstances, each country has presented one case-study, as summarized in the following section.

Summary of case-studies

From the nine case-studies presented, three are related to medical devices/technologies (testing for transfusion transmissible infections); two are about the same situation concerning explosions; one is about the result of a train derailment; one concerns the collapse of an information system; one details an epidemic situation.

The cases reported by the Republic of Moldova, Bulgaria, and Bosnia and Herzegovina (Republika Srpska) relate to medical devices and testing technologies: the Republic of Moldova described a problem of test validation; Bulgaria presented a lack of medical devices supply due to a missing order, plus a lack of control test validity; and Bosnia and Herzegovina/Republika Srpska reported on the use of a new equipment platform, due to discontinuation of the existing test kits by the supplier. For the Republic of Moldova and for Bulgaria, these circumstances were

solved through the cooperation of different BS and other national health institutions. For the Republika Srpska, the situation was solved through the cooperation of the neighbouring BS (in Niksic in Montenegro).

The same case-study involving an explosion of ammunitions was reported by Albania, where the explosion took place, and by the former Yugoslav Republic of Macedonia, who collaborated with Albania and sent blood components. The accident resulted in 26 deaths, and 189 hospitalized patients from a total of 280 injured. The two countries are differently organized in terms of emergency situation management. The former Yugoslav Republic of Macedonia has a well-structured emergency response system in the BS, with specific standardized procedures. Albania does not have, so far, a national strategy response to emergencies. For this reason, the former Yugoslav Republic of Macedonia was able to send 100 red blood cell (RBC) units and 150 fresh frozen plasma (FFP) units to Albania and recovered the blood stocks on the three subsequent days. Albania had a national Plan for Civil Emergency but it had never been tested by a drill, or revised or actualized since 2004. Albania faced problems in terms of general coordination; an inexistence of triage

procedures; a failure in phone communication; and a lack of transport coordination. The problems related to the blood service capacity led to a lack of blood components/derivatives, while the absence of a communication strategy to blood donors contributed to a great afflux of donors who could have helped generate additional blood. The situation was solved with the goodwill of the population, professionals and support from neighbouring countries.

Montenegro reported about the consequences of a train derailment in the mountains during winter, with 260 injured people of which 187 had multiple traumas. Due to the good strategic stock in blood and medical devices, and the communication with other BSs, the BTC was able to cover the clinical request for transfusion therapy. Communication with the media was needed to manage the high number of the population who came to donate blood. The population was advised that blood donations were already sufficient at the time, but would be needed in the near future. In this emergency situation, which involved injured patients, the needs were less than expected and only 47 blood components were transfused.

Serbia has reported the collapse of the information system in the Blood Transfusion Institute of Serbia and the need to switch to another information version. In this particular instance, the major stress for the organization lied in the need to transfer data from one system to another, without interrupting the daily work. Everyday activities had to be performed with the same quality and safety, with modified procedures due to the non-working information system. The situation was overcome due to the quality management system in place.

The epidemic of West Nile virus (WNV) during the summer of 2010 and the measures in place to guarantee the safety and availability of blood supplies was reported by Romania. The lack of nucleic acid amplification testing (NAT)-WNV technology led to implementing measures based on clinical examination/symptoms. Deferrals were made according to EU directives, based on the place of residence, travel, clinical symptoms, mosquito bites, etc. The quarantine of blood units collected in Bucharest and Constanta, the most affected regions, proved the possibility to maintain the blood supply. Blood donors were asked to inform the BTC if

they had a fever or rash within the 15 subsequent days, and monitoring of transfused patients was done, together with look-back procedures whenever needed. The haemovigilance system did not report any case of WNV transmitted by blood. The blood supplies were not significantly affected, except for the stock of platelets in Bucharest and Constanta (due to its short shelf-life) that was compensated for by other blood centres.

Discussion

Health-care services/Blood transfusion services

The translation into practice of national blood policies and plans in SEE Member States led to different developments and various organizational set-ups. These reflect both the historical heritage and the efforts still in progress to upgrade and reform health-care services and BSs for a better response to patient populations' needs. This variety, however, is not specific to the SEE countries. Within the EU, one can distinguish different ways that BSs are organized: centralized systems (France, Netherlands, United Kingdom); hospital-based BS (Denmark, Greece, Italy, Sweden); and mixed systems with national authorities and blood centres still co-existing within a few hospital blood establishments (Portugal). All of these organizational models have both advantages and disadvantages.

The main disadvantage of having blood transfusion services as part of hospitals, or for having independent BTCs co-existing with hospital blood transfusion services, is the difficulty of enforcing the implementation of national policies and harmonization. This is due to the fact that hospitals have their own budgetary provisions and their own priorities.

The lack of centralization does not represent, so far, any obstacle to local or regional emergency or special circumstances response. However, in a national emergency some difficulties can result from the use of different standards, different equipment and different medical devices, unless these are appropriately regulated beforehand.

Only nationally coordinated BS (centralized or not) will allow for:

- ◆ voluntary, non-remunerated blood-donor promotion as a national need (in hospitals, replacement donations are more effective, less expensive, but also less safe), without conflict occurring among the different BS over the same pool of donors;
- ◆ a national donors' register and improved management of blood donors during emergency situations or in the event of unexpected shortages of blood supplies; and

- ◆ an accurate estimation of national needs and a definition of the national strategic stock of blood components.

European countries are moving towards more concentrated BSs due to the escalating costs related to increasing safety and quality requirements for blood components for transfusion therapy.

For the same reason, and despite the existence of mixed services in many SEE countries, some of these countries are carefully moving towards centralization, leaving, for now, the blood collection in hospitals.

Although BSs are financed directly or indirectly by the Government, some countries have a reimbursable price for the blood components they distribute. This price, which usually corresponds to the actual cost to produce safe blood components, is of great significance to the hospitals because it informs the users that the blood components are actually not free; they cost the same or even more money than blood derivatives or medicinal alternatives to a blood transfusion, which are often overlooked because they are considered to be expensive.

In Europe, a diversity of the financing of BSs, as well as the price and the payment of blood components [7] can be seen. This is not only due to financing reasons, but because in many countries blood components are scarce resources and their use should be optimized. The improvement of the clinical use of plasma, together with the implementation and/or revision of the clinical indications of FFP in use is mandatory. Providers and users working together is the best way to achieve a consensus, trying to approve clinical indications and guidelines based on evidence, avoiding the over or under use of blood components.

Therefore, efforts have been made by some countries to increase the number of safe blood donations. For example, Albania, with a donation index of 7.5 donations per 1000 inhabitants, has no more paid first-time donors, and the number of voluntary, non-remunerated donors is increasing. In several countries, blood donation continues to be lower than 20 per 1000 inhabitants.

Good programmes of blood donor promotion are needed, not only to gain more donors, but also to retain the existing donors and increase the number of times they give blood per year. Special attention should be given to young people, women and O Rh negative individuals. Collaboration with a focus on the promotion of safe blood donation should be enhanced, for example with international organizations, blood donor associations or other NGOs, religious communities, schools and universities, and rural or industrial communities.

The differences in mean/median ages in the SEE countries and the predominance of women imply different approaches in blood donor promotion techniques and the countries do invest in targeted blood donor promotion towards particular groups, such as youth, women, O Rh negative donors, etc.

When compared with the majority of European countries, SEE Member States have a low number of blood donations, with the exception of Croatia and Serbia, the only two countries with more than 30% donations (8).

Blood supply management in special circumstances

Legal and regulatory provisions, together with infrastructures and logistics are the cornerstone in the management of emergency situations or special circumstances. This implies a multisectoral emergency response, where each partner should know exactly its own role.

In the majority of SEE countries, the lack or insufficiency of regulatory provisions for the emergency operation of BSs is a reality. The infrastructure (emergency services, ability of the BS to respond to emergencies, ambulances for patient transport, etc.) necessary for proper operation might be working in all countries, but the logistics can fail due to the absence of coordinated emergency management, appropriately designed and implemented.

These can be improved through better teamwork, appropriate education and training of all the partners (9, 10), a national information network and quality management systems. It is advisable that all sectors involved in emergency medical services have dedicated training and that, at least

once a year, simulations of emergency situations are part of the team training.

The majority of European countries have general contingency plans and health contingency plans (11, 12, 13), and the BTCs have elaborated their own internal or external preparedness action plans. This work is performed by the professionals in the BS in collaboration with the health-care structures, taking into account the specific and general responsibilities of the BS.

National guidelines covering emergency situations are of primordial importance, and should be developed by the countries in accordance with the major users. These national guidelines could be based on international guidelines, following procedures based on evidence (14). Specific documentation of BS should include: emergency information management; the number and functions of the personnel prepared to deal with blood emergencies; the list of emergency inventory for special circumstances; information on blood stock availability at regional and national levels; how to communicate with partners and with blood donors (about the needs for blood or not); and information about the transportation necessary in such circumstances.

Although quality management systems are in place in the main BSs in most countries, the lack of a national quality management system implies a variability of standards to perform the same actions, sometimes generating collaboration challenges among staff working in different BSs within the same country. This situation is also encountered in other European countries where centralized systems are not implemented, and different sources of direct financing in different health structures co-exist (e.g. in the BS versus the hospital blood centres).

It is reported that one of the strategic objectives achieved is the strategic stock of medical devices. However, the strategic stock of blood components is subject to various challenges. Many countries report not being able to maintain a minimum of five days of blood component stock. The lack of a national blood donor register in some countries contributes to the blood supply management challenge, in normal circumstances as

well as in special circumstances, and adds to the argument for having a centralized information support system.

The development of strong communication strategies, agreed among the partners, helps the coordination during an emergency situation to be more effective.

Case-studies

During the last five years, the SEE countries (with two exceptions), did not face big disasters and the emergency situations that occurred did not have a great impact on the strategic stocks of blood components.

Transnational cooperation appeared to be a key response mechanism to emergencies in most of the reported national case-studies. The results of transnational cooperation could be improved with the development of legal or regulatory provisions covering the acceptability of blood components from countries with similar quality and safety requirements. The SEE blood safety network is a step forward in this process of transnational availability and acceptability of blood components and products for transfusion therapy.

Good national coordination and cooperation with BSs situated beyond the affected area was the success factor in the response to the WNV epidemic in Romania. This example underlined the added value of a centralized blood transfusion service, and allowed Romania to contribute, together with other affected European countries, to the preparation of an EC dedicated document entitled: *“West Nile Virus and Blood Safety: introduction to a preparedness plan in Europe”*.

A robust and sustainable quality management system was the underlying reason for the good response of the Blood Transfusion Institute of Serbia to the failure of their information system, and helped with the switch to a new system without disrupting their daily work.

All the case-studies presented have demonstrated the ability of the BS or of the countries to respond to uncommon circumstances: some with coordinated actions due to the organization of the BS, others through adaptation mechanisms including national and international cooperation

and support, with a strong commitment from both health professionals and blood donors.

Conclusions and recommendations

The SEE countries' compiled analysis of the capacities for the BS response when facing emergency situations is the first exercise of this kind. The paucity of data made this exercise rather challenging, but allowed for the identification of a number of strengths and weaknesses, including the need for coordinated management taking into consideration the BS at national and regional levels.

Support of the National Health Authorities is needed to increase operational capacity and reach the targets proposed below, as well as to facilitate transnational cooperation.

Organization of blood services

National policies for the BS exist in all SEE countries. These have been updated as a result of the Component One of the project, and represent the starting point in the process of BS reforms where these are taking place. Blood safety policies that are based on common principles facilitate transnational cooperation, give more union to the region, and contribute to the reinforcement of the SEEHN.

National coordination of BS is required for effective integrated management of medical emergencies. This approach, which in some instances is supported by the centralization of the BS, will ensure harmonized standards and procedures to be implemented during operational response.

Legal or regulatory provisions for BS emergency response should be implemented

Although legal and regulatory provisions concerning BS activities in normal circumstances have been implemented in line with the need for compliance with EU directives in most countries, specific matters regarding emergency situations such as, for instance, the importation of blood components, need to be addressed.

The BS, as an important partner, should be included in the preparedness plan at local, regional and national levels, and be included in the

dedicated committees and multidisciplinary teams expected to be operational during emergencies.

Regulatory provisions concerning the use of imported blood components in emergency situations should be defined, taking into account the safety of patients and the urgent need of blood components that might occur.

Quality Management Systems (QMS)

In almost all countries, QMS are implemented and in use in BSs. This indicates that standard procedures are harmonized and supported by the same quality policy. It brings added value to the services, from a technical, organizational and economical point of view, allowing inter-professional exchange.

Implementing national QMS, supported by a national quality policy, should be the target for the near future.

Donors, blood donations and availability of blood supplies

The capacity to sensitize the population towards blood donation is the ultimate determinant in reaching self-sufficiency of blood supplies. Different situations are reported in the SEE region. There are countries with a good index of blood donation (Croatia and Serbia) together with countries with a level of donation less than 1% in the general population. Countries that have in place familiar replacement donation are in this last group. The transition to a 100% voluntary, non-remunerated blood donor pool is in process, but it is recognized as a medium-term task.

The relationship between demand and supply is conditioned by blood donation. Strong and frequent promotion activities should be implemented in countries with a low index of blood donations. Even so, the use of blood components should be improved through use of guidelines and monitoring of use. Indicators should be defined to evaluate BS management.

A minimum strategic stock should be defined and supported by alert mechanisms to avoid shortage of blood components. Good transportation systems should also be in place to cover the national needs.

National information system

Although the majority of BSs have information systems in use, there is no software uniformity and these are not interconnected at national level. A national information system, covering all the activities of the BS is advisable.

Blood banks supported by the same information system, or at least a compatible one, will ensure full traceability of donated blood along the transfusion chain. The use of commonly agreed or compatible software in all blood transfusion services/departments is recommended to facilitate the implementation of a BS network.

The BS network allows real-time monitoring of national supplies, and of available blood donors by blood group and place of residence/work during an emergency situation (provided support mechanisms are in place in case of electricity failure).

A BS network also facilitates, in normal circumstances, the implementation of a national blood donor register, which is essential to the management of blood donors. It also gives, in real time, the supplies of blood components in each of the BSs and the need (or not) to call in blood donors. It contributes to avoiding shortages of blood components.

An information system, and any national networks, should be robust and validated.

Blood supply management in special circumstances

As reported in the case-studies, countries of the SEE region are able to respond to emergencies or special circumstances, with varying degrees of ease. While all countries are able to respond to daily emergency situations, a well-organized response to mass casualties involving the BS is still incipient, due to health service reform in the region.

The different stages of development of emergency medicine and transfusion medicine in the SEE region require an adequate analysis by the responsible entities. Countries with a well-structured emergency medicine postgraduate specialization, like Romania, do not have the same level of

organization for the BS, maybe due to the lack of postgraduate specialization in transfusion medicine.

The BS preparedness action plans should foresee disaster situations that have a great influx of patients needing blood components transfusion, as well as situations that could mean a decrease in blood donations (i.e. epidemic/pandemic situations), or even situations when it is impossible to use the blood components stored, as in nuclear or chemical accidents. The principles of mass casualty incidents (MCI) should also be applied to BSs.

Preparedness plans for BSs at a national level should be part of the QMS. These plans should include an outline of the strategy for emergency response and recovery and should identify trained personnel, appropriate and available transportation, and available blood components at regional and/or national level. BSs should also have mechanisms in place to mitigate special circumstances.

Common approaches in SEE countries concerning education and training should be encouraged, namely regarding the implementation of a transfusion medicine postgraduate speciality.

Integrating BS teams with emergency teams enhances the management of existing blood supplies. Drills should be performed and assessed, at least annually, and the emergency plans should be revised according to the assessment results.

Communication

Communication is one of the most important aspects in the event of a mass casualty or in other emergency situations. Communication strategies do not appear to be developed at a national level, but are implemented institution by institution. This can be sufficient for emergencies but not for mass casualties. The lack of national coordination of the BS seems to be one of the main reasons for this gap.

A defined communication strategy that differentiates the level and channel of information according to the target audience is required. For

example, communication with the public, communication with the partners, and communication with the professionals involved.

Communication with blood donors should be consistent with public information, while at the same time managing any potential excess of donors during an acute phase and preparing these to give blood during the recovery phase. The development of good communication techniques and a common communication strategy at national and transnational levels is recommended as part of the preparedness and emergency response plans.

References

1. Sihler KC, Napolitano LM. Massive transfusion: new insights. *Chest*, 2009, 136:1654–67.
2. Rossaint R et al. Management of bleeding following major trauma: an updated European guideline. *Critical Care*, 2010, 14:R52 (<http://ccforum.com/content/14/2/R52>, accessed 10 November 2011).
3. *Pandemic Influenza: Planning for Blood Organisation. Consolidating the work of the European Blood Alliance Emergency Planning Action Group (EBA-EPAG)*. European Blood Alliance, 2009 (http://ipsangue.org/ipsangue2011/images/stories/Anexos_pdf/EBA_EPAG_Pandemic_Influenza.pdf, accessed 10 November 2011).
4. *Disaster Operations Handbook. Coordinating the Nation's Blood Supply During Disasters and Biological Events V2.0*. AABB Advancing Transfusion and Cellular Therapies Worldwide, 2008 (<http://www.aabb.org/programs/disasterresponse/Documents/disastophndbkv2.pdf>, accessed 10 November 2011).
5. *SEE Blood Safety Project. Implementation of Addendum to Component Two "Increasing Transnational Availability of Safe Blood and Blood Components for Medical Emergencies and Special Circumstances"*. Annex 1. Geneva, World Health Organization, 2006.
6. Seifried E, Schuettrumpf J, Mueller MM. Changing Educational Paradigms in Transfusion Medicine. *International Society of Blood Transfusion Science Series*, 2011, 6:89–95.
7. Philippe R, Claudine H. Blood Transfusion in Europe: The White Book 2005. EuroNet-TMS. Paris, Elsevier SAS, 2005.
8. Poel C, Janssen M. *The Collection, Testing and Use of Blood and Blood products in Europe in 2009* (draft report). European Directorate for the Quality of Medicines and HealthCare.
9. *Recommendation Rec(2004)18 of the Committee of Ministers to member states on teaching transfusion medicine to nurses*. Council of Europe, Committee of Ministers, 2004 (<https://wcd.coe.int/wcd/ViewDoc.jsp?id=802877&Site=COE>, accessed 10 November 2011).
10. *Recommendation Rec(2002)11 of the Committee of Ministers to member states on the hospital's and clinician's role in the optimal use of blood and blood products*. Council of Europe, Committee of Ministers, 2002 (<https://wcd.coe.int/wcd/ViewDoc.jsp?id=312229&Site=COE>, accessed 10 November 2011).
11. *NHS Emergency Planning Guidance: planning for the management of burn-injured patients in the event of a major incident: interim strategic national guidance*. Department of Health, 5 April 2011 (http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_125842.pdf, accessed 10 November 2011).
12. *Emergency planning: UK Reserve National Stock for Major Incidents: How to access stock*. Department of Health, 17 February 2010 (http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_112636.pdf, accessed on 10 November 2011).
13. *Maintaining a Safe and Adequate Blood Supply during Pandemic Influenza. Guidelines for Blood Transfusion Services*. Geneva, World Health Organization, July 2011.
14. *Cross-sectional Guidelines for Therapy with Blood Components and Plasma Derivatives, 4th revised edition*. Executive Committee of the German Medical Association on the recommendation of the Scientific Advisory Board, 2009 (http://www.bundesaerztekammer.de/downloads/Querschnittsleitlinie_Gesamtdokument-englisch_07032011.pdf, accessed 10 November 2011).

Part 2:

**Report of the first training of
trainers in increasing transnational
availability of safe blood and blood
components for medical emergencies
and special circumstances**

Background

The South-eastern Europe Health Network (SEEHN) was established in 2001. It is a political and institutional forum set up by the governments of Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Montenegro, the Republic of Moldova, Romania, Serbia and the former Yugoslav Republic of Macedonia to promote peace, reconciliation and health in the region. From 2001 to 2009, the WHO Regional Office for Europe provided technical support to the SEEHN's various health projects, and supplied its secretariat, along with the Council of Europe. On 1 January 2010, the SEEHN took over ownership of the regional cooperation for health and development under the auspices of the Regional Cooperation Council and the South-east European Cooperation Process (SEEC). The SEEHN proved to be of crucial importance in the development of the public health sectors in the participant countries, and achieved major political and technical results based on enhanced partnership, sharing of experiences and cross-fertilization of ideas.

The SEEHN has identified blood safety as one of the key priorities that require immediate action to ensure public health strengthening and this has been formally endorsed by the National Health Authorities of the participating countries.

The SEE Regional Health Development Centre (RHDC), which was established in Oradea, Romania in 2010, launched its first capacity building exercise for the network: the training of trainers in increasing transnational availability of safe blood and blood components for medical emergencies and special circumstances on 7–9 June 2011.

The training was attended by multidisciplinary teams from the nine SEE countries: Albania, Bulgaria, Bosnia and Herzegovina, Croatia, Montenegro, the Republic of Moldova, Romania, Serbia, and the former Yugoslav Republic of Macedonia. The multidisciplinary curriculum used during the workshop is expected to be developed for a follow-up sequence of national training courses in the SEE participant countries.

Introduction

The meeting was opened by Dr Z. Bitea, representative of the Romanian Ministry of Health and Local Health Authority, Dr G. Carp, representative of the Major's Office, and Dr I. Felea, vice-dean of Oradea Medical University, who welcomed the participants and underlined the importance of the event on a European level. It was seen as addressing a priority in the medical field: increasing regional self-sufficiency in safer blood and blood components in emergencies and special circumstances.

The welcome message was further extended by representatives of the Council of Europe/ European Directorate for the Quality of Medicines and HealthCare (CoE/EDQM), the WHO Regional and Country Office, and the head of the Oradea SEE Regional Health Development Centre for Blood Safety (RHDC-BS). The importance of strengthening the emerging dedicated network was underlined as an operational tool for shared experiences and continuous information exchange.

Action to strengthen safety and availability of blood supplies builds on the successful outcomes of the Blood Safety Project (SEEHN-BS), which to date has implemented its Component One: *Strengthening mutual trust and acceptability of the quality of blood in the SEE region*; and part of Component Two: *Increasing transnational availability of safe blood and blood components for medical emergencies and special circumstances*. To complete the activities not addressed to date within Component Two, a formal Addendum was developed with a subsequent plan of action to be implemented by the RHDC-BS. The event moves forward this work.

Presentations and national reports

For the purpose of this report, as well as taking into account future targeted curricula development, presentations and national reports are grouped separately, irrespective of their actual distribution during the workshop's programme.

European Commission (EC) legal framework and WHO recommendations and guidelines for blood and patient safety

Blood safety challenges in the WHO European Region closely relate to evolving medical technologies and rising "safety" costs, in order to respond to increased requirements for quality and safety of blood components and products. The blood supply reflects the variations that occur at the national and subregional levels in terms of local infrastructure and the organization of health-care services/blood services. Variation relates also to the median age of the population and its morbidity patterns. A slight decrease in the overall blood supply at regional levels has been noticed, with a recommended minimum of 2.5% blood donors in the general European population needed to maintain the baseline for national blood supplies.

This field is regulated by European Union (EU) legislation, the Council of Europe (CoE) and WHO recommendations and guidelines. Work towards implementing the recommendations is still in progress, with the aim to have a standardized approach to quality and safety in the blood service. It is to be noted that the Directive 2002/98/EC contains important links to pharmaceutical legislation, e.g. collection, processing and testing of human blood for all clinical uses, including plasma for fractionation. Annex II of this EC Directive also defines data to be reported by the Member States to their competent authorities. Some SEE countries transposed the EC Directives in their own legal framework, either as new EU members (Bulgaria, Romania), as part of the EU accession process, or simply with the aim of reaching similar standards allowing interchangeable acceptability of blood products (e.g. the former Yugoslav Republic of Macedonia and Albania).

In Europe, participation in World Blood Donor Day, an annual event raising awareness to promote safe blood donation and recognize the contribution of unpaid blood donors, has reached high numbers. Also reflecting these activities are the encouraging results of the Eurobarometer survey issued recently by the EC, indicating that more Europeans are giving blood.

The importance of reorganizing blood services, linked to the reforms of health-care services, was reiterated. The integrated approach, defined by blood service managers in 2007, aims to strengthen blood and patient safety, covering prevention, provision, regulation, education and research. Its overall goal is to secure safe and available blood supplies in line with national and regional needs. The SEEHN-BS is a good example illustrating this strategy.

CoE/EDQM recommendations and guidelines for safe blood components, products and services

The CoE work in the field of blood safety comprises a series of recommendations and dedicated quality guidelines. Work is being continued through the EDQM expert committees that also cover the regulatory aspects for stable blood products/ plasma fractions. Some important achievements were briefly displayed, such as the specific chapters of the European Pharmacopoeia, the Resolution CM/Res(2008)5 on donor responsibility and on limitation of blood donation and blood components, and the Quality Guide to the preparation, use and quality assurance of blood components, the 16th edition of which was published in 2011.

The Transfusion Committee (CD-P-TS) through its dedicated working groups, updates the Quality Guide regularly and supports dissemination of knowledge and best practices in the field of transfusion medicine. Good practice guidelines are currently being developed in conjunction with the EC and will form the first chapter of the 17th version of the Quality Guide, expected to be issued in 2013.

The working parties focus on: (a) the supply of rare blood groups, working on updating the details on preservative solutions, monitoring current

supplies of frozen rare blood groups and performing a feasibility study for a centralized database; and (b) blood supply management, assisting Member States in improving donor management. The sustained efforts undertaken to ensure the safety of plasma derivatives have resulted in no documented virus transmission in the last 15 years (none after 1994). In addition, transfusion-related acute lung injury (TRALI) has been minimized due to the use of male plasma or inactivated pools of plasma.

An annual enquiry on the collection, testing and use of blood components in Europe takes place and, since 2001, annual reports have been published.

Collaboration with WHO and various international and national stakeholders at a European level is part of the coordinated mechanisms to improve blood safety.

Blood donor management and prospective evaluation of blood needs

The main principles of blood services management were presented including: the need to identify factors affecting the balance between blood demand and blood supply; self-assessment of existing gaps to optimal blood supply management (based on voluntary, non-remunerated donors); the elaboration of improvement focused action plans; and the need to optimize blood donor and services management, in each Member State.

In May 2010, the WHO expert consultation on the estimation of blood requirements mentioned that the main factor affecting blood supply management was the relationship between blood use, blood demand and blood needs as well as public expectations. The International Forum on Inventory management (which in 2009 had 37 organizations from 30 countries participating) was equally mentioned.

Blood supply and blood donor management is a four-step process: knowing the demand, following up the inventories, supplying the stocks, and steering the process. The situation can be assessed by compiling a set of basic questions such as:

- ◆ how many red blood cell concentrate units exist;
- ◆ what are the trends in the last few days/weeks/months/years;
- ◆ how is clinical demand followed up and managed; and
- ◆ what are the needs to assess inventory monitoring/stock supplying/ process steering?

A set of commonly agreed general rules, supported by information technology (IT) and sustained cooperation between blood transfusion establishments and hospital transfusion services are needed, and form the quality-management-based customer-supplier relationship.

The project "Donor Management in Europe" (DOMAINE) is a good practical example. It involves five steps: Step 1 - Donor Recruitment; Step 2 - Invitation & Donor Base Management; Step 3 - Donor Selection; Step 4 - Donation Procedure; and Step 5 - Donor Retention. Appropriate donor management, adjusted to actual and estimated needs, is expected to ensure self-sufficiency/adequacy of blood supplies.

Voluntary, non-remunerated blood donation: ethical and social features in emergency situations and special circumstances

Blood collection and blood transfusion activities are a core service within health-care services worldwide, in both routine and emergency medical situations. However, specific challenges need to be considered in relation to the context, both in developed countries and developing/transitional countries.

For each emergency situation, there are specific cultural features, such as presentation rates and motivation and reward mechanisms that directly affect the availability of blood supplies and the possible occurrence of shortages. These are initially shaped by the type of emergency and the size of the needs. Different communication and reward systems can be used for blood donations, according to the requirements for blood and blood components. These are reflected in different management strategies, drawing from psychology concepts, such as planned behaviour and long-term consequences, so that the right proportion of blood is donated compared to real needs. The example of 11 September 2001 in

New York showed mass mobilization leading to excessive blood donation and discard, compared to real needs.

Ethical and social issues were discussed, such as vulnerability, exploitation, informed consent, communication, and confidentiality, including blood donation as a social norm. These all draw from the commonly agreed definition of voluntary, non-remunerated blood donation:

“A voluntary, non-remunerated blood donor gives blood, plasma or cellular components of his or her own free will and receives no payment, either in the form of cash or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation.”

Emergency operation plans for blood transfusion in special circumstances

The main objective of the emergency operation plan for special circumstances is to ensure reliance on appropriate supply of safe blood components. This requires a nationally coordinated blood service and voluntary, non-remunerated donor programme.

Patients' transfusion requirements can often be minimized by optimizing the management of anaesthesiology techniques, correcting anaemia and depleted iron stores as applicable/feasible in relation to the emergency grade, as well as discontinuing anticoagulant and anti-platelet treatments. Alternatives to transfusion as a volume substitution should be available and encouraged.

The key elements of emergency operation plans include the use of all appropriate means to reduce blood loss and maximize the use of the patient's own blood. Patients who are not transfused (or who are transfused with their own blood) seem to have better outcomes. The decision to transfuse should always be based on: a careful clinical assessment; quick transportation to the emergency unit; good anaesthetic techniques; and initial use of replacement fluids to correct hypotension before initiating blood transfusion.

The role of the hospital transfusion committee is essential and a transfusion safety officer (TSO) should be established in hospitals where this position does not already exist. Regular meetings between the blood service and hospital users are a good start to reviewing problems and solutions concerning blood supply and the transfusion process. Regular meetings are expected to contribute to the increased efficiency of blood supply use and the improved patient outcome.

Principles of mass casualty incidents (MCI) and hospital preparedness plans

As a background for the presentation, a case-study scenario was used: a fire in a night club with 150 people resulted in 23 fatalities and 43 people injured. Fourteen ambulances came on site. The closest hospital had 120 beds, with 12 intensive care unit beds and 10 emergency department beds. The tasks were to identify: (a) ten main problems that may occur during the incident management; (b) three missing but very relevant pieces of information about the hospital; and (c) who should be the incident command manager in that hospital.

The case-study opened the floor for a discussion of the management of mass casualty incidents and hospital preparedness plans. These included mitigation of the incident (prevent the accidents that have a high probability of happening or a high vulnerability); preparedness (corrective and protective actions, lessons learned, plans); pre-hospital response (establishing command and control, starting triage, stabilization and documentation, and the important role of communication); and in-hospital action.

The importance of planning resources and having a structured plan were underlined. This includes: having knowledge of the available resources and the needed resources; having an activation mechanism of the plan (who activates, who commands the response); the control mechanism, communication and information management; and the need to perform continuous evaluation and keep the system updated. A common terminology and clear text are also essential, with an English-speaking liaison officer for intervention on an international level. Hospital vulnerability factors, such as dependence on public services (e.g. water, power sup-

plies), the presence of toxic substances (e.g. poisonous gases) and so on, need to be considered and addressed.

The ten Cs for hospital preparedness plans were highlighted in addressing critical emergencies. These include charge (plan activation and operational control); command and control (chain of command); communication; coordination; convergence of the points of control; contamination (and decontamination); capacity and capability; cooperation; chaos management (anticipating potential breakdowns and problems); and critical incident stress debriefing (post-event recovery and community-wide education).

Today, the hospital is a first responder directly linked to the rest of the emergency system, therefore coordinated responses and the existence of guidelines and plans is of the utmost importance. Recovery with interdisciplinary response, multiple organizations returning to normal operations, critical incident stress debriefing, and community involvement were equally mentioned.

Romanian approach to MCI management – a case-study

Access to emergency services in Romania is via a single emergency number (112). Since 2006, the first response is provided by the fire services. Fire fighters and other non-medical professionals were trained to operate automatic defibrillation; so treating a patient with early defibrillation is feasible (fire fighters and hospital ambulances must work together by law). Every first response vehicle is equipped with an automatic defibrillator. Teams are adapted according to the needs, with more specialized or less specialized people. Likewise, medical and non-medical professionals are currently trained in advanced life support. In hospitals, the emergency departments are expected to manage patients in an integrated way. Communication and good cooperation between all those involved are essential. To exemplify the Romanian approach to MCI, three different and real cases were presented: a fire in a maternity ward in August 2010; an explosion and fire in a brick factory; and a mining incident.

The calls received through 112 reach an integrated platform including police, fire, gendarmerie, and medical doctors and are subject to coordinated dispatching. The intention is to reduce the number of dispatching

centres from 41 at the county level to four at the regional level. In the same way, ambulances should be equipped with videos and the ability to transfer data (e.g. ECG) to a medical doctor (telemedicine at a regional level). Currently in Romania there are five 4x4 vehicles equipped with the medical material needed for MCIs and in 2012 there will be seven.

In 2011, a prototype of a command post dedicated to making unique decisions (e.g. sending a helicopter for transporting up to six casualties) is under validation. Seven more command posts are expected in the near future, depending on the validation of the prototype.

The use of blood components, specifically blood group O Rh negative red blood cells, on scene (out of hospital) was advocated for patients in severe haemorrhagic shock. The decision should be taken by a senior expert according to specific protocols and is expected to be a rare occurrence. With this taken into account, blood establishments should be integrated with the emergency response and a system of tele-ordering could be established.

The current rules for emergency response in Romania have been integrated into the law and centralization is a key factor to the success of the coordination process. The amount of equipment and the permanent need for emergency care by the population make this sector attractive. Up to now, Romania resisted pressure from commercial companies and kept the emergency response management in the public sector.

Best practice protocols for clinical safety in disaster situations

In Portugal, disaster plans integrate, among different sectors of civilian life, national health-care services, blood establishments and hospitals. Both blood establishments and hospitals have written preparedness plans. These plans for the blood establishments and hospital blood banks include a list of contacts, detailed information about the disaster, the activation mechanism, the response, the communication, and the recovery. Blood supply inventory is crucial to face an emergency in a hospital. For this reason, the stocks are accessible on a national level by the Portuguese Blood Institute. The stocks should be transferred to the affected regions and, if needed, routine surgeries should be postponed and donors should be called. It is very important to have consistent and

continuous messages to donors, even if only to inform them that blood donation is not needed at the moment.

Trained teams, a good triage system, and a correct identification system of patients are crucial to the emergency services in hospitals and to the blood bank. In trauma injuries, 40% of deaths are caused by massive haemorrhage. Early identification of potential bleeding sources and restoration of the tissue perfusion to achieve haemodynamic stability are the initial goals to treat massive bleeding. The compensatory mechanisms activated by haemorrhagic shock can lead to acidosis, hypothermia and coagulopathy. This triad should be corrected in order to reverse the situation. The use of guidelines, for example, "*Management of bleeding following major trauma: updated European guidelines*" is advisable.

Adequate stock of blood group O RhD positive and negative red blood cells, AB blood group fresh frozen plasma, and platelet concentrates are needed in blood banks to face emergencies. The use of massive transfusion protocols (MTP) are agreed between the emergency and blood bank teams. These need to be validated, disseminated and audited. The hospital transfusion committee plays a central role in disseminating protocols. According to the clinical situations, the MTP should only be activated when more than four red blood cell concentrates during the first hour, or more than ten red blood cell concentrates during the first 12 hours (massive transfusion), are expected to be used. To prevent more coagulation problems, the MTP advocate **for** the initial use of at least four red blood cell concentrates + four fresh frozen plasma units + one apheresis platelet concentrate. Laboratory monitoring to assess the results of the use of protocols is recommended.

Communication is essential in emergency conditions. The chain of command and control should be defined in advance, as well as the people responsible for communicating with peers, the media and with the population. Communication is also essential at the hospital and blood bank level, where failure can endanger the life of the patients.

Maintaining an adequate blood supply in case of a pandemic

The presentation focused on the contingency planning of blood organizations in case of pandemic flu. Important documents that emphasize

the importance of having shortage plans were discussed, such as the European Blood Alliance (EBA) Pandemic Influenza Planning for Blood Organizations (<http://www.sanquin.nl/Eba/eba.nsf/>), and the European Commission Directive 2009/135/EC allowing temporary derogations to certain eligibility criteria for donors of whole blood and blood components in the context of a shortage risk caused by the Influenza A(H1N1) pandemic. "Drill exercises" are considered very important in making these plans operational in case of a real occurrence. The example of a drill performed in Saint Barthelemy-d'Anjou in 2009, during a donor drive, proved that the rules originally proposed were difficult to meet.

A plan to maximize the effectiveness of a national response to any crisis should be developed to ensure equal reaction to severe blood shortages. Usually these plans comprise different phases of inventory of blood components, using colour-coded classifications. The stock of blood components is coded according to traffic lights: green (for a normal blood component inventory level); amber (if the inventory is not sufficient to continue with routine transfusion practices and specific measures are needed to reduce the use of blood components); and red (when the blood components are insufficient to ensure that patients with non-elective indications for transfusion will receive the required transfusion). Perspectives to improve inventory management in a shortage situation point towards the necessity to react in case of a shortage at the European level, particularly in the situation of a pandemic.

West Nile virus outbreak management in Romania in 2010 – a case-study

The impact of the West Nile virus outbreak on the Romanian blood supply in 2010 was presented. Spread by the mosquito (*Aedes albopictus*) and fostered by travel and climate changes, in 2010 the West Nile virus reached several European countries: Albania, Bosnia and Herzegovina, Croatia, Montenegro, Greece, and Slovenia.

The importance of recognizing and being aware of the medical aspects of infection were underlined, bearing in mind its levels of severity, from an asymptomatic situation to a severe disease leading to encephalitis and even death. In establishing response measures to the outbreak, the epidemiology, distribution (risk maps) and transmission routes, and the

experience in the United States were all considered. With respect to this, the international transfusion policies (from July 2010) were applied to the Romanian blood transfusion strategy.

The situation in the region of Constanta (Romania) was used as a case-study. A 1% decrease in annual blood collection was recorded in 2010. During the 3-month period of special measures (31 August–30 November) around 600 units were lost, corresponding to donors deferred due to their residence in locations where infection cases had been identified. The gap in blood collection was covered through increased collection in other infection-free areas. There was no negative impact on patients' treatment, due to the measures taken in accordance with the national provisions plan (e.g. increased mobile collection, written information to hospitals on measures to be taken, etc.). The blood service responded well, with no impact upon transfusion activity.

Transfusion medicine education in medical emergencies: the European School of Transfusion Medicine (ESTM) experience

The ESTM was founded in 1992 and has so far held 76 courses on several issues of transfusion medicine, particularly in central and eastern Europe. The responsibilities of clinicians towards blood donation have been constantly underlined, i.e. phasing out replacement donations, offering their medical authority to publicly promote voluntary donation, clarifying medical misconceptions that hinder safe blood sufficiency, and administering safe blood to their patients.

Since 1992, ESTM has held numerous courses. For example, there have been 85 ESTM courses on clinical transfusion and 44 on transfusion medicine in emergencies and clinical specialties, namely: *Transfusion Medicine and Intensive Care*, ESTM residential course, Linz (Austria), in 1997; *Transfusion Medicine in Disasters and Hospital Emergencies*, ESTM residential course in Pescara (Italy), in 1998; *Therapeutic Haemapheresis – Diagnosis and Transfusion Treatment of Emergencies in Haemostatic Disorders*, ESTM residential course in Prague (Czech Republic), in 1998; and *Blood Therapy in Surgery. Transfusion Medicine and Intensive Care in Surgery*, ESTM residential course in Portorož (Slovenia), in 2001.

A transfusion medicine specialist was defined as “a medically qualified person, having a thorough knowledge and sound experience of clinical medicine and laboratory medicine, having achieved a specific training in general haematology, immunology and blood transfusion practice, who is capable to ensure a maximum of efficacy and safety – for the donor and for the recipient – for any procedure of blood transfusion, who is responsible for the planning and organization of the collection, preparation, storage, distribution and optimal use of blood and blood products under a controlled scheme of quality assurance, who can assist and advise on any diagnostic and therapeutic problem of patients requiring transfusion, who is actively participating in research and development and who is able and willing to teach Transfusion Medicine further to doctors, medical students and any other collaborating professionals.”

Medical emergencies and special circumstances at national and international levels are considered to cover earthquakes, epidemics, wars, and disasters, but also everyday individual medical and surgical problems, for example, orthopaedics, surgery, first aid, intensive care, medicine, paediatrics, obstetrics, and neonatology, etc. These emergencies are not exclusively clinical but also organizational and do require preparatory work and plans as underlined by the previous presenters. Professional responsibility and full involvement are required in the process.

Quick alerts and monitoring systems for transfusion medicine in emergencies

The Swedish experience was taken as the background for this presentation. The organization of the blood services in Sweden is not centralized, with multiple blood services based in hospitals. The average use of red blood cell concentrate is about 50 per 1000 population, but growing in the recent years.

Although there is not a real national plan for emergency situations in Sweden, exchanges of blood components between blood services are possible, supported by the common use of the International Society of Blood Transfusion (ISBT) 128 bar code for blood components.

In the University Hospital of Uppsala, the catastrophe plan includes directions for the blood service. Using thrombo-elastography for manag-

ing blood components therapy in bleeding patients has helped in the management of these situations and has facilitated the decisions regarding plasma/red blood cell ratio transfusion, and also on whether to use tranexamic acid in trauma patients with massive bleeding (a dedicated study was published in *The Lancet*, in 2010).

Quick alerts and monitoring systems for transfusion medicine in emergencies need to be developed at a national level, based on a common denominator already identified by international guidance in the field and adapted to the local circumstances.

Slovenian experience on blood service response in emergencies

In 2010, the blood transfusion service in Slovenia collected an annual average of 95 601 whole blood units from 71 817 blood donors (of which 7950 were first-time donors). There have been more than 1.5 million laboratory tests performed on the donated blood, 128 274 delivered blood components and the 62 229 units of fresh frozen plasma for fractionation. The country has a plan of action for catastrophic situations (pandemics, catastrophic events, terrorist attacks, etc.), and a specific response plan for influenza pandemics, which includes blood safety policies (from 2009).

To exemplify the response to special circumstances in the blood service in Slovenia, a case-study related to the failure of testing equipment was presented.

All collected blood is subject to mandatory testing for transfusion transmissible infections such as hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), and syphilis. Without all these tests, the blood unit cannot be released for use. Samples from all of Slovenia are screened in the Blood Centre in Ljubljana. The two pieces of equipment (one for routine use and one for back-up) used for assays for HIV, HBV and HCV nucleic acid test (NAT) screening broke down within a short interval of each other, during a period of insufficient blood supply. The appointed crisis management team decided to perform anti-hepatitis B core antigen (anti-HBc) test on a certain number of blood units from regular donors with a negative NAT in previous donations.

The crisis lasted ten days and samples were sent to Amsterdam and processed in the Sanquin laboratories. NAT results were delivered the next morning.

The use of the same type of tubes and labelling (ISBT 128 bar code) allowed this back-up to be performed with very little delay. The problem with the equipment (bubbles in the rinsing water) was finally identified and solved. To prevent a recurrence of this situation, an agreement for back-up NAT screening has been established with the Sanquin laboratories. The situation report was essential to review the crisis and draw lessons for improvement.

National reports

The SEE countries presented short national reports on the local capacity of their blood services to deal with emergencies and special circumstances. A questionnaire was drafted through a consultation process and the national report presentations used this questionnaire format as a background structure, providing an opportunity to pilot the accuracy of this data collection/assessment tool.

Albania

Albania has a population of 3.2 million inhabitants.

The Blood Service consists of the National Blood Transfusion Centre (NBTC), an independent institution, with four blood banks in Tirana, accountable to the NTBC. In the whole country there are 31 Blood Establishments as follows: one national centre for testing transfusion transmissible markers and 30 BTCs performing collection, processing and distribution. The NBTC has its own budget received from the government. Blood components are delivered free of charge.

Transfusion therapy is performed in 41 of the 90 public health-care facilities and 31 hospitals. Private hospitals do not perform blood transfusions. Tirana's annual use of blood components ranges around 28 300 transfused units, consisting of red blood cells, fresh frozen plasma, cryoprecipitate and platelet concentrates.

The level of blood donation is 7 donations/1000 inhabitants and the majority of donors are family donors, followed by voluntary non-remunerated donors. Paid donors are still reported, but in a decreasing number. There are strategies to increase voluntary non-remunerated blood donation and donor retention.

The legal framework for medical civil emergency management is currently elaborated by the National Health Emergency Response Committee. To date, the existing laws, regulations and orders do not include blood supply management. Strategic blood stocks are ordered by the Ministry of Health and training in clinical medical emergencies is organized at a national level.

A special fund for the installation of a computerized system covering blood service activities in the Tirana region was recently approved. There is no such system covering pre-hospital or hospital activities.

During the few last years, Albania has been exposed to several natural and technical disasters and outbreaks, but none have had an impact on its blood supply.

Bosnia and Herzegovina

Bosnia and Herzegovina has a population of 3.86 million inhabitants.

The blood service is nationally coordinated in both the Republika Srpska (RS) and the Federation of Bosnia and Herzegovina (FBiH). In the RS there are ten blood services, with an Institute of Transfusion Medicine (ITM). In FBiH there are 17 blood services, with an ITM as an independent institution. The Brcko district (BD) has one blood service. Transfusion services in all of Bosnia and Herzegovina are organized within the public sector. Blood transfusion services are financed through different arrangements in the entities of Bosnia and Herzegovina.

During 2010, 76 486 blood units were collected (46 203 blood donations in the FBiH, 27 753 blood donations in the RS, and 2530 blood donations in the Brcko district). There are no paid blood donors: 48% are voluntary non-remunerated donors and 52% are family replacement donors.

Training in medical emergency management that includes blood transfusion does not exist. Quality management systems are under development.

There is no common information technology (IT) system developed, but there is progress towards establishing a national blood donor register in RS.

The most common medical emergency situation in the past five years relates to trauma from traffic accidents, and subsequent red blood cell (RBC) needs.

Bulgaria

Bulgaria has a population of 7.5 million inhabitants.

The blood service consists of a National Centre of Transfusion Haematology, four Regional Centres of Transfusion Haematology, one Military Blood Centre, 23 hospital-based Departments of Transfusion Haematology, and 57 Blood Banks. In 2010, the number of blood donors was 119 110.

The blood transfusion service is financed by the state budget. Blood and blood components are distributed to hospitals free of charge according to an annual plan approved by the Ministry of Health.

Blood transfusions are performed in 469 of the 502 public hospitals, and in 213 private hospitals. In 2010, 296 238 blood units were transfused, of which 181 466 were red blood cell concentrates. The majority (28) of emergency medical services are public, with only one being in a private hospital.

The national legislation covers the blood supply management and critical medical and laboratory supplies. There is a national multisectoral legal framework represented by a National Committee. Risk communication is assessed and responses organized.

A crisis preparedness plan exists, and a strategic stock of medical devices and blood components is defined at the national level and renewed

according to the shelf life. Education in medical emergency management and transfusion medicine is included in the medical and paramedical management.

A national blood donor register does not exist, although there is relevant software in the National Centre of Transfusion Haematology and at the Regional Centres of Transfusion Haematology. But because the software differs, it is not interconnected.

The most common medical emergency situations faced during the last five years are road and industrial accidents.

Croatia

Croatia has a population of 4.3 million inhabitants (preliminary results from the census in 2011).

The blood transfusion service consists of one Institute of Transfusion Medicine, 12 Blood Establishments and 21 Blood Banks. The restructuring of the national blood service started in 2008 and is under way. Transfusion is performed in 112 public hospitals and 63 private hospitals or other health-care facilities. The health system is state oriented, and the blood policy and blood transfusion activities are under the responsibility of the Ministry of Health. Funding comes from the state budget.

The number of blood donations in 2010 was 177 355 of which 175 014 were units of whole blood and 2341 were apheresis donations. All donors were voluntary non-remunerated. During the same year, a total of 286 061 blood components were issued for transfusion.

A legal framework regarding transfusion medicine and emergency medicine exists. The Crisis Management Committee is responsible for the strategic inventory list. The strategic stock is renewed every two months. Transfusion medicine and emergency medicine are taught to medical and paramedical professionals and recognized as specialties. Documentation regarding Emergency Medical Services (EMS) is in place or in progress and a haemovigilance system is required by law.

The restructuring of the IT system started in 2007 and is expected to be completed in 2011. A risk communication strategy has been implemented.

Montenegro

Montenegro has a population 0.625 million inhabitants.

The blood services are coordinated by the health-care service and there is no national organization in place. There are nine separate BTCs, one of them with the status of a reference institution. The organization and financing of the blood centres is under the responsibility of the hosting hospitals and this means there are related disadvantages, mainly unequal quality of work and products and uneven availability of blood components. The transfusions are paid for through health-care insurance. In 2010, a project funded through the EU Integration Pre Accession instrument to support implementation of a European blood service in the country was signed.

Transfusions are currently performed in nine public and two private hospitals. In 2010, the blood centres collected, at a national level, 15 325 blood units (2.47% of population) from 11 000 active donors: 71% family donors and 29% voluntary, non-remunerated donors. During the same time, 12 321 red blood cell concentrates, 1765 whole blood units, 333 cryoprecipitate units, and 501 platelet concentrates were transfused.

Although there is no specific, national organisation, inventory and emergency stocks are available. There is no specific training for transfusion medicine and emergency medicine, but the specializations performed in a neighbour country are recognized as adequate education.

The recent experiences regarding emergency situations are due to traffic accidents and floods.

Republic of Moldova

Republic of Moldova has a population of 3.5 million inhabitants.

The blood transfusion service consists of one NBTC, three regional BTCs, 19 Transfusion Departments involved in blood collection, storage

and distribution, and 55 blood banks. Blood transfusion is performed in 95 hospitals or health-care facilities, including 11 private medical facilities and six departmental health-care institutions.

In 2010, a total of 57 507 whole blood donors have given 66 790 units of whole blood and 3824 plasma donors have given 5696 units of plasma donations. The clinical use during the same year was 38 844 red blood cells concentrate, 58 737 fresh frozen plasma, 12 998 cryoprecipitate units and 9081 adult doses of platelets, adding up to a total of 117 660 units of blood components.

A National Committee for Emergency Situations exists, as well as ambulances, an inventory list, and a strategic stock of blood units and devices. There is recognized training in transfusion medicine and emergency medicine for medical and paramedical professionals. Good manufacturing practices, standards for emergency medical services and haemovigilance systems are in place.

Information technology has been developed with a national donor registry and software covering blood establishment activities and the clinical use of blood. A risk communication policy is also in place.

Romania

Romania has a population of 21.4 million inhabitants.

In Romania, the blood services are centralized. There is a National Institute of Transfusion Haematology, which coordinates all 41 blood centres, under the authority of the Ministry of Health. Transfusion is performed in 227 out of 431 public hospitals, and in 21 private hospitals. The blood service is financed out of the state budget, and the hospitals are reimbursed according to diagnosis related groups (DRGs) procedures from the Social Health Insurance Fund.

During 2010, 400 285 blood units were donated, of which 5636 were by apheresis procedures. A total of 530 051 blood component units were transfused, including 288 766 red blood cell concentrates, 189 526 fresh frozen plasma, and 16 000 platelet concentrate units.

A crisis preparedness plan and a red plan are available. EMS are available in public and private health-care institutions in normal circumstances. Inventory and strategic stocks for emergencies are available but without systematic renewal. Contrary to emergency medicine, transfusion medicine is not recognized as a speciality and the training is integrated in medical education. There is an e-learning platform dedicated to transfusion medicine in the SEE project.

Regarding information technology, only three blood establishments have software covering blood service activities.

The most common emergencies in Romania are related to cardiovascular surgery and traffic accidents. In 2010, the country experienced a West Nile virus outbreak with 57 cases and five deaths, which was the subject of a presentation in this meeting. In recent years, the H1N1 flu pandemic, with 7000 cases and 122 deaths, did not have any impact on the blood supply.

Serbia

Serbia has a population of 7.32 million inhabitants.

The blood service is nationally coordinated and is non-profit and non-commercial, under the responsibility of the government. The reorganization process of the blood service, started in 2003, is still in progress. There are three regional blood transfusion institutes responsible for the collection, testing, processing and distribution of blood. In addition, there are 44 hospital-based BTCs. The financing of the blood services is based on contractual agreements with clinical centres and direct service delivery to primary and secondary health-care institutions (funding is ensured from the national health-care insurance fund in both cases).

In 2010, approximately 159 000 blood donors gave 247 775 units of blood. All the donations come from voluntary, non-remunerated donors (75% males and 25% females). About 25% of the blood donors were students.

The legal framework is based on the National Blood Act, adopted in 2010. A national committee for emergency situations exists, as well as an inventory list and strategic stocks of albumin and blood grouping sera.

Preparedness emergency plans are available and the Ministry of Internal Affairs is in charge of these. No national data processing is available.

In 2009, Serbia experienced a pandemic flu situation that had an impact on the blood supply. In the Blood Transfusion Institute of Serbia, there was a reduction from 59 000 donations (in 2008) to 58 000 donations.

The former Yugoslav Republic of Macedonia

The former Yugoslav Republic of Macedonia has a population of 2.05 million inhabitants.

Blood transfusion services are part of the health services and consist of 23 public blood establishments and one establishment in a private cardio-surgery service. The public services consist of one National Institute of Transfusion Medicine (NITM), three BTCs and 19 transfusion services in hospitals, under the complete organizational and financial management of the NITM. Transfusion can be performed in 53 public hospitals (23 in Skopje) and in five private hospitals. Financing is done mainly by state health insurance, with additional own financing for private organizations and some donations.

The required number of blood donations per year was calculated as 55 000 blood donations. During 2010, the number of whole blood donations was 58 876 (permanently increasing). The Institute of Transfusion Medicine in Skopje, which covers about 50% of the national collections, collected 23 000 red blood cell concentrate units, 25 000 fresh frozen plasma units, 5500 cryoprecipitate units, and 8000 platelet concentrate units. During the same period of time, 24 744 red blood cell concentrates, 25 346 fresh frozen plasma, 5458 cryoprecipitate, 14 119 platelet concentrates, and 502 units of whole blood were transfused, adding up to a total of 70 169 units of blood components.

National multisectoral emergency management is organized with a national committee and a crisis preparedness plan. There are ambulances and critical supply lists to face emergency situations. The national blood supply management in case of emergencies is organized. The training in medical emergency management is part of basic and continuous medical education.

A donor database/register is in the process of being established in the NITM, but there is no national database available yet. Risk communication is assessed and responses are organized.

In recent years, a swine flu outbreak was experienced on a national level, with no impact on the blood supply.

Development of a 'Moodle' electronic platform for e-learning and information exchange

Considering the needs for information exchange and the development of e-learning programmes for transfusion medicine, the use of an online content management system was proposed, with an electronic platform for teaching purposes (e-learning), named 'Moodle'.

The main benefit of a common site on the web for the courses (whether via Moodle or their own web site) is the easy access to many kinds of material (for example, a syllabus, assignment instructions, hand-outs, reading, images, web links, and so on).

In addition, many routine administrative functions can be handled through Moodle, for example, changing the syllabus or assignments, comments, and preparatory work for discussions. The privacy of a Moodle site allows participants' work and/or discussions that the participants might want to keep restricted access to this information. There is advanced management of users based on access level (e.g. site administrator, course creators, lecturers and participants), and it can be accessed at anytime from anywhere.

The experience of the University of Oradea with their "Distance Learning Department site" that has more than 4000 active users and has been in use for seven years is evidence of good support for an e-learning platform. Moodle is expected to become functional within a very short time.

Conclusions and recommendations

The workshop proved to be a needed training exercise and allowed extensive discussions and sharing of experiences between participants from various countries. The multidisciplinary composition of the national teams added to the complexity of the issues raised and also enabled the identification of key interventions that are required at local and regional levels to develop integrated responses to emergencies.

Issues identified and targets proposed

The main issues identified during the discussions and the targets that were proposed are summarized below.

1. Regulatory provisions for the operation of blood services in emergency and special circumstances need to be developed at national and institutional levels. The use of a common denominator for these plans will allow for similar mechanisms of response and improve coordination and external support when needed.
2. The logistics for operation in emergencies need to be more detailed and improved. Implementing national information technology systems is considered mandatory as part of stock management and response.
3. Enhanced collaboration and coordination between various stakeholders including nongovernmental organizations (NGOs), religious communities and other organizations in blood donor management is part of the strategy to support self-sufficiency at national and regional levels, and mass mobilization in case of need.
4. The establishment of a regional support network for emergencies and special circumstances has been recognized as an important communication, alert and operational support tool.

The proposed targets have a particular focus on the standardization of operations and managerial aspects, sustained by adequate team training and a national action plan. The targets proposed include:

- ◆ standardized facilities, equipment, availability of mobile blood units;
- ◆ a national donor register and standardized donor management;
- ◆ a dedicated national training action plan; and
- ◆ five days blood supply as a strategic reserve

These are expected to lead to a blood supply covering the needs, well-trained staff, an integrated information system, and improved patient care.

Emerging recommendations

The main emerging recommendations are listed below

- ◆ Participants will share the knowledge and information gained in the workshop at all levels, including reporting to national health authorities about the meeting outcomes and the identified needs.
- ◆ To better understand the situation and support shaping targeted and sub regional actions, national assessment reports addressing blood service response in emergencies and special circumstances should be compiled in a comprehensive document supporting dedicated strategic recommendations.
- ◆ Strong communication strategies in case of occurring special circumstances which might involve blood service operations should be developed/made available
- ◆ Effective blood supply management plan should be developed for normal and special circumstances with commonly agreed indicators (at least based on the available inventory) and shortage plans, inspired from existing experience and the national plans in Europe and beyond.
- ◆ Development of standardized steps in addressing emergencies and special circumstances at national level should be considered, with a view of developing a shared and harmonized SEE approach that

could, at a later stage, support the intercountry exchange of blood products if needed.

- ◆ Health authorities should support and promote multidisciplinary teamwork integrating institutional and regional levels in effective blood supply management in special circumstances.
- ◆ Trained staff should be motivated and constantly engaged in harmonized continuous medical education programmes and share best practices between SEE countries
- ◆ A future action to be considered is the development of local, regional, national and transnational coordinated preparedness plans for the response of the blood service in mass casualty incidents.
- ◆ The development of follow-up actions within the SEEHN will be facilitated through the electronic collaborative space, based on an e-platform, allowing for information sharing and learning.

Annex 1

Questionnaire to assess existing blood services capacity of response to medical emergencies and special circumstances

NB: Working paper of limited circulation focused on blood services, to be considered only in conjunction with the following WHO tools: 2008 questionnaire of EMS assessment, hospital safety index, 2009 hospital preparedness safety checklist, 2011 assessment of health system capacity for crisis management

Person completing the questionnaire:

General information

1. Demographics
 - a. Number of inhabitants
 - b. Distribution according to gender (male/female)
 - c. Distribution according to age groups
 - i. 0 – 15 (18) years of age; 15 (18) – 64 years of age; over 64 years of age
 - ii. (mean and median age)

Health care services| blood transfusion services

2. Organization of blood services in relation to health care delivery services
 - a. National coordination
 - b. Independent
 - c. Other

Number	Public	Private	Other
Blood establishments/ blood centers			
Health care facilities *			
Hospitals performing transfusion therapy			

* considered as places where blood transfusion could be administered in case of emergency

3. Related financial schemes/ financial arrangements
 - a. General activity: existing contractual or other arrangements related to response to medical emergencies in normal and special circumstances
 - i. Blood services
 - ii. Hospitals
 - iii. Ambulance services
 - b. Pricing and reimbursement of blood components/ products
 - i. Blood services: who and how calculates price, how is this reimbursed
 - ii. Hospitals: how are blood components paid for
 4. Annual use of transfusion therapy (2010 or latest cumulative figure)
 5. National blood donor pool
 - a. Number of active blood donors in 2010 or latest figure
 - b. Number of total blood donors/ donations in 2010 or latest figure
 - c. Estimates of O negative blood group prevalence in the blood donor population compared to the general population
- #### Blood supply management in special circumstances
6. National multi sector emergency management legal framework including blood supply management
 - a. Legal provisions
 - b. Regulatory provisions
 - c. National multi sector emergency management committee
 - d. Guidelines (national and international) available and in use
 7. Availability of emergency medical services (EMS) in normal circumstances

Availability of EMS	Public	Private	Comments
Out of hospital			
In hospital			
Ambulance services			
Type A (medical transport)			
Type B (basic life support)			
Type C (mobile ICU)			

8. Critical medical laboratory equipment and supplies used for diagnosis and treatment available
 - a. Inventory list
 - b. Strategic stock
 - c. Rate of discard/ revision/ renewal

9. Training in medical emergency management (specify if it includes blood transfusion)

	Transfusion medicine	Emergency medicine	Other
Paramedical training curriculum			
Medical training curriculum			
Postgraduate specializations			
Continuous medical education			
E-learning dedicated platform			

10. Quality management
 - a. Good manufacturing practices in use
 - b. ISO/ other standards certification for the blood services
 - c. National standards of performance for emergency departments
 - d. Documentation
 - i. Crisis preparedness plan for EMS (out of hospital and hospital)
 - ii. Risk assessment and preparedness information system
 - iii. Contingency plans for medical treatment in disasters
 - iv. Written triage system (standards and protocols)
 - v. Procedures for patients without identification system
 - vi. Haemovigilance/ emergency reporting systems
 - vii. Bio security protocols
 - viii. Quality and safety monitoring reports

11. Data processing
 - a. National blood donor register
 - b. National database on standby/ available blood supplies
 - c. Clinical demand/ use of blood components/ products
 - d. Devoted software covering blood service activities

- e. Devoted software covering pre hospital and hospital activities
- f. Integrated stress support systems

12. Risk communication

- a. To the public
- b. To the partners/ stakeholders

13. National and international support mechanisms foreseen for emergency management (please specify)

14. National experience

- a. Indicate the most common medical emergency situations you have faced during the last 5 years
- b. Specify the type of blood and blood components/ products (including main choice) commonly used in emergency situations
- c. Have you faced a pandemic affecting the blood supply during the last 12 months
- d. If yes, please describe measures
- e. What was the recorded impact on the availability of the national blood supply

15. What is your general perception on how the blood service operates/ would operate in emergency situations under the current conditions

16. Please list three main priorities that would require immediate attention in the field, to improve operational response of the blood service in special circumstances

Glossary of terms

Capacity The combination of all the strengths, attributes and resources available within a community, society or organization that can be used to achieve agreed goals. Capacity may include infrastructure and physical means, institutions, societal coping abilities, as well as human knowledge, skills and collective attributes such as social relationships, leadership and management. Capacity also may be described as capability. Capacity assessment is a term for the process by which the capacity of a group is reviewed against desired goals, and the capacity gaps are identified for further action (1).

Contingency planning A management process that analyses specific potential events or emerging situations that might threaten society or the environment, and establishes arrangements in advance to enable timely, effective and appropriate responses to such events and situations. Contingency planning results in organized and coordinated courses of action with clearly-identified institutional roles and resources, information processes, and operational arrangements for specific actors at times of need. Based on scenarios of possible emergency conditions or disaster events, it allows key actors to envision, anticipate and solve problems that can arise during crises. Contingency planning is an important part of overall preparedness. Contingency plans need to be regularly updated and exercised (1).

Crisis An event or series of events representing a critical threat to the health, safety, security or wellbeing of a community, usually over a wide area. Armed conflicts, epidemics, famine, natural disasters, environmental emergencies and other major harmful events may involve or lead to a humanitarian crisis (2).

Disaster A serious disruption of the functioning of a community or a society involving widespread human, material, economic or environmental losses and impacts, which exceeds the ability of the affected community or society to cope using its own resources. Disasters are often described as a result of the combination of: the exposure to a hazard; the conditions of vulnerability that are present; and insufficient capacity or measures to reduce or cope with the potential negative consequences. Disaster impacts may include loss of life, injury, disease and other nega-

tive effects on human physical, mental and social well-being, together with damage to property, destruction of assets, loss of services, social and economic disruption and environmental degradation (1).

Disaster risk management The systematic process of using administrative directives, organizations, and operational skills and capacities to implement strategies, policies and improved coping capacities in order to lessen the adverse impacts of hazards and the possibility of disaster (1).

Disaster risk reduction The concept and practice of reducing disaster risks through systematic efforts to analyze and manage the causal factors of disasters. This includes reducing exposure to hazards, less vulnerability of people and property, wise management of land and the environment, and improved preparedness for adverse events (1).

Early warning system The set of capacities needed to generate and disseminate timely and meaningful warning information, to enable individuals, communities and organizations threatened by a hazard to prepare and to act appropriately and in sufficient timely manner, in order to reduce the possibility of harm or loss (1).

Emergency A sudden and usually unforeseen event that calls for immediate measures to minimize its adverse consequences (3).

Emergency management The organization and management of resources and responsibilities for addressing all aspects of emergencies, in particular, preparedness, response and initial recovery steps (1).

Hazard A dangerous phenomenon, substance, human activity or condition that may cause loss of life, injury or other health impacts, property damage, loss of livelihoods and services, social and economic disruption, or environmental damage (1).

Health information system A well-functioning health information system ensures the production, analysis, dissemination and use of reliable and timely information on health determinants, health systems performance and health status (4).

Incident command system The combination of facilities, equipment, personnel, procedures and communication operating within a common organizational structure designed to aid in the management of resources for emergency incidents (4).

Infection control: Measures practiced by health-care personnel in health-care facilities to decrease transmission and acquisition of infectious agents (e.g., proper hand hygiene; scrupulous work practices; and the use of personal protective equipment such as masks, respirators, gloves, gowns, and eye protection). Infection control measures are based on how an infectious agent is transmitted and include standard, contact, droplet, and airborne precautions (5).

Preparedness The knowledge and capacities developed by governments, professional response and recovery organizations, communities and individuals, to effectively anticipate, respond to and recover from the impacts of likely, imminent or current hazard events or conditions. Preparedness action is carried out within the context of disaster risk management and aims to build the capacities needed to efficiently manage all types of emergencies and achieve orderly transitions, from response through to sustained recovery. Preparedness is based on a sound analysis of disaster risks and good linkages with early warning systems, and includes such activities as contingency planning, stockpiling of equipment and supplies, the development of arrangements for coordination, evacuation and public information, and associated training and field exercises. These must be supported by formal institutional, legal and budgetary capacities. The related term “readiness” describes the ability to quickly and appropriately respond when required (1).

Public awareness The extent of common knowledge about disaster risks, the factors that lead to disasters and the actions that can be taken individually and collectively to reduce exposure and vulnerability to hazards (1).

Risk assessment A methodology to determine the nature and extent of risk by analyzing potential hazards and evaluating existing conditions of vulnerability that together could potentially harm exposed people, property, services, livelihoods and the environment on which they depend (1).

Risk communication Risk communication for public health emergencies includes the range of communication capacities required through the preparedness, response and recovery phases of a serious public health event, to encourage informed decision making, positive behavior change and the maintenance of trust (5).

Risk management The systematic approach and practice of managing uncertainty to minimize potential harm and loss (1).

Surveillance: The systematic ongoing collection, collation and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response, as necessary (5).

Vulnerability The characteristics and circumstances of a community, system or asset that make it susceptible to the damaging effects of a hazard. There are many aspects of vulnerability, arising from various physical, social, economic, and environmental factors. Examples may include poor design and construction of buildings, inadequate protection of assets, lack of public information and awareness, limited official recognition of risks and preparedness measures, and disregard for wise environmental management. Vulnerability varies significantly within a community and over time. This definition identifies vulnerability as a characteristic of the element of interest (community, system or asset) which is independent of its exposure. However, in common use the word is often used more broadly to include the element’s exposure (1).

References

1. *UNISDR terminology on disaster risk reduction (2009)*. Geneva, United Nations International Strategy for Disaster Reduction, 2009
<http://www.unisdr.org/eng/library/UNISDRterminology-2009-eng.pdf>
2. *Risk reduction and emergency preparedness*. Geneva, World Health Organization, 2007.
http://www.who.int/hac/techguidance/preparedness/emergency_preparedness_eng.pdf
3. *Internationally agreed glossary of basic terms related to disaster management*. Geneva, United Nations Department of Humanitarian Affairs, 1992
[http://www.reliefweb.int/rw/lib.nsf/db900SID/LGEL-5EQNZV/\\$FILE/dha-glossary-1992.pdf?OpenElement](http://www.reliefweb.int/rw/lib.nsf/db900SID/LGEL-5EQNZV/$FILE/dha-glossary-1992.pdf?OpenElement)
4. *Key components of a well functioning health system*. Geneva, World Health Organization, 2010
<http://www.who.int/entity/healthsystems/HSSkeycomponents.pdf>
5. *Draft protocol for assessing national surveillance and response capacities for the international health regulations*. Geneva, World Health Organization, 2010.

Annex 2 Programme of work

SEE Blood safety project: Implementation of Addendum to Component Two

“Increasing transnational availability of safe blood and blood components for medical emergencies and special circumstances”

Training of trainers

7-9 June 2011, Oradea, Romania

Tuesday 7 June

08:45 – 09:00	<i>Registration</i>
09:00 – 09:30	Opening of the course: SEEHN framework and the blood safety project Welcome addresses Introduction of participants Adoption of provisional programme Election of chair and reporter
09:30 – 10:00	Course outline and objectives to be met
10:00 – 10:30	EC legal framework and WHO recommendations and guidelines for blood and patient safety
10:30 – 11:00	CoE/ EDQM recommendations and guidelines for safe blood components/ products and services
11:00 – 11:30	<i>Coffee/ tea break</i>
11:30 – 13:00	Blood service response to medical emergencies and special circumstances in SEE countries – national standardized reports (I)
13:00 – 14:30	<i>Lunch</i>
14:30 – 15:30	Blood service response to medical emergencies and special circumstances in SEE countries – national standardized reports (II)
15:30 – 16:00	<i>Coffee/ tea break</i>
16:00 – 17:00	Blood donor management, blood stock management and prospective evaluation of blood needs
17:00 – 17:30	Voluntary non remunerated blood donation – ethical and social particularities in emergency situations and special circumstances
17:30 – 18:30	Maintaining an adequate blood supply in case of pandemic
18:30	<i>Closure day 1</i>

Wednesday 8 June

09:00 - 09:10	Summary Day 1
09:10 - 10:00	Emergency operations plans for blood transfusion safety in special circumstances
10:00 - 11:00	Reports from working groups on emergency operations plans for blood transfusion safety
11:00 - 11:30	<i>Coffee/ tea break</i>
11:30 - 13:00	Principles in mass casualty incidents and hospital preparedness plans
13:00 - 14:30	<i>Lunch</i>
14:30 - 15:30	The Romanian approach to mass casualty incidents
15:30 - 16:00	<i>Coffee/ tea break</i>
16:00 - 17:00	Best practice protocols for clinical procedures safety in disaster situations (presentation & case study)
17:00 - 17:45	The Slovenian experience in blood service response to medical emergencies and special circumstances
17:45 - 18:30	Open forum for emerging issues
18:30	<i>Closure day 2</i>

Thursday 9 June

09:00 - 09:10	Summary Day 2
09:10 - 10:00	Transfusion medicine regional education in medical emergencies: the ESTM experience
10:00 - 11:00	Quick alert and monitoring systems for transfusion medicine in medical emergencies and special circumstances (I)
11:00 - 11:30	<i>Coffee/ tea break</i>
11:30 - 13:00	Quick alert and monitoring systems for transfusion medicine in medical emergencies and special circumstances (II)
13:00 - 14:30	<i>Lunch</i>
14:30 - 15:30	Round table on integrated responses to medical emergencies and special circumstances: comparison of best practices
15:30 - 16:00	<i>Coffee/ tea break</i>
16:00 - 17:30	Delineation of common approaches identified and local priorities
17:30 - 18:00	Conclusions and recommendations
18:00 - 18:30	<i>Closure of event & distribution of attendance certificates</i>

Annex 3 List of participants

Country representatives

Albania

Arben METKA

National Quality Control Manager

National Blood Transfusion Centre

Tirana

Jonida MOLISHTARI

Blood collection Department

National Blood Transfusion Centre

Tirana

Irena SEFERI

National Project Manager, Director

National Blood Transfusion Centre

Tirana

Valbona SELMANI

Department Of Coordination of Blood Donors

National Blood Transfusion Centre

Tirana

Merita XHETANI

Biologist, Department of Quality Control

National Blood Transfusion Centre

Tirana

Bosnia and Herzegovina

Vildana VILIC HASANOVIC

Resident of Transfusiology

Institute of Transfusion Medicine of the Federation of Bosnia and

Herzegovina

Sarajevo

Sandra MITROVIC

Transfusiologist

Institute of Transfusion medicine of Republic of Srpska

Banja Luka

Dragan SARENAC

Transfusiologist, National Project Manager

Blood Transfusion Centre

Trebinje, Republic of Srpska

Bulgaria

Rumiana Ivanova ANDONOVA

Assistant Professor in Pediatric Surgery

Emergency Medical Institute

Sofia

Daniela Atanasova DIMITROVA

Head of Blood Donor Department

Regional Blood Transfusion Centre

Pleven

Elena Georgieva HRISTOVA

Head of Immunohaematology Department

Blood Transfusion Centre

Stara Zagora

Nathalia Georgieva MASHAROVA

Deputy Director, Head of Diagnosis Department

National Centre of Transfusion Haematology

Sofia

Croatia

Zrinka KRUHONJA-GALIC
Specialist in Transfusion Medicine
Department of Haematology of Erythrocytes
Croatian Institute of Transfusion Medicine
Zagreb

Martina LUKIC
Specialist in Transfusion Medicine
Department of Assurance and Quality Control
Croatian Institute of Transfusion Medicine
Zagreb

Vanja NIKOLAC
Head of Department for Monitoring and Inspection of Blood
Croatian Institute of Transfusion Medicine
Zagreb

Dorotea ŠARLIJA
Specialist in Transfusion Medicine
Head of Quality Management
Croatian Institute of Transfusion Medicine
Zagreb

Miljana STOIC-VIDOVIC
Specialist in Transfusion Medicine
Croatian Institute of Transfusion Medicine
Zagreb

The Former Yugoslav Republic of Macedonia

Milenka BLAGOEVSKA
Head of Department of Blood Donation
Institute of Transfusion Medicine of the Republic of Macedonia
Skopje

Olga DAMEVSKA
Quality Manager
Institute of Transfusion Medicine of the Republic of Macedonia
Skopje

Diana DIMITROVSKA
Specialist in Transfusiology
Regional Centre of Transfusion Medicine
Bitola

Risto DUKOVSKI
General Manager
Institute of Transfusion Medicine of the Republic of Macedonia
Skopje

Anita HRISTOVA –DIMCEVA
Head
Institute of Transfusion Medicine of the Republic of Macedonia
Skopje

Republic of Moldova

Alexandru GHERMAN
Division Chief, Manager SMAIM
National Blood Transfusion Centre
Chisinau

Silvia ROSCA
Vice Director, Quality Manager
National Blood Transfusion Centre
Chisinau

Natalia POPUSOI
Laboratory Chief, PCR Specialist
National Blood Transfusion Centre
Chisinau

Oleg SAVENCO
Section Chief
National Blood Transfusion Centre
Chisinau

Angela ZINICOVSCHI
Chief SMEISS
National Blood Transfusion Centre
Chisinau

Montenegro

Senad BEGIC
Epidemiologist
Centre for Disease Control and Prevention
Institute for Public Health of Montenegro
Podgorica

Vladimir DOBRICANIN
Specialist of General Surgery
Director of Emergency Centre
Clinical Centre of Montenegro
Podgorica

Gordana RASOVIC
Specialist of Transfusion Medicine, Director
Blood Transfusion Centre
Clinical Centre of Montenegro
Podgorica

Natalija TRNINIC
Specialist of Anesthesiology and Reanimatology
Blood Transfusion Centre
Clinical Centre of Montenegro
Podgorica

Svetlana VUCINIC
Specialist of Transfusion Medicine
Blood Transfusion Centre
Clinical Centre of Montenegro
Podgorica

Romania

Alina Mirella DOBROTA
Transfusiologist, Director
Blood Transfusion Center
Constanta

Adriana NECULA
Virologist
National Institute of Transfusion Medicine
Bucharest

Laura Eugenia PACURARIU
Transfusiologist, Director
Blood Transfusion Center
Arad

Aurel Marc Andrei ROSIN
Transfusiologist, Director
National Institute of Transfusion Medicine
Bucharest

Georgeta STANESCU
Transfusiologist
National Institute of Transfusion Medicine
Bucharest

Serbia

Snezana JOVANOVIC SRZENTIC
Transfusion Medicine Specialist
Blood Transfusion Institute of Serbia
Belgrade

Radmila JOVANOVIC
Transfusiologist
Institute of Blood Transfusion of Vojvodina
Novi Sad

Dragan ILIC
Epidemiologist
Institute of Students Health Care
Belgrade

Dejan STEPIC
General Surgeon
Emergency Health Centre
Clinical Centre of Serbia
Belgrade

Zaneta TERZISKI
Anesthesiologist
Clinical Center of Serbia
Novi Sad

Lecturers

Raed ARAFAT
Romanian Ministry of Health, State Secretary
Bucharest, Romania

Marie-Emanuelle BEHR – GROSS
Scientific Officer, DBO / Blood Transfusion
European Directorate for the Quality of Medicines & HealthCare
Council of Europe
Strasbourg, France

Hadrian BORCEA
Vice-president of Consultative Committee of Romanian Ministry of
Health for Emergency Medicine and Disasters
Emergency County Hospital
Oradea, Romania

Olivia Ligia BURTA
Regional Project Manager SEEHN- BS
Assistant Professor Faculty of Medicine and Pharmacy
Blood Transfusion Center
Oradea, Romania

Gilles FOLLEA
Executive Director
European Blood Alliance
Brussels, Belgium

Vesna GALVANI
WHO Collaborative Centre for Quality Management for Blood Services
Blood Transfusion Institute of the Republic of Slovenia
Ljubljana, Slovenia

Valentina HAFNER
Programme Manager, a.i., Health Care Quality Programme
WHO Regional Office for Europe
Copenhagen, Denmark

Norbert LUBENOW
Docent
Uppsala University Hospital
Uppsala, Sweden

Fatima NASCIMENTO
Former Medical Director
Intituto Portugues do Sanguae
Lisbon, Portugal

Carmen PANTIS
Lecturer, Faculty of Medicine and Pharmacy
Head of Intensive Care Unit, Emergency County Hospital
Oradea, Romania

Umberto ROSSI
President of European School of Transfusion Medicine
Milano, Italy



SOUTH EASTERN EUROPE HEALTH NETWORK (SEEHN)

*"Health Development Action for
South-eastern Europe"*

Members

Albania
Bosnia and Herzegovina
Bulgaria
Croatia
Montenegro
Republic of Moldova
Romania
Serbia
The former Yugoslav
Republic of Macedonia

Donors and neighbours

Belgium
France
Greece
Hungary
Italy
Israel
Netherlands
Norway
Slovenia
Switzerland
Sweden
United Kingdom

Partner organizations

Council of Europe
European Directorate for
Quality of Medicines & Health Care
Council of Europe
Development Bank
Regional Cooperation Council
WHO Regional Office for Europe



WHO Regional Office for Europe
Division of Health Systems and Public Health
8 Scherfigsvej, 2100 Copenhagen
Denmark

Tel: +45 3917 1717
Fax: +45 3917 1818
E-mail: postmaster@euro.who.int

SEEHN Executive Committee
Mrs. Snezhana Chichevalieva, Chair
Head, Department for European Integration
Ministry of Health
The former Yugoslav Republic of Macedonia

Tel./fax: +389 23 12 11 46
Cell phone: +389 75 25 49 32
E-mail: scicevalieva@gmail.com

SEEHN Regional Health Development Centre for Blood Safety
Dr. Olivia Ligia Burta, Regional Project manager
Assist. Prof. University of Oradea
Director, Blood Transfusion Center
30, Louis Pasteur, Oradea, Romania

Tel/fax: +40 25 9434752
E-mail: oliviaburta@yahoo.com

Council of Europe
European Directorate for Quality of Medicines & Health Care
7 Allée Kastner, F-67000 Strasbourg
France

Tel: + 33 (0) 3 88 41 38 22
Fax: + 33 (0) 3 88 41 27 71
www.edqm.eu/hd

