Multi-Country Workshop on Patient Safety in Transfusion Therapy in Emergency and Special Circumstaces

Bucharest, Romania, on 07-09 July 2014

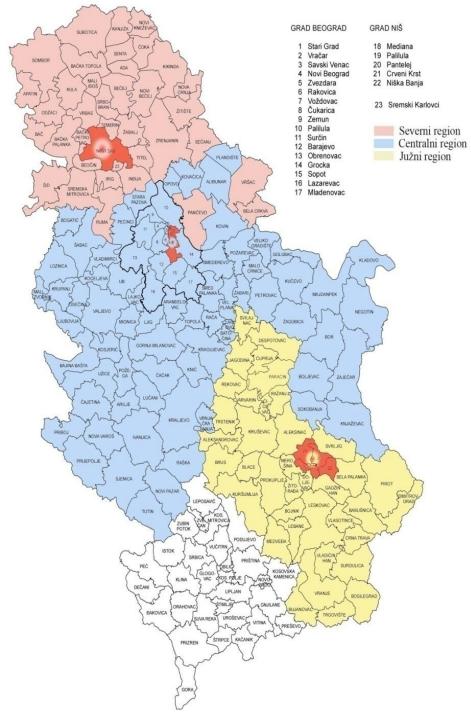
National report submitted by Snežana Jovanović Srzentić, MD, PhD, specialist in transfusion medicine

Director of the Blood Transfusion Institute of Serbia and National project manager of Serbia in the Regional project "Increasing Transnational Availability of Safe Blood and Blood Components for medical Emergencies and Special

Circumastances"



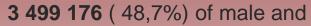




Serbia **General informations**

Number of inhabitants: **7 186 862** (data from 2011)

Distribution according to gender (male/female):

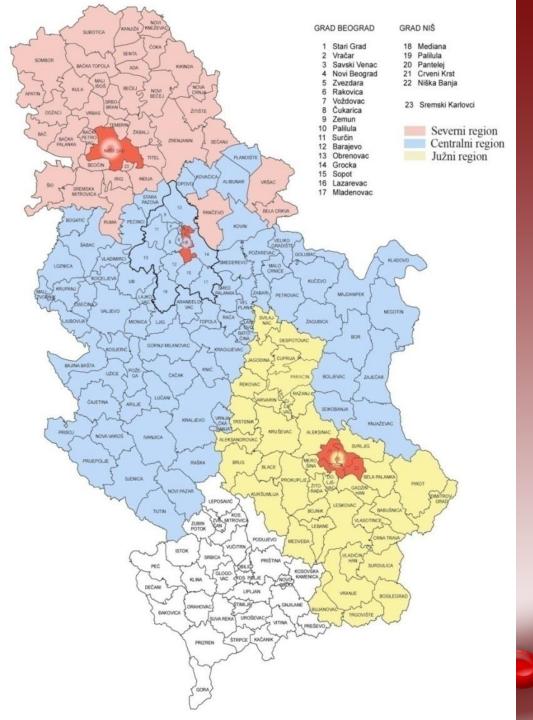




3 687 686 (51,3 %) female inhabitants







Serbia General informations

Distribution according to age groups

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age 15-19, 401 994 (5,6%); age 20-24, 439 741 (6,1 %); age 25-29, 480 286 (6,7 %); age 30-34, 496 362 (6,9 %); age 35-39, 493 934 (6,9%); age 40-44, 469 928 (6,5%); age 45-49, 483 986 (6,7%), age 50-54, 520 344 (7,2%), age 55-59, 596 279 (8,3%), age 60-64, 528 414 (7,4%).
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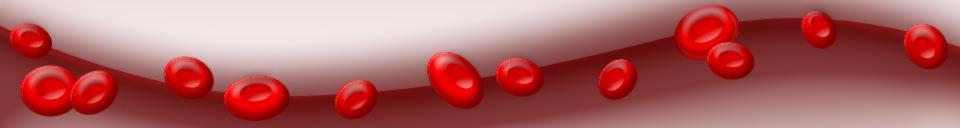
Serbia General informations donors

- mean and median age is
 - for males 40,8 and
 - for females 43.5

Health care services | blood transfusion services Organization of blood services in relation to health care delivery services in Serbia

- Blood transfusion service in Serbia is nationally coordinated, government based, non profit and non commercial organization.
- There are no independent, private or any other types of blood transfusion establishments in the country.
- There are three major blood transfusion institutes (Blood Transfusion Institute of Vojvodina, Blood Transfusion Institute of Serbia and Blood Transfusion Institute of Niš), organized on a regional basis (north, central and south regions)*, responsible for collection, testing, processing and distribution of blood.
- Besides, there are 44 hospital based blood transfusion establishments in most cases responsible for collection, testing and distribution of blood and performing transfusion therapy to hospitalized patients.

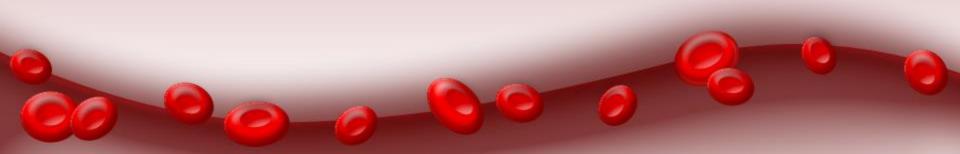
Relation and collaboration between the blood transfusion service of Serbia and other health care delivery institutions are nationally coordinated and government based.



Health care services blood transfusion services Organization of blood services in relation to health care delivery services in Serbia

- *Reorganization of the blood transfusion service in Serbia was took place within the Project entitled "Support of the European Union to the National Blood Transfusion Service in Serbia", supported by the European Agency for Reconstruction (European Union) and the Ministry of Health of Serbia (Government of the Republic of Serbia) from 2003 until 2005.
- The main tasks of the project were to improve and to strengthen the capacity of the national blood transfusion service; to ensure the efficient and timely supply of sufficient quantities of safe blood and blood products to all health care establishments in Serbia; to ensure the rational use of blood and blood products; to find the most optimal solution for reorganization of blood transfusion service; to produce a National Blood Transfusion Strategy.
- However, reorganization of the blood transfusion service in Serbia is a time consuming process which so far has not been finished.
- One of the major tasks to be effectuated soon is to establish unique national information system database.

Number	Public	Private	Other
Blood establishments/ blood centers	3 major institutes and 44 hospital base blood transfusion establishments	none	none
Health care facilities *	40 general hospitals, 37 spec. clinics, 4 clinics, 4 clinical centers, 4 clinical- hospital centers	Official data unavailable	
Hospitals performing transfusion therapy	98	Official data unavailable	



Transposition in our country in legislation of EU legislative and regulatory documents on Blood Safety and inclusion of WHO Recommendations

- <u>Directive 2005/62/EC</u> of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments
- <u>Directive 2004/23/EC</u> on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
- Good Practice Guidelines for Blood Establishments and Hospital Blood Banks Required to Comply with EU Directive 2005/62/EC
- Resolution CM/Res(2013)3 on sexual behaviours of blood donors that have an impact on transfusion safety (Adopted by the Committee of Ministers on 27 March 2013 at the 1166th meeting of the Ministers' Deputies)
- Resolution CM/Res(2008)5 on donor responsibility and on limitation to donation of blood and blood components (Adopted by the Committee of Ministers on 12 March 2008 at the 1021st meeting of the Ministers' Deputies)
- Guide to the Preparation, Use and Quality Assurance of Blood Components, 2011, EDQM, Council of Europe, translated and published in 2013 by the Ministry of Health of the Republic of Serbia and distributed to all transfusion medicine establishments in the country.



National and if appropriate regional structures for the implementation of the above acts

Acts and regulations affiliated with transfusion medicine activities in Serbia

- Act on Health Protection
- Act on Health Care Insurance
- Act on Protection of the Public against Infectious Diseases
- Act on Transfusion Medicine (January 1st, 2010)
- Act on Record Keeping within Health Care System
- Act on the rights of the Individuals

Acts and regulations affiliated with transfusion medicine activities in Serbia

- Rule book defining collection of blood reserves
- Rule book defining the contents of the information given to the person willing to donate blood or blood components, contents of the donor's questionnaire and contents of the consent form to be signed by the person willing to donate blood or blood components
- Rule book defining the extent of the medical check up and criteria for the selection of blood or blood component donors
- Rule book defining detailed conditions regarding the staff, equipment and space required for performing transfusion medicine practice, i.e. tasks performed within transfusion medicine activities

Acts and regulations affiliated with transfusion medicine activities in Serbia

- Rule book defining detailed conditions for storage, management and distribution of blood and blood components
- Rule book defining detailed conditions for blood and blood components testing
- Rule book defining ways and procedures of record keeping in authorised blood transfusion
- Rule book defining prices and compensations for processed blood and blood components intended for blood transfusion
- Rule book defining reporting infectious diseases and other cases defined by the Act on Protection of the Public against Infectious Diseases

Emergency situations in Serbia: Act on Emergency Situations

Amount of Blood reserves required to be available in cases of major emergencies at regional and/or national levels. How are these major emergencies defined

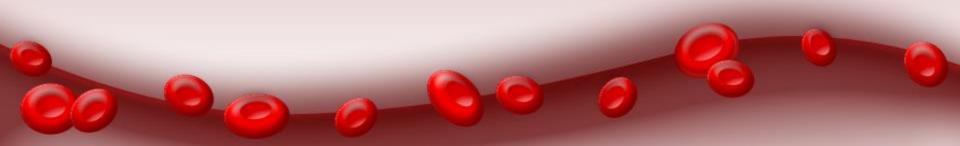
National blood donor pool

There are no exact data on the total number of blood donors on the annual basis in Serbia. In 2013 there were approximately

142 752 blood donors.

Amount of Blood reserves required to be available in cases of major emergencies at regional and/or national levels. How are these major emergencies defined

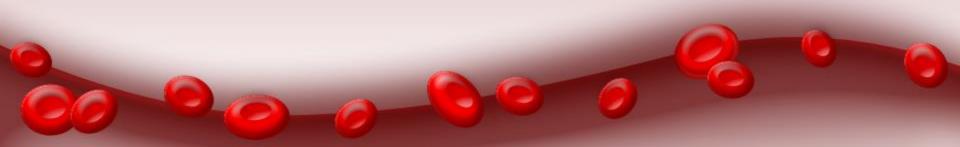
- Demographic characteristics of the blood donor pool in Serbia are the following;
 male 73,6%, female 26,4%.
- Secondary schools pupils and university students above 18 years and students-25,9%, random population 74,1%.
- The average age of blood donors in Serbia is around 38 to 40 years.



Number of total blood donations in 2013 in Serbia

In Serbia in 2013 there were totally 241 846 blood donations:

- northern region (Blood Transfusion Institute of Vojvodina 65 312 blood donations),
- central region (Blood Transfusion Institute of Serbia 127 810 blood donations) and
- southern region (Blood Transfusion Institute of Niš **39 424** blood donations).
- Military Medical Academy (separate system) 9300 blood donations.



Available procedures for rapid mobilisation of blood donors in cases of major emergencies and procedures to ensure the quality and safety of such donations

Blood supply management in special circumstances

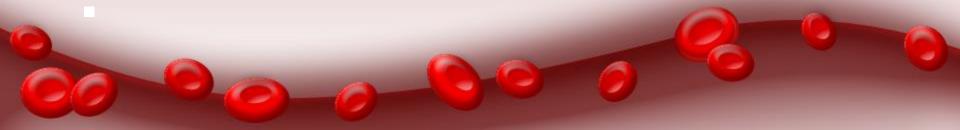
 National multi-sector emergency management legal framework, inccluding blood supply management, is based on legal provisions (The Act on Health Care and Protection, the

Act on Transfusion Medicine Activities and a series of Rule Books defining certain issues related with blood transfusion

- as well as Guidelines for emergency medical service and both
- and blood products).

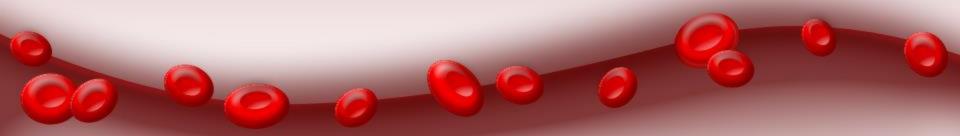
Availability of emergency medical services (EMS) in normal circumstances

- The Republic of Serbia has a well defined health care institutions network consisting of the following hospital facilities (government based): 40 general hospitals, 37 specialized hospitals, 4 clinics, 13 institutes, 4 clinical-hospital centers, 4 clinical centers.
- So far, there are no official data regarding the exact number of private health care facilities, hospitals and clinics.
- Healh care activities in domain of providing emergency medical care services are performed on the primary level of health care within the local health care facilities and emergency medical care establishments for the acutely ill or injured patients, needing immediate medical assistance at the spot, during the transport and in the health care facilities.



Availability of emergency medical services (EMS) in normal circumstances

- Emergency medical care establishments, as well as the local medical care facilities that provide emergency medical care, are also in charge of the ambulance transportation of acutely ill or injured patients to the corresponding health care institutions, including patients unable to walk or partially capable of walking and dialysis patients.
- Within the secondary level health care institutions, there are special units dedicated to medical assistance and care of patients requiring emergency medical care and assistance.
- Clinical centers have their own emergency treatment departments as an integral part of the organization scheme.



Availability of emergency medical services (EMS) in normal circumstances

The network of health care establishments providing emergency medical assistance, i.e. admission and taking care of patients in need of emergency care, are as follows: 120 local health care facilities, 22 general hospitals, 4 specialized hospitals, 3 clinical hospital centers, 4 institutes, 2 clinics, 4 clinical centers and 4 emergency medical assistance establishments.

Within the EMS, ambulance services, i.e. transportation and emergency treatment on the spot, during the transportation and in the facility itself, include medical transport, basic life support and mobile ICU.



Strategic blood stock

At the BTIS there is the Inventory list of stable blood products, i.e. albumin, sera against rabies, tetanus, and other products produced by the BTIS, as well as the Inventory list of blood group test sera also produced by the BTIS.

BTIS has a mandatory obligation to provide available strategic stocks of albumin and blood group test sera, in cooperation with the Government Agency of Stocks and Goods in emergency cases. In 2012, Register of rare blood groups donors was established.

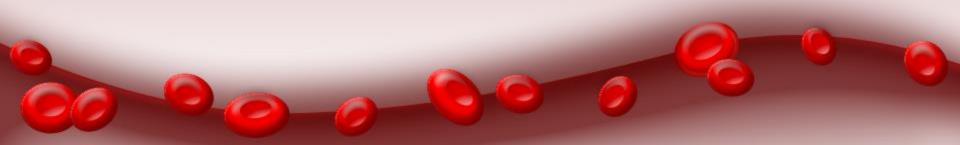
Strategic blood stock

Three to five days blood stocks are available in normal circumstances. In crisis situations (e.g. seasonal deficiencies) 1,5 to three days reserves of O-negative and O-positive red blood cells are mandatory (app. 300 blood units is a daily stock at the BTIS, app. 500 blood units is the mandatory blood stok of the remaining blood transfusion establishments in Serbia, blood stock consisting of 800 blood units is required daily on the national level.

Average daily issues of blood in Serbia are approximately 650 blood units). At all times, Serbian blood transfusion service has available stock of 2,5 days blood units.

Strategic blood stock

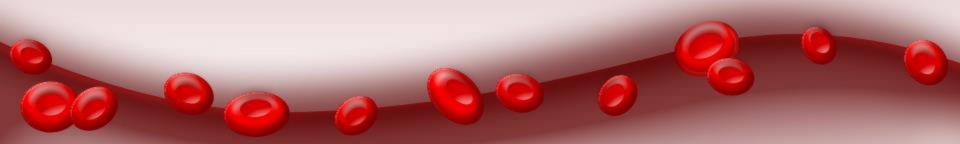
- Rh-negative and Rh-positive blood stock of all bloood types is always available for exchange transfusions.
- National Bone Marrow Register founded in 2005 within the BTIS, as of last year member of the World Bone Marrow Register, has 4583 registered potential bone marrow donors.
- In 2012, Register of Rare Blood group donors was established at the BTIS, with around 600 typed donors. Supported by MoH.
- Apheresis Platelet Donors` Register established at the BTIS has 1408 registered voluntary nonreplacement platelet donors.



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

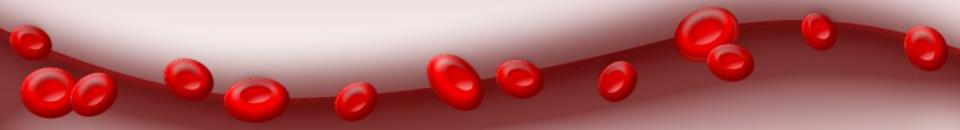
- Training and education in the field of transfusion medicine and emergency medicine are organized within medical training curriculum, postgraduate education and specialization and continuous medical education.
- However, e/learning dedicated platform so far does not exist, as well as paramedical training curriculum.

	Transfusion medicine	Emergency medicine	Other
Paramedical training curriculum	no	no	
Medical training curriculum	yes	yes	
Postgraduate specializations	yes	yes	
Continuous medical education	yes	yes	
e/learning dedicated platform	no	no	



Quality management

- Quality management system (QMS) is implemented and certificated in the Blood Transfusion Institute of Serbia and in the Blood Transfusion Institute of Vojvodina according to standards ISO 9001:2008.
- Blood Transfusion Institute of Serbia implemented SRPS ISO/IEC 17025:2006,
 OHSAS 18001:2007 and ISO 14001:2004.
- Other, hospital based blood transfusion establishments in Serbia have some SOPs and quality procedures but not fully implemented QMS.

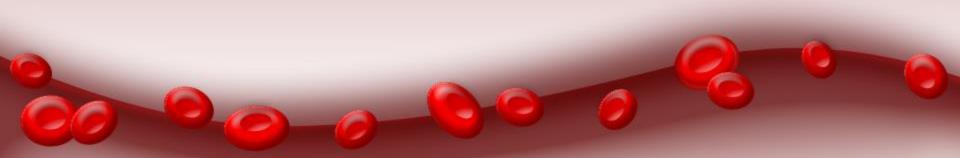


Quality management

Within the health care system of Serbia there are relevant, legally binding documents for the following issues: crisis preparedness plan for EMS (out of hospital and hospital), risk assessment and preparedness information system, contingency plans for medical treatment in disasters, written triage system (standards and protocols), procedures for patients without identification system, haemovigilance / emergency reporting systems, bio security protocols and quality and safety monitoring reports.

National standards of performance for emergency departments

ISO Standards in the Blood Transfusion Institute of Serbia exist as of 2010 and they are covered by the corresponding documents in all relevant areas of work: OH&S 18001, Readiness to react in possible emergency situations and incidents and response to them, Fire protection plan, OH&S 18001 and ISO 14000 procedures for handling dangerous materials, Plan for the prevention of hospital infections dissemination, Act on the assessment of risk on the work post in the work environment with the employee, Action plan of the BTIS for measurements and activities



Documentation - Crisis preparedness plan for EMS

- There are national standards of performance for emergency situations and they include legally binding documents. Ministry of Health and Ministry of Internal Affairs of the Republic of Serbia, Sector for Emergency Situations is the existing mechanism in charge of emergency management.
- Risk assessment and preparedness information system plan
- Contingency plans for medical treatment in disasters in charge of the Ministry of internal affairs, Sector of emergency situations
- Haemovigilance/ emergency reporting systems exists at the BTIS and the BTIS of Vojvodina and Nis.
- Bio security protocols. are established in hospitals and clinics, as well as at the BTIS.
- Quality and safety monitoring reports are prepared in hospitals and clinics, as well as in blood banks.

Risk communication

To the public

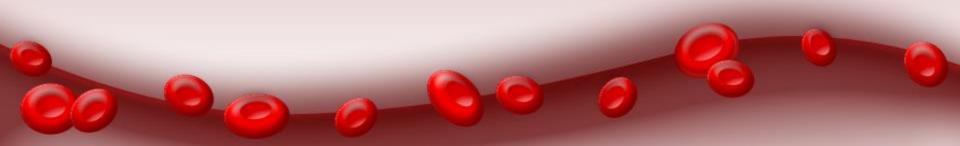
Towards the public, each health care institution has appointed and authorized spokes person in charge of communication with the public in general, and more specifically with the press in emergency and ordinary circumstances.

Risk communication To the public

Blood Transfusion Institute of Serbia

Towards general public and direct communicationn with blood donors from the Donor database: direct telephone and SMS communication with blood donors, scroll alert message broadcasts in prime time news and tv shows, telop with the daily schedule of mobile BTIS teams on the National Public TV

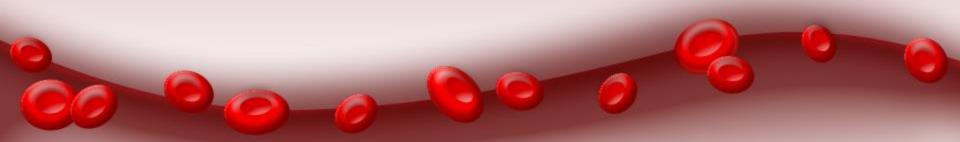
Service and Belgrade Public Service TV



Risk communication

Blood Transfusion Institute of Serbia

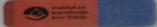
- Broadcasting of over twenty promotional, educational and motivational short videos (made during past 15 years).
- One of 8 most recent videos made in 2013 was awarded as the best nonprofit campaign spot in 2014 by the Taboo Marketing Magazine, official journal of the most eminent profesional marketing association in Serbia.
- The poster from the campaign *Do something good today, give blood save life!* won the silver award for printed materials on the Golden Hammer Competition in Riga, Latvia in 2013.





You know you've been bad. Now do good.

Save life. Give blood.

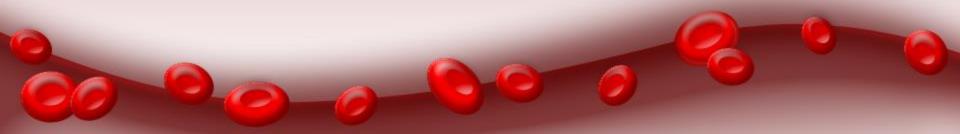


To the partners/ stakeholders

 Director of the BTIS, and any other medical establishment, is authorized to communicate with the partners/stakeholders and government officials (e.g. MoH, Red Cross Otganisation as a partner in the organisation of blood drives).

National and international support mechanisms foreseen for emergency management

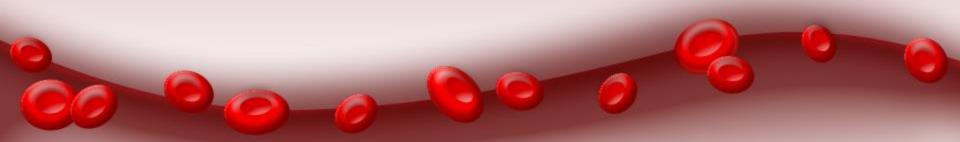
Both nationally and internationally involving issues are dealt with by the Ministry of Health and the Ministry of Internal Affairs of the Republic of Serbia, Sector for Emergency Situations.



National experience Types of blood and blood components/ products (including main choice) commonly used in emergency situations:

All blood types, O RhD-negative red cells and AB fresh frozen plasma in particular, are the main choice and the commonly used blood types in emergency situations.

The most common medical emergency situations faced with during the last several years were seasonal blood shortages, Rh-negative blood groups deficiencies in particular. In 2012 and 2013 only summer seasonal deficiencies were reported.



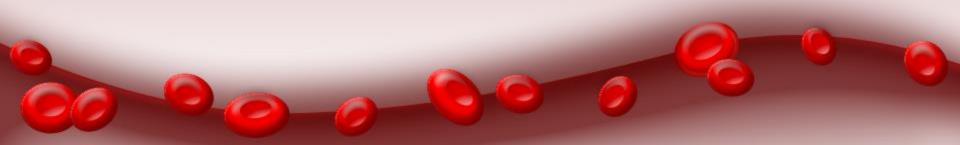
Natural disasters and catastrophies

- In the year 2012, according to the official data, the most extreme temperatures were recorded in a long time history of the official temperature measurements by the Republic of Serbia Hydrometeorological Service: the coldest winter and the wormest summer.
- Blood supply was provided by Winter and Summer Campaigns, cooperation and exchange of available blood supplies among blood transfusion establishments in Serbia, with considerable support provided by the media.
- On July 29th, 2013 the peak of the crisis was recorded. Following gradual decrease of the number of collected blood units at the BTIS, from 1341 in the first week of July, to 931 in the fourth week, when decision was made to alert the public using mass media channels. In the week following the public appeal, total of 1889 blood units were collected and blood stocks were consolidated.

Recent natural catastrophy recorded in Serbia was flood which affected Serbia in May 2014.

Tragic effects were the most striking in the Central Region of Serbia, the teritory of which is in charge of the BTIS. The following measures were immediately taken: blood stocks were provided (in coordination with all blood transfusion establishments in Serbia who offered all kinds of assistance and support), and the blood stocks from the evacuated centers were transffered to BTIS.

Solidarity of citizens was huge. They responded to the crisis in several ways, one of which was blood donation, so that adequate blood stocks were provided in a matter of days.



Recent natural catastrophy recorded in Serbia was flood which affected Serbia in May 2014.

Coordinated action was carried by the MoH. Medical doctors and other staff members of the BTIS were on call 24 hrs a day for immediate taking care of the evacuated citizens from the flooded region.

West Nile Virus

Logistics of the BTIS was available for their transportation and other emergency requirements. WHO congratulated the MoH and other iofficial government nstitutions for the measures and actions taken in the days of crisis, especially for the fact that there were no epidemics despite actual difficulties and circumstances the flood stricken regions were in

- Among other emergency situations worth mentioning is the pandemic flu affecting blood supply. The most recent one was reported in October 2009.
- Action Plan of the Blood Transfusion Institute of Serbia and other two Institutes was prepared for measurements and activities for maintaining continuous functioning of the organization during the flu pandemic.
- The Action plan covered all aspects of work necessary during the pandemic (work organization, staff lists, targeted blood donors with the stress on special blood groups, etc).

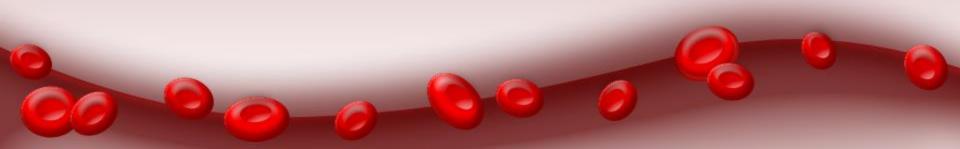


General perception on how the blood service operates/ would operate in emergency situations under the current conditions

In current conditions, and in case of emergency situations, Blood Service of Serbia would operate according to the actual requirements, in accordance with the available resources, as a necessity at a given time (minimum 3 days blood stocks, human resources available on request, solidarity of blood donors, etc).

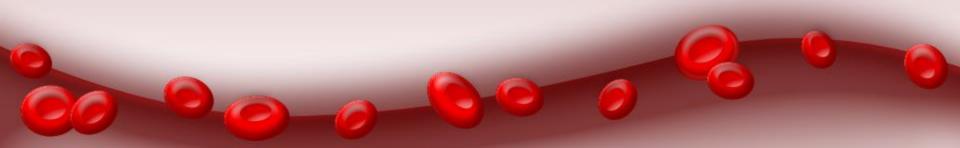
Main priorities that would require immediate attention in the field, to improve operational response of the blood service in special circumstances

- To establish an Emergency Medical Situations National Committee consisting of the Ministry of Health representative, Blood Transfusion Service professionals, Red Cross representatives and volunteers, as well as to prepare National Blood Donors Register,
- To provide sufficient blood stocks (5 days blood supply), to make national action plan (training and education for immediate response in emergency situations) and
- to provide communication channels (public relations) with the public, media and stakeholders and partners.



Formal/informal arrangements with other countries (which ones) to receive blood in cases of major emergencies. What are the steps foreseen to check of the "quality" of the blood received?

- Minister of Health has the power and mandate stipulated by the national legal rules to make decisions, act and make arrangements with the officials from other countries in cases of major regional or international emergencies.
- In regard with the quality of possibly received blood in such circumstances, all activities should be in accordance with the national legislation.







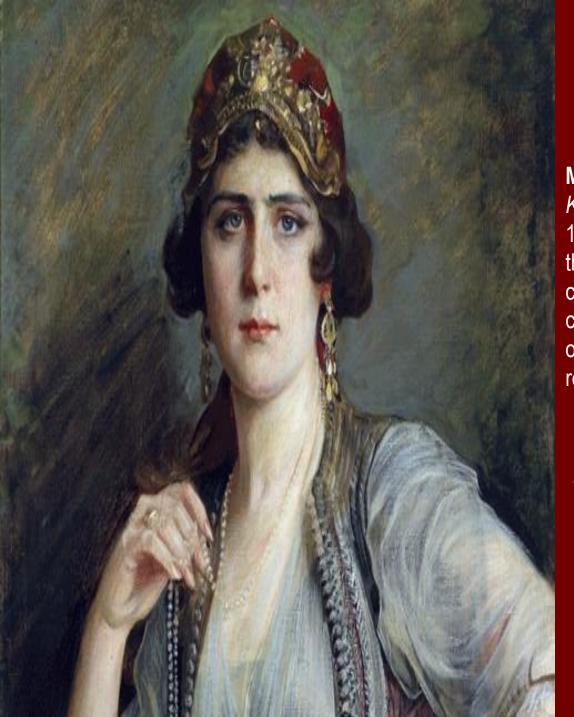












Queen Maria of Yugoslavia

Maria of Romania (Serbian: *Marija Karađorđević*, 6 January 1900 – 22 June 1961) was the Queen of Yugoslavia as the wife of King Alexsander. Her citizenship was revoked and her property confiscated by the communist Presidium of Yugoslavia in 1947, for which she was rehabilitated in 2014.

She was a favorite of Serbian people.