



**THE WORK-SHOP
INCREASING BLOOD AVAILABILITY AND
PROVIDING THE HIGHEST DONOR AND PATIENT
SAFETY IN TRANSFUSION THERAPY IN
EMERGENCY SPECIAL CIRCUMSTANCES**



BUCHAREST JULY, 2014

**EU requirements for donor and patient safety in emergency
special circumstances: case studies from Romania**

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Romania The Design of the Presentation



- (1) Introduction of the Romanian Blood Transfusion Network**
- (2) Transposition of EU legislative and regulatory documents on Blood Safety and inclusion of WHO Recommendations**
- (3) National structures for the implementation of the above acts; available procedures for rapid mobilization of blood donors in cases of major emergencies and procedures to ensure the quality and safety of such donations**
- (4) Amount of blood reserves required to be available in cases of major emergencies at regional and/or national levels; case studies**
- (5) International formal/informal arrangements to receive blood in cases of major emergencies; The steps foreseen to check of the “quality” of the blood received**



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(1) Introduction of the Romanian Blood Transfusion Network

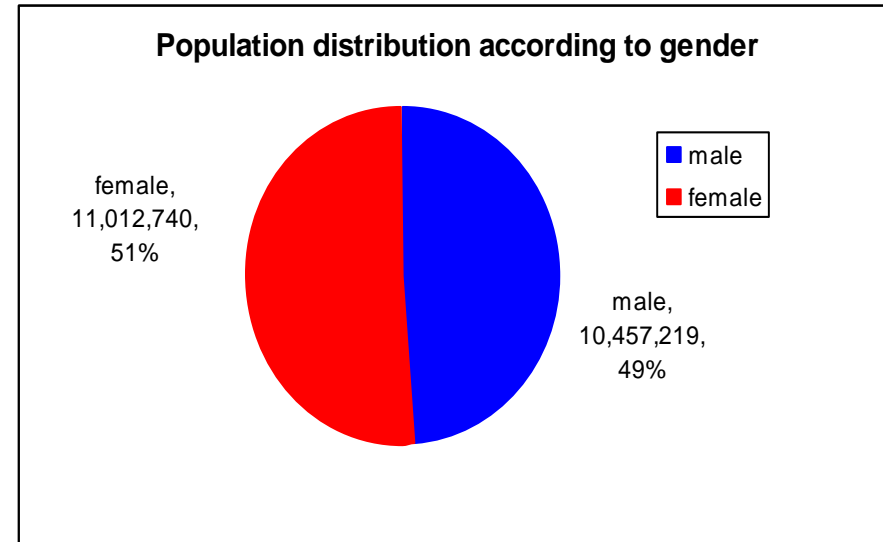
- Romania has the 9th largest territory and the 7th largest population (about 21.5 million people) among the European Union member states
- Its capital is Bucharest, the 6th largest city in the EU countries, with almost 2.2 million inhabitants





(1) Introduction of the Romanian Blood Transfusion Network

- According to the 2010 estimation, Romanian population is represented by 21.5 million persons (10.434.143 males and 10.997.155 females)
- With a GDP of around \$264 billion and a GDP per capita (PPP) of \$12,285 estimated for 2008, Romania is considered a country with an upper-middle income economy
- Romania became an European Union member, starting with 2007, January 1th





(1) Introduction of the Romanian Blood Transfusion Network

In Romania blood donation is:

- voluntary and non-remunerated
- family donors (3-4%)

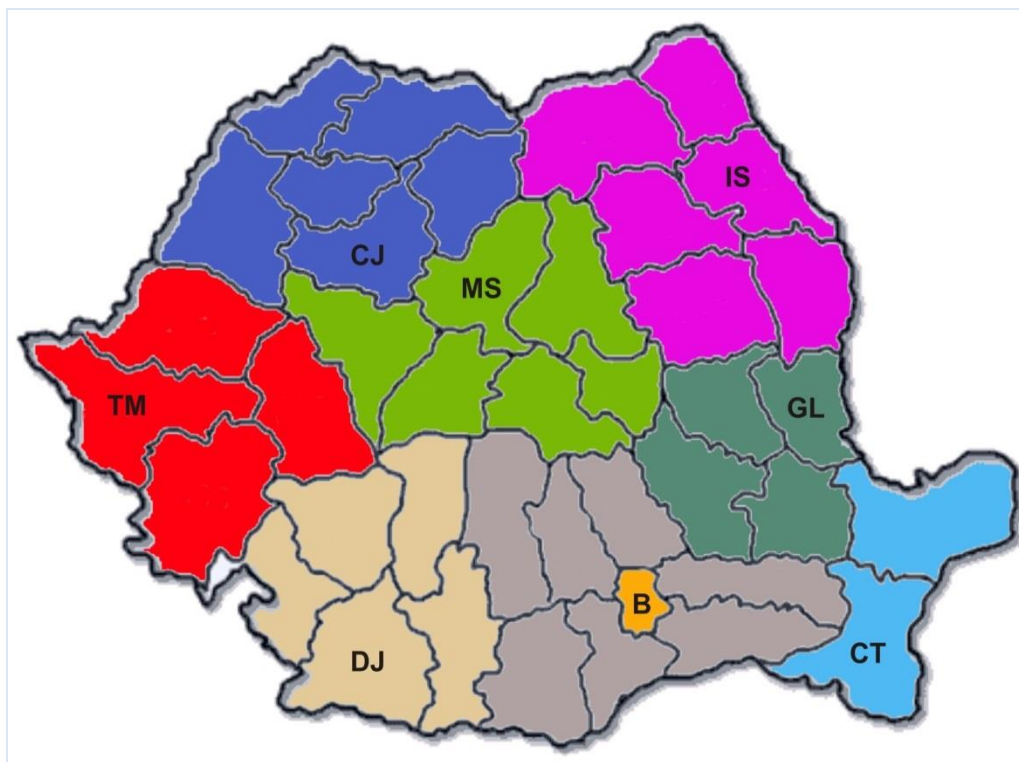
A voluntary non-remunerated blood donor gives blood, plasma or cellular components of his or her own free will and receives no payment, either in the form of cash or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation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

Voluntary donors are recognized to be the **safest donors** because they are motivated by altruism and the desire to help others and by a sense of moral duty or social responsibility. They are the **first line** of defence in preventing transmission viruses through transfusion.

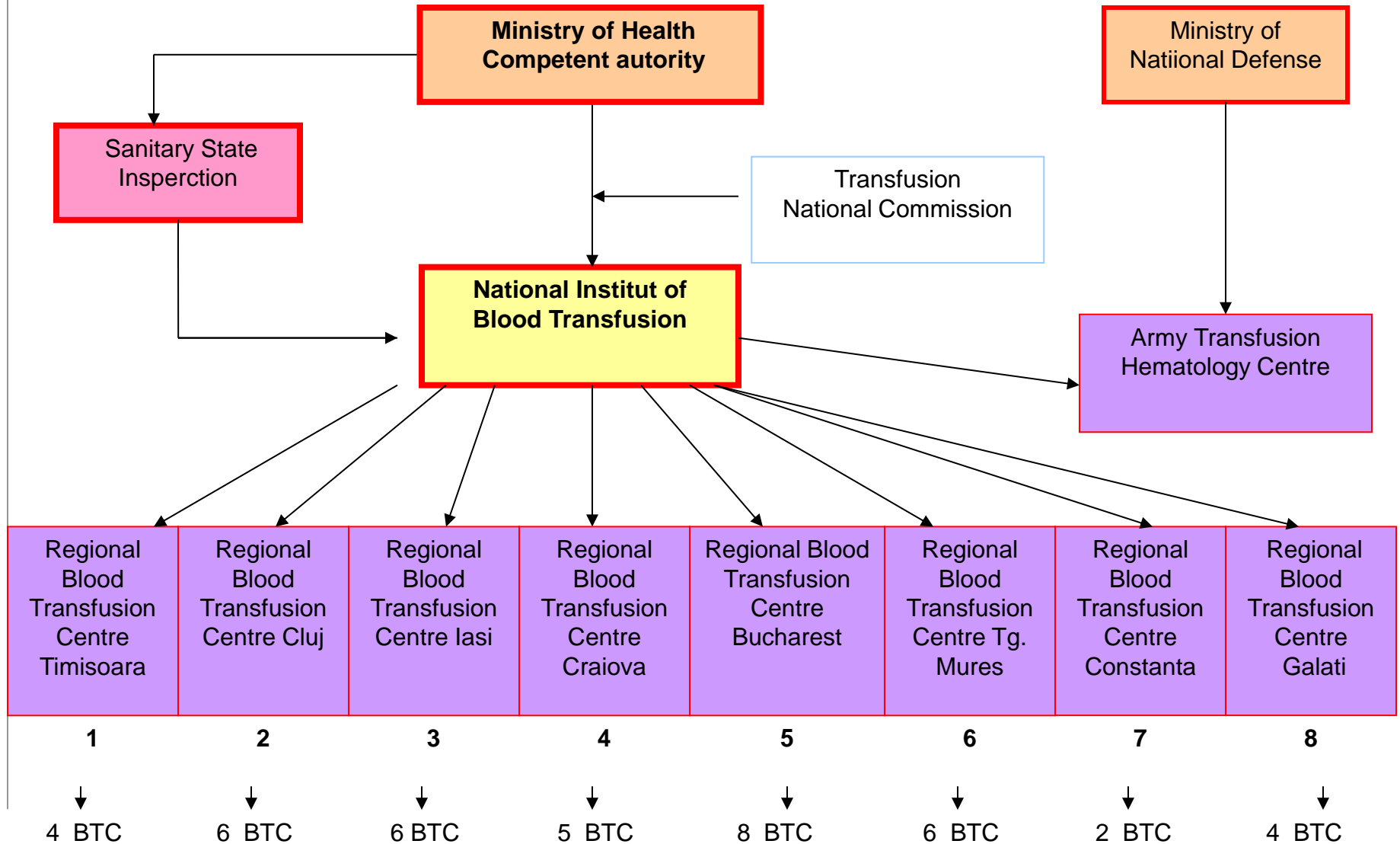
Family donors are donors who give blood to an request by hospital staff, occasionally when BTC have shortage to some blood type.

(1) Introduction of the Romanian Blood Transfusion Network

- Romania is organized into 41 counties (districts), as well as the municipality of Bucharest – having its own administrative unit
- Each county has a Blood Transfusion Center, institution which collects, tests, prepares, stores blood / blood components and distributes them to authorized hospitals

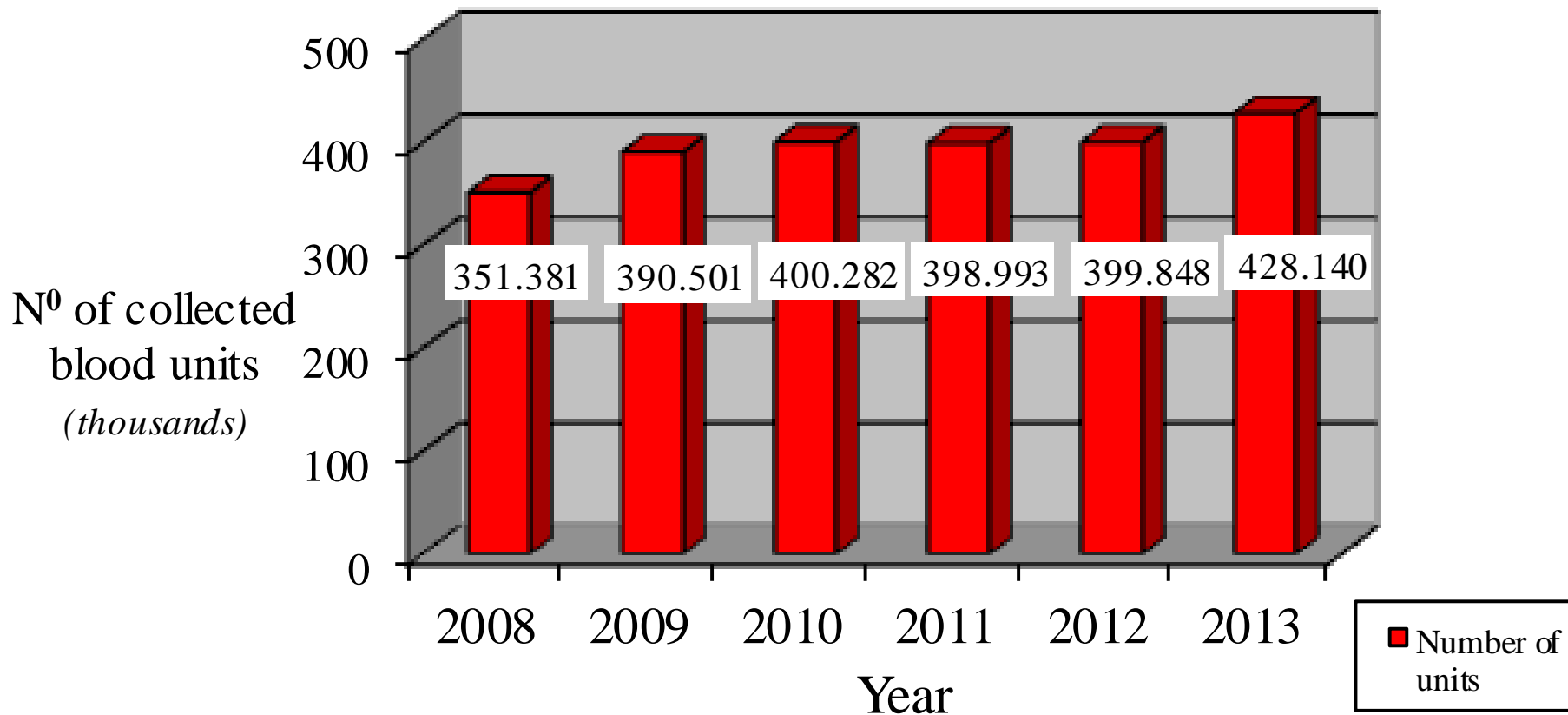


(1) Introduction of the Romanian Blood Transfusion Network



(1) Introduction of the Romanian Blood Transfusion Network

Total donations history. Source: Annual activity reports





(1) Introduction of the Romanian Blood Transfusion Network

Year	N ^o of units			meet of demand %
	ordered	collected	delivered	
2008	503,465	351,381	345,017	68.5
2009	523,456	390,501	386,461	73.8
2010	604,834	400,285	396,312	65.5
2011	570,516	398,993	395,103	69.2
2012	619,188	399,848	396,200	63.9
2013	581,793 ↓	428,140	424,010	72.86 ↑↑



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Directive 2002/98/EC standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components

Law no. 282/2005 concerning the organization of blood donation of blood and blood components of human origin and quality assurance and health security, for therapeutic use*

Directive 2004/33/EC technical requirements for blood and blood components

Government Decision 546 /2006 establishment, organization and functioning of the Consultative Committee for the Promotion of blood donation

Directive 2005/61/EC traceability requirements and notification of serious adverse reactions and incidents

MH Order 1214 / 2006 -Norms on adequate training of personnel involved in setting admission donation, collect, biological control, preparation, preservation, distribution and administration of human blood and blood component

MH Order 1224/ 2006 for the approval of the activity of the hospital blood banks

Government Decision no. 1364/2006 approving the rights and obligations of blood donors

Directive 2005/62/EC standards and specifications relating to the quality system Blood Transfusion Center (BTC), Hospital BBs

Law no. 95/2006 on health care reform on patients' rights

MH Order 1225 /2006 for the approval of authorizing the National Institute of BT, regional BTCs county and blood in hospitals



Law no. 282/October 2005* transposes it, and announces secondary legislation, for technical and organizational aspects: authorization, accreditation, licensing of medical institutions and medical personnel

Article 7 - List of the structures through which the Ministry of Health, as competent authority exercises its powers (ie institutions engaged in role transfusion and control structure)

Article 7. 2 and art. 8 announce reorganization of National Institute and Transfusion Network (were noticed discordance between different laws regarding the titles of the institutions, about collaborative relationships / subordination between different types of institutions, the duties and responsibilities assigned (Army Transfusion Centre is not mentioned in the law, but the specific activity must comply with methodological and organizational rules

Article 18 provides foreseen a system of reporting to the institutions involved in the collection of epidemiological data (no uniform reporting procedure) Proposal: establishment of a centralized reporting data system

Article 28 (1) human blood and blood components will be distributed NI by BEs, at the request of transfusion authorized medical institutions (3) The value of a unit of blood, human blood components and blood products derived from plasma processing will be established by the Minister of Health (a virtual value, actually is non-paid by users



Directive
2002/ 98/
EC

Directive 2002/98 /EC	MH Order 1226 /2006 <i>the Norms regarding the collection, biological control, preparation, preservation, distribution and transportation of human blood and blood components</i>
	MH Order 1227 /2006 <i>the Norms on autologous transfusion</i>
Directive 2004/33 /EC	MH Order 1228 /2006 <i>Norms concerning the organization of the hemovigilance, to ensure traceability and the Regulation on recording and reporting system the occurrence of severe adverse events and reactions related to collect and manage human blood and blood components</i>
Directive 2005/61 /EC	MH Order 441 /2007 <i>the application of art. 16 of Law no. 282/2005 regarding the organization of blood donation of blood and blood components of human origin and quality assurance and health security, to their therapeutic use, with subsequent amendments</i>
Directive 2005/62 /EC	MH Order 1132 /2007 <i>the Norms regarding standards and specifications relating to the quality system for medical institutions active in the field of blood transfusion</i>
	MH Order 1193/2007 <i>the information to be provided to donors of blood and blood components of human origin, and information to be provided by donors at each donation and the eligibility criteria</i>
	MH Order 1237 /2007 <i>the national classification of human blood components for therapeutic use</i>
	MS Order 1343 / 2007 <i>the national guide rational therapeutic use of human blood and blood components</i>



135/2009/CE
Commission Directive
of 3 November 2009
*which allow temporary
derogations to certain
eligibility criteria for
donors of whole blood
and blood components set
out in Annex III to
Directive 2004/33/EC in
the context of risk
shortage caused by the
Influenza a (H1N1)*

MH Order 293/2010 *supplemented the MS Order no. 1193/2007*

MH Order 648 /2012 *amending and supplementing Norms on autologous transfusion, approved by Ministry of Public Health no. 1.227/2006*

MH Order 650 /2012 *amending and supplementing Norms regarding collection, biological control, preparation, preservation, distribution and transportation of human blood and blood components, approved by Ministry of Public Health no. 1.226/2006*

MH Order 814/2012 *modification and completion of Order no. 1.237/2007 approving the national classification of human blood components for therapeutic use*

2011/38/UE Directive
of 11 April 2011
*amending Annex V to
Directive 2004/33/EC
regarding the maximum
pH values for platelets
concentrates at the end of
the storage period*

MH Order 607 /May 2013 *Norms specific authorization blood establishments of health facilities*

MH Order 608 /May 2013 *For the approval of the special authorization for import and / or export of human blood and / or blood components human or other countries*

On going: Gov. Dec. about reorganization of blood transfusion network, review of MH Order 1228/ hemovigilance (procedures)



Provisions for special situation in national transfusion legislation

Stipulate the responsibilities of NIBT in case of shortages due to AH1N1 pandemic flue or WNV epidemic

- **MoH Order no 1193/2007** -Norms regarding the information provided to blood donors as well as information provided by the donors at each blood donation and eligibility criteria for blood donors , and
- **MoH Order 1483/2011** Action plan for in case of WNV outbreak in order to limit the blood transmission to humans



Provisions for special situation in national transfusion legislation

Action plan was elaborated in 2010 and entered into force since 2011.

The plan contained a scheme of information transmission and specific duties/activities to be followed by each institution, at the national and local level, involved in the prevention of WNV transmission by blood:

- Public Health Directorate and Control in Public Health – Ministry of Health, representing the competent authority for blood transfusion in Romania;
- National Institute of Blood Transfusion;
- National Institute of Public Health;
- Local Public Health Authorities;
- Blood Transfusion Centers;
- Hospital Transfusion units.



Provisions for special situation in national transfusion legislation

- a Governmental Decision on reorganizing the transfusion system which provides for the creation of **a national reserve of BBC** for current situation as well as for emergency situation



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Emergency Situations and Special Circumstances

may arise from:

- 1. Unpredictable demand** for blood, involving **mass casualties**. A rapid depletion of existing blood stocks may result in a lack of blood for other patients requiring emergency transfusion (obstetrics, surgery, trauma) or regular transfusion (thalassaemia, haemophilia)
- 1. Unpredictable disruptions** to blood collection – **epidemics** (influenza, WNV), **mass vaccination campaign** - may cause a temporarily loss of both donors and medical staff



Emergency Situations and Special Circumstances

Internal hazard – floods, fire

External hazard – earthquakes, act of terrorism, industrial accidents, pandemic infection diseases, workplace violence

Blood transfusion services face a dual challenge of ensuring both:

- **sufficient supply**, and
- **quality and safety** of blood/blood components for patients whose lives or wellbeing depend on transfusion therapy

Developed countries with well-structured health systems and blood transfusion services based on voluntary blood donation are **generally able to meet the demand for blood/blood components**.

Developing and transitional countries face often with **chronic blood shortages**

Red plan – *pre-hospital approach*

White plan – *hospital approach*

BTCs plan – *transfusion network approach*

**National
Management**

in

**Emergency
Situations**

and

**Special
Circumstances**



*The National Management in
Emergency Situations and Special Circumstances - Red plan*

National System for Management of Emergency Situations, hereinafter nominated as National System, is organized and operational in order to prevent and manage emergency situations, for ensuring and coordinating human, material, financial and other resources necessary to restore the previous (normal) status

The National System is organized by the public administrative authorities and represents qualified in emergency situations management organizations, institutions (designed as a functional network) based on their levels and areas of expertise, infrastructure and resources needed to accomplish the tasks set out in national regulations



*The National Management in
Emergency Situations and Special Circumstances - Red plan*

Specific legislation:

Government Decision No. 2288 December/2004 approving the division, and main support functions that the ministries, other central agencies and NGOs have to rule on prevention and emergency management of emergency situations.

Government Urgent Order No. April/2004 about the National System of Management of Emergency Situations, as amended by EO No. 1/2014.

Government Decision No. 94 February/2014 about the organization, functioning of National Committee for special emergency situations.

Government Decision No. 121 February/2014 regarding the organization, functioning and National Committee for weather calamities and disasters .



*The National Management in
Emergency Situations and Special Circumstances - Red plan*

The National System is composed of:

- Emergency Committees
- General Inspectorate for Emergency Situations
- Professional community public services for emergency situations
- Emergency Operations Center, and
- The Commander of the action.



*The National Management in
Emergency Situations and Special Circumstances - Red plan*

The National Committees:

- National Committee for weather calamities and disasters
- National Committee for special emergency situations



*The National Management in
Emergency Situations and Special Circumstances - Red plan*

The County Committee

At the county level is constituted, under the prefect coordination, as the County Committee for emergency situations

The members of the county committee are represented by:

- the county council president,
- heads of decentralized services
- decentralized municipal and other institutions' managers, and companies that perform county interest functions, supporting emergency management, and
- institutions which, through their specific activities constitute potential risk factors as emergency situation generators.

The organization, and functioning of county committee are established by order of the prefect.



*The National Management in
Emergency Situations and Special Circumstances - Red plan*

The Local Committee

- representing cities/sectors of Bucharest and the municipalities, are established by the mayor, identified as local emergency situations committees

- the members are represented by:
 - the deputy secretary of the city /sector, as appropriate,
 - representatives of key public services and institutions,
 - economic managers of institutions and companies that perform local interest activities, supporting emergency management, and
 - institutions which, through specific activities constitute potential risk factors as emergency situation generators

The organization, and functioning of local committees are established by order of the Mayor.



*The National Management in
Emergency Situations and Special Circumstances - Red plan*

General Inspectorate for Emergency Situations

- as a specialized body under the Internal Affairs and Administration Ministry authority, ensures uniform and continuous coordination for preventing and managing the emergency situations
- organizes:
 - preventive inspections,
 - the national operation centers and other appropriate structures for emergency situations management, with staff assigned to the types of risks, communications, computer and public relations
- the Permanent Operational Center fulfills the functions of monitoring, assessment, notification, warning, pre-alarm, alert and operational technical coordination at national level in emergency situations through the national operations center, supports the Permanent Technical Secretariat of the National Committee for weather calamities and disasters.
- ensures, according to appropriate legal competence:
 - national cooperation and representation of civil protection, fire protection and emergency management.



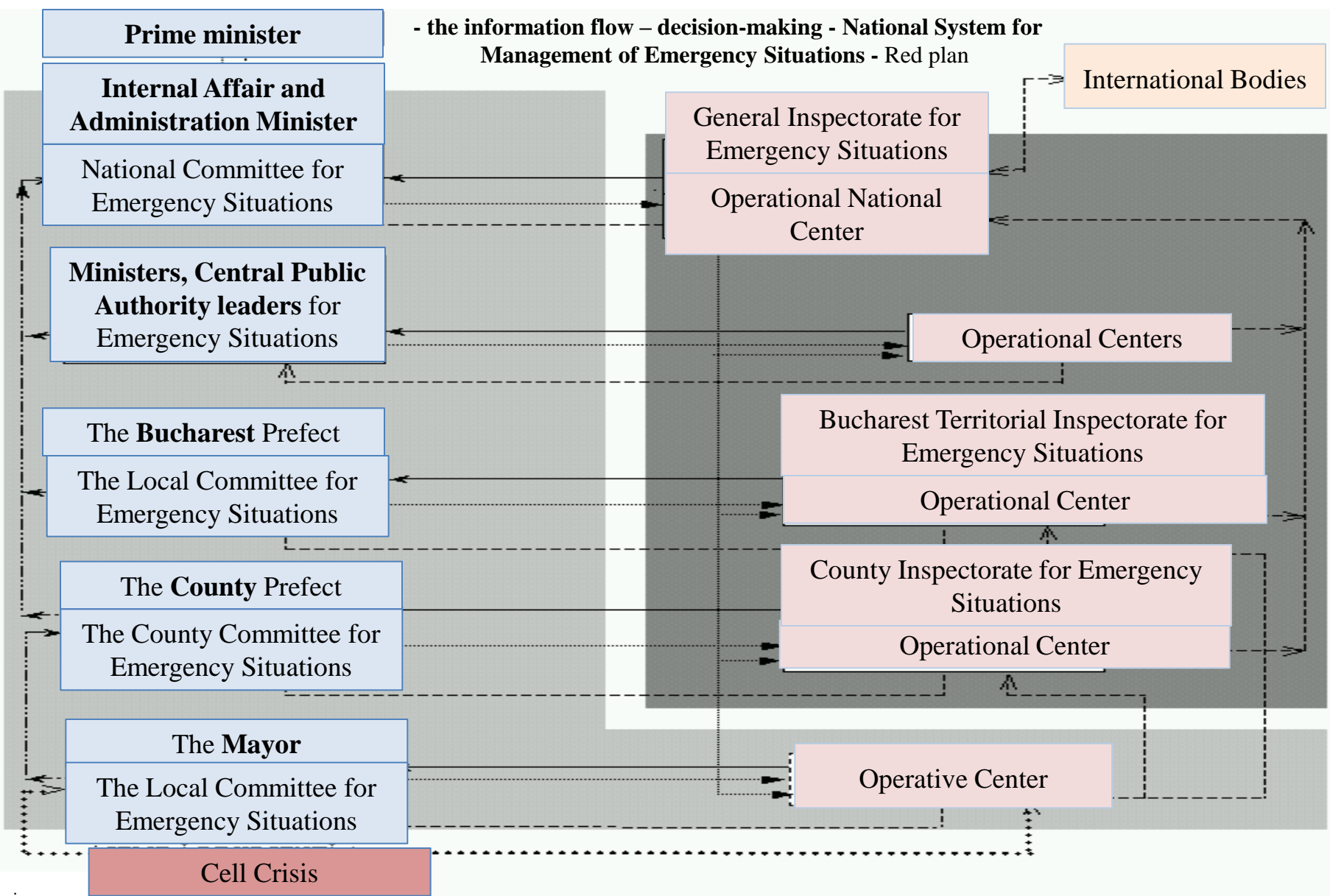
*The National Management in
Emergency Situations and Special Circumstances - Red plan*

The Commander of the Action

In emergency situations, the coordination at event site of the action of all established forces intervention is performed by a processor, where appropriate, by National Committees, ministerial, county / Bucharest, depending on the nature and severity of the event and size categories of concentrated forces, called by the commander of the action

The Commander of the Action may be assisted in carrying out the tasks by the advanced operational point, constituted according to national regulations.

- the information flow – decision-making - National System for Management of Emergency Situations - Red plan



- Temporary activity
- Permanent activity
- Coordination
- Proposals
- Information
- Cooperation



*The National Management in
Emergency Situations and Special Circumstances - White plan*

The White Plan - is an action plan for the hospital organization in case of a disaster, with massive and brutal influx of victims

Objectives

1. To provide care to a larger number of patients - usually urgent - exceeding the daily capacity of the hospital
2. To redistribute to other hospital units the victims of relative emergencies category, if the situation requires
3. If necessary, to participate in medical chain of rescue - to coordinate the triage, clinical stabilization of patients and their re-direction to the Bucharest/some other hospitals



*The National Management in
Emergency Situations and Special Circumstances - White plan*

White Plan tools:

1. Coherent system of alarm and communication

2. gradual mobilization of:

- humans
- materials
- financial resources

3. providing distinct hospital streams for:

- disaster victims
- daily emergencies
- materials
- patients admitted from other hospitals
- authorities and media
- victims' relatives



*The National Management in
Emergency Situations and Special Circumstances - White plan*

General measures – with clear responsibilities

I. It is necessary to configure a *crisis cell*

the location of the *cell crisis* must be:

- predetermined
- equipped with communication tools (in and outside hospital)

II. the White Plan has to be:

- part of the hospital internal regulations
- to be acknowledged by every head of department:
 - Medical -physicians, assistant chief sections / operation blocks
/emergency room
 - Technical Services / Logistics / auxiliary services



*The National Management in
Emergency Situations and Special Circumstances - White plan*

The cell crisis - composition:

1. a pre-nominated physician as hospital coordinator
2. a pre-nominated emergency physician, with disaster medicine competency
3. responsible person for stocks and materials
4. responsible person for staff coordination
5. responsible person for communications
6. responsible person for technical and infrastructure issues
7. coordinator for security and guard services
8. if necessary, a representative of the financial-economic department



*The National Management in
Emergency Situations and Special Circumstances - White plan*

Algorithm intervention

I. Triggering and operating level

Are determined by:

- the Coordinator of the crisis cell
- in his absence, will be replaced by the head of duty service in

Emergency Medicine, based on triggering criteria:

a) **Quantitative** - Number of victims:

- 15 - Green alarm
- 40 - Red Alert

b) **Qualitative** - the type of the disaster - those involving a large number of victims (eg, subway accident, natural disaster) → direct red alarm



The National Management in Emergency Situations and Special Circumstances - White plan

II. The Trigger decision must take into account:

1. The information received from ambulance services /Civil Defense Department/ Police / Fire Department, etc.
2. Information from the site of the event (permanent radio communication).
3. Received information from witnesses of catastrophic event, when they alert direct the hospital

III. Stage of informational flow

1. Regular reporting to the crisis cell, by each head of department about:
 - The number and qualification staff available at the time
 - Occupancy of beds
 2. reports about the status of quantitative and qualitative materials and existing stocks within each compartment
 3. Dialing the medical and auxiliary medical staff whose not working at the time of the event (green / red alarm), and informing the cell crisis about it (feedback system) - Telephone - pager - radiotelephone - Mass media
- Lists with the phone numbers of staff will be in triplicate (- The head of each department /- The centralist/ - Personal on duty)
- The lists will be - updated regularly (quarterly)
- Contain distinct names of people contacted at any time (paggers, radiotelephone)



The National Management in Emergency Situations and Special Circumstances - White plan

IV. Conclusive Step

- Assessment of needs / demand of human resources
- Assessment of needs / demand of material resources

V. Decision Step

- takes place sequential, based on the alarm type (green / red) and with the informational stage
- hospital structural readjustment , by marking with arrows the access roads for transport and destinations flows for:
 - victims of the disaster
 - urgent daily
 - authority and media
 - materials
 - personal, and
 - deceased individuals

VI. Communication phase - Communication of the hospital capacity with the authorities (civil defense Department, Prefect) Police, Fire Department...



*The National Management in
Emergency Situations and Special Circumstances – Blood Transfusion
Network plan*

Actors:

1. LOCAL

- BTC
- Hospital
- UPU (Emergency Receiving Units)
- SMURD (Mobile services for emergency, resuscitation and extrication)
- Ambulance services
- ISU (Inspectorate for Emergency Situations)
- Mayor
- Prefect
- County Committee for Emergency Situations
- Professional community public services



*The National Management in
Emergency Situations and Special Circumstances – Blood Transfusion
Network plan*

2. NATIONAL

- National Committee for emergency situations and special circumstances
- National Committee for weather disasters
- Ministerial Committee for emergency situations
- GIES (General Inspectorate for Emergency Situations)
- National Institute of Blood Transfusion
- Transfusion National Commission



*The National Management in
Emergency Situations and Special Circumstances – Blood Transfusion
Network plan*

- All these actors are aware that:
 - blood is lifesaving, must be kept at certain temperatures, storage capacity is limited, and blood may have to be transported in different location for storage
 - BTC are critical health entities, included in state and local emergencies plans
 - BTC have a good **communication** system: land line phone, wireless cell phone, email, internet, fax, web site, unique emergency line 112, direct connection line phone with local emergency entities. We should improve with satellite phone, and direct radio communication
 - **Transportation**: BTC use their own transport vehicle (use for mobile blood collections, blood transport, or donor transport if there are emergency situations), ambulances. In the country there are 4 special buses used for mobile collection. Air transport if it's necessary- 2 SMURD helicopters, who belong to GIES with national cover.
 - Medical **Supplies** and equipments: contracts with local suppliers (energy, water) and national suppliers for blood bags, testing reagents and equipment, storage equipments.
 - Trained **Staff**: mobilize transfusion trained staff from other location to affected area, recall retired staff if necessary



*The National Management in
Emergency Situations and Special Circumstances – Blood Transfusion
Network plan*

Emergency response plan – Specific actions

- **verifies the communication system:** phone service, internet. If it's necessary BTC will use the *special telecommunication line* which is linked directly to SMURD (mobile service for emergency, resuscitation and extrication), IES (Inspectorate for Emergency Situations), police, and local authorities. Notices if the hospital phone service is affected by a disaster (if yes determine the alternative communications)
- Ensure a **secure transport** of blood and blood product in affected area, if it's necessary
- If disaster has national impact will be activated the **Red Plan** for emergency situations
- Determines if the hospital transfusion service and blood product usage are jeopardized. Arranges transport of blood products if needed in affected hospital
- Determine the effects of the disaster on the donor base (BTC)



*The National Management in
Emergency Situations and Special Circumstances – Blood Transfusion
Network plan*

- In BTC plan is named responsible persons for:
 - Coordination of actions (director of BTC)
 - Communication with hospital, media
 - Communication with blood donors
 - Transport
 - Evaluation of stocks (blood, materials, other supplies)
 - Staff coordination
 - Financial resources
 - Technical and infrastructure



*The National Management in
Emergency Situations and Special Circumstances – Blood Transfusion
Network plan. Specific actions*

- 1. evaluates the emergency stock**, which exist in every BTC, according to the needs of hospital/hospitals (responsible: director of BTC).
 - facility must have a 3 day stock blood products, which may expand to 5 day. If the local blood stock is insufficient the BTC will contact the closest BTC to complete the blood inventory.
 - efficient transportation system to move the blood units from a region to another region. Recall of blood unit from unaffected hospitals to regional centers, and redistributes to affected hospital

Color code alert	Nr. of “O” RBC units	Management strategy
Green	80-150	monitor
1-2 days inventory projection		
Yellow	60-100 units	<ul style="list-style-type: none"> - Contact major hospitals - Forecast supply for 2 days - complete blood stock from other regional BTC
1-2 days inventory projection		
Orange	40-70 units	<ul style="list-style-type: none"> - Monitor and reduce hospital blood usage - Transfusion committee review all elective transfusion requests and consider deferral if it can be safely deferred - Communicate with local services to facilitate recall regulate blood donors
1-2 days inventory projection		
Red	10 – 40 units	<ul style="list-style-type: none"> - Activate National Transfusion Committee and local Transfusional and Haemovigilance Committee (members are hospital specialist and chief of BTC) - Communicate with Red Cross, other voluntary organizations to organize mobile blood collections , with the 4 existing specialized buses. - Appeling to media to increase nr. of blood donors - The BTC director and Hospital Transfusion Committee communicate with National Disaster Committee and agencies to assist with transport of donors and blood supplies, to provide public utilities (electricity, communication chanel)



*The National Management in
Emergency Situations and Special Circumstances – Blood Transfusion
Network plan. Specific actions*

- 2. communication with hospital** (chief of Transfusion Committee), which needs to evaluate carefully all transfusion requests;
- reviews all impending elective surgery for potential blood use and consider deferral if it can be safely deferred (if surgeries will be deferred, patients must be notified).
 - Encourages increase in blood conservation practices where feasible, including: autologous donation, use of erythropoietin, use of medication to reduce blood loss and perioperative blood salvage where applicable



*The National Management in
Emergency Situations and Special Circumstances – Blood Transfusion
Network plan. Specific actions*

3. mobilize regular donor from BTC database

- regular donors are familiar with the blood donation process and can be handled more quickly than first-time donors.
- every BTC have a local donor database (manual or personalized soft – 25% of Romanian BTC have IT system), with all donor details, including phone number, email, address.
- designated staff call the regular voluntary donor to an urgent blood collection session; donor loyalty is very important in such cases
- the regular donor assures **safety and quality** of blood and patient



*The National Management in
Emergency Situations and Special Circumstances – Blood Transfusion
Network plan. Specific actions*

4. Supporting mobile collection

- identification of suitable places/institutions and planning for emergency blood donor sessions – mobile blood collections
- if blood stocks are adequate to meet emergency needs, *over-collection* should be avoided
- an excess in number of new donors, places pressure on facilities, staff and resources and may result in the wastage of donated blood

Key characteristics of the Romanian blood inventory and supply

- Romania has a **national, daily, centralized monitoring system of Blood and blood components (BBC) inventory** at the NIBT level with function as follows:
 - BTCs, according to an internal procedure, manage blood inventory which is structured in **current blood inventory** and **stock reserve** by each type of blood group
 - Current blood inventory ensure local needs according to hospital requirements.
 - The reserve stock can be made available to any other BTC, upon request, in case it has a deficit.
 - At the level of the **NIBT**, BTCs communicate, on a daily basis, the blood inventory, so there's a constant monitoring by an authorized person of the stock.



Key characteristics of the Romanian blood inventory and supply

- NIBT monitor and ensure the safety, availability and logistical requirements of blood
- NIBT has the ability to assess BTC's and hospitals needs, in order to provide supply coverage during shortages.
- BTC's have the ability to influence blood collection or distribution according to blood inventory

Blood inventory in emergency situation

- If there is an emergency situation in a certain county/region that requires a high demand for a particular type of blood group which leads to limiting stocks of BBC, the responsible person authorizes to redistribute BBC in the affected region.



NIBT – Responsibilities for special situation

Responsible person, according to these norms:

- review current inventory information and determine if further information is required
- analyses info received
- initiate control measures based on findings
- assure that the decisions and recommendation o are appropriately communicated to BTC's



Challenges for Romanian transfusion system in special situations in the last 4 years

- Every summer RO faces blood shortages related to WNV epidemia.
- WNV infection is an important topic in relation to blood transfusion due to the risk to collect blood from **viremic asymptomatic donors**. In order to prevent WNV transmission through blood, in affected areas, **measures with regards to donors and blood products must be taken**.
- The European regulatory context for blood donation in relation to WNV infection refers to the deferral policy, respectively to the exclusion of donors who have travelled in affected areas.
- Thus deferral for 28 days of WNV potentially infected blood donors, starting with the day they left an area with ongoing transmission of WNV to humans, is mandatory in Romania, according to the 1193/2007 MoH Order, which transposes the EU blood Commission Directive 2004/33/EC, Annex III.2.2.1.

2010 WNV epidemic

- In August 2010 a WNV epidemic broke out
 - 57 WN neuroinvasive cases
 - 3 deaths.
- Cases were scattered all over the country, unlike previous years with sporadic cases in the southern part of the country.
- NAT testing technology was not available
- Deferral of donors and quarantine of donated blood led to difficulties for NIBT in maintaining an appropriate supply for hospital requirements.

Impact of safety measures on blood inventory

- Competent Authority and NIBT permanently evaluated the impact of safety measures
- Initially, the inventory of BBC was not affected as the first cases were diagnosed in small localities with a very limited contribution to the pool of blood donors and mobile collection were not usually organised in that areas.
- After the confirmation of the first cases of WNV neuroinvasive disease in Bucharest (district 4) and then in Constanta city , very populated affected areas, BTCs where in the situation to defer all the potential donors residents in this
- As in Romania NAT facilities were not available for the screening of viral infection in blood donations the implementation of EU Directive 2004/33 was a real challenge for the transfusion system.

Impact of safety measures on blood inventory

- In this situation, NIBT together with the local management of Constanta and Bucharest BTCs decided **to quarantine blood collected for 15 days**, period in which donors could inform the blood establishment about the appearance of a febrile episode +/- skin rash.
- A critical issue – the supply with platelets concentrates, as the viral inactivation techniques were not available.
- In Bucharest, **a 30% reduction in available** blood inventory was recorded. To this percentage contributed the fact that on 12 August, Greek national authorities reported and confirmed outbreak of WNV infection in Central Macedonia, a place where many Romanian tourists spent their holidays.



Measures to compensate blood shortages

NIBT had a crucial role

- BTCs without affected areas increased the collection.
- Redistribution of the reserve inventory
- Hospitals - Elective surgery cancelled

Measures to compensate blood shortages

- In 2013 WNV NAT screening for blood donors was introduced for affected areas.
- By introducing this measure blood inventory has not been affected nationwide, on the contrary an increase of the number of donors was registered.
- Viral inactivation techniques for PC – will be implemented in near future

Bus accident in Montenegro with Romanian citizens

Proved a very good collaboration between Romania's and Montenegro's health systems

- road accident of 23 June 2013, when 18 people were killed and another 29 were wounded nearby Podgorica, capital of Montenegro.

-all 47 were Romanian citizens

- the injured were hospitalized in hospitals in Montenegro

- they needed blood and the local people came to BEs to donate blood.



Bus accident in Montenegro with Romanian citizens

- After they have been operated and stabilized the 27 injured were transported to hospitals in Bucharest.
- This situation was not difficult for the transfusion system in terms of blood supply, but in terms of the influx of donors who have been presented all over the country to donate as a result of the media campaign.

Bus accident in Montenegro with Romanian citizens

- Media campaign on blood donation has been emotional, aggressive, uncoordinated with messages from NIBT, and some BTCs have managed with difficulty the large number of donors because of the:
- lack of staff, limited storage and testing capacity
- A good communication was necessary for donors who were refused, so they may return

Conclusions

- WNV epidemic was the only situation that has had a significant impact on the blood inventory in Romania
- The development of an action plan with provisions for special and emergency situations is crucial
- Efficient communication between the institutions involved and the media; messages transmitted to the population must be adapted to the situation

Conclusions

- We propose the inclusion in the EU Directives of derogations from the donor's eligibility criteria when local stocks are affected, in emergency special situations:
 - reducing the interval between donations
 - lowering the acceptable level of donors hemoglobin