



**Applied quality and safety
requirements for blood donor
and patient management in
emergency special circumstances
in the Republic of Moldova**

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General information



Located in south-eastern Europe and has borders with Romania to the west and the Ukraine to the north, east and south

Area - 33 700 sq.km;

Population - 3, 560 mln, including 42% urban and 58% rural;

The average density of population - 105, 65 population sq.km;

Female/male ratio :

- 52% - women
- 48% - men;

Average life expectancy - 69,3 years;

Administrative structure - 36 units

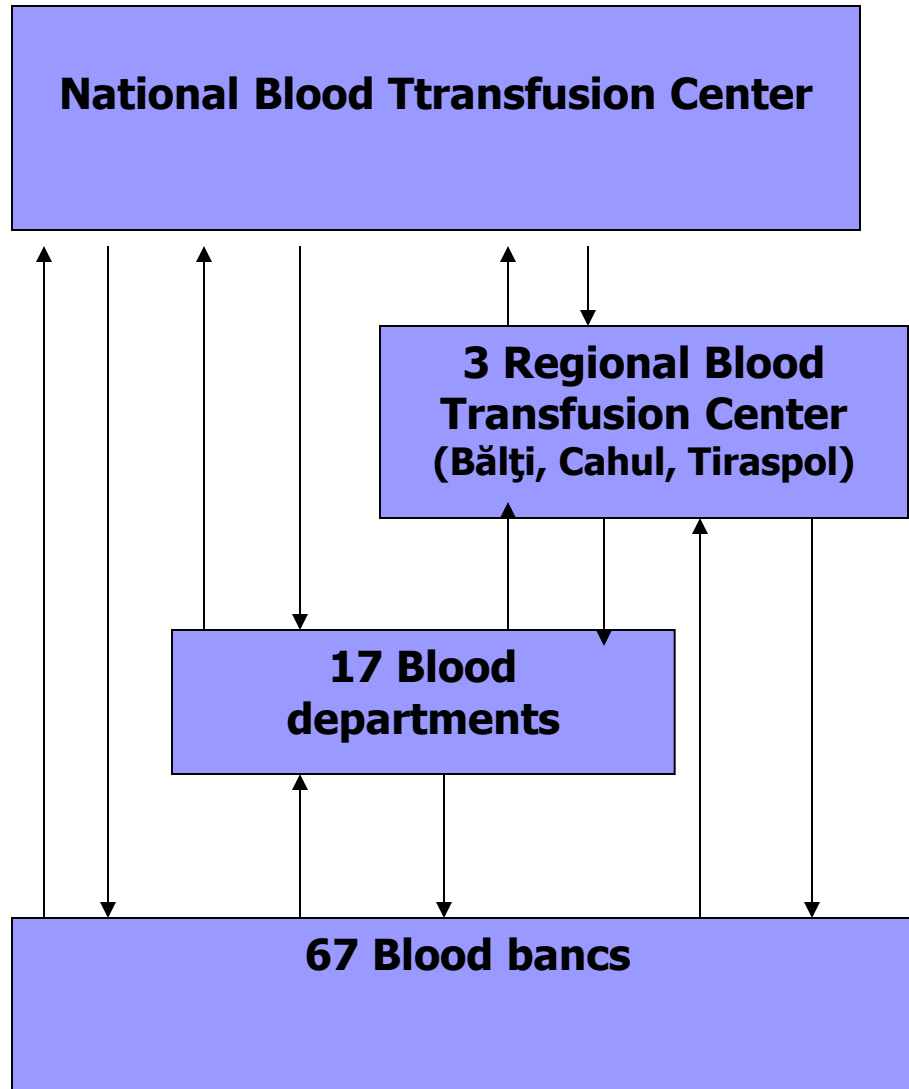
National Policy for Blood Safety

- to increase the availability of safe blood, blood components quality, in accordance with the International standards requirements.
- sustainable partnerships with public authorities, NGOs and the community in promoting civil values, with regards to voluntary non-remunerated blood donation.
- to assure national blood products self-supply with blood products for healthcare, including special circumstances.

Laws and normative acts in blood safety

- The Law on Blood Donation and Blood Transfusion, No. 241, from 20.11.2008
- The National Program “Transfusion Safety – blood products self-supply”
- National regulations, quality standards and guidelines, in accordance with the European Directives and WHO Recommendations

Blood Transfusion Service



Responsibilities in the implementation of the Policy for National Transfusion Safety

Ministry of Health – development and periodical review of the policy, approving normative documents for the implementation of the policy;

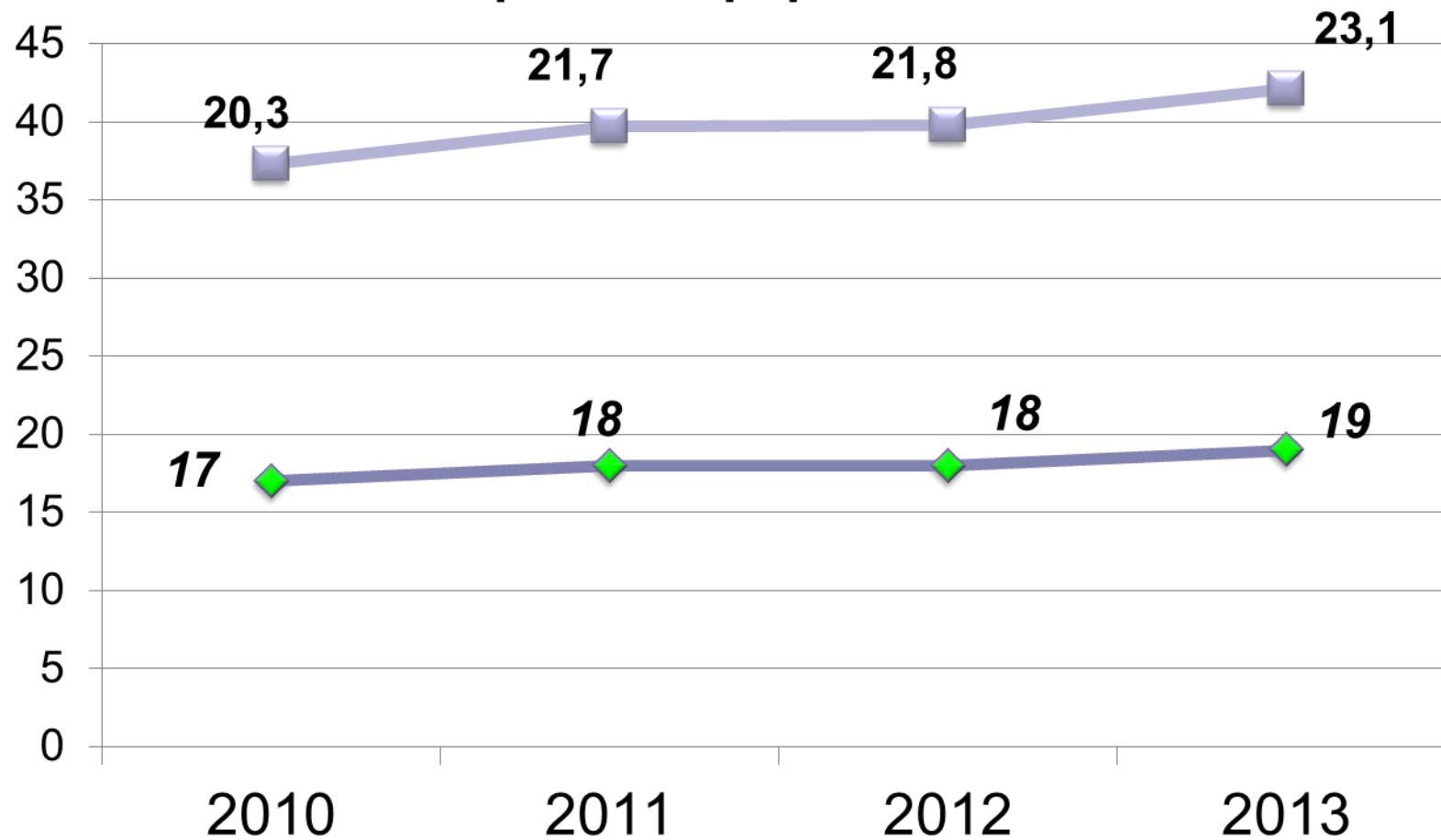
National Blood Transfusion Center – methodological organization of the national policy implementation, monitoring the service activity at the national level; implement policy of the center region of the country

Regional Blood Transfusion Centers (North, South and Transnistria) implement policy in the region;

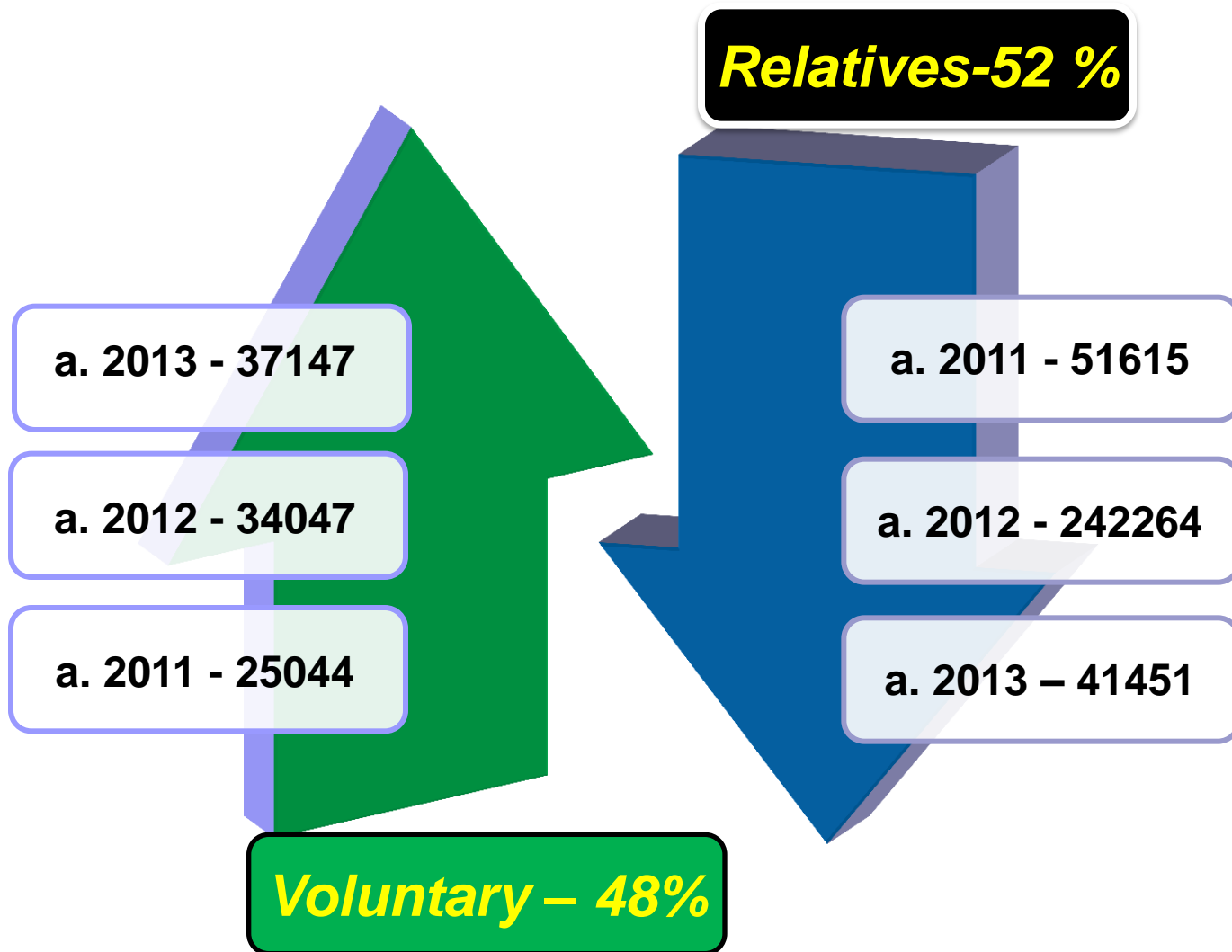
Medical institutions with blood banks implement policy in the institution.

Blood donors and donations

per 1000 population



Blood donations



Blood safety

testing the infections markers

infection	consecutive steps of testing		
	I	II	III
hepatitis B	HBsAg	Antibodies anti HB cor IgM și IgG only blood samples is missing in HBsAg	Antibodies antiHBs only blood samples is missing in HBsAg antibodies anti HB cor IgM și IgG
hepatitis C	Antibodies anti HCV	ARN HCV only blood samples is missing in anti HCV	-
HIV	Antibodies/antigen HIV	ARN HIV only blood samples is missing in Ab/Ag HIV	-
Syphilis	Antibodies anti Treponema Pallidum	-	-

BLOOD SAFETY

erythrocytes antigens and antibodies

In all donations

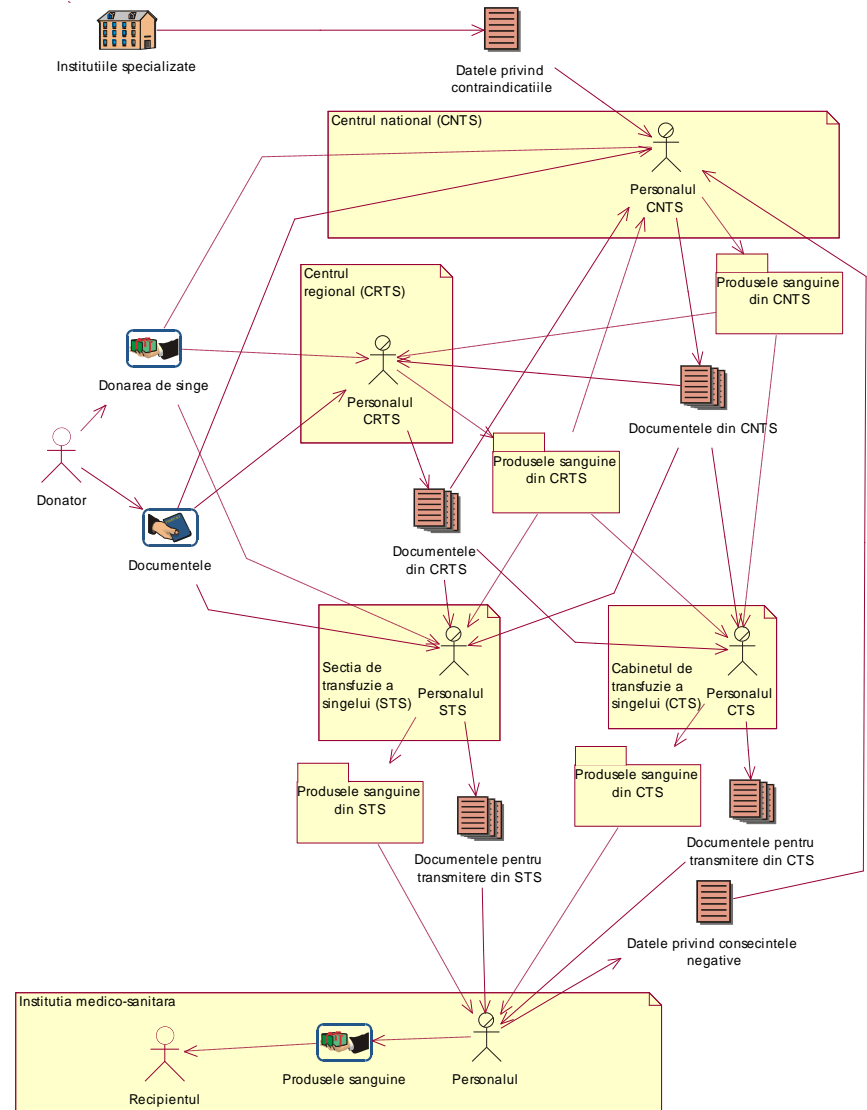
1. Erythrocytes antigens by system

- ❑ OAB
- ❑ Kell
- ❑ RhD
- ❑ in the RhD negativ – C and E

2. Erythrocyte antibodies

Blood Service Computerization

The existing information system at the national level representing a system of computer networks between all blood collection points and medical institutions that use blood products.



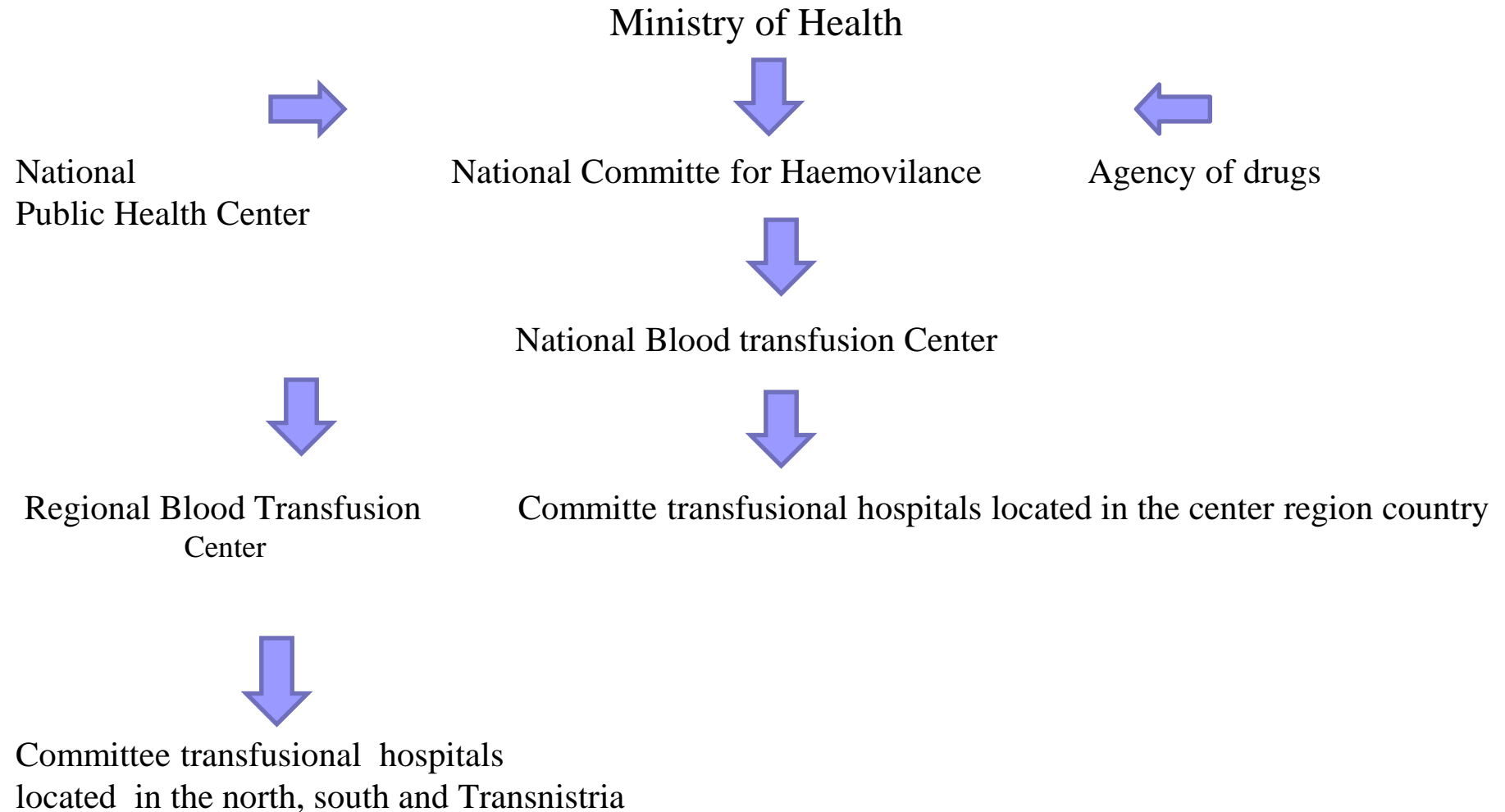
Blood Service Computerization

1. allows evaluating availability of and access to the national Registries of donors and blood products, including rapid identification donors and blood products in exceptional situation (circumstances);
2. monitoring the traceability of blood products and haemovigilance information;
3. data management system at the institution level (BTC, BB) and national blood service.

Haemovigilance system

- Haemovigilance is a set of standardized procedures surveillance for serious adverse reactions occurring in the patients and donor after blood donation
- Moldovan health system has a regulatory framework that regulates haemovigilance in the institution, region and national level.

structure of the haemovigilance



Reporting system for transfusion adverse reaction

Ascertained transfusion adverse reaction



first 2 hours of the finding

information transmission and convening hospital transfusion committee

no later than 6 hours after finding



Assessing the situation



to 7 days after finding

Reaching a conclusion and reporting of National Committee for Hemovigilance



Reporting of NBTC



12 hours after receiving information

Reporting of National Committee for Hemovigilance

National system for monitoring blood transfusion activity

Set of national indicators, developed in accordance with recommendations of WHO and the EU:

- Indicators of impact;
- Indicators of process/product;
- Indicators of result.

Quality system management

- Quality management – implemented standard operating procedures for each activity and process documents; Blood Transfusion Centers have quality manuals;
- Modern supplies in blood collection and processing departments;
- Highly performance diagnostic products for testing transfusion transmitted infectious markers;
- Modern medical equipment that assures compliance with technological processes requirements in blood products production.

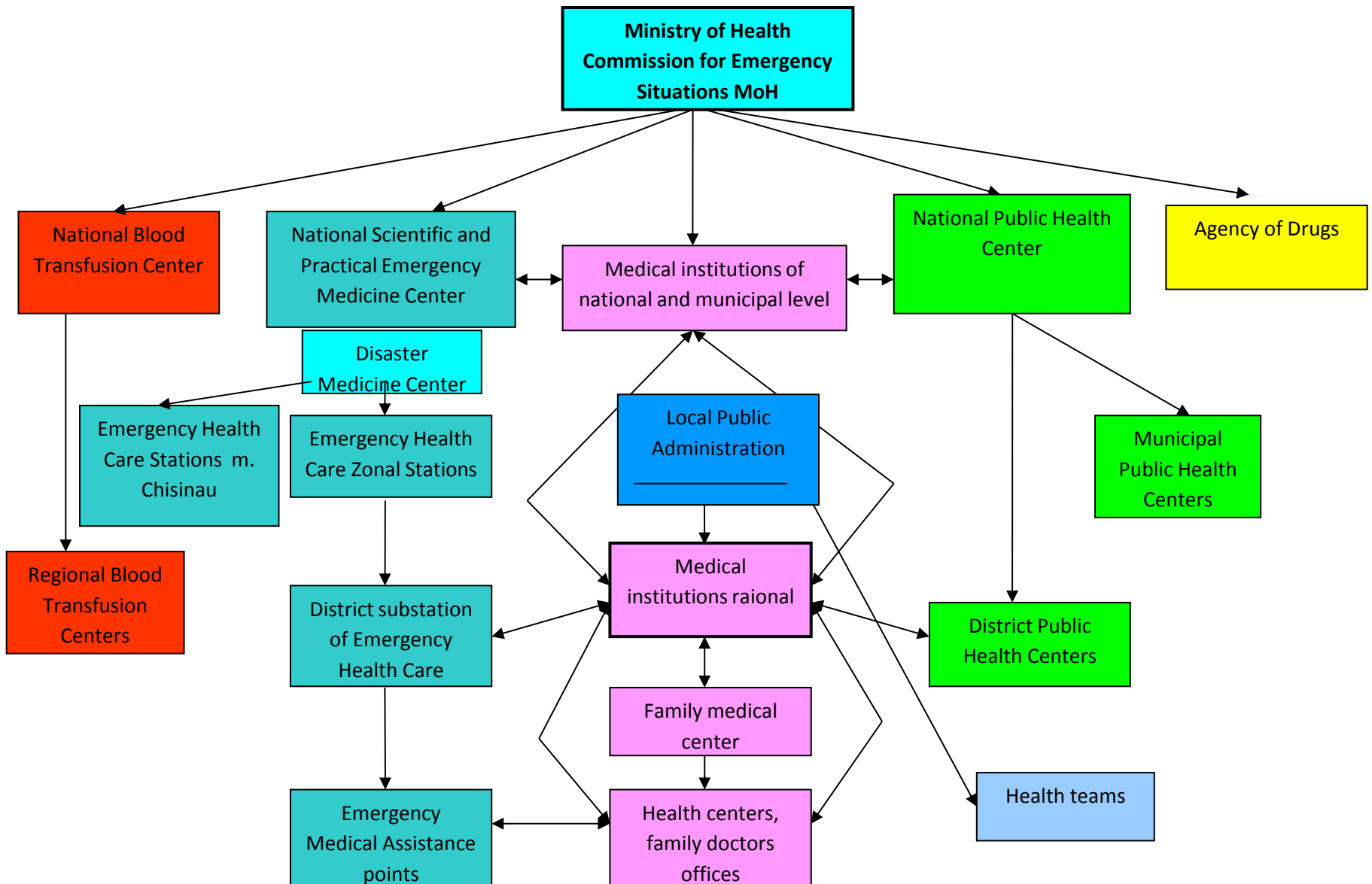
Degree Compliance EU Directive

DIRECTIVE	conclusion	
	transposition	implementation
Directive 2002/98/EC	86%	86%
Directive 2004/33/EC	100%	100%
Directive 2005/61/EC	100%	100%
Directive 2005/62/EC	100%	100%

Blood supply management in special circumstances

Moldova has national legislative (9 laws and 11 government' decisions) and normative acts, which organize and ensure activity of all partners in achieving response actions in case of emergencies, including medical institutions.

National medical response system in exceptional circumstances in Republic of Moldova



Blood supply management in special circumstances

- Register of blood donors available in the information system and document paper, taking into account the place of residence, age and blood group of the donor.
- Register blood products available, including the strategic reserved for assistance in case of emergencies.
- Strategic reserves of consumables, laboratory reagents and tests, intended for collection and testing of blood in emergency situations.

Blood supply management in special circumstances

The reserve of blood products containing:

1. blood components (red blood cells and FFP) in quantity, evaluated according to the number of inhabitants and the prevalence of blood group
2. Human Albumin 10% evaluated according to the number of inhabitants.

Renewal of strategic stocks is executed in accordance with the term of validity, but not before reaching the remaining period of product' validity of 80% of total validity term.

Blood supply management in special circumstances

Blood Service has staff trained in achieving fast response in special circumstances; Is trained staff according to the programs of the University of Medicine and cooperation of the National Civil Protection Service;

The training program includes plan of intervention in crisis, medical triage and treatment in disaster, in other.

Blood supply management in special circumstances

- Health system has normative act regulating the import and export procedure blood products.
- A commission of specialists take a decision on the import or export of blood products;
- Commission check in the original documentation, which includes mandatory information on blood group, laboratory results, donor and donation code, product validity and conditions of transportation.

Conclusions

- Efficient collaborations among all stakeholders: the Government, the Ministry of Health, International organizations and experts, has contributed to the achievement of the expected goals in blood safety.
- The Blood Service of the country has been included in the list of priorities, and blood safety has become a component part of the National Safety;
- The results obtained by the Blood Service are closely related to the degree of collaboration, succession in solving and management of the identified problems.

Future purpose and objectives

Purpose: To meet safety and biosecurity requirements for blood products.

Specific objectives:

1. Strengthening the institutional capacity to implement EU Legislation.
2. Assuring quality, traceability and haemovigilance in blood transfusion assistance.
3. Assuring blood products self-supply for the country.
4. Continuous development of voluntary blood donors.



Thank You!