# Cooperation mechanisms and the role of the SEE Regional Development Center on ACQI in promoting a harmonized approach to blood and blood products management

**Workshop on Increasing Blood Availability and Providing the Highest Donor and Patient Safety in Transfusion Therapy in Emergency Special Circumstances**
**7-9 July 2014, Bucharest, Romania**

**Workshop on Increasing Blood Availability and Providing the Highest Donor and Patient Safety in Transfusion Therapy in Emergency Special Circumstances**
**7-9 July 2014, Bucharest, Romania**

# AZUS's background

## Public authorities of AZUS:

- Establishing accreditation standards
- Assessing the quality of provided healthcare to the population
- Making resolutions in administrative issues on accreditation of HCI
- Issuing public documents on accreditation(certificates)
- Keeping records of issued certificates

# SEE HN

- SEEHN was set up by the governments of Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Montenegro, Republic of Moldova, Romania, Serbia and Macedonia. In 2011, Israel became a 10th member of the Network.
- South-eastern Europe Health Network (SEEHN) was founded in 2001 as one of the initiatives in social cohesion initiative of the Stability Pact for South-Eastern Europe. The Stability Pact was the first comprehensive strategy of the international community launched with the aim to help the countries of our region in the process of reconciliation, restoring confidence, peace, stability and security, development of democracy, respect for human rights and the provision of economic progress.

# RHDC on ACQI in SEE HN

- RHDC on ACQI was established in 2011 on proposal of Ministry of Health of Serbia, by SEE HN, Plenary meeting, Bulgaria
- Agency for Accreditation of Health Care Institutions of Serbia(AZUS) plays roll of RHDC
- RHDC is finansed partialy by Budget of Republic of Serbia and partialy by the funds of AZUS
- Ttranslating policy into specific action to improve quality of health care and patient safety in Southeast Europe

# Mission of RHDC on ACQI in SEE HN

Is to coordinate, facilitate and accelerate **continuous improvement in the quality and safety of healthcare** across all SEEHN countries:

- being a leader and advocating for accreditation and quality improvement;
- generating and sharing evidence-based knowledge and expertise;
- supporting members in their implementation of quality and safety standards.

# Role of the SEE Regional Development Center on ACQI in promoting a harmonized approach to blood and blood products management

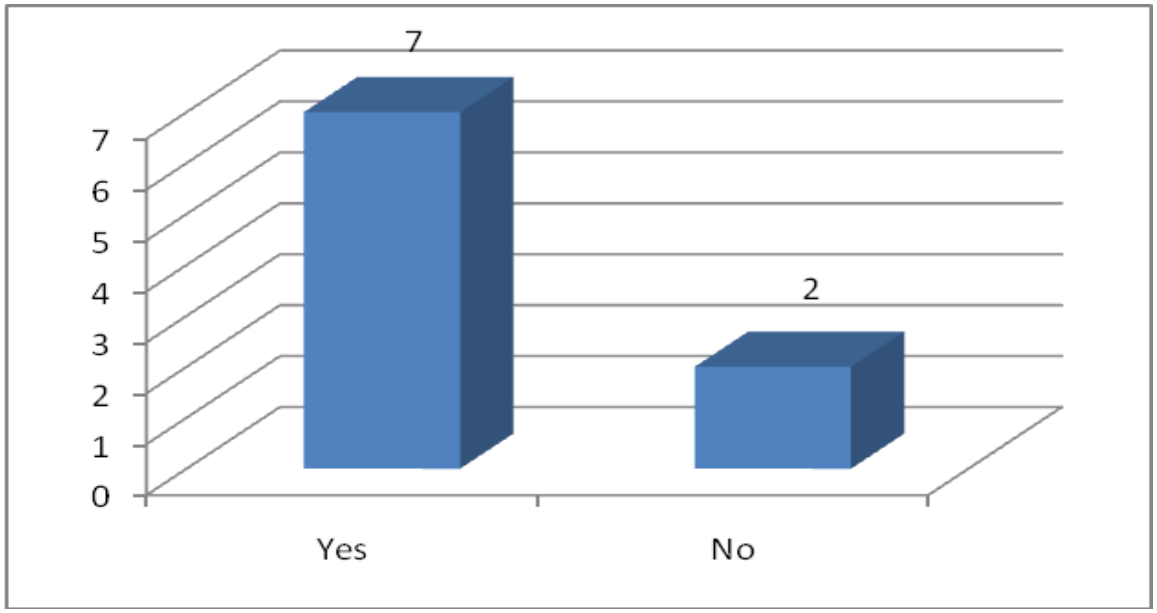
1) To apply common approach in all SEE HN member states in order to assure quality sytem in the field of transfusion
2) To establish structured close cooperation between the National Blood Transfusion Centers within the framework of the SEEHN and with the EU Member States in emergency special circumstances, so that immediate measures can be taken to ensure the availability and safety of blood and blood products.

# Common approach in all SEE HN member states in order to assure quality sytem in the field of transfusion

- A quality system based on the principles of good practice must be introduced by each blood establishment and hospital blood banks.
- The traceability of blood and components, from donor to recipient must be guaranteed.
- Notification of serious adverse events and reactions.

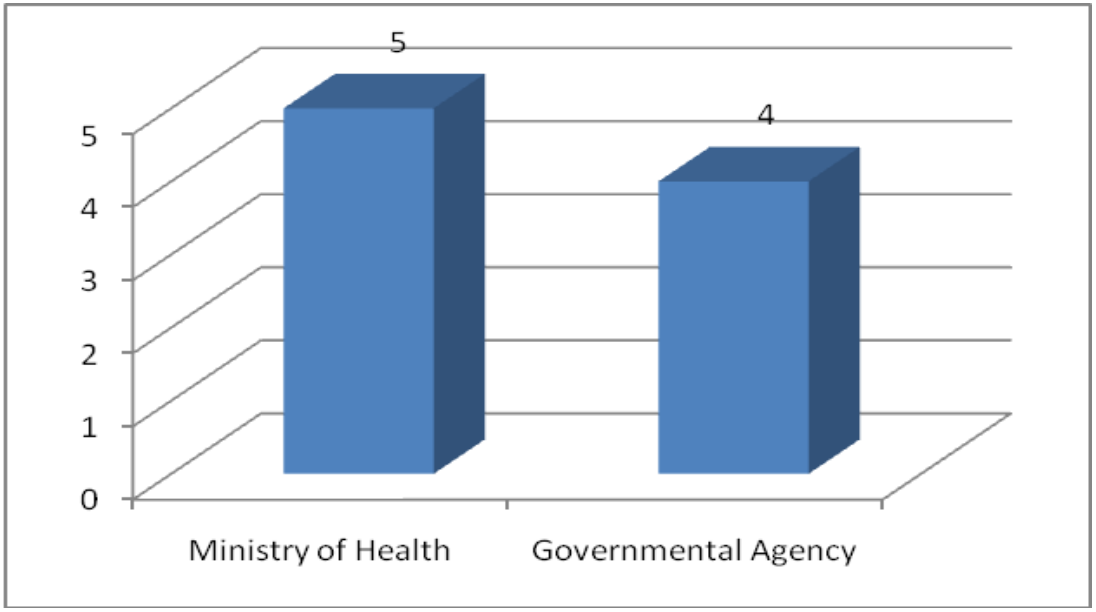
# SEE HN survey on current state-of-art in the field of quality, safety and accreditation, 2012.

| Have you developed and implemented set of quality and safety standards? | |
|---|---|
| Yes | 7 |
| No | 2 |



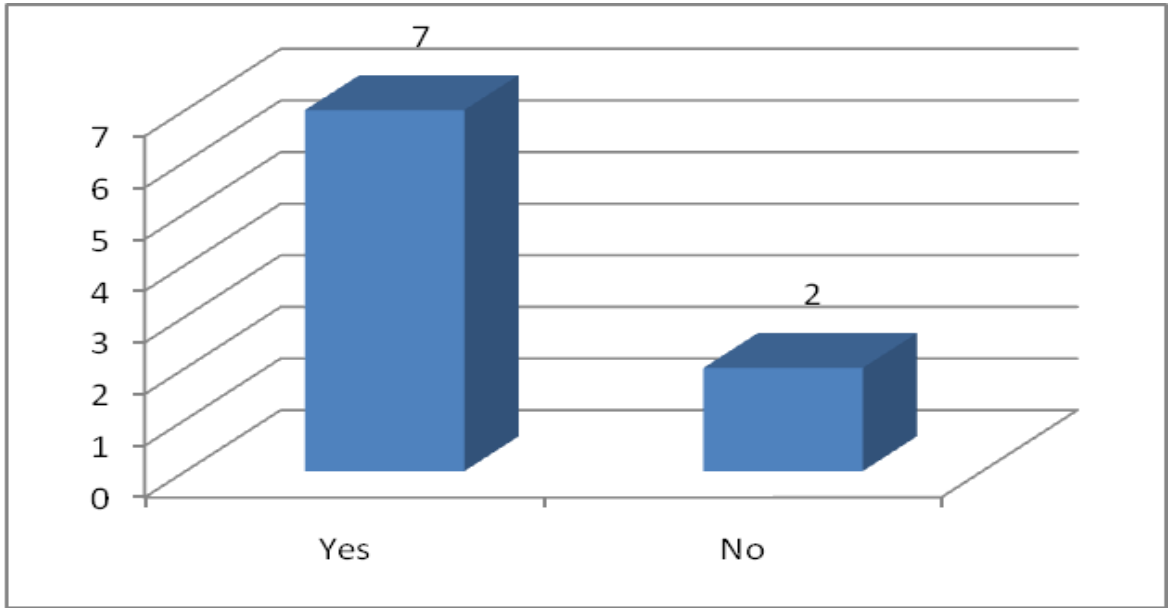
# SEE HN survey on current state-of-art in the field of quality, safety and accreditation, 2012.

| Who is authorized for developing and implementing of standards? | |
|---|---|
| Ministry of Health | 5 |
| Governmental Agency | 4 |



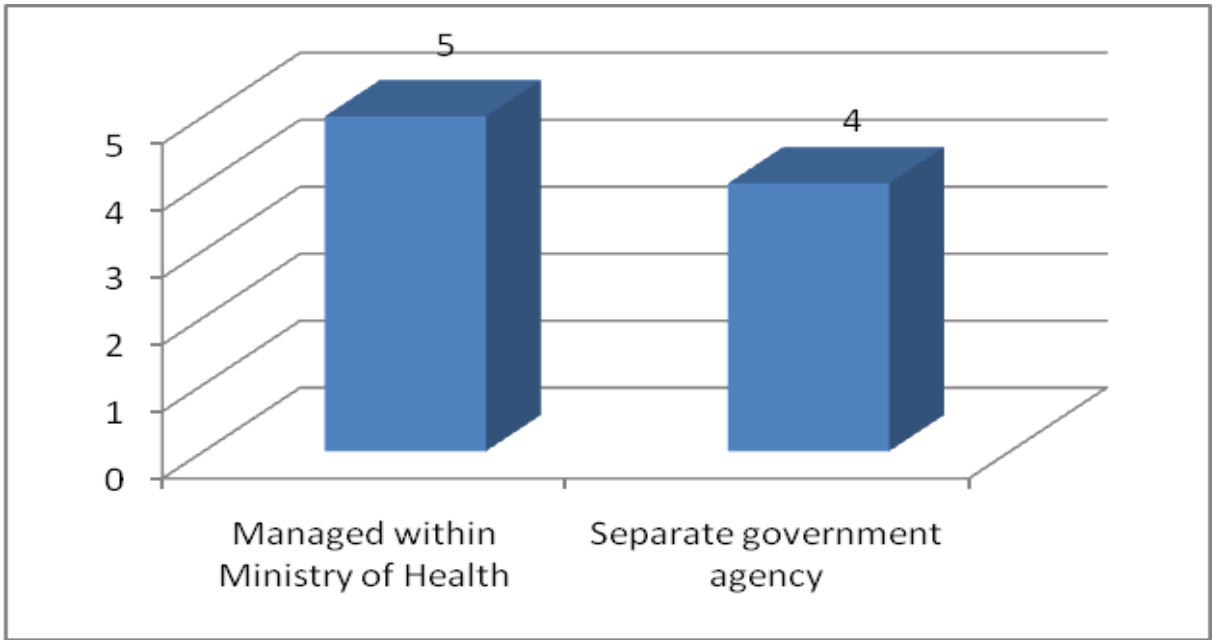
# SEE HN survey on current state-of-art in the field of quality, safety and accreditation, 2012.

| Is quality of work assessed by implementation of pre established standards called accreditation/certification? | |
|---|---|
| Yes | 7 |
| No | 2 |



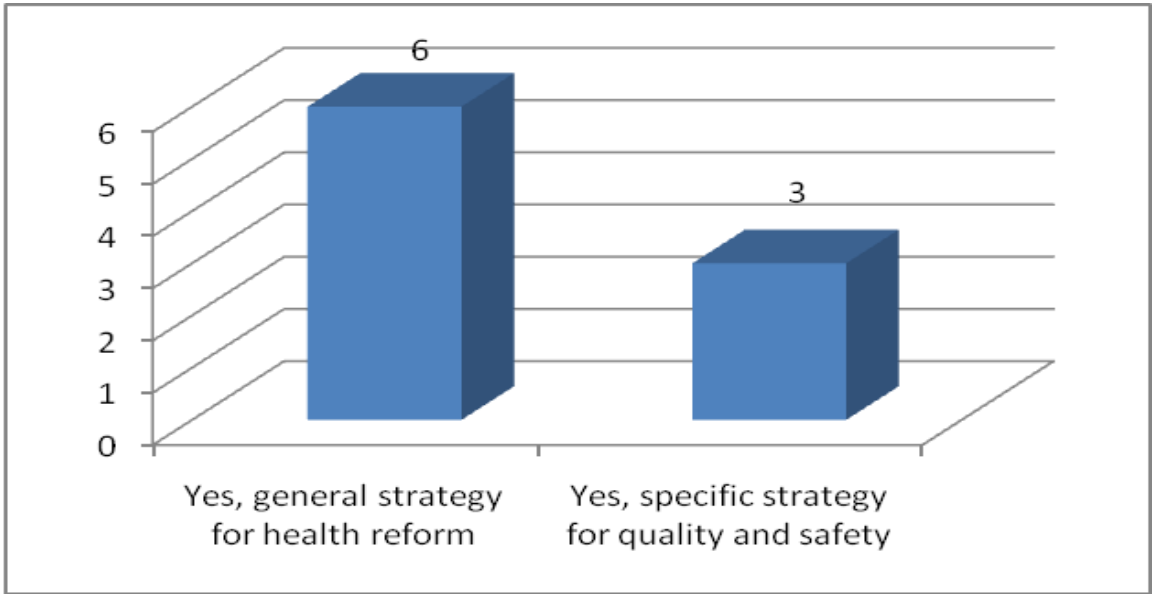
# SEE HN survey on current state-of-art in the field of quality, safety and accreditation, 2012.

| How is accreditation/certification program related to government? | |
|---|---|
| Managed within Ministry of Health | 5 |
| Separate government agency | 4 |



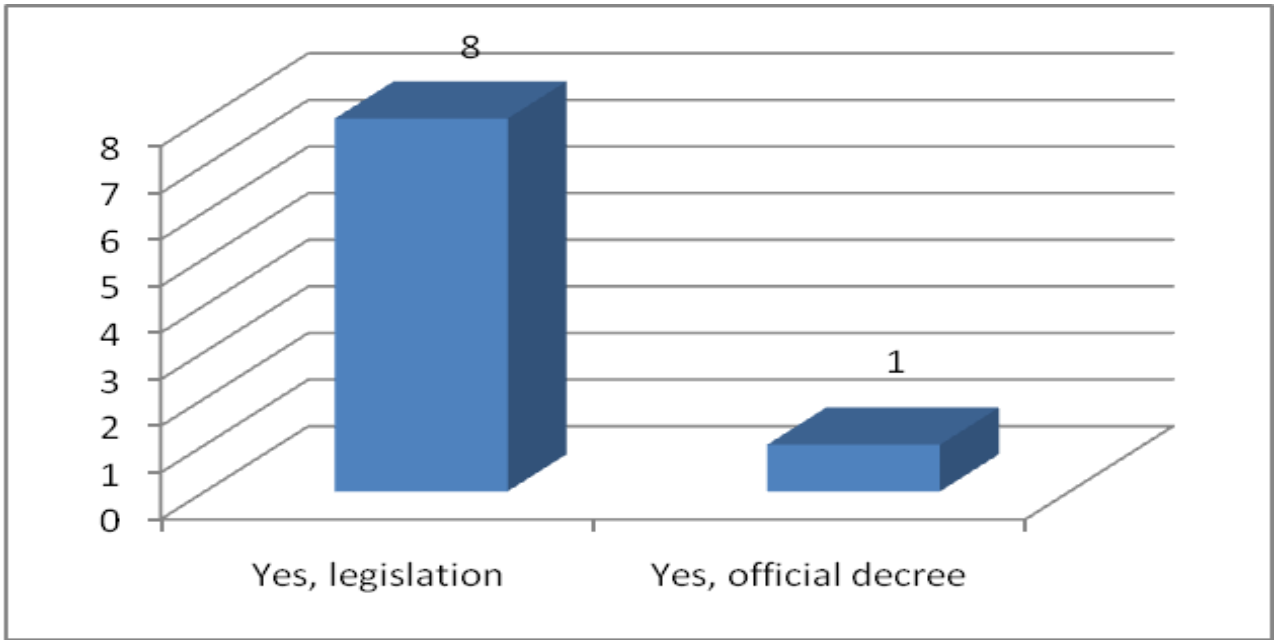
# SEE HN survey on current state-of-art in the field of quality, safety and accreditation, 2012.

| Is accreditation/certification an element of government strategy for healthcare? | |
|---|---|
| Yes, general strategy for health reform | 6 |
| Yes, specific strategy for quality and safety | 3 |



# SEE HN survey on current state-of-art in the field of quality, safety and accreditation, 2012.

| Is accreditation/certification authorized by legislation? | |
|---|---|
| Yes, legislation | 8 |
| Yes, official decree | 1 |



# Good practice examples

- Medicines and Healthcare products Regulatory Agency (MHRA) in UK
- SHOT is the United Kingdom's independent, professionally- led haemovigilance scheme, that collects and analyses anonymized information on adverse events and reactions in blood transfusion from all healthcare organizations.
- Accreditation Canada's Transfusion Services Standards are based on CSA Standards Z902-10
- The Advancing Transfusion and Cellular Therapies Worldwide-AABB Accreditation program promotes the highest standards of care for both patients and donors in all aspects of blood banking, transfusion medicine, relationship testing, hematopoietic, cord blood and other cellular therapies. (USA)

# The EU-Blood-Inspection System

The EuBIS manual European Blood Inspection System aims to provide assistance to EU Member States in their implementation of regulatory requirements set out in Directives 2002/98/EC, 2004/33/EC7, 2005/61/EC8 and 2005/62/EC9

These includes:

- designation, authorisation, accreditation or licensing of blood establishments (BEs)
- authorisation of the activities which can be undertaken and the applicable conditions for blood collection
- provisions for ensuring the quality and safety of blood and blood components,
- requirements for imported blood and blood components.

The manual defines:

1. common inspection criteria and standards for the inspection of blood establishments
2. requirements for the implementation or expansion of quality management systems to be inspected
3. the development of inspection checklists which closely follow Directive 2002/98/EC and its technical annexes
4. evaluation criteria for inspections and a benchmark system for deviations and improvements

# ISO vs ISQua standards

- ISO standards does not fully meet the requirements of the Blood Directives in the areas of Traceability and Haemovigilance

- ISQua approach provides completely implementation of EU Directives 2002/98/EC, 2004/33/EC7, 2005/61/EC8 and 2005/62/EC9

# Developing accreditation standards for transfusion therapy

- Member states should develop Accreditation standards for quality and safety in transfusion therapy, with emphasis on blood availability in special circumstances whit aim to ensure quality and patient safety management.

# Establishing close cooperation of SEEHN member states in emergency special circumstances

- New EU Rapid Alert platform for human Blood and Blood Components (RAB), allows authorities to exchange information so that cross-border incidents are prevented or contained and immediate measures can be taken to ensure the safety of patients
- SEE HN should establish close cooperation on national level between member states for immediate action in emergency special circumstances, assuring blood availability and providing highest donor and patient safety

**Workshop on Increasing Blood Availability and Providing the Highest Donor and Patient Safety in Transfusion Therapy in Emergency Special Circumstances**
**7-9 July 2014, Bucharest, Romania**


**Workshop on Increasing Blood Availability and Providing the Highest Donor and Patient Safety in Transfusion Therapy in Emergency Special Circumstances**
**7-9 July 2014, Bucharest, Romania**


**Workshop on Increasing Blood Availability and Providing the Highest Donor and Patient Safety in Transfusion Therapy in Emergency Special Circumstances**
**7-9 July 2014, Bucharest, Romania**

# THANK YOU