# 1ST ANATOLJAN BLOOD DAYS

17-18 November 2012 / Starlight Hotel - Side / Antalya - Türkiye





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Dear Colleagues,

Blood Banks and Transfusion Society of Turkey (BBTST) established at 1996 by a group of dedicated doctors who were involved in the field of Blood Banking and Transfusion Medicine (BBTM).

The main strategies of BBTST were based on training of blood bank and clinical staff, establishing official and academic education programmes, integration with international BBTM community and close collaboration with the national health authority.

BBTST has organised 14 national courses, 5 national congresses, 1 international congress (VIII. European ISBT Congress 2003; Istanbul/Turkey), 106 national symposia and 25 special sessions at the national congresses of related clinical branches so far.

BBTST has also been in close contact with global BBTM community since 1996. BBTST has been receiving numerous requests by international colleagues especially countries at our close geography about organising an interactive meeting on "sharing the experiences of regional countries" since last few years.

BBTST has decided to response this request and will organise an international meeting as "Anatolian Blood Days" (ABD) at 17-18 November, 2012 at Antalya / Turkey two days before BBTST annual national congress.

"National Guidelines on Blood Banking & Transfusion Medicine" will be the topic of First Anatolian Blood Days. An official declaration will be issued depending on the discussions on the final decisions. We believe that experiences and comments of the participants and key experts will help the countries at the region while they will be establishing or re-evaluating their National Guidelines.

Prof. Mahmut Bayık President

### 1<sup>st</sup> Anatolian Blood Days Committee

### **Scientific Chairs**

Prof. Dr. Mahmut Bayık, Turkey

Dr. N. Nuri Solaz, Turkey

Prof. José Manuel Cardenas, Spain

Dr. Gamal Gabra, UK

Prof. Brian McClelland, UK

### **Secretary of Anatolian Blood Days (ABD)**

Dr. Ramazan Uluhan, Turkey

### **Venue**

Starlight Hotel Convention Center, Side, Antalya-Türkiye

### **Date**

17 – 18 November 2012

### 1st Anatolian Blood Days Program

### **17 November 2012**

09:00 - 09:30	Opening
09:30 - 10:30	Country presentations – 1
	Afghanistan Albania Bosnia and Herzegovina Egypt
10:30 - 11:00	Coffee break
11:00 – 12:30	Country presentations – 2
	Iran Kosovo Morocco Palestine Tajikistan Turkey
12:30 - 14:00 14:00 - 15:30 15:30 - 16:00 16:00 - 17:30	Lunch break Interactive discussion – 1 Coffee break Interactive discussion – 2

### 18 November 2012

09:00 - 11:00	Preparation of final declaration
11:00 - 11:30	Announcement of final declaration & Closing

Language: English

## NATIONAL GUIDELINES ON BLOOD BANKING & TRANSFUSION MEDICINE

Irena Qendro, Director NBTC Albania

#### Introduction

Ethics and legislation, organization and quality assurance, selection of blood donors with lowest possible risk, screening of blood for infectious markers, judicious clinical use of blood, careful assessment of risks and benefits before transfusion, continuous training and education are basic prerequisites for national health policies to improve the safety and effectiveness of Blood Transfusion Medicine.

According to WHO, the national guidelines based on international recommendations, recognized effective therapeutic interventions and safe transfusion practices need to be adapted to existing local infrastructure and degree of health system development. Their aim is to promote national consensus on management of patients with conditions requiring transfusion therapy and to provide a stepwise standardized approach for the whole process.

### Background

The Albanian Blood Transfusion Service has been created 60 years ago. Since its creation there was a National Blood Transfusion Centre. This particular feature (in the region Blood Transfusion Centres were mainly hospital based) enabled a gradual development of a national network so that consolidation now results an easier task for Albania compared to other countries. Since its creation NBTC has been a national regulator of transfusion service and during time more and more responsibilities have been recognized to this Institution and now all these responsibilities are designed in the new Law "On Transfusion Service in the Republic of Albania".

In 2005, with the main purpose of getting Albanian Transfusion Medicine up to the European Standards of quality and safety, the National Strategy of Transfusion has been designed and initiated. Significant efforts were oriented towards ensuring adequate supply of high-quality blood and components to meet the national demand as well as the recognized international and newly developed national regulations.

### Current legislation, implementation, achievements and problems

A new legal frame has been drawn-up by the Law no. 9739/21.05.2007 "On Transfusion Service in the Republic of Albania". It served as bases for systematic reorganisation as well as initiated profound changes of the blood transfusion system at institutional and national level.

#### The New Law:

- Based on Directive 2002/98/EC
- Greater accent given to standards of quality and safety.
- For the first time recognizes the value of voluntary nonremunerated donation and regulates promotion activities.
- Common minimal European standards.
- Description of the responsibilities of NBTC
- · Competent authorities
- Obligations + recommendations.
- Dispositions for quality management, quality of blood and components.

**The working group** for the preparation of the Law has been approved from the Minister of Health and was made up of transfusion specialists, public health specialists and specialists of the Ministry of Health. Since the new Law recognized NBTC as the responsible authority for developing and implementing guidelines and regulations, all these documents were predicted to be prepared from NBTC specialists with the support of other specialists depending on the regulation, for example: "Testing blood for

infectious agents" had to be prepared in cooperation with public health specialists. The regulations developed until now are all signed from the Minister of Health and are as following:

- Regulation on selection of blood donors and donation of blood/components.
- Basic technical and organizational requirements of the transfusion structures.
- o Regulation on testing procedures of donated blood.
- Regulation on the procedure of requesting and issuing blood and components in the Republic of Albania
- Constitution and functioning of the National Blood Committee.
- o Import/export of blood and components.
- o Regulation on the inspection of transfusion structures
- Regulation on the evaluation of quality and safety of blood/components.
- Regulation on the system of documentation, traceability, haemovigilance.

The main discouragement for the preparation of the documents has been the difficulty to involve in the process specialists out of the transfusion field for those regulations that needed them: "Regulation on the procedure of requesting and issuing blood and components in the Republic of Albania", "Regulation on the system of documentation, traceability, haemovigilance", "Regulation on testing procedures of donated blood". Therefore, being almost impossible to involve the appropriate clinicians in the preparation of these documents, they have been prepared from transfusion specialists and from specialists of the Ministry of Health.

Unfortunately all those parts of the Law or regulations, or entire regulations that cover the clinical side of transfusion that were prepared without the clinicians are still not implemented:

 Hospital Transfusion Committees (requested from the Law, still not in place in none of the hospitals).

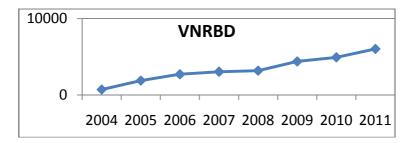
- Notification of serious adverse events and reactions (requested from the Law and from the regulation on haemovigilance, still not implemented).
- Competent authority for inspection (Institute of Public Health, recognized from the Law, never accepted, not implemented).
- Regulation on clinical use of blood, still not prepared as documentation.

Therefore, we can say that involvement and participation in the preparation of laws, guidelines and regulations is the bases for acceptance and implementation.

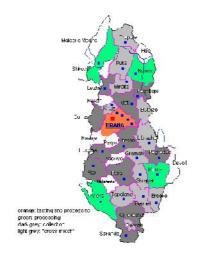
**The main encouragements** have been the support of the Ministry of Health in preparing and approving guidelines and regulations and the Stability Pact Project for South Eastern European Countries that helped us a lot in preparing all our documents by sharing experiences with other neighbor countries and by making us gain a deep understanding of all EU Directives in transfusion field.

Most of parts of the Law/regulations or entire regulations that recognized as responsible Institution for implementation NBTC have been successfully implemented:

- Organization of voluntary non remunerated donation
- Cooperation with Red Cross and Organization of VNRBD has resulted in significant increase of voluntary donations as shown in the graph:



- Reorganization of the service
- Based on the Law and Regulation consolidation of transfusion service began and we actually have only one testing center in Tirana for the whole country. Strategic objectives: 1 National testing center, 5 regional processing center, 14 collection centers, 11 hospital blood banks.



- Implementation of quality system.
- We have implemented a quality control system for components and procedures, and have created in this way the bases for implementation of quality management system.
- All regulations covering transfusion site such as: "Regulation on selection of blood donors and donation of blood/components", "Regulation on testing procedures of donated blood", "Basic technical and organizational requirements of the transfusion structures", "Regulation on the evaluation of quality and safety of blood/components", "Regulation on the system of documentation, traceability, haemovigilance (transfusion part)", have been successfully implemented.

### Conclusion

Transfusion therapy meeting high quality and safety standards should be available and accessible for all patients. For ensuring this of course an appropriate legal and regulatory framework is needed, covering adequate organisation of transfusion service, clinical use of blood and haemovigilance. The last two parts need close cooperation with clinical side since in the phase of preparation of legal framework, otherwise the implementation could never be provided. Only constant communication between Blood Transfusion Service and the clinical site in preparing and implementing regulations that cover clinical part of transfusion, will create bases for ongoing improvement of the entire chain of transfusion safety of transfusion service and strengthen patient safety.

# SHORT BRIEFING ON NATIONAL GUIDELINES ON BLOOD BANKING AND TRANSFUSION MEDICINE IN FEDERATION OF BOSNIA AND HERZEGOVINA

Jasminka Kurilić, Blood Transfusion Specialist Aida Đozo, Blood Transfusion Specialist Institut of Transfusion Medicine of FBH Sarajevo, Bosnia and Herzegovina

#### INTRODUCTION

**Bosnia and Herzegovina** got the independence in 1991. It consists of three parts: Federation of Bosnia and Herzegovina, Republic of Srpska and Brcko District.

According to the international estimation from 2006, the population of BH is 4.498.976.

Transfusion in BH also consists of three parts: Federation of Bosnia and Herzegovina, Republic of Srpska and Brcko District.

Bosnia and Herzegovina collect between 65.000 and 70.000 blood units annually.

At the BH level there is no nationally coordinated activity planning and organization of work within the transfusion activity.

Different levels of organizing and equipment of transfusion institutions, centers and cabinets, working conditions, inequality in range and complexity of activities are some of the characteristics of current transfusion service in BH.

BH, as a member of WHO and European Council accepted and gave priority and complete support to the implementation of coordinated and sustainable programme for blood with proper regulatory systems, in accordance with the WHO, directives 2002, 2004 and 2005 of the EU and European Council. BH has set the direction of development of transfusion service in accordance with

the concept of obtaining adequate quantities of safe blood and European standards.

### **Federation of BH**

The national authority for Blood Banking and Transfusion Medicine Service in F BH is Ministry of Health. In F of BH the blood supply and transfusion statistics are obtained from the blood centres by the MoH as paper work in a limited adequacy. The statistics form is filled monthly and annually by the responsible person in the blood centre and is sent to the MoH .

According to the statistics of the MoH, the number of citizens in Federation of BH is approximately 2 900 000, and about 42 000 blood units is collected annually. In that way we can see that the number of blood donors is about 1,5%.

In order to meet needs for blood and blood products, F of BH has developed blood donation system without the help of Federation Red Cross.

The need for transfusion treatment in Federation of BH is covered by the Institute for transfusion medicine, the biggest and bestequipped transfusion institution, of four transfusion centers and eleven hospital transfusion units.

#### SITUATION ANALYSIS

### Blood donation, blood supply, blood screening in F of BH

- All blood donors are voluntary, non-remunerated donors. With 15 donations/1000 citizens, F of BH is insufficient in blood components.
- TransFusion service collects a total of approximately 42 000 blood units per year and produces about 60000 blood components units.
- 5%-80% of collected blood units are transfused as whole blood, whereas plasma is separated from the remaining blood units.
- -Leucodepletion is performed in aproximately of 10% of red cells.
- All collected plasma is only for transfusion not for fractionation.

- Total number of aphaeresis thrombocytes prepared in 2011 is 400 and performed only in one place (Institute for transfusion of medicine of F of BH)
- Bacterial inactivation is not performed.
- Confirmation test is performed only in one place (Institute for transfusion of medicine of F of BH)
- NAT donor testing of hepatitis B and C , and HIV infecion is performed only in one place (Institute for transfusion of medicine of F of BH)  $\,$
- A questionnaire distributed by Transfusion units in 2011 revealed that all the 16 blood centers responded the questionnaire, 24.2 % run a quality system.

### LOWS, REGULATIONS AND STRATEGIC DOCUMENTS IN THE FIELD OF TRANSFUSION MEDICINE

### I. LOW ON HEALTHCARE PROTECTION (2010);

In acordance with this Low The Institute of transfusion medicine of Federation BH forms the doctrine and brings regulations into accordance with application with standards for collecting blood and blood products, procesing, storage, distribution, dilivery, issue of blood products and medicaments from blood and their clinical application , practices quality control of work, reagents and products in transfusion medicine.

### II. LOW ON BLOOD AND BLOOD PRODUCTS (2010)

The new blood law (Law on Blood and Blood Products, published in 2010) describes a decentralized system composed of Institute for transfusion of medicine of F of BH, transfusion centres and hospital blood department as blood establishments.

The law on blood and blood products (2010) harmonizes the legal regulative in F of BH within the transfusion area with the blood directives of EU. This law regulates the organization of transfusion

activities, conditions and quality standards, safety and monitoring in collecting, testing, processing, storing, distribution, issuing and use of human blood and human ingredients within Federation of BH.

### III THE LAW ON TRANSPLANTATION OF ORGANS AND TISSUES FOR THE TREATMENT PURPOSE (2009)

### IV REGULATIONS ON BLOOD, BLOOD PRODUCTS, TISSUES AND CELLS

- 1. Regulation on certain technical requirements for blood and blood products (2011);
- 2. Regulation on the quality assurance and safety of blood and blood products(2011);
- 3. Regulation on the System of the Traceability of Blood and Blood components and Monitoring of Serious Adverse Events and Serious Adverse Reactions (2011).

According to this regulation, Healthcare institutions, using transfusion treatment are obliged to establish systematic reporting of serious adverse events and serious adverse reactions associated with the quality and safety of blood, blood products and blood donors, and to notify any severe adverse reaction/event. These data than forwarded to MoH. Reporting is obligatory, however, as a network of operative connections among clinical departments, hospital blood banks, blood establishment and federal authorities is still lacking. Although a standardized reporting form has been defined, as consensus on definitions and interpretation of particular reactions/events has not been achieved, they are not systematically analyzed.

1. Regulation of wrking premises, medically-technical equipment and professional staff, that transfusion center and transfusion department must meet (2011);

- 2. Regulation of education within transfusion medicine for the nurses/technicians and laboratory technicians (2011).
- 3. Ordinance on establishments of bodies, faces and health institutions for the implementation of transplatantion procedures in Federation of BH, (2005);
- 4. Regulation on the sphere, way of work and the Committee for transplantation medicine, (2010);
- 5. Regulation on procurement, storing and use of HSCs (stem cells) of perifery blood collected from separated umbilical cord of a newborn child, (2010).
- 6. Regulation on closer space conditions, equipment, staff, as well as the procedure of verification of the health institution for performing explantation, transplantation of tissue and the health istitutions that perform the function of tissue bank, (2012).
- 7. Regulation on the procedure of collecting and use of stem cells of perifery blood, (2012).

A law has been prepared by the MoH during 5 years, with participation of professional Transfusion Medicine Committee. Participants of the preparing Committee are:

- one representative of MoH
- director of The Institute of Blood transfusion of F of BH
- one representative of transfusion medicine, a specialist from hospital transfusion unit
- one Red Cross representative
- one immunology specialist

This Committee is responsible for developing regulation guidelines and standards at the level of Federation of BH.

This low is expected to contribute primarily to the institutional capacity of the Ministry of Health to regulate, supervise, inspect

and audit blood banking and transfusion system in the Federation BH.

# IV - AIMS OF THE LOW AND REGULATIONS ARE TO ENSURE EFFECTIVE IMPLEMENTATION OF THE FOLLOWING EU LEGISLATION IN F BH:

- 1. Commission Directive 2005/62/EC standards and specifications relating to a quality system for blood establishments.
- 2. Commission Directive 2005/61/EC traceability requirements and notification of serious adverse reactions and events.
- 3. Commission Directive 2004/33/EC certain technical requirements for blood and blood components.
- 4. Directive 2002/98/EC setting standards of quality and safety for the collection, testing,
- 5. processing, storage and distribution of human blood and blood components
- 6. Guide to the preparation, use and quality assurance of blood component (CoE )
- 7. Guide to the Safety and Quality Assurance for Organs, Tissues and Cells (CoE)

#### CONCLUSIONS

Table 1.

SUCCESSFUL ACTIVITIES OF TRANSFUSION SERVICES OF F BH	ACTIVITIES ARE IN PROGRESS
<ul> <li>100 % voluntary non-remunarated donors</li> <li>Increase of donors</li> <li>Increase young and first time donors</li> <li>High level of automatisation</li> <li>Great progress for more safe blood (NAT)</li> <li>Increase of component therapy</li> </ul>	<ul> <li>Late Low regulations</li> <li>Big differences in progress between blood establishments of F BH</li> <li>No transfusion activities (recruitment of donors) in rural areas.</li> <li>Strong decentralisation is trouble</li> <li>Progress of implementation of standards is slow and late</li> <li>Lack of computerized system</li> </ul>

There are no federal guidelines of blood banking and transfusion medicine in F BH.

The main discouragments at preparation of federal lows and regualtions were: decentralisation of transfusion services, financial difficulities, organization problems etc.

The main encouragments at preparing federal lows and regulations were: humanity od donors, low end regulations of Gaverment of FBH, EU, CoE, WHO.

The Blood transfusion service in F of BH is still hospital based and decentralized one and lacks many vital resources like adequate infrastructure and financial base, lack of supervisory control by regulatory authorities at the national/federal level, lack of national uniform quality management system and biovigilance (haemovigilance and materiovigilance) network, lack of standardized curricula for training of the staff , lack of proper

motivation, recruitment, and retention of blood donors, lack of record keeping etc.

Collecting, testing, procesing, storage, distribution and usage of blood and blood products in Fedration is in accordance with Lows of Federation, Directives of EU, recommendations of WHO, recommendations of CoE, GLP, GPP and GCP and appropriate regulations from transfusion medicine.

## PROCUREMENT OF NATIONAL BLOOD GUIDELINES, EGYPT EXPERIENCE

Dr. Faten M Moftah

### Introduction

Egyptian MOH started a major reform project for the restructuring of blood services. The project started in 1997 and lasted till 2011, with the support of the Swiss Government. The project was implemented in two phases, and aimed at converting the previously existing fragmented hospital based blood banks system into a state of the art regionalized blood services.

The task of the new blood system is to increase the blood donation, replace family replacement donors by volunteers, testing all the donated units to the internationally recommended parameters, ensure the availability of components to all patients, and increase the awareness of the clinicians on the rational use of blood components.

### Subject

The providers of blood products and services in Egypt are several stakeholders. MOH is the national authority for the main provision and regulation of blood activities.

The only law that regulates the blood activities was established back in 1960 by a presidential decree. The national blood policy was put into effect in 2007 by a ministerial decree.

The national blood policy is supplemented by five other guidelines documents that include all the necessary needed details. These are; National blood standards, technical manual, strategy, safety manual, and appropriate clinical use of blood. It is planned to procure soon the donor counseling guidelines.

The national blood policy was prepared in three years, and all the stakeholders shared in writing the first draft. Stakeholders are; MOH, 3 university hospital blood banks, military and police hospitals blood banks, private sector, Egyptian Red Crescent, etc.

The policy was matured through 4 drafts, and then was the logistics of printing.

During the exercise of policy establishment and implementation, the task force was faced by several obstacles; e.g. fear of power or control loss, fear of job change or degrading, fear of income decrease, old fashion decision makers, conflict of interest, etc.

On the other hand they as well got supported by other encouragements; e.g.; strong leadership, the donor country, the young enthusiastic staff, WHO, ISBT, etc.

The policy and guidelines cover all the blood practice areas and all the blood centers levels as regional blood centers, hospital blood banks, and regulators.

The organization of the blood pillars has been rearranged in a new organogram to separate the producers from the users and the regulators of blood components and fractions. The help and support of the Swiss government especially in the field of know how transfer and human resource capacity building helped a lot the fulfillment of the restructuring.

### **Conclusion and Recommendations**

Each country should work on having national guidelines on blood banking and transfusion. It is very important to learn from other successful countries. The authorities should take into consideration the local epidemiology and the health services set up.

National guidelines should be implemented by the support of the government.

### IRAN BLOOD TRANSFUSION ORGANIZATION

Dr. Leila Kasraian
Community Medicine Specialist
Assistant Professor
Manager of Education Department of Shiraz BTO

Iranian Blood Transfusion Organization (IBTO) is the only nationally accredited organization in Iran that performs blood transfusion procedures ranging from blood donor recruitment as well as blood distribution.

IBTO was established in May 1974. This government-based organization provides its services free of charge. Before its establishment, blood services were provided through hospital-based systems.

IBTO is managed by the Supreme Council, which consists of five experts in hematology and the field of transfusion medicine and relevant disciplines appointed by the Minister of Health.

The High Council of IBTO is the main policy maker in IBTO organization chart which is chaired by the Minister of Health consisting of five specialists in the field of transfusion medicine and relevant disciplines.

Out of these five one is selected as the managing director of IBTO responsible for executing responsibilities for a three year term.

The Managing Director of IBTO, elected by the Supreme Council, ensures proper implementation of the decisions adopted. The financial resources of IBTO are covered by a government-approved budget.

The activities of IBTO are followed based on the laws and regulation of Ministry of Health and under its supervision in simultaneous abidance to definitions and criteria of Iran National Regulatory Authority. All donor recruitment, blood collection, and testing procedures and fundamentally the establishment of any blood centers in the country require the approval and audit of IBTO so that

compliance with the national standard across the whole country is guaranteed.

IBTO has been successful in excluding family replacement donation system since the year of 2007 and reached to 100% voluntary and non-remunerated blood donation.

In Iran screening of blood donations for HBsAg became mandatory since 1974. However screening of blood units for HIV and HCV started from 1989 and 1996, respectively. For improvement of the blood safety anti-HIV I/II test was changed to HIV Ag/Ab in 2005. The prevalence of HTLV infection is evaluated in 1993 and according the results of this research anti-HTLV1 (anti then Anti-HTLV I/II) became mandatory in north east of Iran in Khorasan provinces.

Use of uniform regulations and standards, donor questionnaires, standard Operating Procedures (SOPs), guidelines, testing kits, blood bags, instruments, validation of procedures and training courses across the country.

Efficient donor selection, similar deferral criteria and self-deferral procedure since 1997, confidential unit exclusion since 2002, removing replacement donation, increasing in number of regular donations, educational efforts to increase public knowledge on TTI, improvement in automation, data registry of blood donors with history of screening positive results and hepatitis B immunization.

Usage of high sensitivity and best quality screening test kits, uniform confirmation procedure, similar proficiency and technical capabilities of screening laboratories and external quality assessment. Regular audits and inspections by internal auditors and external inspectors.

The mission of IBTO is to provide and ensure a safe and adequate blood supply in Iran. IBTO fulfils its goals through 52 regional blood centers, which are located in 30 different provinces with more than 217 blood donation sites throughout the country to meet the demands of the Iranian community for blood. It also aims at promoting transfusion medicine in Iran.

#### **Technical Activities**

Preparing necessary technical guidelines on all blood transfusion procedures ranging from registration of potential blood donors, pre-donation interview, blood donation deferral criteria, blood collection, processing and preparation of blood products, know-how of screening tests, transportation and handling of blood and blood products, preservation of cold chain, know-how of handling and transportation of screening kits, to look back system, error management in blood transfusion, autologous blood transfusion, plasmaphresis, plateletphresis, and the rest for all blood transfusion centers across the country,

Addressing technical problems of all blood centers,

Making all necessary measures to start running cord blood banking,

Carrying out corrective actions in error cases reported by quality assurance unit,

Making coordination and supervision over transportation process of plasma intended to be fractionated,

Implementing oversight programs over refrigerators of blood centers,

Monitoring over and setting up the blood transfusion software on the basis of ISBT 128,

Exerting oversight over blood banks and hospital blood transfusion committees,

Cooperating with contract parties in auditing blood centers for the purpose of plasma fractionation.

### **Quality Assurance Process**

The quality assurance process is implemented to ensure the compatibility of prepared blood and blood components with all national standards of IBTO. This process ranges from blood donor selection, collection of blood donations, preparation of blood components, screening tests to detect blood transmitted infections in blood units, Rh and ABO blood typing of blood

donations, storage of blood and blood products, equipment, and staff training. These activities are done in a set of units in headquarters and blood centers. Units headquarters are responsible to monitor over all technical affairs, conduct periodical inspections, prepare and issue guidelines and SOPs, transfer the samples of external control for the assessment of the procedure screening tests are conducted, to implement qualitative evaluation of donated blood units, investigate documentations of screening tests, study the results of quality control exerted over all prepared blood products, and hold training workshops that are all measures to promote quality. Quality evaluation of screening kits, blood bags, and all lab commodities and equipment jointly with institutes affiliated to Iran Ministry of Health, Treatment, and Medical Education is among the other activities of IBTO headquarters units aiming to enhance quality.

Since IBTO enjoys a centralized national system; therefore, there are quality assurance and quality control units in all blood transfusion center across the country addressing the important issue of quality control. These units directly supervised by managers of blood centers are responsible to make oversight over all technical units of provincial and satellite blood centers; they do periodic inspections based on special forms and guidelines, carry out the quality control of prepared blood products, and do surveillance and analysis of the received data all aiming to improve quality control procedure. The results of periodical inspections and quality control runs are investigated and the feedbacks are used for corrective and preventive measures, and anticipation of the needed practical training programs to raise quality.

Measures to safeguard the personnel health and environment protection are among the goals of labor safety and health units operating both in IBTO headquarters and all blood centers.

WOI (Work Instructions) & SOP (standard operation procedures) are made based on AABB & European council's criteria & the laws and regulation of ministry of health & IRAN National Regulatory Auditory.

Supreme councils, experts of fields of Transfusion medicine & relevant disciplines specialists in the field of blood transfusions and the managing director are preparing and providing these SOP & WOI.

Regular Audits of these SOP or WOI prepared for 2 year period and any changes of guidelines or operating standards, procedures, testing Kits, blood bag causes to revise the SOP and provide new one. The SOP will be established and training courses across the country will be followed.

The main encouragement of our organization is the support of volunteer blood donors who donate their blood for altruistic reasons.

The main discouragement of our organization is due to improvement in clinical practice and Doing a lot of transplantations and complex surgeries in our country which require a lot of blood and blood products the need for blood and blood products increases that needs a lot of efforts to recruit safe blood donors to provide adequate and safe blood supply.

## ANATOLIAN BLOOD DAYS REPORT FROM KOSOVA

M. Belegu, H. Sadriu National Blood Transfusion Center of Kosova

### Background

Blood Transfusion Service is consisted from National Blood Transfusion Center of Kosova and seven Regional Blood Transfusion Centers, located in Regional Hospitals of Kosova. There is a functional vertical connection between NBTCK and Regional Centers: NBTCK supply all Transfusion centers by reagents, equipments and other needs for regular work and supervises professional work, but other needs (salaries, maintenance of the building, administration and other) Regional Blood Transfusion Centers regulate by Regional Hospital.

Professional work in Blood Transfusion Service is centralized: all tests of donors for infective diseases transmissive by blood transfusion, are performed in NBTCK and results are dispersed during the same day in Regional Centers.

National authority for Blood Banking and Transfusion Medicine is Ministry of Health of Republic of Kosova. Ministry of Health in collaboration with NBTCK produced and Assembly of Republic of Kosova accepted the Law No. 02/L-101: The Law for Blood Transfusion, control of the blood and blood products, by which are regulated activities relating to blood donation, testing, processing , safeguard, transfusion and quality control of the blood and its components.

Actually, in Kosova there is no National Regulation or guideline for Blood Banking and Transfusion Medicine Service. In use are European guidelines. NBTCK is planning to start preparation of National Regulations and Guidelines for Blood Banking and Transfusion Medicine Service. In this Project will be included staff from MoH, NBTCK, Association of Voluntary Blood Donors and Red Cross of Kosova. Estimated deadline to complete these Regulations and Guidelines is December, 31, 2013.

### **Blood components**

In Kosova, there is not National Standards for use of Blood and Blood components.

Mostly, Blood Transfusion Service of Kosova is able to provide adequate and timely supplies of safe blood and blood components. Majority of the blood is provided from voluntary, no remunerated blood donors. Partly, in providing sufficient amounts of blood and blood components, there are family or replacement donations.

#### **Donation and Donor Selection Criteria**

NBTCK has its recruitment program. This program is prepared in the last trimester of the year, for the next year and includes all institutions which are ready to participate in this activity. The main institutions are High schools and Faculties. In high schools and faculties we find blood donors quite easy. Blood donation promoters go to each classroom and talk shortly about importance of providing sufficient amounts of blood and blood products for treatment of people in need for blood or blood components and answer in questions of students.

Before donation, each potential blood donor fulfill the questionnaire, which is obligatory and has to be signed up. This questionnaire is standard and is in use for whole country.

Haemoglobine screening is in use also before donation for all potential blood donors. It is performed by  $ChSO_4$  or haemoglobinometer.

Then, blood donors are evaluated by physicians. This is very important for us, because the promise during promotion of blood donation, that "their health will be safe, as they will be controlled by doctor – specialist of Transfusion Medicine.

Fortunately, in Kosova there are no paid blood donations. The most use type of blood donation is voluntary, non remunerated donation.

Kosova established Association of Voluntary Blood Donors, which is a regular member of FIODS/IFBDO. This Organization is not yet as active as we would like. The main problem of function of Association is lack of financial support of it activities. We are sure that Association of Voluntary Blood Donors can have very positive role on promotion of voluntary blood donation.

Among voluntary or replacement blood donors, about 30% are female. In high schools, percentage of female among blood donors is higher than in other institutions. In Kosova, in 100.000 population, there is annually 1.50 donation (or 1.5%)

Among other, in Kosova is performing donor apheresis. This is only in NBTCK, in Prishtina.

### Clinical use of the blood

In Transfusion Medicine Service of Kosova, we don't have National; guideline for Transfusion indications nor for transfusion complications. Unfortunately, connection between clinics and Transfusion Medicine is not as good as we would like. We are now preparing National Guideline for Transfusion indication and complications.

Percentage of use of whole blood in Kosova is 5%.

### **Screening tests**

According to the Law of Kosova, those screening tests are obligatory to perform:

- HBsAg,
- Anti-HCV,
- Anti-HIV 1/2, and
- Syphilis.

In Kosova, there is no National algorithm for donor screening. Standard method for screening of blood donors is ELISA. NAT is in use in National Institute for Public Health (NIPH), from 2010, but not in routine use.

Confirmatory tests for positive results of the screening, we did in NIPH.

In emergency, we don't release blood components without doing screening tests.

We don't use bacterial detection system for blood components.

Before releasing, we quarantine the plasma.

We don't use pathogen inactivation system.

### Hemovigilance

In Kosova, there is no any hemovigilance system at national level. There is a standard form for request and follow up transfusion. Unfortunately, we have serious problems getting feedback results from clinics, even when there is some troubles with used blood or blood components.

There is no Regulations to set up Hospital Transfusion Committee in Kosova. In 2002, we have established Hospital Transfusion Committee in University Clinical Center of Kosova. This Committee have had some meetings, in which we tried to established Regulations for using the blood and blood components. Clinicians lost interest for this activity and they stopped to continue with participation in this meeting. Now, we have some initiatives to

reestablish this Committee in which participants will be representatives from clinics which use more frequently blood and blood components and from Blood Transfusion Service.

#### **Documents**

Documents of blood donors in Kosova's Blood Transfusion Service are in both forms: computerized and manual system (cartels). There is no yet computer program to fellow up the destiny of the blood or blood components.

### **Organization of Blood Banks**

All activities of Blood Banks and Transfusion Medicine Service are regulated by The Law for Blood Transfusion, Control of the Blood and Blood Components. This Law was accepted in 2007 by Assembly of Republic of Kosova.

Government doesn't have a control system for new initiatives and blood supply system. All initiatives come from NBTCK.

In NBTCK there is a Department for therapeutic apheresis, which is not very active. According to therapeutic phlebotomy, they are performed in Internal Clinic and NBTCK.

In Department for Immunohematology, we take care about specialized patients with: alloantibodies, rare blood groups, multitransfused patients, fetomaternal blood problems and other testing. But, there is no Department for tissue processing and distribution, organ procurement or cord banking.

### **Quality Management System**

In Kosova, there is not yet guideline about Blood Banking and Transfusion Medicine. Clinicians use standard blood component request, which is obligatory. But, our hospitals don't have a model for blood ordering schedule.

Education and training of students in Transfusion Medicine in Medical Faculties is realized by a subject of Transfusiology, which previously was in the third year (with preclinical subjects), but now is in the fifth year, in on semester teaching (one h theoretical and two h practical teaching, in a not obligatory, but subject of choice) for student of General Medicine and of Nursery branch of Medical Faculty.

Clinicians have education and training on clinical use of the blood and blood components in duration of one month of their specialization.

Every second year is organized a course for specific training and education program for blood bank staff and on clinical use of the blood and blood components.

Every unit of blood and blood components is registered in computer and has ID as a number and barcode. But hospitals don't have information technology system for monitoring blood from donor to recipients.

There is no official request of QMS running in Kosova about Blood Banking and Transfusion Medicine.

There is no any national system for complains and/or component recalls and there is no in the national level any no confirmatory reports, adverse events and reactions.

There is no any system at national level for no confirmatory reports, adverse events and reactions.

According to external audit programs, we have had only once a control (from Canada) of testing of Infective diseases transmissible by transfusion of blood and blood components, which happened in

2008. After that, we centralized testing of Infective disease transmissible by transfusion.

### Conclusion

On the basis of answers in this questionnaire, can be concluded that situation of Blood Banking and Blood Transfusion Medicine of Kosova is far to be satisfied. First of all, in collaboration with Ministry of Health, we have to promote faster preparation of National Regulations and Guidelines, which will be a promoter of faster progression not only in administration. It is known that good administration lead to better result in any professional work.

This questionnaire was a good stimulus to think about our lack. So it is good that we "waked up" and started to think what to do to improve our documentation and by this, functioning of Blood Banking and Transfusion Medicine Service of Republic of Kosova.

## MORROCAN BLOOD TRANSFUSION SYSTEM

The national blood transfusion and haematology centre (CNTSH) is located at Rabat. The national authority for blood banking and transfusion medicine services is the ministry of health.

The CNTSH administer 16 regional blood transfusion centers (CRTS). The mission of the CRTS is to collect, process, qualify and distribute blood components to hospitals, blood banks and deposits.

The mission of blood bank is to collect whole blood and send it to the CRTS for processing and qualification. It also distribute blood components to hospitals.

The CRTS manages also deposits which are responsible for distributing blood components to hospitals.

All the activities of CNTSH are regulated by legislation.

Since 1995, the law 3.94 regulate all the processes of blood transfusion centers and medicines transfusion services. It covers mandatory testing, quality and blood safety and haemovigilance for reporting of events of transmission of infection It has been introduced in 1995 for donation and blood testing, and for haemovigilance in 2005

This law has been reviewed in 2002 and 2006.

Since 2004, CNTSH published the first national guidelines for blood banking services. The aim objective is to implement accepted criteria and standards to ensure safety of blood components in all the country.

The reference for preparing this manual was the French guidelines. Due to remarks of national auditors after audit of CRTS, this version was reviewed by a national commission on 2006 and 2009.

The third version is currently reviewed by the national quality committee.

The national guidelines cover only blood banking services.

A project to set up national regulation and guidelines will be submitted to the ministry of health. The director of the project is the director of CNTSH. A national committee was created on 2010, in order to elaborate the new strategy for the development of Moroccan transfusion system. The project is very ambitious and it will contribute to the improvement of transfusion in Morocco.

## NATIONAL BLOOD BANK - MINISTRY OF HEALTH PLASTINE

Quality Management Officer Mohammad A. Mazloum National Blood Bank -Ministry of Health Palestine

In Palestine Ministry of Health (MOH) is the national authority for blood banking and transfusion medicine services.

Till now there is no any national regulation and guidelines for blood banking and transfusion medicine.

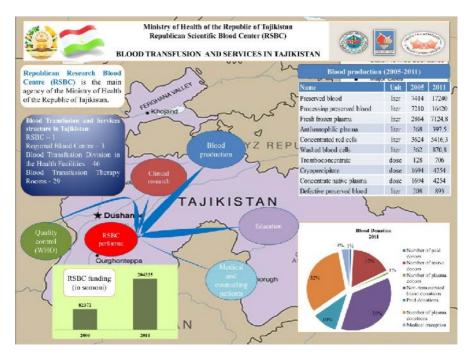
National Blood Bank Established since 3 years is the main body which held the responsibility of blood banking and transfusion medicine in which the main goal is provision of enough, safe, highly qualified & free blood to all members of Palestinian society in need. NBB has been established Quality management system and still in the development phase and still depend AABB & British regulations & guidelines in different issues.

NBB works hard to evaluate its independent regulation and guidelines according to our own social &cultural structure, human resources, education, beliefs, behavior & tradition without concessions of scientific facts and quality.

We hope your efforts in Anatolian blood days helps us to create our own regulation and guidelines in Palestine by sharing experiences, opinions, problems and solutions of participating countries.

### **BLOOD TRANSFUSION AND SERVICES IN TAJIKISTAN**

### Ministry of Health of the Republic of Tajikistan Republican Scientific Bord Center (RSBC)



### **BLOOD BANKING & TRANSFUSION MEDICINE in TURKEY**

Dr. N. Nuri Solaz Blood Banks & Transfusion Society of Turkey

Based on 2007 census statistics actual population of Turkey is 77.000.000. Annual population increase is 1.04% and 70.5 % of the population lives in cities. Almost half of the population is youngerthen28.3 years; 66.5 % of the population is between 15 - 64 years. Depending on 2005 statistics average life expectancy is 68,9 years for men and 71.3 years for women.

Blood Banking and Transfusion Medicine (BB&TM) have been practiced until early 1920's in Turkey since then Turkish Ministry of Health (MoH) has been the national authority in Turkey for BB&TM. Both of those services provided by hospital still 1957 when first public Blood Banks were established by Turkish Red Crescent (TRC). While Transfusion has been provided by clinical disciplines Blood Banking (BB) services have been provided by both hospital blood banks and public blood banks; a mixed system. National Blood Policy of Turkey is changed at 2002 and "centralisation" was chosen as a main BB strategy. TRC was addressed as an official BB organization by MoH. TRC has succeeded to supply actually almost 65% of the annual blood consumption of Turkey, rest is supplied by temporary blood banks at the hospitals. Temporary blood banks at hospitals have been closed since 2002 and rest will be closed when TRC will cover complete annual blood consumption of Turkey in a few years time.

Main blood donor supply was the military at the early stage of BB&TM in Turkey. First blood donor recruitment department was officially established by TRC at 1974and had a great success for a while. TRC re-organised its blood donor recruitment department at 2002 and had very important positive impact and managed to keep this success table. Actual blood collection is supplied by civilian

volunteer non-remunerated blood donors; 65%. Rest is supplied by relatives of the patients; 30% and directed donations; 5%. Paid donor system is not existing inTurkey. Although great progresses has achived since 2002 in blood donor recruitment women blood donation is still less then 10% of whole blood donation.

Annual blood demand of Turkey is around 2.000.000 units. Turkish Red Crescent supplies around 65% of this demand, rest is supplied by hospital blood banks. Donor deferral rate is around 6,5-10 %. 10 % of the collected blood is destroyed due to positive screening results, expiry date, etc.

Donorapheresis service has been available in Turkey since late 1980's. Around 250 apheresis machines from all major manufacturers are in service and annual platelet apheresis is around 40.000 units in Turkey.

Since early 1990's blood irradiation is available in Turkey not only in major metropoles but also in other cities.

Blood donation has been screened from the begining of BB&TM in Turkey. Blood group typing and syphilis screening were the preliminarytests. HBsAg (1983), anti-HIV (1985) and anti-HCV (1997) were followed. Main screening system is ELISA for transfusion transmitted infections (TTI). More sophisticated techniques are on use for confirmations such as NAT, etc. Major TTI and frequencies are as follows; anti-HIV ½ 0.12 %, anti-HCV 0.45 %, HBsAg 1.99 %, syphilis 0.11 %.

Alldonated blood is typed for ABO and Rh. ABO typing should be performed both "forward and reverse typing". All anti-D negative samples should be confirmed by "weak D" typing. Slide, tube, micro column and automated blood group typing methods are used for blood group typing.

Major blood group types and frequencies are as follows; A Rh +38%, A Rh -5%, B Rh +14%, B Rh -2%, AB +7%, AB -1%, O +29%, O -4%.

First Blood Law was issued at 1983; number 2857 even there had been some official regulations and recommendations before it was issued. First Blood Law was followed by different regulations, directives and recommendations due to needs in BB&TM since actual Blood Law is issued at 2007; number 5625.

National Guidelines on BB&TM is issued by MoH at 2009 and revised at 2011. There are very limited information on TM at National Guidelines while BB is evaluated in details.

Hemovigiliance is not still established in Turkey even many basic activities of hemovigiliance have been on practice at different topics.

Actual documentation system of BB&TM is based on computerised systems.

Although Turkey has had first blood transfusion practice in early 1920s there has been no specific education programme for BB&TM either in pre or post graduate medical education until 2000. The negative impact of this situation became a major threat for safety of the blood transfusion. A group of dedicated doctors who were involved in the field of BB&TM decided to solve this problem by a civilian initiative and established a national blood society; "Blood Banks and Transfusion Society of Turkey (BBTST)" in 1996. The main strategy was based on education of blood bank staff, education of clinical staff, getting integrated with international BB&TM society, establishing official and academic education programmes and establishing close collaboration with the national health authority. By education below listed topics were selected as main goals;

- a) promoting the safety, adequacy, quality and appropriate use of blood and blood products.
- b) encouraging there cognition and establishment of national blood programme.
- c) establish collaboration among national and international organizations, agencies and institutions involved in the safety of blood products and transfusion practices

Residential national courses for the blood bank staff have been organized annually since 1997 at different main topics (from very basic to highly sophisticated topics). One-day symposia with a standard curriculum have been organized since 1996 at hospitals in different parts of the country. 14 national courses, 5 national congresses, 1 international congress (VIII. European ISBT Congress 2003; Istanbul/Turkey), 106 symposia and 25 special sessions at the national congresses of different clinical branches have been done so far. First master's degree programme for medical doctors with a curriculum in compliance with EU started in 2000. Residential certificate courses programme for blood bank doctors and other medical staff are being organised since 2000 in collaboration with the MoH. Depending on those training activities there are major changes in BB&TM practice in Turkey such as increase in blood component (red blood cell) usage from 4% to around 90%.





### Blood Banks and Transfusion Society of Turkey

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