INTERCOUNTRY MEETING ON QUALITY MANAGEMENT FOR DIRECTORS OF BLOOD TRANSFUSION SERVICES IN THE EUROPEAN REGION

Report on a WHO meeting

Ljubljana, Slovenia
25–27 September 2002
ABSTRACT

The meeting was aimed to sensitize decision makers toward the quality management project in blood transfusion services and need of quality management training to promote and improve blood safety and prevent transmission of HIV and other infectious agents through blood and blood products. It reunited representatives from 14 Central and Eastern European countries and provided the opportunity of a forum for discussion on the status and importance of quality management in blood transfusion services in Member States in the European Region.

A common understanding was created in what concerns the concepts and principles of quality, as well as awareness towards the necessity to develop quality systems in the blood transfusion service. There is a need for training to increase competency, enable re-assessment and orientation of the personnel.

The major importance of supportive action of Directors and Managers in quality systems and management was recognised and main priorities for action were identified in general terms and in relation to specific country needs.

Keywords

BLOOD TRANSFUSION
QUALITY CONTROL
HIV INFECTIONS – prevention and control
HEALTH PERSONNEL – education
EUROPE

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EXECUTIVE SUMMARY

A second intercountry Meeting of Directors for Quality Management Training in Blood Transfusion Services in the European Region was organized by the WHO Regional Office for Europe. It was held at the Blood Transfusion Centre of Slovenia, Ljubljana, Slovenia, from 25 to 27 September 2002.

The meeting was held as part of the Quality Management Project (QMP) for Blood Transfusion Services, an initiative to build capacity in quality management at global level through comprehensive training, monitoring and follow-up. A core element of the project is the organization of Quality Management Training (QMT) courses in all regions supported by the (National) Directors of Transfusion Services. The first Meeting of directors of blood transfusion services altogether with the Quality Management Training course in the European region were held in Groningen, the Netherlands, July 2001.

The present meeting was attended by representatives and Directors of Blood Transfusion Services from 14 countries, respectively Armenia, Azerbaijan, Belarus, Bulgaria, Estonia, Georgia, Kazakhstan, Latvia, Lithuania, Moldavia, Romania, Russian Federation, Ukraine and Uzbekistan. The directors of the blood transfusion services from Kyrgyzstan, Poland, Tajikistan and Turkmenistan were unable to attend.

The main objectives of the meeting were:

- To ascertain status of Quality Management in Blood Transfusion Services in Member States in the European Region;
- To sensitize participants toward Quality Management Project in Blood Transfusion Services and need of Quality Management Training to promote blood safety;
- To impart main principles of Quality Management in every aspect of Blood Transfusion Services;
- To develop a plan of action and follow-up on Quality Management, including training needs at country level and staff development.
REPORT OF THE MEETING –
Summary of presentations and discussions

Introduction

The WHO Quality Management Project (QMP) is a long term initiative aimed to assist member states in improving the safety and adequacy of the blood supplies, build capacity in quality management in all aspects of blood transfusion, through integrated approach of training and assessment and support the establishment of sustainable national quality systems at country level.

Considering the constantly evolving training needs, the Quality Management Training constitutes an important component of the project that includes different levels of advocacy – intercountry meeting for decision makers and training course for subsequently selected staff, dedicated to quality management and implementation.

Opening ceremony

The second intercountry Meeting of Directors for Quality Management Training in Blood Transfusion Services in the European Region was held at the Blood Transfusion Centre of Slovenia, Ljubljana, 25 to 27 September 2002, and was attended by participants from 14 countries.

Dr Božidar Voljč, Director of the Blood Transfusion Centre of Slovenia, extended a warm welcome to all present, and acknowledged the importance of the quality systems and quality management in the blood transfusion service.

The WHO Quality Management Project and of the Quality Management Training were introduced by Dr Valentina Hafner, WHO Regional Office for Europe, Copenhagen, Denmark.

In the opening remarks, Mrs Vesna-Kerstin Petrič, WHO Liaison Officer for Slovenia, underlined the value of intercountry collaboration and the opportunity for Slovenia to host the meeting.

Election of Chairman and Rapporteur

Following a brief introduction of all participants a proposal for election of a chairman and rapporteur was carried.

According to the well established WHO selection and election procedure, the first day was chaired by Dr Božidar Voljč, Director of the Blood Transfusion Centre of Slovenia. Chairs of day 2 and 3 of the meeting were respectively: Dr Esfir Svirnovskaia – Republican Station for Blood Transfusion, Minsk, Belarus, and Dr Vasilij Mihalchuk – Ministry of Health, Kiev, Ukraine.

Dr Cees Th. Smit Sibinga, WHO Collaborating Centre Groningen, was unanimously elected as rapporteur.
Overview of the Quality Management Project (QMP)

Quality systems have been recognised as playing a key role at all levels of the blood transfusion chain, from blood donor, the blood transfusion service, to the clinical administration at the bedside.

WHO has developed the global Quality Management Project (QMP) as an immediate response to the existing shortage of trained manpower in many countries and the need for quality management comprehensive training. The history, principles and organization of the project were presented.

The project is based on the four key issues of the integrated strategy to reduce transfusion-transmitted infections, listed briefly in the Aide Mémoire for national blood programmes:

- Establishment of a nationally coordinated blood transfusion service;
- A system based on voluntary non-remunerated regular donors, from low-risk population groups in the community;
- Testing of all donated blood, including screening for transfusion transmissible infections, blood grouping and compatibility testing;
- Reduction of unnecessary transfusions through effective clinical use of blood and alternatives to transfusion.

QMP is designed to develop regional and national capacity in quality management and to promote the establishment of effective quality systems in BTSs in all WHO Member States. The principal objective of this project is thus to promote the concept of quality systems and to assist BTSs and national authorities in implementing quality systems including quality assurance, quality control, standard operating procedures and external quality assessment schemes.

An essential element of the QMP is the Quality Management Training which brings together leaders and managers of BTS as well as the staff identified as responsible for quality at national level from each of the member states in the region to carefully structured training course, to cover all aspects of blood transfusion practice.

Directors and (prospective) quality managers should commit themselves to active implementation of quality systems in the BTS, along the lines of a plan of action to be developed during the training courses to follow.

The co-ordinating WHO Collaborating Centre/training centre should actively monitor the outcome of the course and will report periodically to the WHO Regional Office for Europe and to WHO Headquarters in Geneva.

In the long-term, the project focuses to assist Member States in monitoring, evaluating and re-planning; as well as to implement and support the quality systems in BTSs in countries committed to achieving a safe and adequate blood supply for all patients requiring blood transfusion.

The instrumental role of the WHO Liaison office at country level was underlined.
**Expectations of Directors**

Directors’ expectations and discussion highlighted the following common issues of interest:

- Necessity of: information exchange and discussion of national experiences, problems encountered and solutions identified;
- Information on how to structure and reorganize a national blood transfusion service, harmonization of a national blood programme with quality requirements;
- Steps to develop and implement quality systems in the blood transfusion service;
- Quality management principles and ways to put them into practice, at institutional and national level;
- How to switch from a practically paid system to full voluntary non-remunerated blood donations;
- Technical issues related to testing, bed/side practice, rational use of blood and the quality approach;
- Improvement of performance, information on various blood safety issues.

**Background presentations**

*A broader view on quality development in health systems – WHO Regional Office for Europe vision.*

Quality in health systems relates to outcomes and improvement of health where appropriateness, effectiveness and safety together with access, availability and continuity of care are important, as pointed out by Dr Isuf Kalo, Regional Adviser Health Systems Technology, Pharmaceuticals and Quality, WHO Regional Office for Europe.

Health as an objective of a system is based on responsiveness and fair contribution to be achieved through stewardship, creating resources and financing to allow proper delivery of services. Quality and equity are central issues. To reach a Quality Health System (QHS) indicators have to be defined and analysed such as type of Health System (macro and micro), health technologies, people, resources and policies, providing the tools for Health Technology Assessment.

The need for QHS improvement is generated by inefficiency, dissatisfaction of users and providers, unaffordability (both waste and cost) and unequal access (practices and outcomes). It was recommended that National Medical Associations should promote the professional responsibility for Quality of Care Development (QCD) and institute the establishment of internal self-evaluation among their members.

Quality culture needs to be developed, where every employee (or citizen) is aware of the quality concept and makes it an integral part of personal responsibilities. In this respect changes in culture should target policy makers (governments), communities as shareholders, as well as the medical profession as the providers and protectors of health.
**Status of Blood Transfusion Services in the European Region and the importance of Quality in the BTS.**

The different stages of economic and social development of countries in the European Region has also been reflected in the development of their national blood transfusion services. Marked differences occurred since 1990, linked to the social, economical and political developments in the region. The new democratic openness and freedom lead to priorities being considered and to the setting up of internationally recognised standards.

Based on the regional epidemiological data on HIV and other transfusion transmitted infections, Dr Hafner underlined the need for an integrated approach to blood safety with focus on Central and Eastern Europe.

The main challenges for the region are:

a) to strengthen and support the development of well organized and funded BTS;

b) to address the need to educate and motivate the general public to participate and support voluntary non remunerated blood donation – the cornerstone of a safe and adequate national blood supply;

c) to establish internationally recognised quality standards, all along the blood transfusion chain from ‘vein to vein’, with appropriate quality management and external quality assessment schemes.

The quality approach needs to be appropriately introduced and supported by the policy makers, taking into consideration all factors involved, including personnel, equipment and consumables, methodology and environment.

Quality system implementation and management is essential to safety and efficacy, possible to achieve even with limited resources.

Two Quality Management Training courses have been planned in the near future, in the European Region, likely to take place in Estonia and Russian federation, subject to the approval and choice of the national authorities.

**Visit to the Blood Transfusion Centre of Slovenia**

The participants visited the Blood Transfusion Centre of Slovenia. Special emphasis was made upon the existing organization and work flow, quality systems and applied quality management. Opportunity was given to exchange thoughts and discuss principles and practicalities with staff in the various departments of the centre.

**Country Reports**

Each country representative made a brief overview of the existing status of their national blood transfusion service.

**Armenia** has about 3 million population. Blood transfusion has started in 1949. In 1990 the National Institute of Haematology and Blood Transfusion was renewed and now serves as the Republican Haematology Centre. There are 5 ‘blood stations’ and 35 substations, 18 municipal and 17 rural. There is one commercial blood bank located in Yerevan.
In 1996 an Academic Chair for Haematology and Transfusion Medicine was instituted at the University of Armenia in Yerevan.

Currently there is a shortage of blood donors. Most donors are family replacement, with either direct or indirect payment. Instructions issued by the Ministry of Health (MoH) regulate donor selection procedures and testing for transfusion transmissible infections (HIV, HCV, HBV and syphilis).

There is a need for the renewal of the blood supply system in the Republic following a centralized management and standardization. The approach reported would consider organizational issues, change in the legal environment, financing and logistics, training and education, introduction of national standards and accreditation through monitoring of the services.

**Azerbaijan** has about 8.2 million population. The blood supply system was hospital based (1985–1992) and controlled by the MoH. Currently there is a Scientific Research Institute with a complete Blood Transfusion Centre, 5 regional centres and 64 departments in hospitals and maternity clinics that collect in case of emergencies. Blood products in use are erythrocyte concentrate, fresh frozen plasma and cryoprecipitate, dried plasma and fibrinogen. Due to old equipment there is a problem with the provision of components.

Since 1987 there has been a decrease in blood collection due to the collapse of the former regime (130,000 to 60,000 units). Hampering factors during this transition period are the many refugees (1 million) and the fact that 20% of the country is occupied. Donor system is family replacement based, with recognised high transfusion risk (relatively high incidences of HBV, HCV and syphilis infections).

Full support of the Government is needed for a new legislation, to promote voluntary low risk non-remunerated donors, education, the implementation of quality systems and international guidelines, promotion of effective clinical use of blood.

**Belarus** has about 10 million population. Since 1995 there is a Law on blood donation and blood component donation that allows a nationally co-ordinated blood donor system. There are 20 regional centres and 67 hospital blood banks and the services operate under the direct control of the MoH. There is a centralized organization and QC with decentralized administrative functions. The Republican Blood Bank in Minsk is responsible for setting national guidelines and supervision of methodology and organizational issues.

Currently there is no shortage and donors receive two working days off and breakfast and lunch for the day of donation. In certain areas of the country there is direct payment (reimbursement, 7.8%), but family replacement and directed donations do no longer exist. Most donors are repeat donors. Transfusion transmissible infections reported incidences are: for HBV: 0.13%, for HCV: 0.39%.

**Bulgaria** has about 8 million population. The system is regulated by a Law on blood donation and blood transfusion (1994). MoH defines the policy, approval and issue of regulatory documents, organization and management, control and budgeting of the BTS. There is a National Centre of Haematology and Blood Transfusion and 4 Regional Centres. Additionally, there are 23 District Hospital Blood Transfusion Centres still involved in processing, testing, storage and distribution and 56 hospital based Blood Facilities involved in patient services. A project
supported by the World Bank and the European Development Bank was developed to reform and refresh the existing structure.

Blood donors receive two days off work and recent statistics show 4.37% paid donors, 14.81% military donors, 54.5% replacement donors and only 26.29% truly voluntary non-remunerated donors. In 2001 a national campaign was successfully launched to change the donor system into an all voluntary non-remunerated system. About 40% of collections comes from mobile teams, where the 5 major institutions collect and process 52%. Since June 2001 testing for transfusion transmitted infections (TTI) is concentrated in these 5 centres and reagents are centrally supplied through the MoH. At the moment 92.34% of collected units is processed into components. Since 1994 there is a National operational EQAS.

Current statutes require the implementation of GMP, GLP and GCP. There is still inappropriate clinical transfusion practice with a considerable abuse of plasma. The country is not self-sufficient in plasma derivatives and there is still an old fractionation plant for albumin and immunoglobulins in use. Other derivatives are imported. Several national regulations cover the clinical transfusion practice including the need for hospital Blood Transfusion Committees and control of transfusion practices.

**Estonia** has 1.3 million population. There are 3 regional centres: North Estonian Blood Centre in Tallin, covering 50% of collections; the Blood Centre of Tartu University Clinics – South (30% of collections) and the Pärnu Blood Centre – West (20% of collections). Additionally there are 2 hospital based blood departments in Kohtla-Järve and on the Island Saaremaa in Kuressaare. The Ministry of Social Affairs is responsible for the policy, legislation, and regulatory affairs, while the State Medicines Agency is responsible for the inspection of the quality and the safety of blood products.

There are 3 reference laboratories respectively for hepatitis, HIV and immunohaematology. The standards in use are based on the EC Directives, the CoE recommendations, European Pharmacopoeia, ISO 9000 and the WHO recommendations and guidelines. Quality policy focuses on assuring safe and efficacious transfusion therapy based on voluntary non-remunerated blood donation, self-sufficiency and a quality plan. There are already various national guidelines in place such as a guideline for donor selection, for microbiological and virology testing of blood, for standard production and for blood transfusion. Future steps relate to the new regulatory framework to be adopted, that promotes national centralization of the existing structures.

**Georgia** has about 4 million population. The system is highly fragmented, although the Ministry of Labour, Health and Social Affairs has recognised blood safety as a priority for the Health Care policy in the country.

The donor system is almost exclusively based on family replacement donations, with payment. Many donors come from socially unprotected groups and 68% are women. Most facilities and equipment are old and worn out, with a largely bottle driven collection and processing procedures.

Testing of collected blood is performed, but not always according to state of the art (outdated technologies). There is one national reference centre in the capital Tbilisi. There is no allo-antibody testing performed on donated blood.
There is an urgent need for training.

**Kazakhstan** has 16 million population. Blood transfusion started in 1934. The system has been renamed and currently there are 23 regional centres (3 centres specifically involved in component production including albumin and i.m. immunoglobulins), 111 departments in larger hospitals and 56 hospital based small blood transfusion department.

There is no law in place. Since over 10 years a draft is circulating, but hasn’t been adopted yet. National standards are in progress where blood is considered a pharmaceutical product.

Donor system is mixed with 80% family replacement donations and 20% directly paid donors (USD 10). Tests are done before donation and some centres have a computerized data base. There is a large HLA-typed number of donors for transplantation purposes.

**Latvia** has 2 million population. There is a Latvian State Blood Centre in Riga and a Regional Blood Centre in Rezekne together with 18 hospital blood collection departments.

Riga collects about 42%, Rezekne 15% and the hospital departments altogether 43% of the blood. Processing and testing (HIV, HCV, HBV, Syphilis, ALT and CMV) is performed in the 2 main centres. There is a programme to develop ISO 17025 accreditation of all testing laboratories by the Latvian National Accreditation Bureau (Latvian National Accreditation Council). Financing comes from the State budget and is run by the Insurance Agency of the Ministry of Welfare. There is a plasma fractionation enterprise (Baltic Therapeutic Service) producing cryoprecipitate, albumin and immunoglobulins (polyvalent and specific) from 17,500 litres of plasma.

There is a need for an Integrated Management System (IMS) where all components of the blood supply will be considered into one coherent system for quality management. Problems encountered relate to staff motivation and education, development of appropriate methodology for processing and use, including the monitoring and evaluation of customers satisfaction.

**Lithuania** has about 4 million population. In 1996, the Law on blood donation defined the main principles for procurement and use of blood, based on State co-ordination and control, stressing the importance of the blood services in the National Health Care System. Initiated by European experiences major organizational changes have been made. There are currently 3 main centres in Vilnius, Kaunas and Klaipeda, and 2 Blood Transfusion Departments in Siauliai and Panevezys. There are National Guidelines issued by the MoH Blood Council. Processing technology is still lacking behind as is the effective use of blood in the hospitals, although whole blood transfusions have been substantially reduced.

Donors are still largely paid with only 4% voluntary non-remunerated donors. All blood is tested for HIV, HCV, HBV and Syphilis and recently NAT testing, although expensive, has been introduced.

**Moldova** has 4.5 million population. Due to the very poor economical conditions between 1991 and 2001 the situation deteriorated, with a highly fragmented system. Since October 2001 changes have been introduced. A National Programme for the Blood Transfusion Service Development is covering the period of 2002–2006. The focus is on organizational and economic improvement of the Blood Transfusion Service performance, assurance of both quality and
safety of blood and provision of health care facilities with an appropriate stock of blood components and products according to actual needs.

Development include organizational and geographical restructuring of the Blood Transfusion Service; harmonization of the regulatory framework in compliance with international standards, updated equipment, effective clinical use of blood products. The budget has already increased some 2 to 3 fold. Advocacy for non-remunerated blood donation is considered a priority as well as development of training in the field of blood transfusion.

Current donor system is based on 60% family replacement, 37% voluntary non-remunerated and 3% paid donations. HBV and HCV are endemic and HIV incidence in the population is increasing. Of the blood collected, 93% is used for emergency medicine and only 7% for elective surgery.

Recently the country was visited by a CoE Task Force and WHO representatives resulting in valuable recommendations, with a positive impact on further reforms.

**Romania** has 22.2 million population. The national network has been reorganized on a centralized basis in the context of the specific legal framework adopted in 1995. The National Institute of Transfusion Haematology responds directly to the Ministry of Health and coordinates the activity of the whole network (41 blood transfusion centres) through 8 major regional blood transfusion centres

Blood donation is considered voluntary non-remunerated by law (1995), however, in real practice donors receive food compensation, two days off and free transportation, for each donation.

The existing regulatory framework has to be updated and harmonized. There is a need for introducing quality systems and focused training.

**Russian Federation** has about 160 million population over a vast geographical area. The quality of the blood supply is now high on the agenda of the Russian Federation Government. The urgency of drastic changes is caused by a number of factors: the legal instruments related to the regulation of blood service institutions have not been revised for more than 10–15 years, the lack of financing is causing major difficulties, the equipment is worn out and has to be replaced. The production of blood products fails to meet the demand and the GMP requirement are not fulfilled.

To improve the blood transfusion services, including the system of safe transfusion, the MoH of the Russian Federation has taken certain steps: the Department of Public Health Care Delivery and Development of the MOH of Russia is now responsible for the management of Blood Transfusion Services in the Russian Federation. Since May 2002, a decision was made to set up an Interagency Working Group of key national experts to improve the performance of the Blood Transfusion Service in the Russian Federation, and to draft two important Prikazes (former #155 and 700) which stipulate many aspects related to the activities of the blood transfusion services.

Scientific and methodological management of the blood transfusion service network is carried out by the MoH of the Russian Federation in close co-operation with the Russian Research Institute of Haematology and Transfusiology, the Scientific Centre of Haematology of RAMS,
the Kirov Research Institute of Haematology and Blood Transfusion, the Centre of Production
Transfusiology.

A decision was made to establish a Federal Blood Transfusion Centre of the Russian Federation
which should contribute to improve the BTS management system in Russia. The managerial
problems faced by the BTS are considered by the MoH as part of the health care quality
management programme.

Currently, 195 Blood Transfusion stations are covering 67.8% of production, 1100 Blood
Transfusion Departments in hospitals cover for 36% of production, while in 319 hospitals is
performed some component preparation (0.4%).

Blood donation is rewarded with a variety of incentives such as free public transportation, 50%
discount on medication, days off work and others. In this approach about 84% of donors is
voluntary. Despite the economical, financial and social hardships the Russian federation is
moving towards reaching the goals of a comprehensive safe and efficacious blood supply within
the entire Federation.

Ukraine has 49 million population. There are 69 blood transfusion stations and centres (25
independent and 44 municipal ones), 568 blood collection and processing sites and 28 hospital
blood transfusion departments. The 2 major institutions which include science, research and
education are in Kiev and Lvov. The legal and regulatory framework include the Law on Blood
and Blood Component Donation (1995), and a number of resolutions of the Cabinet of Ministers.
In 2001: the Cabinet of Ministers approved “The Programme of Blood and Blood Component
Donation covering the period of 2002–2007” which stipulates a partial financing of the Blood
Transfusion Service from the state budget, and for the first time in history the term “Blood
Transfusion Service of Ukraine” was introduced. The existing regulatory and analytical
framework is being reviewed and adapted to the recommendations of World Health Organization
(WHO). The reviewing process of all available guidelines/ documents is to be completed during
this year.

Blood donation is largely non-remunerated (93%), but 7% is still paid. Around 66% is collected
in the main centres and 34% in the periphery. All blood is tested for HIV, HCV, HBV and
syphilis. MoH tenders for the purchase of test kits and currently a ‘home made’ ELISA is used.
Plasma quarantine storage is foreseen, but not yet implemented. In 2001, 5% of the total
collected blood was rejected. Distribution of rejected blood is as follows: 33.5% – HCV
antibodies; 21.1% – HBV antigen; 9% – syphilis; 10.2% – high bilirubin; and 4.7% – HIV
antibodies. Since 1987 a total of 720 infected blood donors has been found.

The increase of HIV infection in the population is a major concern, effecting the blood safety
priority. In Kiev and Lvov plasma is fractionated in albumin and immunoglobulin preparations
(no Factor VIII or IX production).

Uzbekistan has 25 million population. The main institute is the Republican Institute for
blood services has been developed towards the goal of securing safe and efficacious blood
supply all over the country. The system is still fragmented, with many hospital based blood
services.
Around 83% of blood donations are voluntary and non-remunerated, although as kind of a social protection gifts are provided. Testing for viral infections are performed by the Research Institute of Haematology and Blood Transfusion of the MoH, which has several centres distributed in the country.

In June 2002, a Republican Blood Service Programme covering the period of 2003–2005, was adopted. The Law “on blood donation and blood components” was adopted this year in the Republic. A Working Group with a mandate including the revision of documentation and working instructions in use for the Blood Transfusion Service of the Republic has been instituted. A step-by-step development of regional blood banks, including autologous donation, is envisaged in Uzbekistan.

**Specific information – constraints in developing countries**

1. **Developing quality systems in the BTS – the Slovenian experience.**

Dr Božidar Voljič, director of the Blood Transfusion Centre of Slovenia presented the project for the development of a quality system in Slovenia.

In Slovenia a comprehensive project respecting WHO's elements for reforms in health care was started in 2001, focused on quality and sound financing, reorientation of human resources and strengthening of management.

A new legislation was prepared in the framework of a bilateral project on quality systems between Slovenia and the Netherlands, and was adopted in 2000. The necessary regulatory framework follow the dynamics of reorganization and will be completed within the process.

The participants of WHO courses for quality management in Groningen have become actively involved in training courses on quality management in transfusion services, at national level. Activities are developed in close collaboration with the Red Cross Society of Slovenia and the blood donor associations.

Altogether with the clinical site, attention has started to focus on haemovigilance and the role of blood transfusion committees. Under the existing circumstances the reorganization of the blood transfusion service (collected blood to be tested and processed on only two locations out of the existing ten) will be completed by the year 2004.

2. **Constraints in developing quality systems in the BTS – point of view**

Every country has its own peculiarities, connected with existing legislation and regulatory system, economic development and tradition. Dr Vera Bogdanova from Delrus, Ekaterinburg, Russia presented her experience in the Russian Federation.

There is a need of implementing quality systems in the blood transfusion service, and the success of the Quality Management Project depends on awareness, resources and applied training.

There are different levels of quality awareness: Government – MoH and BTS. At Governmental level, in Russia, there is a formal quality concept and basic elements of quality such as legislation, state standardization and systems of certification, accreditation and license.
The quality concept is not clearly defined for the blood transfusion service. There is no national policy or guidelines on the clinical use of blood. However, standardization policies are approved, licensing is performed, but certification and accreditation systems are not available.

During the last decade, efforts concentrated on the use of state-of-the-art technology to prevent transfusion related risks. It is obvious today that the risk associated with transfusion can be reduced only through implementation of quality systems and quality management in the blood transfusion service, for an adequate supply of safe blood and blood products and their effective clinical use.

One of the major constraints lies in the available resources – normative base, finances and people. There is lack of modern normative base in Russian BTS – GMP, guidelines, blood component specifications and SOPs.

The development of a quality system requires team work. The main condition of success of the quality approach in the blood bank is the commitment and support of BTS management.

3. Basic concepts of quality in a blood transfusion service – the City Blood Centre ‘Sanguis’ – Ekaterinburg, Russia.

Further on, the ‘Sanguis’ City Blood Centre that serves the city of Ekaterinburg (4 million population), was presented as a case study.

The Centre has chosen to implement ISO because of the National ISO 9000 based GOST R 9000 standards, that does not conflict with cGMP. Both systems require documentation of every function of the Quality System. The objectives are to control the production of blood components, to improve the quality of procedures and processes and to solve the problems of organization.

The document control is based on a Master List and coding system with various sections. Procedures follow precise steps and standards: development, approval, issue and review; authorization, registration and archiving.

The process control follows critical points and processes, suitability of working environment and equipment, monitoring and SOPs. This includes control of incoming materials and internal Quality Audits.

Major problems were encountered towards the lack of clarity concerning management responsibilities, lack of development of management structures, poor involvement of personnel and lack of team spirit.

The positive side lies in designing the tools for monitoring progress, as the Centre now operates on documented facts and figures, and follows basic operational rules. Internal auditors have been trained and the Quality Management Team is competent to identify and overcome potential problems.
Key issues in Quality Systems and Management

1. General concepts of Quality applied to the BTS

The main quality principles and definitions, were presented explaining the benefits of quality and improvement. Quality needs to be developed as a culture in any organization and supported by systematically enforced capacity building. Operational quality management will guarantee the consistency of procedures and processes, and subsequently the fitness for purpose of products and services.

Quality standards define the minimum quality requirements for an organization or institution, in order to ensure that all activities consistently meet these requirements. Such standards, relevant to the BTS and applied on a voluntary/regulatory basis, will need an inspection mechanism to monitor and evaluate compliance of processes, procedures and outcomes, involving all staff of the BTS.

2. Human resources development: selection and training of personnel in quality in the BTS.

Dr Cees Smit Sibinga, WHO Collaborating Centre Groningen, the Netherlands explained the importance of developing human resources with an emphasis on motivation, competency and awareness. Proper management makes systems work and personnel forms a defined section of any quality system describing the necessity to motivate, educate, train and evaluate acquired skills, knowledge and competency.

Positions need to be clearly defined in the organigram. Job descriptions should clearly define what the job is, what is required for the job and what authorities and responsibilities are to be assigned. Training is essential and should be well organized, monitored and evaluated based on assessed needs at each level.

Delegation is an important part of management that allows the manager to overview a wider range of activities and it is an important indicator of efficient management.

3. The Regional External Quality Assessment Schemes

The External quality assessment schemes are a WHO initiative to establish a mechanism for monitoring quality systems in blood transfusion services in all Member States. The objectives are the monitoring and evaluation of laboratory performance, the establishing of inter-laboratory comparability, the improvement of future testing reliability and enforcement of credibility. The system aims to stimulate performance improvement, encourage the use of standards and provide mechanisms to remedy deficiencies and facilitate information exchange.

External Quality Assessment Schemes (EQAS) are a recognised component of the quality system and assist in monitoring the quality of staff performance and helps identify areas for improvement.

4. The role of regulatory authorities in the BTS

Legislation aims to improve the safety, quality and efficacy of the blood transfusion system, with the ultimate goal to promote and protect public health Dr Cees Smit Sibinga presented the recently developed WHO legislative framework for a National Blood Transfusion Policy.
Blood transfusion legislation and regulation is a process encompassing various activities expressing government support for the establishment of a nationally coordinated blood transfusion system. The system should be financially viable and transparent. All citizens should have equal and affordable access to blood products. National standards must ensure that products are of uniform and high quality.

Health policy decisions should be considered with reference to basic human rights and values, and consistent with fundamental ethics of the blood transfusion system. Blood represents a national resource and blood donation is an act of human solidarity.

The legislative framework should be in accord with national policies, the degree of regulation that the government considers desirable and practicable to exercise, and the level of development in the country's blood supply sector. It should express government commitment and responsibility to organize the blood transfusion programme and system, based on a national policy.

**Group work outcomes**

**Group work 1**

*Need for developing Quality Systems in the BTS*

Discussions during the group work on identifying the need for the development of quality systems in blood transfusion services, identified the following consensus statements:

- Quality approach ensures that products and services meet customers needs, maximum safety and efficacy of blood and blood products;
- Implementation of quality systems in the blood transfusion service protects blood donors health, but also the recipients and personnel;
- Quality applies to all activities in the blood transfusion chain and involves all staff in an active process.

**Group work 2**

*Define the role of management and directors in the quality systems*

As a result of the discussions during the group work for defining the role of management and directors in the quality system, consensus was recognised on the following:

- Directors and management should define the quality policy and strategy
- Managerial level should involve staff into the planning process
- Delegation of action to the lower level managers is an indicator of efficiency
- The final responsibility lies with the director, who should show commitment and support to the quality approach.

**Group work 3:**

*Action planning*

The discussions during the group work on action planning underlined a clear consensus on several points.

- There is a recognised need for a change of attitude and new understanding of the quality approach.
Existing regulatory and legislative framework needs to be up-dated, with harmonization of national standards, documentation and relevant guidelines.

Clear authorities and responsibilities must be defined for appropriate implementation of quality systems and quality management in the blood transfusion service.

There is a need for training to increase competency, enable re-assessment and orientation of the personnel.

This complex and extensive process involves different partners, including: MoH, hospitals, managers, employees, suppliers, the general public.

**Evaluation and Recommendations**

A common understanding among participants was created in what concerns the concepts and principles of quality, quality systems and quality management.

Awareness was created towards the need to develop quality systems in BTSs and the major importance of supportive action of Directors and Managers in quality systems and management.

Main priorities for action were identified in general terms and in relation to specific country needs and priorities.

**Recommendations**

The following recommendations, made in consensus, were discussed in the presence of Dr D. Keber, the Slovenian Minster of Health, who emphasized the importance of the meeting and expressed his continuous support to further development of WHO collaborative activities.

1. **Recommendations to participating directors:**
   - To actively support the WHO’s initiative of the Quality Management Training by selecting appropriate participants within the national BTS for training in quality management;
   - To implement WHO resolution WHA 28.72 by encouraging full voluntary, non-remunerated blood donation as the basis for all BTS activities;
   - To encourage the participation of regular blood donors to assist in the recruitment of other voluntary, non-remunerated donors;
   - To liaise with existing national regulatory authorities and establish a mechanism, where blood is included into the existing regulations;
   - To ensure the reporting, recording and analysis of incidents which may affect the quality of blood at a national level and at the regional level;
   - To ensure that the participants to the quality management training courses have a key role in the implementation of quality in the BTS through an agreed work plan;
   - To establish a network of all BTSs in the region and share knowledge, experience and expertise.

2. **Recommendations to the Ministries of Health:**
   - To introduce, in collaboration with the appropriate ministries, training in blood transfusion medicine, into all health education syllabi where applicable;
- To assist the blood donor programme by introducing voluntary, non-remunerated donation as the safest source of blood into all public health education campaigns;
- To ensure an appropriate infrastructure that will provide an environment for the implementation and continuous progress in quality management of the BTS.

3. Recommendations to WHO:
- To strengthen the QMP and assist with the establishment of quality management in the BTSs in each Member State of the region;
- To promote the implementation of a national set of quality standards for blood transfusion medicine overseen by a nationally coordinated blood transfusion service;
- To continue to support the region by holding regular meetings of directors of blood transfusion and further development and follow-up of the QMT courses.
**Annex 1**

**SCOPE AND PURPOSE**

The scope and purpose of the meeting are to strengthen quality in all aspects of blood transfusion services and prevent transmission of HIV and other infectious agents through blood and blood products, for improving the safety of the blood supply, in the European region.

The main objectives are:

- To ascertain status of Quality Management in Blood Transfusion Services in Member States in the European Region;
- To sensitize participants toward Quality Management Project in Blood Transfusion Services and need of Quality Management Training to promote blood safety;
- To impart main principles of Quality Management in every aspect of Blood Transfusion Services;
- To develop a plan of action and follow-up on Quality Management, including training needs at country level and staff development.
Annex 2

PROGRAMME

Ljubljana, Slovenia 25 – 27 September 2002

Wednesday, 25 September 2002
08.30–09.00 Registration
09.00–10.00 Inauguration
- Welcoming remarks
- Selecting of a chairperson and a rapporteur
- Introduction of trainers/facilitators and participants
- Objectives and expectations of the meeting
10.00–10.30 Coffee break
10.30–10.50 Quality Management Project and Quality Management Training for Blood Transfusion Services: WHO initiative Dr Valentina Hafner
10.50–11.10 A broader view on the quality development in the health systems – WHO EURO vision Dr Isuf Kalo
11.10–11.30 Status of Blood Transfusion Services in the European Region and the importance of quality in the BTS Dr Valentina Hafner
11.30–12.30 Country reports: Armenia, Azerbaijan, Belarus, Bulgaria, Estonia, Georgia Country representatives
12.30–14.00 Lunch
14.00–15.10 Country reports (continued): Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Poland, Moldova, Country representatives
15.10–15.30 Constraints in developing quality systems in the BTS – the Slovenian experience Dr Bozidar Voljc
15.30–16.00 Coffee break
16.00–17.30 Visit of the Blood Transfusion Centre Ljubljana

Thursday, 26 September 2002
09.00–09.30 Summary of day 1 Dr Bozidar Voljc
Dr Esfir Svirnovskaia
09.30–10.00 Country reports (continued): Romania, Russian Federation, Tajikistan, Ukraine, Uzbekistan Country representatives
10.00–10.30 General concepts of quality and the BTS Dr Valentina Hafner
10.30–11.00 Coffee break
11.00–11.20 Constraints in developing quality systems in the BTS – point of view Dr Verra Bogdanova
11.20–12.30 Group Work 1: Need for developing Quality Systems in the Blood Transfusion Services Moderator: Dr Cees Smit Sibinga
12.30–14.00 Lunch
14.00–15.00 Conclusions from Group work 1 and discussion
15.00–15.30 Basic concepts of quality in a blood transfusion service Dr Vera Bogdanova
15.30–16.00 Coffee break
16.00–17.00 Human resources development: selection and training of personnel in quality in the BTS Dr Cees Smit Sibinga
17.00–17.30 Discussions
### Friday, 27 September 2002

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<td>Summary of day 2</td>
<td>Dr Esfir Svirnovskaiia</td>
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<td>Group work 2: Define the role of management and directors in the quality systems</td>
<td>Dr Vasilij Mihalchuck</td>
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<td>10.30–11.00</td>
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<td>12.00–12.30</td>
<td>The Regional External Quality Assessment Schemes</td>
<td>Dr Valentina Hafner</td>
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<td>12.30–14.00</td>
<td>Lunch</td>
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<td>The role of regulatory authorities in BTS</td>
<td>Dr Cees Smit Sibinga</td>
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<td>Group work 3: Action planning</td>
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<td>Conclusions and recommendations</td>
<td>Dr Cees Smit Sibinga</td>
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<td>Official closure</td>
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Annex 3

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