**QUALITY MANAGEMENT PROJECT**

**FOR BLOOD TRANSFUSION SERVICES**

... enhancing the safety of the global blood supply

**Background**

Blood transfusion is an essential and life-saving support within the health care system. Yet the quality and safety of blood transfusion therapy continues to be threatened, particularly in developing countries where 80% of the world’s population lives, through:

- An inadequate supply of blood and blood products for patients requiring transfusion
- The risk of transfusion-transmissible infections (TTIs)
- Laboratory technical errors
- Errors in the administration of blood and blood components.

WHO has identified the safety of the global blood supply as one of its priorities and has established an innovative initiative — the Quality Management Project (QMP) — as a cornerstone of its goal of achieving a safe and adequate global supply of blood.

**Quality in blood transfusion**

There are many definitions of the term ‘quality’. One of the simplest and most appropriate is 'fit for the purpose', in this case the purpose being safe transfusion. Quality systems and quality management are designed to ensure the consistent and reliable performance of services or products against given sets of standards.

For blood transfusion services (BTS), this means continual quality improvement to ensure the adequacy, availability, efficacy and safety of blood and blood products. Quality management aims at ensuring the highest possible standards in all aspects of blood transfusion — from ‘vein to vein’ — and the prevention of errors, which may be fatal.

**WHO Quality Management Project**

The WHO Quality Management Project is designed to build regional and national capacity in quality management and to promote the establishment of effective quality systems in blood transfusion at all levels of the health system in Member States. It was launched in 2000, with funds secured from efficiency savings within WHO, and will continue beyond 2005.

The Quality Management Project is coordinated at global level by the Blood Transfusion Safety Team in the Department of Blood Safety and Clinical Technology, WHO Headquarters.

At regional level, the QMP is coordinated by WHO Regional Offices, in partnership with Regional Quality Training Centres, WHO Collaborating Centres, national blood transfusion services, international nongovernmental organizations and experts in quality and transfusion medicine.

**Components of the QMP**

The Quality Management Project has six integrated components:

- Quality Management Training
- Regional Quality Training Centres
- External Quality Assessment Schemes
- Regional Quality Networks for blood transfusion services
- Post-training support and follow-up
- Development of advocacy and training materials.
Quality Management Training
Evidence from the WHO Global Database on Blood Safety indicates a lack of trained quality management staff in blood transfusion services, particularly in developing countries.

To address this challenge, WHO has launched a series of regional and sub-regional Quality Management Training (QMT) courses, with the following objectives:

- To assess the current status of quality systems in participants’ countries
- To develop participants’ knowledge and skills in quality management
- To assist participants to develop realistic plans for the establishment of national quality systems
- To identify future training needs in quality management training.

The courses are taught through a combination of formal presentations and a series of individual and group activities. The interactive nature of the courses, including informal discussion and the sharing of country experiences, is designed to promote active learning and the application of quality principles in participants’ own blood transfusion service.

Customized teaching materials and WHO guidelines, recommendations and learning materials are provided for facilitators and participants.

Regional Quality Training Centres
One or more blood transfusion centres in each region or sub-region are being designated as Regional Quality Training Centres (RQTCs) at which the QMT courses will be held. These centres, which include WHO Collaborating Centres and other centres of excellence, should have adequate teaching facilities, good communication networks and logistical and administrative support. Where necessary, assistance may be provided in upgrading existing facilities.

In addition to hosting QMT courses, RQTCs will serve as a resource for the region or sub-region and provide guidance and follow-up for course participants. This may include annual meetings of quality managers to strengthen regional networking in blood safety.

Facilitators
In collaboration with WHO, QMT courses are organized and facilitated by Regional Quality Training Teams, comprising the Regional Quality Course Coordinator and Regional Facilitators. A team of International Facilitators provides additional technical support, where required.

Curriculum
Each QMT course follows a core curriculum that has been developed by an international team of experts in quality in blood transfusion services. The curriculum has been developed in a modular form and addresses quality principles and quality management in all aspects of blood transfusion, including the organization, management and financing of blood transfusion services, donor management and blood collection, laboratory testing, component production, the issue of blood and the clinical interface.

The number of participants to receive training will depend on the size of each country. The courses, which last for 18 working days, will initially be attended by two participants from each country, normally the BTS quality manager and a senior laboratory technician.

Follow-up courses have also been planned. These may focus on quality issues or on specific technical issues, such as screening for transfusion-transmissible infections, blood group serology or blood component production, depending on participants’ needs.

External Quality Assessment Schemes
External Quality Assessment is the assessment of a laboratory’s performance by an external source, using samples of known but undisclosed content and including comparison against other laboratories. Regional External Quality Assessment Schemes (REQAS) will be established;
The aim of this integrated approach to the provision of training courses and the introduction of REQAS is to enable participating blood transfusion services to upgrade their knowledge and expertise while at the same time providing them with information about the performance of their laboratories and guidance on how they might improve it.

Blood transfusion services that have participated in Quality Management Training will be encouraged to join an external quality assessment scheme (EQAS) for TTIs and blood group serology as part of a cycle of continuous quality improvement.

Regional EQAS centres are being established for selected blood transfusion centres participating in the QMT, with the following objectives:

- To monitor trends, identify concerns and recommend corrective action
- To ensure good laboratory practice using standardized procedures and high quality reagents, and based on quality assurance and quality control measures
- To stimulate information exchange and networking at all levels.

Regional Quality Training Centres may, in some cases, serve as the location for regional and national external quality assessment schemes. International External Quality Assessment (EQA) panels will be sent to Regional EQA organizers who, in turn, will send their panels initially to participating laboratories, two or three times a year. Subsequently, the capacity of Regional EQA will also be strengthened to prepare their own proficiency panels and standardize them with international standards.

Regional Quality Networks

Many blood transfusion services work in isolation, particularly in developing countries. There is a clear need for an organized network to promote communication and information sharing between blood transfusion services to support the implementation of effective national quality management systems and enable them to keep abreast of the latest developments in transfusion medicine.

One of the objectives of the Quality Management Project is to develop a formal structure for interaction between Regional Quality Training Centres and national blood transfusion services, in partnership with WHO Collaborating Centres, individual experts and nongovernmental organizations. The RQTCs will coordinate and support quality networks at regional, sub-regional and national levels.

The effectiveness of the regional networks will, in part, be determined by the quality of the channels of communication that are available. Each participating centre will, where required, be equipped with computer hardware and software, including internet access.

Technical information available on the internet will be supplemented by newsletters, reports on the results of external quality assessments, facilities to encourage teleconference networking and antranet e-mail exchange to share and resolve concerns related to quality management.

The networks will also facilitate the dissemination of the WHO learning materials, Safe Blood and Blood Products and The Clinical Use of Blood, and the establishment of distance learning and other education programmes in blood safety.

Post-training support and follow-up

Evaluation, close follow-up and post-training support are essential elements in ensuring the sustainability of the project. In addition to External Quality Assessment Schemes, follow-up of course participants will include visits by QMT Coordinators to participating blood transfusion services to assess the level of implementation of quality systems at country level and cross-country quality audits.

Development of materials

A wide range of materials is being developed for the Quality Management Project, including advocacy documents, course materials and learning aids. These materials — designed for policy makers, course coordinators and facilitators, as well as BTS quality managers and other BTS staff — will be produced in several language versions and will be regularly updated. A Facilitators' Toolkit to support the QMT has already been developed and is being translated into French, Chinese and Portuguese.
Monitoring and evaluation

All QMT course participants will present a quality status report on their own BTS during the course. This will provide a baseline for the evaluation of the impact of the QMP.

Participants’ knowledge and understanding of quality concepts will be assessed at the beginning, during and at the end of each course and they will be assisted to prepare a plan of action for the establishment of a quality system in their own blood transfusion service. Their performance will also be formally evaluated by course facilitators.

Quality Management Training will also be evaluated as the Quality Management Project develops, using indicators such as the number of participants and countries trained, and the impact on the quality of work at national blood transfusion services.

Progress to date

The first regional QMT course was held in Harare, Zimbabwe, in September 2000 for participants from twelve Anglophone African nations. In 2001, regional courses have been held in:

♦ Bangkok, Thailand, for South-East Asian countries
♦ Abidjan, Côte d’Ivoire, for Francophone African countries
♦ Groningen, the Netherlands, for Eastern and Central European countries
♦ Amman, Jordan, for Eastern Mediterranean countries.

It is anticipated that by the end of 2001, at least one QMT course will have been held in each region. In addition, country-specific courses are being held in Indonesia, Myanmar and India in 2001.