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Quality Management Training in Blood Transfusion Services in South-East Asia Region

*Report of an Intercountry Workshop
National Institute of Biologicals, NOIDA, India
5-8 February 2001*

WHO Project: ICP RHR 001



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1. INTRODUCTION

An Intercountry Workshop on Quality Management Training in Blood Transfusion Services was held at the National Institute of Biologicals, NOIDA, Uttar Pradesh, India from 5 to 8 February 2001. It was attended by nine facilitators and 22 participants from various countries of the South-East Asia Region of WHO as well as by WHO staff. A list of participants and secretariat is attached as Annex 1.

This workshop is the first activity under the Quality Management Project (QMP) in Blood Transfusion Services initiated by WHO in 2000. WHO has identified blood safety as one of the seven priority areas. The theme of the World Health Day for 2000 was *'Blood saves life: safe blood starts with me'*. The Member Countries of SEAR recognize blood safety as an important issue. It finds mention as one of the 13 chosen areas wherein WHO has been requested to accelerate technical cooperation.

Concerted efforts have been initiated by WHO to assure blood safety especially in developing countries, where not only is the availability of blood inadequate, but its quality is also considered questionable. In various workshops/training courses on blood safety in SEAR countries, it was observed that health professionals were not well versed with the principles and practices of quality management in blood transfusion services (BTS). Accordingly, QMP is being implemented from 2001 in all the Regions of WHO to introduce/strengthen quality in all aspects of BTS with the broad objective of improving the safety, adequacy and quality of blood. One of the important components of QMP is capacity-building in quality management training to improve the skills of BTS professionals in assuring the quality of its services and products. WHO has developed a generic curriculum for this training that can be modified to suit the needs of Member Countries in different regions.

2. OBJECTIVES

- (1) To review the status of/and need for quality management training in blood transfusion services in the South-East Asia Region;
- (2) To assess generic curriculum and training material developed by WHO/HQ for quality management training courses and to develop a detailed training programme appropriate to the needs of the SEA Region, including tools for evaluation, and
- (3) To sensitize programme managers on the importance of quality management as a part of blood transfusion services and on the need for training in this vital area.

Dr Palitha Abeykoon, Director, Health Technology and Pharmaceuticals, WHO-SEARO, New Delhi opened the meeting. It was chaired by Dr Rajesh Bhatia, Director, National Institute of Biologicals, NOIDA, India and Dr RM Bindusara, Director, National Blood Transfusion Services, Sri Lanka acted as rapporteur. The programme of the workshop is placed at Annex 2.

Presentations on the essentials of Quality Management Project (QMP), global activities already undertaken under QMP and salient features of the generic curriculum for quality management training courses developed by WHO were made by Dr S. Kumari, RA-BCT, SEARO, Dr Neelam Dhingra-Kumar, Medical Officer, BCT-WHO/HQ and Dr Rajesh Bhatia, Director, National Institute of Biologicals, NOIDA.

Dr S. Kumari outlined the need for quality in BTS and development of QMP by WHO. She described the four components of QMP as: (1) Capacity-building through quality management training courses (QMT); (2) Identification of regional quality training centres; (3) Establishment of regional external quality assessment schemes for blood serology and transfusion transmissible infections, and (4) Development of regional quality networks of BTS.

She outlined the proposed plan of action for QMP in SEAR countries during 2001 with emphasis on training and development of training material.

Dr Neelam Dhingra-Kumar reported on the activities that have already taken place under QMP during 2000. These included global consensus on strategy for QMP, development of generic curriculum for QMT courses and lessons learnt from the pilot QMT course held in Harare, Zimbabwe during

September-October 2000 for Anglophone countries of AFRO Region of WHO. She also discussed the activities being undertaken by WHO to develop a facilitators' tool kit and other teaching materials.

The salient features of generic curriculum, its inherent capability of encompassing various issues of quality with their application to all activities of BTS and its flexibility to match the local needs were presented by Dr Rajesh Bhatia. The course commences with introduction of basic concepts of quality, development of policy and planning, mechanism for implementation of strategies and evaluation of activities and progresses to devote quality issues in relation to blood donor selection, blood collection, testing for transfusion-transmissible infections, blood group serology, blood cold chain and BTS/clinical interface.

3. GENERIC CURRICULUM FOR QMT

The generic curriculum was discussed extensively by the facilitators and a programme of work for regional QMT was developed. Recognizing the importance of international standards, the facilitators agreed that the terminology and concepts enunciated in the recent edition of ISO document should be adopted for QMT. It was agreed that instead of four weeks, the courses could be conducted in three weeks with 15 working days. The course would have theory lectures of duration not exceeding 45 minutes. The emphasis would be predominantly on interactive group discussions. Accordingly, 35 sessions for group discussions were developed. The participants would be taken to a mobile blood collection camp as well as to static blood centre.

The proposed scope, elements and learning outcomes of the course based on process-oriented approach highlighting the principles, planning, procedures and performance evaluation of quality were discussed to prepare the final programme. The programme of activities for SEAR-Regional QMT are placed at Annex 3.

4. FORMATS FOR QUALITY REPORTS

Two questionnaires were developed; one for quality status report and second for pretest evaluation of the participants. Apart from providing data on the

status of quality in respective countries, these will also provide a basis for subsequent evaluation of both the effectiveness of the course and QMP as a whole.

5. COURSE MATERIAL

The course material required for QMT courses was reviewed. The facilitators were also briefed about the material that was under preparation, especially the facilitator's tool kit to be made available to them before the first SEAR regional QMT course. Keeping in view the large number of group discussions that would require case studies/scenarios, facilitators were requested to develop these during the next four weeks. These will be reviewed in an informal meeting likely to take place in SEARO New Delhi in March 2001.

6. MONITORING AND EVALUATION

Dr Neelam Dhingra-Kumar briefed the meeting about the need for development of measurable quantitative and qualitative indicators at the global, regional, national and local levels. She also addressed the issue of utility of these indicators for QMP as a whole and QMT in specific. The participants agreed with the importance of indicators and their effective utilization in improving the quality of services and products.

7. MEETING OF COUNTRY PROGRAMME MANAGERS

The country programme managers were introduced to the basic concepts of quality in blood transfusion services and briefed about the quality management project, its various components and the activities already undertaken under QMP by WHO during 2000. The status of BTS and requirements of developing quality systems in Member Countries of SEAR were also discussed.

The programme of work for regional QMT course as developed by the facilitators during the first two days of the meeting was circulated for opinion, comments and endorsement by the country programme managers. The curriculum and the duration of the QMT course (three weeks) were agreed to by the participants.

8. COUNTRY REPORTS AND STATUS OF QUALITY IN BTS IN SEAR

Country reports presented by programme managers have been compiled in a tabular form as Annex 4. A brief summary of status in SEAR (excluding DPR Korea) is as follows:

The blood transfusion services in the South-East Asia Region of WHO are mainly in the public sector in six countries. In Indonesia, Nepal and Thailand these are run by the Red Cross. The private sector plays a significant role in India. The main source of funding of these services is the Government/Red Cross. Cost-recovery contributes to some extent in India, Indonesia and Thailand.

National blood policy has been formulated in seven countries but it is being implemented only in four countries. Concepts of quality policy and quality managers are established only in Thailand. Regulation of blood transfusion services is well defined in three countries but weak in the remaining countries.

A total of 2 373 blood banks exist in the Region which collect 7.347 million units of blood annually. Of these, 10% to 100% donors are voluntary non-remunerated donors. Bangladesh has only 10% as voluntary non-remunerated donors (Regular donors 1-50%). Donor questionnaires are available in all the countries, but their usage in different settings is variable. Pre-donation counselling is a common feature, but post-donation care/counselling is negligible and restricted to selected blood centres.

Regular training to staff in BTS is imparted in all the countries. However, proficiency testing of staff is uncommon. Concepts of audit and accreditation are gaining ground in the Region, but are not mandatory till date.

Except Thailand, well-defined and regular external quality assessment programmes are not in operation in SEAR for blood serology and screening for transfusion transmissible infections. Most, but not all the blood banks in most of the countries have SOP and apply internal quality control measures. The mechanism for selection and procurement of reagents and kits as well as that of maintenance of equipment are available in some countries for selected reagents/kits and equipment. Application of uniform biosafety and waste management guidelines is also variable in SEAR and also within the countries.

9. GROUP DISCUSSIONS

The participants deliberated on various issues that concern quality in BTS in the Region. These were: (1) Constraints in implementing quality in BTS and their possible solutions; (2) Role of country programme managers in improving quality in BTS; (3) Identification of steps that can make QMP/QMT a success; (4) Profile of participants for QMT courses, and (5) Development of definitive action plan for implementation of QMP.

The discussions not only sensitized the programme managers about the need of quality in BTS, but also identified areas where action could be initiated by them. Technical support available from WHO and its integration in national programmes was also discussed.

10. SUMMARY AND CONCLUSIONS

The participants in the meeting unanimously agreed that there was an urgent need to infuse quality in all the aspects of BTS and the initiation of quality management project by WHO was a timely step in the right direction. Capacity-building is an important component of this project for which the modified three weeks' curriculum with emphasis on extensive interactive group discussions was adopted for use in SEAR. The recommendations that emerged from these discussions are described below.

11. RECOMMENDATIONS

11.1 To WHO

- (1) Quality Management Project is a timely, appropriate and need-based initiative of WHO that was fully endorsed by all the participants. There is a greater need of implementation of QMP in SEAR countries where blood safety has emerged as a major issue. WHO must ensure its sustenance so that concepts of quality get integrated into all the activities of blood transfusion services.
- (2) WHO must provide technical cooperation and guidance, and wherever required, appropriate post-training funding to country programme manager trained in quality aspect.
- (3) WHO should develop training/teaching material to match the needs of various echelons of professionals in BTS.

- (4) WHO should develop measurable indicators (qualitative and quantitative) for monitoring and evaluation of QMP and assessment of impact of QMT.
- (5) Immediately after the first Regional QMT course, WHO should organize a review meeting with experts who have acted as facilitators for the course to modify the curriculum, training material and methodology based on feedback received.
- (6) Regional External Quality Assessment Scheme for blood serology and transfusion transmissible infections should be introduced before the end of 2001.
- (7) Electronic networking between participants of QMT courses, various blood transfusion centres, WHO collaborating centres and WHO should be established for rapid access to information and sourcing of technical inputs.

11.2 To Member Countries

- (1) All staff members of blood transfusion services and prescribers of blood should commit themselves to improve blood safety.
- (2) Quality Policy and Quality Plans should be developed as part of National Blood Policy and Quality Managers in BTS should be appointed/designated.
- (3) Member Countries should ensure active participation in Regional QMT course by nominating suitable candidates for this course. The candidate should preferably be a middle level medical/technical professional who can be subsequently designated as Quality Manager for his blood bank/country.
- (4) The participant of the QMT course should be fully supported after training in employing his skills in improving the quality of BTS. His services should also be utilized for training other staff members of BTS.
- (5) Member Countries should support the organization of national training courses and CMEs for various categories of health care professionals working in BTS to train them in quality management of various aspects of BTS.
- (6) The participants trained in Regional QMT should participate in Regional External Quality Assessment Scheme for blood group serology and TTI.
- (7) Wherever required, Member Countries should translate the WHO training material into local languages for use by technical staff.
- (8) The impact of QMP and QMT courses should be periodically assessed by the Member Countries and observations shared with WHO so that realistic planning of future activities can be undertaken.

Annex 1

LIST OF FACILITATORS, PARTICIPANTS AND SECRETARIAT

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Annex 2
PROGRAMME

Date/Time	Activity/subject
5 February 2001	
0900-0930	Registration
0930-1015	Inauguration
1030-1100	Quality Management Project (QMP) for blood transfusion services: WHO initiative
1100-1130	Review of global activities under QMP during 2000
1130-1200	Salient features of generic curriculum of QMT: Issues for modifying it to suit needs of SEAR
1200-1300	Development of Programme of Work for the first week of QMT course
1400-1545	Development of Programme of Work for the first week of QMT course contd...
1600-1700	Development of Programme of Work for the second week of QMT course
1700-1730	Wrap up of the days proceedings
6 February 2001	
0900-1045	Development of Programme of Work for the second week of QMT course contd
1100-1330	Development of Programme of Work for the third week of QMT course
1430-1515	Proposed mechanism of organization of first QMT at Bangkok in March- April 2001
1530-1615	Monitoring, evaluation and follow up of training courses
1615-1700	Conclusions and next steps
7 February 2001	
0900-0930	Registration
0930-1000	Opening remarks and introduction to WHO Quality Management Project in Blood Transfusion Services
1000-1045	Basic concepts of quality in BTS

Date/Time	Activity/subject
1100-1330	Country reports on quality in BTS in order to identify needs to strengthen quality system
1430-1515	<ul style="list-style-type: none">• Status of BTS in SEAR,• Need for developing quality systems in BTS
1530-1615	Brief review of global activities under QMP during 2000
1615-1700	Review of QMT curriculum in SEAR countries
8 February 2001	
0900-1000	Constraints and possible solutions to improve the quality in BTSs
1000-1030	Presentation of work group
1030-1100	Regional external quality assessment scheme
1115-1200	Working groups <ul style="list-style-type: none">• How do you see the role of directors and quality managers and other staff, discuss organigram• Role of country managers and directors of BTSs in developing quality systems
1200-1230	Presentation and discussion
1230-1330	Working groups <ul style="list-style-type: none">• Identification of steps they can take to make QMP/QMT a success• Discussion and agreement on the profile of the participants for QMT• Development of definitive action plan for countries for implementation of QMP
1415-1515	Presentation of group reports and formulation of recommendations
1530-1630	Valedictory and closure

Annex 3

PROGRAMME: QUALITY MANAGEMENT TRAINING COURSE

Week/Day/time	Activity	Principal speaker
Week 1/ Day 1, 26 March 2001		
0830-0930	Registration	Dr S Kumari
0930-1000	Inauguration	
1030-1100	Pre-course evaluation	
1100-1130	Introduction to Quality Management Project (QMP)	
	Objectives of Quality Management Training (QMT)	
1130-1200	Status of Blood Transfusion Service in South-East Asian Region (SEAR)	
1200-1230	Need for Quality	
1230-1300	Quality terminology	
1400-1515	Quality terminology (contd.)	
1530-1700	Group Work 1 on Quality terminology	Participants
Week 1/ Day 2, 27 March 2001		
0830-0900	Review and discussion	Participants
0900-1115	Presentation of Quality status reports – 10 minutes each	
1130-1215	Quality systems	Participants
1215-1300	Group work 2 Development of quality policy for their BTS by the participants	
1400-1430	Organizational structure and organogram	Participants
1430-1530	Group work 3 Development of organograms	
1545-1630	Job description of BTS personnel in the organization	Participants
1630-1700	Group Work 4 Job description of quality officer in BTS	

Week/Day/time	Activity	Principal speaker
Week 1/ Day 3, 28 March 2001		
0830-0900	Review and discussion	Participants
0900-0945	Flowchart as a tool for mapping processes and identifying critical control points (CCP)	
0945-1100	Group work 5 Development of a flow chart	
1115-1200	Quality Planning	Participants
1200-1300	Group work 6 Preparation of quality plan	
1400-1700	Visit to BTC to have an overview of a working quality system	
Week 1/ Day 4, 29 March 2001		
0830-0900	Review and discussion	Participants
0900-0930	Documentation: Types, Necessity and Importance	
0930-1030	Group work 7 on documentation	
1045-1115	SOP/work instruction on structure, use, how to write	Participants
1115-1215	Group work 8 Write a SOP on a sample procedure	
1215-1300	Group work 9 Validation of SOP	
1400-1430	Document control	Participants
1430-1500	Revision of documents	
1515-1545	Error management: Reporting, analyzing and corrective / preventive action	
1545-1700	Group work 10 Error management : Reporting, analyzing and corrective / preventive action	Participants
Week 1/ Day 5, 30 March 2001		
0830-0900	Review and discussion	
0900-0945	GMP as essential component of BTS	
0945-1100	Consequences of failure of Good Manufacturing Practices (GMP) in BTS	

Week/Day/time	Activity	Principal speaker
1115-1300	Group work 11 Identification of critical control points and Flow charts preparation for GMP	Participants
1400-1530	Group work 12 GMP role play	Participants
1545-1700	Assessment of the week's work and discussion	
Week 2/Day 1, 2 April 2001		
0830-0900	Review and discussion	
0900-0945	Introduction to Quality Audits	
0945-1030	Group Work 13 Role play on audit process	Participants
1045-1215	Group Work 14 Identifying non-conformities in audit scenario Documentation of audit	Participants
1215-1300	Review of Group Work 14	
1400-1445	Validation of processes, equipment, reagents and software	
1445-1545	Group Work 15 (in two groups) Preparation of validation plan for an equipment (Group1) and reagent (Group 2)	Participants
1600-1700	Group work 16 Preparation of validation plan for a process	Participants
1700-1730	Review of Group work 16	
Week 2/ Day 2, 3 April 2001		
0830-0900	Review and Discussion	
0900-0945	Role of training in quality system	
0945-1030	Training: needs and plans	
1045-1145	Group Work 17 Development of an effective training plan in BTS	Participants
1145-1215	Documentation of training	
1215-1300	Monitoring and evaluation of training	
1400-1500	Biosafety in BTC – I Hygiene, prevention of infection and contamination of environment	

Week/Day/time	Activity	Principal speaker
1500-1530	Biosafety in BTC - II	Participants
1545-1700	Group work 18 Identify safety issues and risk management	
Week 2/ Day 3, 4 April 2001		
0830-0900	Review and discussion	Participants
0900-0930	Procurement of equipment	
0930-1000	Maintenance and calibration of equipment	
1000-1100	Group work 19 Identify key maintenance and calibration needs of equipment and prepare an appropriate schedule	
1115-1200	Inventory management of perishable and non-perishable items in a blood centre	Participants
1200-1300	Group work 20 Inventory/stock preparation	
1400-1430	Quality monitoring tools – basic concepts	Participants
1430-1515	Monitoring and performance of assays, blood donations, blood products	
1530-1700	Group work 21 Analysis of data from BTS/lab and identify the trend	
Week 2/ Day 4, 5 April 2001		
0830-0900	Review and Discussion	Participants
0900-0945	Costing of activities in BTS - Principles and benefits, WHO model	
0945-1030	Cost of quality and additional costs of poor quality	
1045-1215	Group work 22 (in two groups) Calculation of testing cost (group 1) Calculation of cost of donor recruitment (group 2)	
1215-1300	Review of Group work 22	
1400-1445	Quality in donor recruitment and selection	
1445-1530	Collection of blood and care of donors	
1545-1615	Donor satisfaction and feedback	

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Week/Day/time	Activity	Principal speaker
1000-1100	Group Work 27 Flowchart of blood component production process	Participants
1115-1145	Documentation in blood component production	
1145-1230	Monitoring and evaluation of blood component production	
1230-1300	Quarantine and release	Participants
1400-1500	Group work 28 Development of a plan for monitoring and evaluation of blood components	
1500-1530	Storage, transportation and distribution of blood and blood components	
1545-1615	Blood stock management	Participants
1615-1715	Group work 29 Blood stock management	
Week 3/ Day 3, 11 April 2001		
0830-0900	Review and Discussion	Participants
0900-0945	Applying quality principles to clinical interface	
0945-1015	Essential information required on a blood request form	
1015-1045	Quality at bedside	Participants
1100-1215	Group work 30 Development of an appropriate and effective blood request form	
1215-1300	National policy and guidelines for clinical use of blood	
1400-1500	Group work 31 Monitoring and evaluation of the use of blood	Participants
1515-1600	Documentation and transfusion records	Participants
1600-1630	Haemovigilance	
1630-1730	Group work 32 Quality issues in post transfusion monitoring	

Week/Day/time	Activity	Principal speaker
Week 3/ Day 4, 12 April 2001		
0830-0900	Review and Discussion	Participants
0900-1100	Group work 33 Review of quality and its implications in BTS	
1115-1300	Group work 34 Development of action plan for respective BTS	Participants
1400-1700	Group Work 35 Presentation of individual blood centre plans	Participants
Week 3/ Day 5, 13 April 2001		
0900-1000	Group work 36 Discussion on respective plans (in four groups)	Participants
1015-1115	Post-course assessment	
1115-1300	Course evaluation by participants	
1400-1500	Open discussions	
1500-1600	Closing and valedictory	

Annex 4
STATUS OF QUALITY IN BTS IN SEAR COUNTRIES, 2001
(EXCLUDING DPR KOREA)

	BAN	BHU	IND	INDO	MAV	MMR	NEP	SRL	THA
Organization	Govt	Govt	Govt/Pvt/ NGO	NGO	Govt	Govt	NGO	Govt	NGO
No of blood banks	44	2	1549	163	1	359	48	57	150
Blood units collected annually	225000	6000	3000000	1100000	6000	1500000	60000	150000	1300000
National Blood Policy	No	Yes	Formu- lated	Imple- mented	Yes	Formed	NA	Formed	Yes
Quality policy	No	Yes	No	Yes	Yes	Yes	Yes	No	Yes
Quality manager	No	No	No	No	No	Yes	Yes	No	Yes
Training of staff in BTS	Partial	No	No	Yes	No	No	No	Yes	Yes
Proficiency test of staff	No	Yes	Partial	Partial	Yes	Partial	Partial	Partial	Yes
Regulations in BTS	No	Partial	Yes	Yes	No	Yes	Yes	Yes	Yes
Accreditation	No	No	Yes/volun- tary	No	No	No	No	No	Yes
VNR donation	10%	85%	40%	81%	95%	65%	100%	53%	90%
Regular VNR donors	Nil	10%	NA*	NA	10%	20%	40%	50%	50%
Predonation counselling	Yes	Yes	Yes	Partial	Yes	Yes	Yes	Yes	Yes
Postdonation counselling	No	Yes	Partial	Partial	Yes	Yes	No	Yes	Yes
Donor questionnaire available	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Donor questionnaire used in camps	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Donor selection criteria followed	Partially	Yes	Partial	Partial	Yes	Partial	Yes	Yes	Yes

	BAN	BHU	IND	INDO	MAV	MMR	NEP	SRL	THA
Private interview held	No	Yes	Partial	No	Yes	Yes	No	Yes	Yes
SOP available	No	Yes	Partial	Partial	Yes	Yes	Yes	Partial	Yes
Internal controls in serology	No	Yes	Partial	Partial	Yes	Yes	Yes	Yes	Yes
Internal controls used in TTI	No	Yes	Partial	No	Yes	Yes	Yes	Yes	Yes
Mechanism for validating results	Partially	Yes	Partial	No	Yes	Yes	Partial	Yes	Yes
Mechanism for equipment maintenance	Yes	Yes	Partial	Partial	Yes	Yes	Partial	Yes	Yes
Mechanism for selection and procurement of reagents/kits	Partial	Yes	Partial	Yes	Yes	Yes	Yes	Yes	Yes
Quality audit carried out	No	No	Partial	Partial	No	Yes	No	No	Yes
NEQAS organized	No	No	No	No	No	Yes	No	Yes	Yes
Uniform biosafety measures	Partial	Yes	Partial	No	Yes	Partial	Partial	No	Yes
System for waste management exists	Partial	Yes	Partial	No	Partial	Yes	No	Partial	Yes
Mechanism for quality assurance of incoming goods	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes
Funding of BTS	Govt	Govt	Govt/ NGO/ Cost-recovery	Govt/ Cost-recovery	Govt	Govt	NGO/ Cost-recovery	Govt	Govt/ Cost-recovery

* NA: Information not available

** Based on country reports presented at Inter-country Workshop on Quality Management in BTS at NIB NOIDA, (5-8 Feb.01)