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Distribution General

Quality Management Training in Blood Transfusion Services for Bangladesh, Maldives and Bhutan

*Report of a Sub-regional Training Course
Chittagong, Bangladesh, 2–18 September 2002*



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1. INTRODUCTION

The sub-regional training course on Quality Management Training (QMT) in Blood Transfusion Services (BTS) was organized at Chittagong, Bangladesh from 2 September to 18 September 2002. Twelve participants representing Bangladesh, Bhutan and Maldives attended this training course. Staff from WHO Regional Office for South-East Asia along with experts from India and Thailand facilitated the training course. The List of Participants is at Annex 1 and the Programme of Work at Annex 2. The course was rescheduled as one day (1 September 2002) was lost due to a nation-wide strike.

WHO has identified blood safety as one of its seven priority areas. Safety of blood was also identified as the theme of World Health Day 2000. Quality management of BTS has been identified by WHO as one of the significant components to achieve safety, adequacy and quality of blood in all the Member Countries. Accordingly, a quality management project (QMP) for BTS was initiated in 2000. Under QMP, capacity building through quality management training courses is an important activity. The Regional Office of WHO has organized one regional training course and four national training courses on QMT to create a core group of quality managers for BTS in various Member Countries who will also act as trainers in their respective countries.

2. OBJECTIVES

The following were the objectives of the training course:

- (1) To ascertain the status of quality management in blood transfusion services in Bangladesh, Maldives and Bhutan;
- (2) To sensitize trainees towards quality management project in blood transfusion services and the need for quality management training to promote blood safety;
- (3) To impart training in the theoretical and practical aspects of quality management in every aspect of blood transfusion services;
- (4) To upgrade the skills of participants in the planning, management and implementation of quality systems, including preparation of SOPs and assuring quality implementation, and

- (5) To develop a plan of action and follow-up on quality management, including training needs at the country level and staff development.

3. INAUGURAL SESSION

Inaugurating the training course, Dr Md. Abdur Rashid, Director of Health, Chittagong Division, Chittagong, Bangladesh, emphasized the need for safe blood and the role of voluntary non-remunerated blood donors in achieving this objective. WHO's support to promote safety, adequacy and quality of blood took the form of a quality management project that WHO has initiated recently. Dr Rajesh Bhatia, STP-BCT, South-East Asia Region, WHO, described the various components of QMP and the importance of quality management training (QMT) in improving overall quality in blood transfusion services. He also detailed various activities undertaken by WHO during the recent past to develop a curriculum and learning material for the QMT courses and organization of training. Dr Bhatia emphasized that all efforts needed to be directed to sustain the programme so that quality was integrated into all the activities of BTS.

4. TRAINING COURSE

4.1 Pre-course Assessment of the Participants

A questionnaire with 45 multiple-choice questions was used to assess the pre-course knowledge of the participants. Twenty-three of the questions related to pure quality issues, while the remaining pertained to quality as applied to BTS. Participants were given 30 minutes to provide answers to these questions. An analysis of the result showed that only 42% of the trainees could give more than 50% correct answers to all the questions.

4.2 Mechanics of Training

The main aim of the training course was to provide the participants with the tools of quality management and demonstrate how to use them in BTS. The training was largely in the format of short presentations followed by group activities and extensive interaction with the participants to reinforce the teaching aims and learning objectives. The activities involved carrying out an assigned task in groups and then reporting back for discussion with all the participants and

facilitators. Some activities involved the whole class using scenarios and role plays (See Annex 2).

The participants visited the Chittagong Medical College, Chittagong, to see the quality management system in operation in BTS. They prepared an audit report and presented the same on the last day. Handouts of all the presentations were provided to the trainees as part of their workbook.

4.3 Summary of Subjects Covered

First week

The participants briefly presented their expectations from the course which included improvement in their skills to institute quality systems in their respective BTS to generate quality products and results. They also opined that after being trained in this workshop they would be able to impart training to their colleagues and other personnel in BTS in their respective countries. The participants also believed that after three weeks' training, they would be in a better position to advocate the need for quality in BTS, handle organizational constraints and optimally utilize the resources made available to them.

The major objective of the activities in the first week was to provide the basics of quality and create firm foundations for implementing quality systems following the ISO model. The terminology used internationally in quality was extensively discussed. Other important topics covered included: quality systems; quality policy; a quality officer's job description; documentation, with emphasis on standard operating procedures (SOPs); organizational structure; and process flow charts and validation. All activities and examples used were based on everyday activities or objects but, where appropriate, examples pertaining to the blood transfusion service were used.

Second week

Participants were introduced to the concepts of good manufacturing practice (GMP) and started to apply the quality principles learnt in week one to blood transfusion activities. Job descriptions and delegation as specifically applied to a blood transfusion service were emphasized. Flow charts and SOPs were applied to selected BTS activities. Monitoring and evaluation activities in the form of error reporting, corrective and preventive action and quality audits were introduced. Validation of processes and equipment was also covered.

The role and value of training in the quality system were highlighted. Procurement, maintenance and calibration of equipment; monitoring of assay performance and the documentation of testing and processing were also discussed in detail. The costing of activities in a BTS was discussed using the WHO Module (Costing blood transfusion services WHO/BLS/98.8) as the basis. The week also concentrated on quality aspects of blood donors, including donor education, motivation, recruitment and retention. Donor selection, screening and handling of donated blood and donor records as well as safety in BTS, including environmental factors were discussed.

Third week

The week concentrated on applying quality to the main BTS activities. All aspects of testing for transfusion transmissible infections (TTIs) were covered, including quality elements in laboratories and selection of test kits. An introduction to the concepts of external quality assessment schemes (EQAS) was given. Applying quality concepts to immunohaematology and component preparation, documentation of activities, process flow and related critical points, and monitoring and evaluation in the immunohaematology laboratory were discussed. The clinical interface learning included a general presentation and work on the role of the BTS in the clinical use of blood. Participants also began a draft plan for implementing quality into their own particular BTS which was finalized in consultation with the facilitators. Advice was given on generating a plan of action with a template. Where quality systems already existed, some problems were encountered on exactly what the participants should plan for, but they were advised to concentrate on critical areas of their immediate concern and to ensure that they communicated with the appropriate management personnel to ensure that a collaborative effort was put into the proposed plan.

4.4 Post-course Assessment of the Participants

A comprehensive evaluation of the training course was completed on the last day. The results revealed significant improvement in the knowledge of the participants. The pre-course questionnaire was used for post-course assessment as well. The number of participants who answered more than 50% questions correctly increased to 93% from 42% as was observed in precourse-assessment.

4.5 Valedictory Session

The valedictory session was chaired by Dr Pimol Chiewsilp wherein participants expressed their gratitude to WHO and the Government of Bangladesh for arranging the training course. They appreciated the QMP initiative of WHO and enumerated the benefits that had accrued to them by attending this training course. Dr Pimol requested them to commit themselves, and their respective organizations, to the cause of quality in BTS to ensure safety, adequacy and quality of blood and blood products. She also assured them of all possible technical support from WHO in achieving their goals.

5. RECOMMENDATIONS

5.1 To WHO

- (1) WHO should assist in the implementation of quality systems at the country and regional levels through advocacy, support organization of QMT courses and provide technical support to Member Countries in implementing QMP. Periodic reviews of all activities of BTS under QMP should also be performed.
- (2) WHO should provide technical support in identified areas in improving technical skills of personnel working in BTS.
- (3) Technical support should be continued to provide to organize regional EQAS in blood group serology and anti-HIV antibody detection for various blood banks in the Region.
- (4) WHO should continue to support the Regional Quality Training Centre which should follow-up the progress made by the participants as well as act as a resource centre for providing technical assistance to the participants of this, and other similar courses.

5.2 To Member Countries

- (1) The Ministry of Health should provide the support and infrastructure to implement quality systems in Blood Transfusion Services as per the PoA. Adequate budget should be earmarked for blood safety.
- (2) QMT courses should be organized at the country level with trained personnel as trainers.

- (3) The participants of this course should be permitted to participate in the WHO-supported regional EQAS on blood group serology and anti-HIV antibody detection.

5.3 To Participants

- (1) A plan of action in keeping with the priority needs of the participants' centres may be developed and discussed with the Programme Director. They should make an all-out effort to advocate the need to implement the plan of action to improve blood safety.
- (2) The participants should provide monthly feedback to the Regional Quality Centre and also seek their technical support to overcome the problems being encountered in establishing quality management.

Annex 1

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Annex 2 PROGRAMME

Week 1/ Day 1 - 2 September 2002
Registration Inauguration Introduction to Quality Management Project (QMP) and objectives of QMT Pre-course evaluation Introducing quality Fitness for purpose Quality characteristics Group work presentation Quality systems
Week 1/ Day 2 - 3 September 2002
Quality management Writing a quality policy for a biscuit factory Quality planning Preparing a quality plan for the biscuit factory Organizational structure and chart Drawing an organizational chart for biscuit factory Job description and delegation
Week 1/ Day 3 - 4 September
Writing job description of quality officer in biscuit factory Flowcharting as a tool for mapping processes and procedures Preparing a flow chart of the process of making biscuits Presentation of group work on flow chart Documentation in quality systems Quality failures due to lack of documentation

Week 1/ Day 4 - 5 September
Writing standard operating systems Writing an SOP for making a cup of coffee Validation of SOP Validation of SOP written in Group Work 8 Document control Understanding document control systems Good manufacturing practices
Week 2/Day 1 - 7 September
Standards CCP Identifying critical control points in BTS activities from vein to vein Preparing flow chart for BTS activities Briefing on plan of action and development of plan of action by the participants Assessment of quality
Week 2/ Day 2 - 8 September
Monitoring and evaluation in quality system Validation Preparing a validation plan for equipment and reagent Preparing a validation plan for process or software Presentation of validation plans Quality monitoring tools
Week 2/ Day 3 - 9 September
Monitoring performance Audits and auditing Analyzing data Presentation of Group work 18 Error Management Scenario of audit

Week 2/ Day 4 - 10 September
Role of training in a quality system Training needs and plans Use of WHO Distance Learning Material Visit to the blood bank at Chittagong Medical College, Chittagong for audit Report writing for audit
Week 2/ Day 5 - 11 September
Documentation and assessment of training Preparation of national training plan Discussion on national training plan Hygiene and general safety in BTS Biosafety in BTS Safety issues and minimizing risk
Week 2/ Day 6 - 12 September
Maintenance and calibration of equipment Developing maintenance and calibration plans Presentation of group work 20 Logistics of stock control Costing activities in BTS The cost of quality Calculating the cost of quality failure
Week 3/ Day 1 - 14 September
Quality system in blood donor management Donor recruitment and selection Donor recruitment and selection Blood collection Blood collection Presentation on blood collection GW

Week 3/ Day 2 - 15 September
Quality records in donor clinics Identifying monitoring points for donor selection and blood collection activities Donor care, satisfaction and retention Basic quality systems in laboratories Essential quality elements in laboratory WHO strategy for screening of blood for HIV Selection and validation of reagents and test kits
Week 3/ Day 3 - 16 September
Selection and validation of reagents and test kits Selecting reagents and test kits Validation of test results Documentation in laboratories Essential quality systems in component preparation Documentation in component preparation Quality monitoring in component preparation Evaluation and monitoring of component production activities
Week 3/ Day 4 - 17 September
Quarantine and release Storage, transportation and distribution Storage, transport and distribution Blood stock management Applying quality principles to clinical interface Clinical interface Quality at bed side Quality at bed side Haemovigilance Essential information on blood request form

Week 3/ Day 5 - 18 September

Monitoring and evaluation of clinical use of blood

Documentation : transfusion records

Quality aspects in contingency planning and success story of establishment and sustenance of quality systems in blood transfusion services in Thailand.

Post-test evaluation

Presentation of audit report for the blood bank visited on 10 September along with recommendations for establishment/improvements in quality system

Follow-up of the course and concluding session