

SEA-HLM-385
Distribution: General

Standard Operating Procedures in Blood Centres

*Report of a Workshop
Yangon, Myanmar, 14-17 September 2004*

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1. INTRODUCTION

Blood safety continues to be one of the priority areas of WHO both at regional and global levels. To create awareness on the issue, the World Health Day theme for 2000 was "Safe blood starts with me". Concerted efforts have been initiated by WHO to assure blood safety especially in developing countries where not only the availability of blood is inadequate its quality is also considered doubtful. At various workshops and interactions on blood safety it has been recognized that blood bank professionals are not fully aware of the quality aspects of management of blood transfusion services that can significantly improve their output. A Quality Management Project (QMP) for blood transfusion services was initiated in 2001 in all the regions of WHO to introduce/strengthen quality in various aspects of blood transfusion services with the objective of improving safety of blood.

The QMP is based on technical fundamentals that have been enunciated by the International Standards Organization (ISO). These can be grouped under a quality system which comprises of five key elements viz. organizational management, training, standards, monitoring & evaluation and documentation. One of the important documents that are essential to ensure consistency, and thus quality in blood centres, is the standard operating procedure (SOP). The inadequacies in Member Countries to develop their own SOPs was observed in various quality management training courses conducted by WHO during the past three years in which a preliminary introduction to SOPs was provided to the participants. To meet this demand, the Regional Office published a Model SOP for selected procedures for use in blood centres. These have since been distributed to Member Countries. On the basis of these model SOPs, the blood centres have to develop their own SOPs appropriate to their infrastructure, type of reagents used and other requirements. Before the SOPs can be utilized, they need to be validated, authorized and controlled. At present, these SOPs are in use only in Thailand.

To orient nationals in the appropriate utilization of SOP after their development in a scientific way, a workshop was conducted at Yangon, Myanmar from 14-17 September 2004. The workshop was attended by 14 participants from Bhutan, India, Indonesia, Myanmar, Nepal and Sri Lanka and facilitated by experts from the WHO Collaborating Centre at the National Blood Centre, Bangkok, the Bureau of Laboratory Quality Standards of Thailand and WHO/SEARO. For the list of participants and the programme of work, please see Annexes 1 and 2 respectively.

2. OBJECTIVES

The following were the objectives of the workshop:

- (1) To orient blood transfusion professionals on the quality system in blood centres;
- (2) To discuss the utility of WHO Model SOPs for blood transfusion services;
- (3) To train in development, validation, revision, control and use of SOPs, and
- (4) To develop a draft action plan to develop, and use SOPs in respective blood centres.

3. INAUGURAL SESSION

The workshop was inaugurated by H.E. Dr Kyaw Myint, Health Minister of Myanmar. In his inaugural address the Minister said that appropriate policy guidelines and effective strategies were essential for the planning and organization of nationally coordinated blood transfusion services. He informed that the National Blood Law had come into effect from January 2003 and a task force had been established to develop a National Blood Policy. Appreciating the efforts of WHO in promoting blood safety, the Minister referred to the WHO Global Strategy for Safe Blood which advocates establishment of nationally coordinated blood transfusion services; collection of blood only from non-remunerated blood donors belonging to low risk population; testing of donated blood by appropriate technology to ascertain blood group and assure freedom from transfusion transmissible infections;

conversion of blood into components to optimize its use and rational administration of blood and only when alternatives are not available. In addition, all procedures in blood banks have to be performed with quality as the central theme. The development of standard operating procedures for use in blood centres would ensure consistency in performing various activities and guaranteeing the safety and quality of blood and blood products, the Minister added.

Dr Agostino Borra, WHO Representative in Myanmar addressing the participants said that provision of safe blood to all those who needed it in an efficient, coordinated and cost-effective manner was an essential function of the health services. With the emergence of transfusion transmissible infections especially HIV/AIDS, hepatitis B and hepatitis C as important public health problems, the safety and quality of blood had assumed greater importance in developing countries. The countries of the South-East Asia Region were estimated to have more than six million carriers of HIV, 85 million of hepatitis B and 25 million of hepatitis C, all of whom could be potential blood donors and thereby transmit serious infections to recipients of blood. Dr Borra informed that WHO had made concerted efforts to assure the quality and safety of blood in developing countries. During the last three years, nearly 150 blood bank professionals from all SEAR countries have been trained as quality managers in various quality management training courses. One of the key elements recommended under quality management is the use of standard operating procedures (SOPs) which ensure consistency in processing and thus quality of blood. To overcome the existing inadequacies in capacity of the Member States to develop their own SOPs and to stimulate the blood centres to develop their own SOPs, WHO had been providing technical support and this workshop was one in the series of several activities already undertaken.

4. WORKSHOP METHODOLOGY

The workshop was designed 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.

Dr Tin Nyunt, Director, National Health Laboratories, Myanmar was elected as chairperson and Dr Panadda Silva, Director, Bureau of Laboratory Quality Standards, Thailand as the co-chairperson.

Dr Rajesh Bhatia, Regional Adviser – Blood Safety and Clinical Technology, WHO/SEARO introduced the concept of quality and the key elements of a quality system. He stated that quality was defined as meeting the standards or match between the expectation and realization of the customer who is the user of the laboratory results. The quality system referred to the organizational structure, procedures, processes and resources needed to implement quality. The key elements of the quality system are: organizational structure and management; standards, training, documentation and assessment. He also discussed the importance of quality in any blood transfusion service (BTS) with implications for the donor, patient, staff of BTS, community and the organization. Quality could be achieved through a systematic approach and by commitment of all the staff members of the BTS. Dr Bhatia also traced the history of QMP in SEARO and cited several activities conducted under this project during the past four years. Upgrading the skills of blood transfusion professionals was one of the key components of QMP. Through several training courses, more than 150 quality managers had been trained in SEAR countries. The National Blood Centre of Thailand, Bangkok was designated as the Regional Quality Centre and selected blood centres of SEAR have been included in a Regional External Quality Assessment Scheme (REQAS) for blood group serology and screening for transfusion transmissible infections.

Dr Panadda Silva, Director, Bureau of Laboratory Quality Standards, Thailand, discussed the concept and utility of a quality system in organizations including blood centres. She traced the evolution of quality system and the contributions made by Deming and Japanese workers after the Second World War.

A quality system was defined as the organizational structure, procedures, processes and resources needed to implement quality management. The quality system needed to be as comprehensive as required to meet the quality objectives of the organization. The quality system of an organization should be designed primarily to satisfy its internal managerial needs. It was broader than the requirements of a particular customer, who evaluated only the relevant part of the quality system, she added.

| Development of quality system | | |
|-------------------------------|---|-------------------------------------------------|
| Quality policy | ⇒ | Mission statement |
| Quality plan | ⇒ | Implementation of policy |
| Quality manual | ⇒ | Policy, plan and implementation of standards |
| Procedures | ⇒ | Development and application of policy |
| Work instructions | ⇒ | Methodology to carry out specific tasks |
| Training of staff | ⇒ | Implementation of quality system |
| Monitoring and evaluation | ⇒ | Assessment of quality and correction procedures |

Dr Pimol Chiewsilp, National Quality Manager of Thailand said that documentation was an important element of any quality system. She discussed the definition of documents, their types, utility and classification by ISO. The mechanism for controlling documents, which ensured availability of only those documents that needed to be currently in use with systematic removal of the previous documents was also deliberated upon. Standard operating procedures (SOPs) were critical sub-elements of the quality system and were essential to ensure that every procedure was undertaken in a standardized way and consistent results generated.

Dr Rajesh Bhatia described various steps in the writing and utilization of SOPs. This included validation, authorization, training of staff, controlling and reviewing SOPs on a regular basis and whenever there was a change in technology or reagents/kits were elaborated upon. The process of writing SOPs was explained to the participants. It involved identification of the need for SOPs for a particular procedure, designating the writer who is well versed with the procedure, review of performance of SOPs by a group of knowledgeable persons, validation of SOP by demonstrating and documenting that the SOP does what they are supposed to do, authorization of SOP by the top management and training of users in efficient use. The participants themselves wrote SOPs as group-work which was discussed in a plenary session.

Dr Panadda Silva presented the mechanism of validation of SOPs. It included setting up criteria for acceptance of results generated by SOPs,

formulating a protocol for detecting the criteria, undertaking testing using SOPs, comparing the observed results with the predefined criteria and, if matched, declaring that the SOPs had been validated. The concept and importance of validation of SOPs was also presented and the mechanism for validation discussed at length.

The participants validated two SOPs that were made available to them for the WHO Model SOP.

Dr Pimol Chiewsilp discussed the importance of document control which denoted availability and use of only those documents that were authorized at that point of time by the top management. In the absence of document control, unauthorized techniques and procedures may be followed leading to poor quality of the product and services.

The process and mechanism of documentation control were deliberated upon during the group work and discussed in a subsequent plenary session.

Every SOP needs to be reviewed at a defined frequency, usually not exceeding one year. The review was targeted to improve the quality as well as to incorporate the changes in techniques, reagents and methodology that may be necessary to improve the quality. A review may lead to revision. The revised SOPs would carry an appropriate revision number and undergo validation and authorization process as is done for a new SOP. The control of new/revised SOP also needed to be done as per the principles and practices of document control.

Two SOPs were provided to the participants for review and revision. This was achieved in discussions in group work and at the plenary session.

Dr Panadda Silva pointed out that the use of SOP required training of staff which could be provided formally or informally. The training needs should be understood and efficiently met. Training of staff for use of SOP was needed whenever a new SOP was introduced as well as whenever a SOP was revised. The competence of staff in using SOP should be assessed by the supervisor. The training plans and activities also needed to be documented.

Various activities pertaining to quality in any set up could be coordinated by a designated quality manager. The role, responsibilities and

authority of a quality manager was elaborated upon by Dr Pimol Chiewsilp. A quality manager should ensure that processes needed for quality system were established, implemented and maintained. He acted as an interface between the technical units and top management and reported to the higher authorities on the performance of quality system and needs for improvements, if any. The quality manager also ensured the promotion of awareness of customer requirements throughout the organization. He was also responsible for maintaining various quality documents and providing assistance to the technical units in developing their documents. The review and revision of the documents, approval of the documents and archival activities were also undertaken by the quality manager.

Dr Rajesh Bhatia briefed the participants on the need for planning and the method of development of an action plan with specific activities. Various parameters that needed to be considered and included in the action plan were: activity, time-frame, type of activity, the person designated to undertake the same and the resources required to accomplish the activity. The participants developed generic action plans in group work and presented these in a plenary session.

Several issues that needed to be considered by the participants in implementation of quality system in their own settings were thoroughly discussed in a plenary session. The technical problems raised by the participants were addressed by the faculty. Extensive discussions led to the formulation of the recommendations described hereunder.

Valedictory session

The valedictory session was chaired by Dr Tin Nyunt wherein participants expressed their gratitude to WHO and the Government of Myanmar for arranging the workshop. They appreciated the QMP initiative of WHO and enumerated the benefits that had accrued to them by attending this training course. Dr Tin Nyunt 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. Dr Rajesh Bhatia assured them of all possible technical support from WHO in achieving their goals.

5. RECOMMENDATIONS

5.1 For WHO

WHO should:

- (1) assist in the implementation of quality systems at the country and regional levels especially development of SOPs through advocacy, support, organization of training courses and provide technical support to Member Countries in implementing these.
- (2) undertake on-site reviews, using regionally developed guidelines, on the progress made by countries, especially the institutes from where blood bank professionals have been trained through WHO activities with the help of selected regional experts.
- (3) continue to support the Regional Quality Training Centre which should continue to act as a resource centre for providing technical assistance to the participants of this, and other similar courses.

5.2 For Member States

- (1) The Ministry of Health should provide the support and infrastructure to implement quality systems in Blood Transfusion Services.
- (2) Training courses on SOPs should be organized at the country level by trained personnel.

5.3 For Participants

- (1) A plan of action in keeping with the priority needs of the participants' centres may be developed and discussed with the top management. 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 approach the Regional Quality Centre and also seek its technical support to overcome the problems being encountered in establishing quality management and writing as well as implementing SOPs.
- (3) The participants should send a quarterly report to SEARO/WHO on the progress made and technical support required to accomplish the implementation of SOPs.

Annex 1

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Annex 2

PROGRAMME

Day 1, 14 September 2004

| | | |
|---------------|--------------------------------------------------------------------------|------------------|
| 0830-0930 hrs | Registration | |
| 0930-1000 hrs | Inauguration | |
| 1015-1100 hrs | Introduction to Quality and its importance in blood transfusion services | Dr Rajesh Bhatia |
| 1100-1145 hrs | Quality system | Dr Panadda |
| 1145-1230 hrs | Documentation in quality system | Dr Pimol |
| 1230-1300 hrs | Model SOP: genesis | Dr Bhatia |
| 1400-1500 hrs | Writing standard operating procedure | Dr Rajesh Bhatia |
| 1500-1700 hrs | Writing an SOP for making a cup of coffee | Group work 1 |
| | Presentation of group work | All facilitators |

Day 2, 15 September 2004

| | | |
|---------------|-------------------------------------------|------------------|
| 0900-1000 hrs | Validation of SOP | Dr Panadda |
| 1000-1300 hrs | Validation of SOP written in Group Work 1 | Group work 2 |
| | Presentation of group work | All facilitators |
| 1400-1445 hrs | Document control | Dr Pimol |
| 1500-1700 hrs | Understanding document control systems | Group work 3 |
| | Presentation of group work | All facilitators |

Day 3, 16 September 2004

| | | |
|---------------|----------------------------------|------------------|
| 0900-0930 hrs | Revision of SOP | Dr Rajesh Bhatia |
| 0930-1100 hrs | Review and revision of SOP | Group work 3 |
| | Presentation | |
| 1115-1200 hrs | Training of staff for use of SOP | Dr Panadda |

| | | |
|---------------|--------------------------------------------------------------------|----------|
| 1200-1300 hrs | Role of Quality Managers in development, validation and use of SOP | Dr Pimol |
| 1400-1700 hrs | Development, validation and control of a BTS specific SOP | Group 4 |

Day 4, 17 September 2004

| | | |
|---------------|--------------------------------------------------------------------|------------------|
| 0900-1100 hrs | Presentation of Group 4 | All facilitators |
| 1115-1200 hrs | Development of PoA for SOP development in respective blood centres | Dr Bhatia |
| 1200-1300 hrs | Open session | All facilitators |
| 1400-1500 hrs | Presentation of PoA | |
| 1515-1630 hrs | Concluding session | |