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

Report of a Regional Workshop
Bangkok, Thailand, 26 March – 13 April 2001

WHO Project : ICP BCT 001

World Health Organization
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Contents

1. INTRODUCTION

The first Regional Workshop on Quality Management Training (QMT) in Blood Transfusion Services (BTS) was organized at Bangkok, Thailand, from 26 March to 13 April 2001. Twenty two participants representing all the ten Member countries of the South-east Asia Region (SEAR) of WHO attended this workshop. Staff from WHO Headquarters as well as from the Regional Office along with experts from South Africa, the United Kingdom, India and Thailand facilitated the workshop. The List of Participants is at Annex 1 and the Programme of Work at Annex 2.

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 and will be implemented in all Member countries. Under QMP, capacity building through quality management training courses is an important activity. The Regional Office of WHO organized the first Regional Workshop on QMT to create a core group of quality managers for BTS in all Member countries who will also act as trainers in their respective countries.

2. OBJECTIVES

The following were the objectives of the workshop:

(1) To ascertain the status of quality management in blood transfusion services in the Member countries of SEAR;

(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 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

The workshop was inaugurated by Dr Mongkol Chetthakul, Senior Officer, Ministry of Public Health, Government of Thailand. He 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 was reflected in the address of the Regional Director, that was read out at this function by Dr Sudarshan Kumari, Regional Adviser, BCT, South-East Asia Region, WHO. The adoption of the theme of safe blood for World Health Day 2000 with the slogan *'Safe blood starts with me: blood saves lives'* also demonstrated the priority accorded by WHO to this subject. Dr Neelam Dhingra-Kumar, Blood Safety Team, WHO, headquarters presented the objectives and mechanics of the course. Earlier the participants were welcomed by Mr Phan Wannamethee, Secretary-General, Thai Red Cross Society. Dr Srivilai, Tanprasert Director, National Blood Centre, Thai Red Cross Society and local organizer for the workshop proposed a vote of thanks.

Dr Neelam Dhingra-Kumar outlined the quality management project that WHO has initiated recently. She described the various components of QMP and the importance of quality management training (QMT) in improving overall quality in blood transfusion services. She also detailed various activities that were undertaken during the past one year by WHO to develop a curriculum and learning material for the QMT courses. Dr Dhingra emphasized that all efforts needed to be directed to sustain the programme so that quality was integrated into all the activities of BTS.

4. WORKSHOP

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 and 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 7 (35%) of the trainees could give more than 50% correct answers to all the questions.

4.2 Status Report on Quality in BTS

The participants were sent a questionnaire before they left their respective countries. They were advised to fill up these in consultation with their colleagues and superiors. A wide variation in quality was seen between the various countries. Many countries reported some form of quality control within the laboratories but few had a fully or even partially implemented formal quality system that covered all major aspects of a BTS. A summary of salient features of quality in their BTS is given at Annex 3.

4.3 Mechanics of Training

The main aim of the workshop 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 group 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 National Blood Centre, Bangkok, to see the quality management system in operation in BTS. They also visited a mobile blood donation session organized by the National Blood Centre. Both these visits were followed by extensive discussions on quality aspects of visits.

Handouts of all the presentations were provided to the trainees as part of their work book. In addition, they were given a list of references on quality. They were also requested to indicate their requirements of WHO publications on BTS which will be sent to them in due course of time by WHO.

4.4 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 will 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 will be in a better position to advocate the need for quality in BTS, handle organizational constraints and optimally utilize the resources that are 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 that were 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 emphasised. 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 were discussed. Safety in BTS, including environmental factors were discussed. A mid-course evaluation of participants through a 20 open-ended questions was also undertaken.

Third week

The week concentrated on applying quality to the main BTS activities. All aspects of the 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 immuno-haematology and component preparation, documentation of activities, process flow and related critical points, and monitoring and evaluation in the immuno-haematology 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 with a template on generating a plan of action. Where quality systems already existed, some problems were encountered on exactly what the participants should plan for but the participants 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.

4.5 Post-course Assessment of the Participants

A comprehensive evaluation of the training course was completed on the last day. The results revealed a 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 95% from 35% as was observed in precourse-assessment.

4.6 Hand outs Provided to the Participants

All the participants were provided with handouts for the presentation. Additional notes were also circulated by some of the facilitators. A list of BTS publications of WHO was circulated to participants who desired that they be sent all the documents that have been published by WHO and are available gratis. A few participants requested supply of selected priced publications of WHO.

4.7 Evaluation of Course by the Facilitators

The facilitators also reviewed the course. They expressed their satisfaction with the duration of the course, curriculum, quality of the teaching material provided by WHO and the response and involvement of participants in various activities undertaken during the workshop. However, some additional information was provided by most of the facilitators to fill in the gaps. They also volunteered their technical services for assisting in the implementation of QMP.

4.8 Evaluation of Course by the Coordinator

The contents and duration of the course were adequate. The teaching material was usually appropriate and the programme of work logical. Field visits to mobile and static units were educative. A second field visit to the blood centre may be incorporated so that a functional quality system can be seen by the participants.

The implementation of the quality system requires sustained efforts by participants, country programme managers and WHO. A mechanism with indicators should be developed for monitoring and evaluation of QMP in Member countries.

4.9 Valedictory Session

The valedictory session was chaired by Dr Sudarshan Kumari, Regional Adviser for Blood safety and Clinical Technology wherein participants expressed their gratitude to WHO and the National Blood Centre, Bangkok, for arranging this workshop. They appreciated the QMP initiative of WHO and enumerated the benefits that had accrued to them by attending this workshop. Dr Kumari 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 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) WHO should provide technical support to organize regional EQAS in blood group serology and anti-HIV antibody detection for participants of this Regional QMT course.

(4) WHO should identify and support a Regional Quality Training Centre which should follow-up the progress made by the participants as well as act as a resource center 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 plan of action. Adequate budget should be earmarked for blood safety.

(2) QMT courses should be organized at country levels 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 OF WORK

Week/Day/time	Activity	Principal speaker
Week 1/ Day 1 **26 March 2001**		
0830-0930	Registration	
0930-1000	Inauguration	
1030-1100	Pre-course evaluation	
1100-1130	Introduction to Quality Management Project (QMP)	Dr Neelam Dhingra-Kumar
	Objectives of Quality Management Training (QMT)	
1130-1230	Need for Quality: Quality terminology	Mr Neil Rosin
1230-1300	**Group work 1** Fitness for purpose	Mr Neil Rosin + Mike Clark Drs Kumari, Dhingra, Bhatia
1400-1530	Quality terminology (contd.)	Mr Neil Rosin
1545-1730	Quality terminology (discussion contd)	Participants + Mr Mike Clark Drs Kumari, Dhingra, Bhatia
Week 1/ Day 2 **27 March 2001**		
0830-0900	Review and discussion	
0900-1000	Presentation of expectations from course by the participants: 5 minutes each country	Participants Chairperson: Dr S. Kumari
1000-1045	Quality system	Mr Neil Rosin
1100-1230	**Group work 2** Development of quality policy	Participants + Mr Neil Rosin Mr M Clark Drs Kumari, Dhingra, Bhatia
1230-1300	Organizational structure and organizational chart/ organogram	Mr Mike Clark

Week/Day/time	Activity	Principal speaker
1400-1530	**Group work 3** Development of organograms	Participants + Mr Mike Clark Mr Rosin Drs Kumari, Dhingra, Bhatia
1545-1615	Job description	Mr Mike Clark
1615-1730	**Group work 4** Write job description of quality officer in a biscuit factory	Participants + Mr Neil Rosin Mr Mike Clark Drs Kumari, Dhingra,Bhatia
Week 1/ Day 3 28 March 2001		
0830-0900	Review and discussion	
0900-1000	Elements of quality system	Mr Neil Rosin
1000-1100	Flow chart as a tool for mapping processes and identifying critical control points (CCP)	Mr Neil Rosin
1115-1300	**Group work 5** Development of a flow chart	Participants + Mr Neil Rosin Mr M Clark Drs Kumari, Dhingra, Bhatia
1400-1430	Quality planning	Mr Mike Clark
1430-1600	**Group work 6** Preparation of quality plan	Participants + Mr Rosin + Mr Clark + Drs Kumari, Dhingra, Bhatia
1600-1730	Visit to BTC to have an overview of a working quality system	Dr Pimol
Week 1/ Day 4 29 March 2001		
0830-0900	Review and discussion	
0900-0930	Documentation : Types, necessity and importance	Mr Neil Rosin
0930-1030	How to write SOP/work instructions	Mr Neil Rosin
1045-1300	**Group work 7** writing a SOP on making a cup of Nescafe	Participants + Mr Neil Rosin Mr M Clark Drs Kumari, Dhingra,Bhatia
1400-1430	Validation of SOP	Mr Neil Rosin
1430-1515	**Group work 8** Validation of SOP	Participants + Mr Neil Rosin Mr M Clark Drs Kumari, Dhingra, Bhatia
1515-1545	Document control	Mr Neil Rosin

Week/Day/time	Activity	Principal speaker
1545-1700	**Group Work 9**: SOP Revision	Participants + Mr Neil Rosin Mr Clark Drs Kumari, Dhingra,Bhatia
Week 1/ Day 5 30 March 2001		
0830-0900	Review and discussion	
0900-0930	Error management: Reporting, analysing and corrective / preventive action	Mr Mike Clark
0930-1100	**Group work 10** Error management: Reporting, analysing and corrective / preventive action	Participants + Mr Mike Clark Mr N Rosin Drs Kumari, Dhingra, Bhatia
1115-1145	Quality policy for BTS, organogram and job description	Mr Mike Clark
1145-1300	**Group work 11** Quality policy for BTS, organogram and job description	Participants
1400-1445	Introduction to quality audits	Mr Mike Clark
1445-1530	**Group work 12** Role play on process of Audit	Participants + Mr Mike Clark Mr N Rosin Drs Kumari, Dhingra,Bhatia
1545-1730	**Group work 13** Identifying non-conformities in audit scenario Documentation of audit	Participants + Mr Mike Clark Mr Rosin Drs Kumari, Dhingra,Bhatia
Week 2/ Day 1		
0830-0900	Review and discussion	
0900-1015	GMP as essential component of BTS and consequences of failure of good manufacturing practices (GMP) in BTS	Mr Mike Clark
1015-1130	**Group work 14** GMP Role Play	Mr Neil Rosin Mr Clark & Dr Bhatia
1115-1300	Identification of critical control points	Mr Neil Rosin
1400-1430	Principles of validation	Mr Mike Clark

Week/Day/time	Activity	Principal speaker
1430-1600	**Group work 15** (in two groups) Prepare validation plan for an equipment (Group1) and reagent (Group 2)	Participants
1615-1700	**Group work 16** Prepare validation plan for a process pr software	Participants + Mr Mike Clark Mr Rosin, Dr Bhatia
Week 2/ Day 2: 3 April 2001		
0830-0900	Review and discussion	
0900-1115	Role of training in quality system Training: needs and plans Documentation of training Monitoring and evaluation of training	Mr Mike Clark
1130-1300	**Group work 17** Development of an effective training plan in BTS	Participants + Mr Mike Clark Mr Rosin, Dr Bhatia
1400-1515	Biosafety in BTC – I Hygiene, prevention of infection and contamination of environment	Mr Neil Rosin
1530-1630	Biosafety in BTC - II Disposal of waste	Mr Neil Rosin
1630-1730	**Group work 18** Identify safety issues and risk management	Participants + Mr Neil Rosin Mr Clark, Dr Bhatia
Week 2/ Day 3: 4 April 2001		
0830-0915	Inventory management of perishable and non-perishable items in a blood centre	Mr Neil Rosin
0915-1030	**Group work 19** Inventory/stock preparation	Participants + Mr Neil Rosin Mr Clark, Dr Bhatia
1030-1100	Quality monitoring tools	Mr Mike Clark
1100-1200	Monitoring and performance of assays, blood donations, blood products	Mr Mike Clark
1200-1300	Mid-term review	Mr Neil Rosin et al

Week/Day/time	Activity	Principal speaker
1400-1445	**Group work 20** Analysis of data from BTS/lab and identify the trends	Mr Mike Clark + Participants Mr Rosin, Dr Bhatia
1445-1530	Procurement of equipment	Mr RS Khandpur
1530-1615	Maintenance and calibration of equipment	Mr RS Khandpur
1615-1730	**Group work 21** Identify key maintenance and calibration needs of equipment and prepare an appropriate schedule	Participants Mr Khandpur Dr Bhatia
Week 2/ Day 4 5 April 2001		
0830-0900	Review and discussion	
0900-0945	Costing of activities in BTS - Principles and benefits, WHO model	Dr Zarin Bharucha
0945-1030	Cost of Quality and Additional costs of poor quality	Dr RN Makroo
1045-1215	**Group work 22** (in two groups) Calculation of testing cost (group 1) Calculation of cost of donor recruitment (group 2)	Participants + Drs Bharucha, Bhatia and Makroo
1215-1300	Review of Group work 22	Participants + Drs Bharucha Bhatia and Makroo
1400-1445	Quality in donor recruitment and selection	Dr RN Makroo
1445-1530	Collection of blood and care of donors	Dr RN Makroo
1545-1615	Donor satisfaction and feedback	Dr Zarin Bharucha
1615-1645	Quality records in donor clinics	Dr RN Makroo
1645-1730	**Group work 23** Preparation of a check list of CCP for field visit	Participants+ Dr RN Makroo Drs Bharucha and Bhatia
Week 2/ Day 5 6 April 2001		
0900-1500	Visit to mobile blood session and blood centre	Dr Pimol Dr Zarin Bharucha Dr RN Makroo
1515-1700	**Group work 24** Discussion on post visit donor issues	Participants Dr Zarin Bharucha Dr RN Makroo, Dr Bhatia

Week/Day/time	Activity	Principal speaker
Week 3/ Day 1 **9 April 2001**		
0830-0900	Review and discussion	
0900-0945	Quality in BTS laboratories and essential quality elements in Immunohaematology	Dr Zarin Bharucha
0945-1015	Quality in BTS laboratories and essential quality elements in Transfusion Transmitted Infections (TTI)	Dr V Ravi
1015-1045	Run validation	Dr V Ravi
1100-1200	**Group work 25** Essential quality elements in immunohaematology (Group 1) and TTI (Group 2)	Participants Dr Bharucha Dr Ravi, Dr Bhatia
1200-1300	Selection of test kits/reagents, blood bags and other disposables	Dr Bharucha
1400-1500	**Group work 26** Choice of test kits and reagents	Participants Dr Bharucha Dr Ravi, Dr Bhatia
1500-1530	Documentation in laboratories	Dr Z Bharucha
1600-1700	External quality assessment schemes Importance, organization, participation	Dr R Bhatia and Dr R Soisangwan
Week 3/ Day 2 **10 April 2001**		
0830-0900	Review and discussion	
0900-1000	Quality in blood component production GMP Processes and procedures Documentation Maintenance and calibration Labelling	Dr VL Ray
1000-1100	**Group work 27** Flowchart of blood component production process	Participants Dr VL Ray Dr Bharucha, Dr Bhatia
1115-1145	Documentation in blood component production	Dr VL Ray
1145-1230	Monitoring and evaluation of blood component production	Dr Zarin Bharucha
1230-1300	Quarantine and release	Dr VL Ray

Week/Day/time	Activity	Principal speaker
1400-1500	**Group work 28** Develop a plan for monitoring and evaluation of blood components	Participants Dr Zarin Bharucha Dr VL Ray, Dr Bhatia
1500-1530	Storage, transportation and distribution of blood and blood components	Dr VL Ray
1545-1615	Blood stock management	Dr VL Ray
1615-1715	**Group work 29** Blood stock management	Participants + Dr Zarin Bharucha Dr VL Ray, Dr Bhatia
Week3/ Day 3 11 April 2001		
0830-0900	Review and discussion	
0900-0945	Applying quality principles to clinical interface	Dr Zarin Bharucha
0945-1015	Essential information required on a blood request form	Dr VL Ray
1015-1045	Quality at bedside	Dr Zarin Bharucha
1100-1215	**Group work 30** Development of an appropriate and effective blood request form	Participants + Dr Zarin Bharucha Dr VL Ray Dr Kumari, Dr Bhatia
1215-1300	National policy and guidelines for clinical use of blood	Dr Zarin Bharucha
1400-1500	**Group work 31** Monitoring and evaluation of the use of blood	Participants Dr Zarin Bharucha Dr VL Ray Dr Kumari, Dr Bhatia
1515-1600	Documentation and transfusion records	Dr VL Ray
1600-1630	Haemovigilance	Dr Zarin Bharucha
1630-1730	**Group work 32** Quality issues in post transfusion monitoring	Participants Dr Zarin Bharucha Dr VL Ray, Dr Kumari, Dr Bhatia
Week3/ Day 4 12 April 2001		
0830-0915	Development of action plan	Dr S Kumari

Week/Day/time	Activity	Principal speaker
0900-1000	Contingency plan in BTS	Dr VL Ray
1115-1300	**Group work 34** Development of action plan for respective BTS	Participants Chairperson: Dr S Kumari
1400-1700	**Group work 35** Presentation of individual blood centre plans	Participants Chairperson: Dr S Kumari
Week 3/ Day 5 13 April 2001		
0900-1000	**Round Table Discussion** Discussion on respective plans	Participants Dr S Kumari
1015-1115	Post-course assessment	Dr S Kumari, Dr Rajesh Bhatia
1115-1300	Course evaluation by participants	Dr S Kumari, Dr Rajesh Bhatia
1400-1500	Open discussions	
1500-1600	Closing and valedictory session	Dr S Kumari

Annex 3

STATUS OF BTS ACTIVITIES IN DIFFERENT INSTITUTIONS IN THE COUNTRIES OF SOUTH-EAST ASIA

Feature	BAN		BHU	IND			INO	MAV		MMR	NEP	SRL	THA	
	1	2		1	2	3		1	2				1	2
Units in thousands collected/year	6	10	4	7	15	2.6	210	2.8	2.3	24	60	50	380	7.2
Components prepared	-	-	+	+	+	-	+	-	+	+	+	+	+	-
% VNRD	3	10	65	100	10	18	85	98	98	60	40	83	100	100
Quality manager	-	-	-	-	-	-	-	-	+	-	-	-	+	+
Organogram	+	+	V	-	+	-	+	-	+	-	+	+	+	+
Job description	v	v	V	v	-	+	+	+	+	+	+	v	+	+
Documented quality policy	-	-	+	+	+	-	-	-	-	-	+	+	+	+
Quality manual	-	-	V	+	+	-	-	-	-	-	-	-	+	+
SOPs	-	-	+	v	+	V	+	-	-	-	V	v	+	+
Training policy/strategy	+	+	+	+	+	-	+	-	V	-	+	+	+	+
SOP for training	+	+	+	+	+	V	+	-	+	-	-	+	+	+
System of stock control	+	+	+	+	+	+	+	+	+	-	+	V	+	+
Policy on audit	-	-	-	+	+	-	-	-	-	-	+	-	+	+
Trained auditors	-	-	-	-	+	-	-	-	-	-	-	-	+	+
Critical equipment listed	+	+	+	+	+	+	-	+	+	+	+	V	+	+

Feature	BAN		BHU	IND			INO	MAV		MMR	NEP	SRL	THA	
	1	2		1	2	3		1	2				1	2
Equipment calibrated	v	v	V	+	+	V	-	+	+	+	+	V	+	+
Equip maintained	v	v	V	+	+	+	v	-	V	+	+	V	+	+
Policy on safety procedures	-	-	V	+	-	V	+	+	+	+	-	V	+	+
SOP for safety	-	-	V	+	+	+	+	+	V	+	+	V	+	+
Policy on error management	+	+	+	+	+	+	+	+	V	+	+	V	+	+
Separate donor management deptt	-	-	-	+	+	-	+	-	-	-	+	+	+	-
Donor questionnaire	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Data for screening analyzed	-	-	+	+	+	+	+	+	V	+	+	+	+	+
Policy on screening for TTI	-	-	+	+	+	+	+	+	+	+	+	+	+	+
SOP for TTI	-	-	+	+	+	+	+	+	V	+	-	+	+	+
SOP for IH	v	v	+	+	+	+	+	+	v	+	-	+	+	+
Test run validation	-	-	-	-	+	V	-	-	-	-	-	V	+	V
EQAS participate	-	-	-	-	-	-	+	-	+	+	+	+	+	+
Specifications of products made	-	-	+	+	+	-	+	-	-	-	+	V	+	+
SOP for production	-	-	-	+	+	-	+	-	-	-	-	+	+	-
Record of quality monitoring	-	-	-	-	+	-	+	-	-	-	-	-	+	-
Guidelines for clinical use	-	-	v	-	-	v	-	+	-	+	-	+	+	-
Haemovigilance	-	-	-	-	+	-	-	-	-	-	-	v	+	-

v: variable-