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Distribution: General

Strengthening of Quality Assurance in HIV and Viral Hepatitis in Blood Banks

*Report of a Regional Consultation
Bangkok, Thailand, 22-25 July 2003*

WHO Project: ICP BCT 001



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1. INTRODUCTION

WHO has identified blood safety as one of the seven priority areas. The theme of the World Health Day 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, but its quality is also considered uncertain. Safe blood also indicates its freedom from micro-organisms especially HIV, hepatitis B virus and hepatitis C virus.

The HIV/AIDS pandemic has focused particular attention on the importance of transfusion transmissible infections. WHO estimates that even today, up to 13 million units of blood collected globally are not screened for HIV, hepatitis B and hepatitis C viruses. A majority of such blood units are in the developing countries where the prevalence of these dreadful infections is high or growing at an alarming rate. In the SEA Region alone, six million people are infected with HIV, 25 million with hepatitis C virus and 80 million with hepatitis B virus. All of them act as potential reservoirs of these infections unless the quality of screening is assured.

During the current year itself, a situation analysis of quality assurance for screening of HIV and viral hepatitis in the SEA Region was undertaken using a common predesigned proforma. On the basis of information gathered, salient problems being encountered were identified. The consultants who undertook this analysis also suggested recommendations to be discussed in this consultation. To strengthen quality of screening for these blood-borne microorganisms in Member Countries of the SEA Region, a regional consultation was convened at Bangkok from 22 to 25 July 2003.

The detailed programme of the Consultation is placed as Annex 1. Twenty-three participants from all Member Countries of the SEA Region, except Democratic Republic of Korea and Timor-Leste (Annex 2) attended this consultation. Six experts from Thailand and United Kingdom facilitated the workshop.

Dr John Parry, Deputy Director, Agency for Health Protection, United Kingdom was elected as the Chairperson and Dr Rachanee O'Charoen, Director of National Blood Centre, Bangkok, Thailand as the Co-chairperson of the Consultation. Dr Yunyun, National Blood Transfusion Centre, Jakarta, Indonesia was elected rapporteur.

2. OBJECTIVES

The objectives of the consultation were as follows:

- (1) To review and discuss the status of quality assurance in screening of HIV and viral hepatitis in blood banks of all countries of the SEA Region and identify major constraints;
- (2) To suggest various tools at regional and national levels that could be adopted to strengthen quality assurance;
- (3) To orient national programme managers to the concepts and implementation of quality assurance through field visits to central and intermediate blood banks in Thailand, and
- (4) To develop an effective follow-up mechanism for quality assurance in screening of HIV and viral hepatitis in blood banks of all countries of the SEA Region.

3. INAUGURAL SESSION

Mr Phan Wannamethee, Secretary-General of the Thai Red Cross Society, welcomed the participants and the facilitators of the consultation. He assured the participants that they would benefit immensely from the lectures of various experts as well as visit to the National Blood Centre which will help them in assuring safety of blood in their own countries.

Dr S Kumari, Regional Adviser, Blood Safety and Clinical Technology, WHO South East Asia Regional Office described the background for the conduct of this consultation, its objectives and expected outcome of this congregation of scientists from different parts of the SEA Region.

Mr Richard Kalina from WR Thailand Office read out the address of Dr Uton Muchtar Rafei, Regional Director, WHO/SEARO, New Delhi. Dr Uton said that blood transfusion services had become an integral part of the health care system and were bound to play a greater role in health care due to

increased use of blood, because of lifestyle diseases and modern technological advancements in the management of various diseases. It was an essential function of the health services to provide safe blood to all those who need it in an efficient, coordinated and cost-effective manner. While developed countries had established quality systems that ensure adequacy, safety and quality of blood and blood products or blood components, developing countries were yet to strengthen their blood transfusion services to fulfil these criteria.

Dr Uton added that the safety of blood had assumed greater importance and relevance in developing countries where HIV, hepatitis B and hepatitis C were becoming diseases of greater public health importance and the HIV/AIDS pandemic was growing at an alarming pace. Blood transfusion is the most efficient mode of transmission of HIV and viruses of hepatitis B and hepatitis C. Globally, 5-10% of transmission of HIV was estimated to be through transfusion of blood. Meticulous screening of blood with reliable kits and reagents would prevent such infections. In spite of tremendous advances in microbiology, the quality system in blood banks has not reached optimal level. Various issues that require strengthening pertain to management, standards, training, documentation and assessment. The present Consultation was organized to improve the quality of blood testing, which is very critical for ensuring safety of blood. All countries would benefit through sharing of experiences from developed countries and also from within the Region. This would help to update their skills and knowledge, and their application in the respective work places, which would go a long way in ensuring blood safety.

4. PROCEEDINGS

4.1 Review of Status

Global and Regional Perspectives

The global scenario was presented by Dr Gaby Vercautern, WHO/HQ, Geneva. She highlighted the disparities in the availability and safety of blood and quality systems between the blood banks from countries with low HDI (as most countries in the SEA Region are) and high HDI (including most developed countries). Of the 80 million units of blood that is collected globally, 98% is screened for HIV and hepatitis B and 97.3% for hepatitis C. Most of the blood that is not screened is from countries with low HDI. She also emphasized the need for assuring quality and improving collection of blood from voluntary non-remunerative blood donors.

Dr S Kumari elaborated upon the importance given to blood safety at the global and regional levels. Blood safety was the theme of World Health Day 2000 and this acted as an advocacy tool and stimulated developing countries to strengthen BTS and quality. The countries of the SEA Region need 15 million units of blood, of which only 7 million is collected annually at present. Of this 62% is from voluntary non-remunerative donors. Apart from the shortage of blood in the SEA Region, quality of screening for infectious markers was also a cause of concern. Though almost 100% collected blood is being screened for HIV and hepatitis B and the number of blood units that are being screened for hepatitis C is also increasing, she expressed concern on the quality of screening for infectious markers which was assessed by WHO STCs in various blood centres recently. She also briefed the participants about the various activities undertaken by WHO in strengthening quality. These included implementation of a Quality Management Project of WHO which trained 119 blood bank staff as quality managers, 16 of which were provided access to an external quality assessment scheme through Thai EQAS on blood group serology and TTI. WHO is also providing technical support on quality issues through the Regional Quality Centre located at the National Blood Centre, Bangkok.

Review of current status in the SEA Region

The status of quality system in screening for HIV and viral hepatitis in the SEA Region is summarized in the Table 1. Screening of blood for viral TTIs is almost universal with the exception of hepatitis C. This is also because of the recent availability of HCV kits. It is expected that all countries will achieve 100% screening of HCV in the near future. Prevalence rates for HIV, HBV and HCV in donors varies from 0-0.9 %, 1.42-7.0 % and 0.14 – 2.5 % respectively. The WHO strategy which clearly defines use of various tests for screening of blood, surveillance, and diagnosis of HIV is not followed in many countries in the right spirit. Quality policy, quality audit and quality manuals are operational only in Thailand. Training of various categories of staff of BTS on quality issues is on *ad hoc* basis and lacks any planning or review mechanism. Equipment is available in almost all blood banks; however, their validation, calibration and maintenance are areas which require strengthening. Access to quality screening kits and infrastructure for evaluation of diagnostic devices is pretty weak and are crucial areas requiring attention and immediate action. The concept of a good documentation system is in its infancy. Development of SOP, their validation and use require greater advocacy and efforts. EQAS are in operation in India, Indonesia, Maldives, Myanmar and Thailand with only Thailand having a comprehensive national EQAS.

Table 1: Status of Quality in TTI screening in the countries of the SEA Region

Country(No of blood banks)	BAN (97)	BHU (2)	AP* (173)	INO (158)	MAV* (2)	MMR (363/38)	NEP (51)	SRL (64)	THA (159)
Number Of units collected per year	170,000	6,000	279,000	1,028,000	3,000	180,000	60,000	150,000	1.3 mil
National standard	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes
Quality policy	Nil	No	No	No	No	No	No	No	Yes
Quality manual	Nil	No	No	No	No	No	No	No	Yes
Training plans and need assessment	Nil	No	No	Yes	No	No	No	Yes	Yes
Training review	Nil	No	No	No	No	No	No	No	NA
Training courses	Nil	Ad-hoc	Yes	Yes	Ad-hoc	Yes	Ad-hoc	Yes	Yes
WHO strategy for screening HIV	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
Inventory management	NA	Yes	No	No	No	Partly	No	No	Yes
Quality audit	Nil	No	No	No	No	No	No	No	Yes
Availability of equipment	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Validation of equipment	No	Yes	No	No	Yes	No	No	No	Yes
Maintenance of equipment	Weak	Weak	Weak	Weak	Yes	Weak	Weak	Weak	Yes
SOP for safety	No	No	No	No	No	No	No	No	Yes
SOP for error management	No	No	No	No	No	No	No	No	Yes
SOP for screening	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
% screened for HIV	100	100	100	100	100	100	100	100	100
% screened for HBV	100	100	100	100	100	85	100	100	100
%screened for HCV	100	100	100	70	100	15	100	26	100
Prevalence of HIV in donors	0.002	0	0.90	0.091	0	0.6	0.187	0.0012	0.16
Prevalence of HBV in donors	1.42	2	1.67	2.0	2.64	7.0	0.89	0.075	1.51
Prevalence of HCV in donors	0.144	0.02	0.76	0.08	1.10	2.5	0.52	NA	0.32
Validation of test runs	No	No	No	No	No	No	No	No	Yes
Ever used expired kits	NA	No	No	NA	No	No	No	No	No
Participation in EQAS	No	Yes	Yes	Yes(35%)	Yes	Central	Central	Central	Yes

*Institution/area specific; BAN: Bangladesh, BHU:Bhutan; IND:India; INO:Indonesia; MAV:Maldives; MMR:Myanmar; NEP:Nepal; SRL:Sri Lanka; THA:Thailand; NA: Not available

The WHO strategy for screening of donated blood for HIV has been in existence for the last 15 years. Any unit of donated blood that is reactive to one test needs to be rejected. Some countries confirm the diagnosis of the presence of HIV antibody by use of other tests. The results are communicated to the donors even when adequate infrastructure for counselling and management of the case are not available. The status of strategies is shown in Table 2 below.

Table 2: Status of implementation of WHO strategy

Country	WHO strategy 1	VCTC	Reference to national Centre	System for counselling/ management
Bangladesh	+	-	+	-
Bhutan	+	-	-	-
India	+	+	+	+
Indonesia	+	+	+	-
Maldives	+	-	+	+
Myanmar	+	-	+	-
Nepal	+	+	+	-
Sri Lanka	+	+	+	-
Thailand	+	+	+	+

Orientation on Tools for Implementation of Quality System

Dr Rajesh Bhatia STP/BCT/SEARO gave an overview of the concept and utility of quality and its implementation in a systematic way. The five key elements of a quality system comprising organizational management, standards, training, documentation and assessment were introduced. Various tools for internal and external assessment of the quality system including quality audit and EQAS and IQAS were also discussed.

Dr Gaby Vercautern, WHO/HQ, Geneva described the testing strategies for TTI for HIV advocated by WHO for the last 15 years and brought out the anomalies in its use in some Member Countries of the SEA Region, as was discussed by country representatives in their respective presentations on Day 1 of the consultation. The objective of testing for HIV is to prevent the transmission of contaminated blood, and this requires a highly sensitive screening test, so that blood infected with HIV is not transfused. WHO is

currently in the process of developing strategies for use of laboratory tests for screening, surveillance and diagnosis of hepatitis B and hepatitis C which would be made available to the member Countries shortly. The utility of these kits shall be dependent upon the quality of these kits. Ideally, countries should have their own infrastructure to regulate the quality of kits, as in India. Other countries take the help of international agencies such as WHO. WHO has a scheme of procurement of quality kits and is supplying these to desirous countries. Currently around 11% of the kits purchased by WHO are supplied to countries of the Region. Dr Gaby also provided the participants with the details of the manufacturers and the cost of the kits etc for the bulk purchase of kits during 2003.

Dr Christine Burgess, WHO/HQ discussed the WHO evaluation scheme for diagnostic test kits of HIV, HBV and HCV. HIV evaluation on serum, whole blood, urine and saliva panels is being undertaken at Institute of Tropical Medicine, Belgium, while HBV and HCV are tested at the Health Protection Agency, UK.

Panels include seroconversion panels obtained commercially as well as those obtained from various countries. Somehow the number of serum samples of the countries of the SEA Region was limited and efforts are being made to augment same. The WHO global procurement of kits is based upon the results of this evaluation.

Dr John Parry from the Health Protection Agency, UK gave a history of the evaluation of kits in his country and changes taking place for the grant of CE certification in Europe that would guarantee that the products meet the standards. Evaluation is a part of the licensing process and focuses on the final product. It is a means of assessing the quality and performance characteristics of an assay to ensure fitness for the purpose.

Dr Rachanee O'Charoen, Director, National Blood Centre, Bangkok briefed about the procurement of equipment and their maintenance. Various factors that influenced the selection and use of equipment included infrastructure (electricity, water, efficient disposal of waste product); technology (kind of tests needed for screening of blood), training of qualified personnel in use and maintenance of equipment; documentation of equipment, stock maintenance; preventive maintenance. She also discussed the management issues of crucial importance for the implementation of quality system.

Training of the staff is extremely important for implementation of a quality system. Dr Pimol Chiewsilp described the process by which fruitful training could be imparted to various categories of staff. The training needs should be assessed and appropriate training programmes developed. A review of training and continuous post-training support was equally important to translate the benefits of training into an efficient quality system.

The quality system also required good waste disposal practices and biosafety measures to protect the staff of blood banks, its environment, as well as the material being processed in the blood banks. Dr Chantapoing Wasi, Head of Virology, Siriraj Hospital, Bangkok elaborated upon the methods for assuring biosafety and infection control measures in blood bank and laboratory settings.

Dr John Parry emphasized the importance of use of externally procured internal quality controls in every run of the screening procedures, so that quality of every run could be guaranteed.

Documentation is an important element of any quality system. Dr Rajesh Bhatia 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 (SOP) were critical sub-elements of the quality system and are essential to ensure that every procedure is undertaken in a standardized way and consistent results generated. Various steps in the utilization of SOP including writing of SOP, its validation, authorization, training of staff to use it, controlling it and reviewing it on a regular basis and at those times whenever there is a change in technology or reagents/kits were elaborated upon. The participants themselves wrote SOP as group work which was discussed in a plenary session.

Assessment of quality system is undertaken with the help of a variety of tools. Dr Rajesh Bhatia gave an overview of various methods and tools for assessment of quality and their utility in monitoring and evaluation of quality system. Dr Suda, Department of Virology, Siriraj Hospital, Bangkok demonstrated the use of various statistical process tools in monitoring quality on a day to day basis. Dr John Parry narrated the process of internal audit, its benefits and quality of an auditor. The details of the organization of an external quality assessment scheme (EQAS) and the experience of organizing a regional EQAS for anti-HIV in the South-East Asia Region were presented by Dr Willai, Department of Medical Sciences, National Institute of Health, Ministry of Public Health, Thailand. Data generated during the previous four cycles of regional EQAS were shared.

4.3 Visit to National Blood Centre

Participants visited the National Blood Centre, Thai Red Cross Society, Bangkok to observe a functional quality system in place and discussed the mechanism of implementation and other issues with staff members of the National Blood Centre. The participants were taken around to all the areas of the National Blood Centre that included donor selection and bleeding area, screening for TTI, blood group serology, component preparation and database management. Participants interacted with the staff to ascertain the ways by which they could implement all the elements of a quality system in their own settings to assure quality and safety of blood.

4.4 Development of Plan of Action for Implementation of Quality System and a Follow up Mechanism

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

Several issues that need 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.

5. RECOMMENDATIONS

To Participants

- (1) The participants should develop standard operating procedures (SOP) for priority procedures, validate and use these in undertaking the procedure.
- (2) The participants should use internal quality control sera while screening for TTI.

To Member Countries

- (1) Member Countries should formulate a quality policy and implement it in all the blood banks.
- (2) The Blood Transfusion Services should screen the donated blood for HIV using one reliable screening kit as per WHO strategy. The management of donors whose blood is reactive should be undertaken only through a well defined national policy and with adequate infrastructure.
- (3) The procurement of the quality kits should be assured based upon the recommendations of a technical expert group. Bulk purchases make it economical and facilitate quality assurance by national authorities. Blood banks should preferably be supplied the same kit for long periods so that confidence in use of these kits is built up and data regarding their utility generated. Frequent replacement of makes and types of kits adversely influence the quality of screening.
- (4) Member Countries should strengthen infrastructure and skills to produce and distribute internal quality control sera.
- (5) Member Countries should impart training to their staff in BTS in quality aspects as a priority. WHO support may be sought in those areas where expertise and infrastructure are not available within the respective countries.

To WHO

- (1) WHO should support supply of internal quality control sera for HIV and hepatitis B and C to national laboratories/centres through regionally identified institutions for a period of two years.
- (2) Guidelines for the proper disposal of blood units that renders its disposal safe and environment-friendly should be developed.
- (3) Through a recognized centre in Region, WHO should assure continuous technical support to Member Countries in the quality of BTS.
- (4) WHO should develop a strategy for screening and testing of hepatitis B and hepatitis C in various settings and disseminate the same through national programme managers.

- (5) WHO should orient the national programme managers in proper use of WHO strategies for testing for HIV to bridge the existing gaps in use of these strategies.

6. CONCLUDING SESSION

The concluding session was chaired by Dr S Kumari. She thanked the organizers and the facilitators for making the Consultation a success and hoped the participants would be able to translate the knowledge gained in strengthening quality assurance practices in their own settings. She assured continuation of WHO support in this area.

Annex 1
PROGRAMME

Tuesday, 22 July 2003

0900 hrs	<ul style="list-style-type: none">➤ Registration➤ Inauguration➤ RD's address➤ Objectives➤ Introduction of participants➤ Election of chair and rapporteur	
1030 hrs	WHO global strategies for blood safety Global status of quality in HIV/viral hepatitis screening : Regional status	Dr Gaby/ Dr Kumari
1100 hrs	Country presentations 10 minutes each including discussion	Country Representatives
1330 hrs	Country presentations (contd.)	
1545 hrs	Overview of quality system	Dr Rajesh Bhatia
1645 hrs	Synthesis of major constraints faced by Member Countries in assuring quality of screening for HIV/Viral Hepatitis (Based upon presentations made on day I)	Chair/Rapporteur

Wednesday, 23 July 2003

0900 hrs	Synthesis of major constraints faced by Member Countries in assuring quality of screening for HIV/Viral Hepatitis (Based upon presentations made on day I)	Chair/Rapporteur
0930 hrs	Management issues in implementing quality system	Dr Rachanee

0930-1015 hrs	Selection and quality of test kits HIV/viral hepatitis testing strategies <ul style="list-style-type: none">• Technology• International cooperation• Guidelines for national agencies• Role of WHO• Evaluation of screening kits for HIV/viral hepatitis at national/subregional level in the SEA Region• Guidelines and requirements	Dr Parry Dr Gaby
1130 hrs	Evaluation of screening kits for HIV/viral hepatitis at national/subregional level in the SEA Region Guidelines and requirements	Dr Parry
1130-1145 hrs	Equipment procurement and maintenance	Dr Rachanee/ NBC
1145 hrs	Training of staff in quality Competence evaluation of staff	Dr Pimol
1300 hrs	Training of staff in quality Competence evaluation of staff	Dr Pimol
1400 hrs	Use of Internal quality controls as part of good laboratory practices	Dr Parry
1430 hrs	Biosafety Disposal of wastes	Dr Wasi
1500 hrs	Documentation How to write an SOP?	
1545 hrs	Biosafety Disposal of wastes	Dr Wasi
1600 hrs	Management issues in implementing quality system	Dr Rachanee
1630 hrs	Documentation How to write an SOP?	Dr Bhatia

Thursday, 24 July 2003

0900 hrs	Group work on writing a SOP Presentation of group work	Group work
1000 hrs	Overview of assessment of quality	Dr Bhatia
1100 hrs	External quality assessment scheme: Regional Scheme: Process and experience so far How to establish a NEQAS?	Dr Wilai
1130 hrs	Monitoring of assay performance	Dr Suda
1230 hrs	How to establish a NEQAS? External quality assessment scheme: Regional Scheme: Process and experience so far Implementation of quality audit	Dr Wilai
1400 hrs	Visit to National Blood Centre, Bangkok for demonstration of a functional quality system in HIV/Viral Hepatitis screening Two groups: one for HIV and second for viral hepatitis To demonstrate and observe all key elements of a quality system	Dr Rachanee Local facilitators of National Blood Centre

Friday, 25 July 2003

0900 hrs	Issue and challenges in quality screening of HIV/viral hepatitis in SEAR countries based upon country presentations and discussions during the consultation	All Facilitators
1000 hrs	Development of plan of action	Dr Kumari/ Dr Bhatia
1115 hrs	Development of plan of action for individual countries/institutions	Country Representatives
1330 hrs	Presentation of action plan and draft recommendations	
1530 hrs	Valedictory session and closure	

Annex 2

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