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Quality Assurance and Accreditation

*Report of Intercountry Consultation
Yangon, Myanmar, 16-19 November 1999*

WHO Project: ICP THC 001



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1. INTRODUCTION

An Intercountry Consultation on Quality Assurance and Accreditation was held in Yangon, Myanmar, from 16 to 19 November 1999. A total of 25 participants from 9 Member Countries of the WHO South-East Asia Region participated in the Consultation, which was assisted by experts from UK, Kenya, India, Myanmar and from WHO headquarters and the Regional Office. There were technical presentations by the experts. The Programme and the List of Participants are given in Annexes 1 and 2, respectively.

2. OBJECTIVES

The Objectives of the Consultation were:

- To review the progress made in quality assurance in health laboratory services in Member Countries;
- To formulate country programmes for National External Quality Assessment Schemes in microbiology, haematology and clinical chemistry;
- To orient and encourage Member Countries in initiating the process of accreditation of laboratories;
- To identify gaps and formulate strategies in implementing QA programmes, and
- To identify future areas of support in strengthening quality assurance activities in health laboratory services in the Region.

3. INAUGURAL SESSION

The Consultation was inaugurated by the Minister of Health, Myanmar, Major-General Ket Sein. The Deputy Minister of Health, Myanmar, and the Director-General of Health Services, Myanmar, also graced the occasion. The WHO Representative in Myanmar, Dr A Borra, read the Regional Director's address. In his address, the Regional Director stressed that the unparalleled progress in the field of diagnostic medicine could benefit humanity only if the data generated were relevant and reliable. There was also the need to

develop accreditation models relevant to the Region. WHO had been advocating the need for quality assurance and for adequate resource allocation. Technical support would continue to be provided and would be enhanced to strengthen quality assurance programmes in the Region and help in improving the quality of care to patients..

Dr J.J.S. Snell was designated Chairman and Dr Y.N. Rao as Rapporteur for the Consultation.

4. OVERVIEW OF QUALITY ASSURANCE PROGRAMMES IN SEARO

Dr Sudarshan Kumari, Regional Adviser, Blood Safety and Laboratory Technology, WHO SEARO, presented the objectives of the Consultation as well as an overview of the activities in the Region on quality assurance. She described the present status of these activities as regards clinical chemistry, clinical microbiology and haematology. She listed the constraints experienced by some of the laboratories in the Region, at the same time sharing her vision of the future course of action.

Dr J.J.S. Snell gave an overview of the concept of quality, internal quality control and external quality assurance. He referred to the differences between procedure manual and SOP and highlighted the fact that the laboratory should have a quality manual and take up the training of its personnel. This training should be documented in the log book of each staff member.

Dr C.C. Heuck then presented an overview of WHO IEQAS, mentioning the conditions that needed to be met for participation in WHO IEQAS as well as the reasons for considering dropping a participating laboratory. He suggested that it might be useful to establish a regional scheme rather than a global one for parasitology, while a global scheme was most appropriate for antimicrobial susceptibility testing.

Dr A.S. Kanagasabapathy and Dr J. Carter presented their experiences with running NEQAS in clinical chemistry and microscopy respectively.

5. COUNTRY PRESENTATIONS

5.1 Bangladesh

The Bangladesh Health and Family Planning Programme has made remarkable progress over the last two decades. The success of the

immunization campaign is most impressive. The under-five mortality rate has declined from 133 for the period 1989-93 to 116 during 1992-96; over the same period the infant mortality has also declined from 87 to 82 per 1000 live births. Less than 40% of the population has access to basic health care. An area of concern is the overall poor utilization of government services, as well as the cost-effectiveness, sustainability and quality of services.

Bangladesh has a number of laboratories ranging from the international (ICDDR) to the autonomous (BIRDEM), with laboratories specializing in pathology, haematology and biochemistry. It also has an Armed Forces Institute of Pathology, government laboratories (IPGM&R and IPM), 13 medical colleges and one medical university. There are 933 hospitals, 382 thana hospitals, 1362 rural dispensaries, 35 urban dispensaries and 23 school health clinics. Three laboratories are participating in IEQAS in clinical microbiology, clinical pathology and clinical biochemistry. NEQAS has yet to be initiated. There is no national laboratory policy and consequently no separate allocation of funds for laboratories.

5.2 Bhutan

Health care services are provided entirely by the Government through a four-tier delivery system. The primary unit is the basic health unit (BHU). The district laboratories are manned by laboratory technicians. Regional hospitals have laboratories designated as regional referral laboratories. The National Referral Laboratory (NRL) is attached to the Jigme Dorgi Wangchuk National Referral Hospital, Thimphu. The NRL has been participating in IEQAS in clinical chemistry and microbiology. No NEQAS has been initiated.

5.3 India

The health set-up in the government sector consists of major hospitals at the centre and super speciality institutions at state level: 128 medical colleges, 440 district hospitals, 2289 upgraded PHCs, 21009 PHCs, 131 470 subcentres and 27403 dispensaries. The laboratories are located up to PHC level. In metropolitan cities there are many private laboratories, and in many towns laboratories in the private sector have mushroomed.

A number of laboratories are participating in IEQAS: a global scheme was most appropriate: in clinical microbiology (7), clinical chemistry (3), haematology (3), blood coagulation (2), and parasitology (1). A number of

these laboratories are conducting NEQAS in clinical chemistry (3), clinical microbiology (1), haematology (2) and immunology (2). A National Accreditation Board for Testing and Calibration Laboratories (NABL) has been established under the Department of Science and Technology, guidelines for accreditation for clinical laboratories have been framed, and accreditation of laboratories is being carried out. The National Institute of Biologicals (NIB) has been given the mandate to strengthen the quality assurance in laboratories. The Government of India has started a pilot project for updating and standardizing clinical chemistry laboratories.

5.4 Indonesia

Primary health care (PHC) in Indonesia is provided at the health centre (Puskesmas). Government hospitals have been classified into class A,B,C and D. The following is the number of general hospital laboratories under the Government: four Class A, in Jakarta; 34 Class B, located in provincial hospitals; 167 Class C and 131 Class D laboratories, which are located in the district capitals. There are 6984 health centre laboratories in addition to about 400 laboratories in other ministries, environment laboratories and TB laboratories. The number of private laboratories is about 1700. Many laboratories are participating in IEQAS: clinical chemistry (3); clinical microbiology (11), and haematology and blood coagulation (2). NEQAS is being organized in a number of specialties: clinical chemistry; haematology; bacteriology; microscopy for AFB; blood banking; environmental chemistry; parasitology and immunoserology. There are EQAS at the provincial level, too, with five organizers for haematology and six for clinical chemistry. Guidelines for accreditation have been drafted. Guidelines on laboratory safety are available and attempts are being made to comply with all aspects of safety. Training of health care personnel is continuing and in 1999 over 5000 have been trained. Participation of private laboratories in EQAS is a prerequisite for licensing and accreditation.

5.5 Maldives

The first contact for a person requiring curative medical care is the atoll health centre (there are 19 of these in the country), which has basic laboratory facilities. Patients in need of secondary and tertiary care are referred to the regional hospitals (4) and / or the Indira Gandhi Memorial Hospital (IGMH) at Male. There are a few privately owned clinic-cum-laboratories functioning in Male. Laboratories at regional hospitals have testing facilities for clinical

chemistry, haematology, microbiology and immunology. The IGMH participates in IEQAS in clinical chemistry. No NEQAS has been organized.

5.6 Myanmar

The laboratories have been graded into three types: A,B and C. The type A laboratories (N=15) have facilities to do clinical chemistry, haematology, histopathology, microbiology and blood banking and are located in teaching and specialist hospitals. The type B laboratories (N=33) are located at the 100–150-bed district hospitals while the C type laboratories (N=252) are located at the 25-bed township hospitals. The National Health Laboratory located in Yangon is the only reference laboratory in the Department of Health. It has two components: clinical pathology and public health microbiology. The NHL participates in IEQAS in clinical chemistry, syphilis serology, bacteriology and virology. NEQAS is organized in clinical chemistry, haematology, bacteriology, syphilis serology and virology by NHL Yangon.

5.7 Nepal

There are four health laboratories at the central level, two each at regional and subregional levels, eight at the zonal level, 61 at the district level, seven at health centre level, 46 at health post level and 18 at the primary health centre level. The National Public Health Laboratory (NPHL) is the only national referral centre in the country. It has been participating in IEQAS in blood coagulation and clinical chemistry. It organizes NEQAS for 50 participating district laboratories in haematology, biochemistry, malaria, TB microscopy and Gram staining. The NPHL also trains laboratory personnel, supplies laboratory reagents and equipment and monitors the activities of laboratories at all levels.

5.8 Sri Lanka

There are 63 laboratories in Sri Lanka in the government sector located at teaching hospitals (6); provincial hospitals (9); base hospitals (10); district hospitals (28); Armed Forces (4), and universities (6). There are also some 106 private diagnostic laboratories. Many laboratories participate in IEQAS: clinical chemistry (1); clinical microbiology (4) and haematology (2). NEQAS in haematology and clinical chemistry has been organized by the Medical Research Institute.

5.9 Thailand

Apart from the Department of Medical Sciences (DMS), which has the key Institute for EQAS and is under the Ministry of Public Health, other laboratories are located in regional medical science hospitals (12); regional hospitals (17); provincial hospitals (73); community hospitals (707) and in health centres (8012). The DMS and Mahidol University participate in IEQAS and conduct NEQAS and the regional laboratories supervise the provincial laboratories, which in turn supervise the community hospital laboratories. Participation in NEQAS is extensive with 650 laboratories participating in haematology; 329 in clinical chemistry; 823 in clinical microbiology; 650 in parasitology; 653 in immunology and 522 in blood banking. A Quality Assurance Management Manual has been introduced. There is a national policy on quality assurance and accreditation. Hospitals need to comply with ISO 9002 norms while laboratories should comply with ISO/IEC Guide 25. The National Accreditation Council has been given the responsibility for accreditation of laboratories. Under the Ministry of Public Health, the Bureau of Laboratory Quality standards has four sections: (i) Section of quality system development, (ii) Section of audit: compliance with ISO 10011, (iii) Section of proficiency testing : compliance with Guide 43 and conduct of NEQAS, and (iv) Section of laboratory accreditation : compliance with Guide 58.

6. CONCLUSIONS

During the course of the Consultation it emerged that quality assurance activities in the Region were at different levels of development. Some countries were striving for ISO norms and had a vibrant, well developed system (Thailand); other countries, on the other hand, were experiencing a number of constrains which prevented them from making quality assurance activities fully operational. It was the unanimous view that quality assurance activities needed to be strengthened and encouraged. To achieve this objective, activities should be undertaken at various levels in the Region. The following recommendations were drafted and unanimously adopted.

7. RECOMMENDATIONS

7.1 At Laboratory Level

- (1) Each laboratory must have or write and/or adapt a procedure manual detailing all procedures undertaken by it. Central

laboratories should make appropriate procedure manuals available to peripheral laboratories. The procedure manual should serve as the basis for training within the laboratory and interlaboratory training.

- (2) Internal quality control (IQC) must form an integral part of diagnostic or public health work undertaken by the laboratory.
- (3) Central laboratories should organize NEQAS for peripheral laboratories.
- (4) Laboratories conducting NEQAS should in turn participate in IEQAS.
- (5) Laboratories running IQC and participating in NEQAS/IEQAS should strive for accreditation from recognized accreditation authorities.
- (6) Each laboratory may deploy a quality manager and a safety manager on a rotational basis from the existing staff to oversee these activities.

7.2 At National Level

All Member Countries should:

- (1) Formulate and implement a national laboratory policy.
- (2) Identify suitable central laboratories for conducting NEQAS in all relevant disciplines of diagnostic and public health medicine and provide support -material, financial and manpower - to these designated laboratories.
- (3) Collate an information inventory of laboratories, tests and support networking.
- (4) Transmit information regarding QA activities to WHO for dissemination among other countries.
- (5) Introduce orientation training for clinicians and nurses in order to strengthen appropriate use of laboratory services.

7.3 To WHO/International Agencies

They should:

- (1) Reiterate the need for quality assurance in health laboratory services and the need for resource allocation by Member Countries.

- (2) Facilitate the development of a QA programme in the Region and help designated central laboratories to conduct NEQAS by providing appropriate technical assistance.
- (3) Assist and support Member Countries to formulate their national laboratory policy.
- (4) Encourage laboratories in the Region to implement good laboratory practices by making available suitable reference material.
- (5) Encourage networking of laboratories in the Region and further promote intercountry cooperation and exchange of information.
- (6) Organize regular annual informal consultations on laboratory quality assurance.

8. ACTION PLAN

Participants from each Member Country then developed an action plan for the next two years for their respective countries to overcome the problems identified by them and to facilitate the delivery of quality laboratory support from diagnostic and public health laboratories.

Annex 1
PROGRAMME

Tuesday, 16 November 1999

0830 – 0900 hrs	Registration	
0900 – 0930 hrs	Inaugural Session	
1000 – 1100 hrs	Objectives and mechanics of the meeting Overview of QA in SEAR	Dr S Kumari
1100 – 1200 hrs	Overview of quality assurance programme	Dr J.J.S. Snell
1200 – 1300 hrs	Country presentation regarding status of Quality Assurance followed by discussion <ul style="list-style-type: none">• Bangladesh• Bhutan	
1400 – 1545 hrs	Country presentation regarding status of Quality Assurance followed by discussion <ul style="list-style-type: none">• Indonesia• Maldives• Thailand	
1600 – 1700 hrs	Global IEQAS in health laboratories	Dr C.C.Heuck
1700 – 1730 hrs	Summing up of day's proceedings	Dr Ashok Rattan

Wednesday, 17 November 1999

0900 – 1000 hrs	National External Quality Assessment Scheme (NEQAS) in Clinical Microbiology: Concepts, methodology and possible strategies for Member Countries	Dr J.J.S. Snell
1000 – 1030 hrs	Discussions	
1100 – 1215 hrs	NEQAS in Clinical Microbiology – (contd) <ul style="list-style-type: none">• Recording, reporting and analysis• Scoring system in microbiology• Improving the poor performers	Dr J.J.S. Snell
1215 – 1300 hrs	Discussions	
1400 – 1500 hrs	Overview of National External Quality Assessment Scheme (NEQAS) in Clinical Chemistry Concept, methodology and possible strategies for Member Countries	Dr A.S. Kanagasabapathy

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1500 – 1530 hrs	Discussions	
1600 – 1700 hrs	QA programme for primary health care level: Concept, methodology and possible strategies for Member Countries	Dr (Ms) Jane Carter
1700 – 1800 hrs	Discussions	

Thursday, 18 November 1999

0830 – 1000 hrs	<ul style="list-style-type: none">• Various methods of accreditation of health laboratories• WHO policy on issues related to accreditation	Dr J.J.S. Snell Dr C Heuck
1000 – 1030 hrs	Introduction to group work	
1100 – 1300 hrs	Group work for the development of country-specific plans for implementation of QA/NEQAS/accreditation	
1400 – 1530 hrs	Group work (continues)	
1600 – 1800 hrs	Group work (continues)	

Friday, 19 November 1999

0900 – 1030 hrs	Group work (continues)	
1100 – 1300 hrs	Presentation of group reports – Group discussions	
1400 – 1530 hrs	Finalization and Recommendations	
1530 – 1600 hrs	Closing Ceremony	

Annex 2

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