SEA-HLM-378
Distribution: General

Quality Assurance in HIV Testing

Report of a Regional Workshop
Pune, India, 24-28 November 2003

WHO Project: ICP BCT 001

World Health Organization
Regional Office for South-East Asia
New Delhi
March 2004

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1. INTRODUCTION

The AIDS epidemic continues to spread in the South-East Asia Region (SEAR), which is the second most affected Region in the world, after sub-Saharan Africa. To date, close to 42 million people throughout the world have been infected with human immunodeficiency virus (HIV), the virus that causes AIDS. Of these, almost 6 million are in the SEA Region. Estimated population prevalence rates per 100 000 population range from less than one in DPR Korea to over 1 200 in Thailand. Over 99% of cases have been reported from four countries, Thailand, India, Indonesia, and Myanmar.

The epidemiological patterns of HIV/AIDS in the Region are diverse. There is a potential for rapid spread of HIV in all countries, as risk behaviours and vulnerabilities, which fuel the spread of the infection, exist in all countries. After a prolonged period of low HIV prevalence, many countries, such as Indonesia and Nepal, recently experienced a rapid increase in prevalence among injecting drug users and subsequently in commercial sex workers after a prolonged period of low prevalence. The epidemic in the Region is considered highly dynamic and rapidly evolving.

The Member Countries of the SEA Region continue to give high priority to AIDS prevention and control to fight the epidemic. They are implementing the national strategic plans with the involvement of a number of government sectors, the private sector and non-governmental organizations. Priority is being given to scaling up effective targeted interventions. While prevention should be the primary aim, people with HIV/AIDS also need adequate counselling and care. The emphasis of the Regional Office is on increasing access to treatment with antiretroviral drugs in prevention of mother-to-child transmission and care of infected persons.

For all the issues pertaining to prevention and control of HIV/AIDS, laboratory support is the most basic and fundamental tool. WHO has developed three strategies to assist laboratory support in various areas of HIV/AIDS, namely, screening of blood and blood products, surveillance and diagnosis of AIDS. Though these strategies are widely in use, it is essential to ensure the reliability of results generated through their employment. Integration of a quality system in laboratories providing such support has become mandatory in the contemporary era. The Regional Office has been

advocating quality assurance in health laboratories and blood banking for the last few years.

To review the status of quality assurance and to strengthen the quality of HIV testing in Member Countries of the SEA Region, a regional workshop was convened at the National AIDS Research Institute, Pune, India from 24 to 28 November 2003. See Annexes 1 and 2 for the detailed programme of the workshop and list of participants. Sixteen participants from all Member Countries of the SEA Region, except Democratic Republic of Korea and Myanmar attended. Five experts from India, Thailand and WHO facilitated the Workshop.

2. OBJECTIVES

The objectives of the Workshop were as follows:

(1) To review the status of laboratory support to the HIV/AIDS control programme in SEAR countries;

(2) To orient nationals in implementation of a quality system for laboratory support for HIV/AIDS;

(3) To develop a national mechanism for external quality assessment scheme for HIV/AIDS, and

(4) To formulate institution-specific plans of action on integrating quality in laboratory support to the National HIV/AIDS Control Programme.

3. INAUGURAL SESSION

Dr Arun Risbud, Deputy Director, National AIDS Research Institute (NARI), Pune, welcomed the participants and the facilitators. Dr Rajesh Bhatia, STP/BCT, SEARO described the objectives and the mechanics of the workshop. Dr Ramesh Paranjape, Officer In-charge, NARI presented the activities of the institute in the field of prevention and control of HIV/AIDS.

Welcoming the participants on behalf of WHO, Dr N Kumara Rai, Director, Communicable Diseases, WHO South-East Asia Regional Office, inaugurated the workshop. Dr Kumara Rai said that recent years had witnessed tremendous advances and expansion in various specialties of health laboratories including virology. The time was ripe to strengthen the quality system in laboratories. On-site assessment by various WHO experts during the

current year revealed the deficiencies in proper testing methodologies for HIV. Various issues that required strengthening pertained to management, standards, training, documentation and assessment. Collectively, these could provide an efficient quality system. WHO was also endeavouring to overcome these constraints being faced by a large number of laboratories in the South-East Asia Region through advocacy and technical support.

Dr Kumara Rai reiterated that for the prevention and control of HIV/AIDS, laboratory diagnosis was an essential tool. There was no other method by which a person could be labelled as HIV positive or suffering from AIDS. Monitoring of antiretroviral therapy, diagnosis of HIV-associated infections and evaluation of response to therapy in the individual and various public health interventions could not be accomplished until reliable laboratory support was available for both clinical and public health areas. The International Standards Organization (ISO) was an international nongovernmental organization dedicated to improve quality in all spheres of life including health laboratories. WHO was striving to integrate quality system, as suggested by ISO, in health laboratories and blood transfusion services and the present workshop was aimed at achieving this objective of WHO.

4. WORKSHOP

4.1 Review of Status

The global scenario was presented by Dr Mehendele, Deputy Director (Epidemiology), NARI. According to WHO estimates, currently 42 million people worldwide are infected with HIV, 95% of them in developing countries. As many as 6 million of these are living in the Member Countries of the South-East Asia Region of WHO, of which India has the largest number (4.58 million) of cases. The number of HIV cases in all Member Countries is mounting gradually and there is also an increase in cases with transmission in low risk population.

Various diagnostic and screening laboratory tests for HIV that are available currently were presented by Dr RS Paranjape. Laboratory tests are targeted to assay antibody to HIV, detect specific HIV antigen, estimate viral load, enumerate CD4 cell count, isolate causative agents of HIV-associated opportunistic infections and undertake basic research on different facets of HIV. Various types of tests that are in-use include dot blot and Mac-ELISA,

immuno-chromatography, Western Blot, polymerase chain reaction (PCR), flow cytometry and conventional virological and microbiological isolation techniques.

Review of Status in the SEA Region

The status of quality system in screening for HIV in the laboratories of the participants from SEA Region is summarized in the table. Quality policy, quality audit and quality manuals are operational only in Thailand. Training of various categories of laboratory staff on quality issues is on *ad hoc* basis and lacks any planning or review mechanism. Equipment is available in almost all laboratories; 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. External quality assessment schemes (EQAS) are in operation in India, Indonesia, Maldives, and Thailand with only Thailand having a comprehensive national EQAS.

***Table**. Status of quality system in HIV testing in the countries of the SEA Region*

Country	BAN	BHU	IND	INO	MAV	NEP	SRL	THA
Number of laboratories participating in Workshop	1	1	2	2	1	2	1	3
National standard	Yes	No	Yes	Yes	No	Yes	Yes	Yes
Quality policy	Nil	No	No	No	No	No	No	Yes
Quality manual	Nil	No	Yes	No	No	No	No	Yes
Training plans and needs assessment	Nil	No	Yes	Yes	No	No	Yes	Yes
Training review	Nil	No	No	No	No	No	No	NA

Country	BAN	BHU	IND	INO	MAV	NEP	SRL	THA
Training courses	Nil	Ad-hoc	Yes	Yes	Ad-hoc	Ad-hoc	Yes	Yes
Inventory management	NA	Yes	No	No	No	No	No	Yes
Quality audit	Nil	No	No	No	No	No	No	Yes
Availability of equipment	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Validation of equipment	No	Yes	No	No	Yes	No	No	Yes
Maintenance of equipment	Weak	Weak	Weak	Weak	Yes	Weak	Weak	Yes
SOP for safety	No	No	No	No	No	No	No	Yes
SOP for error management	No	No	No	No	No	No	No	Yes
SOP for testing	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Validation of test runs	No	No	No	No	No	No	No	Yes
Ever used expired kits	NA	No	No	NA	No	No	No	No
Participation in EQAS	No	Yes	Yes	Yes	Yes	No	Yes	Yes

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

4.2 Orientation on Quality System

Dr Rajesh Bhatia introduced the concept of quality and outlined the key elements of a quality system. Quality is defined as meeting the standards or a match between the expectation and realization of the customer who was 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 were: organizational structure and management; standards, training, documentation and assessment. The assessment could be man-driven or material-driven. Man-driven assessment was also known as quality audit and formed a part of the accreditation process. Material-driven assessment was achieved through distribution to a

large number of participants by an organizer of samples of known but undisclosed contents. On the basis of the results obtained, the quality system of the laboratory was assessed and suggestions made to improve it.

Documentation was 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 were essential to ensure that each procedure was 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 whenever there was 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 was 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 Willai, National Institute of Health, Department of Medical Sciences, Ministry of Public Health, Thailand, Bangkok demonstrated the use of various statistical process tools in monitoring quality on a day to day basis. Dr Rajesh Bhatia explained the process of quality audit, its benefits and quality of an auditor. He also briefly discussed the concept of error management and its contribution towards achieving the quality-oriented objectives of health laboratories.

Laboratory Tests and Internal Quality Control Measures

Various tests like ELISA, rapid diagnostic tests, Western Blot assay and line EIA were demonstrated to the participants. The participants performed some of the techniques themselves. Several internal quality control measures that were needed to minimize variations were demonstrated and discussed while the tests were being performed. Common causes of errors were identified and their solutions suggested. The documentation of various important steps was explained to the participants.

Visit to National AIDS Research Institute

Participants visited the National AIDS Research Institute, Pune to observe a functional quality system in place and discussed the mechanism of

implementation and other issues with faculty of NARI. The participants were taken around the institute to observe the quality system in various areas.

4.3 Formulation of National External Quality Assessment Schemes

The details of the organization of an external quality assessment scheme (EQAS) and the experience of organizing a national EQAS for anti-HIV in India were presented by Dr Arun Risbud of NARI and Dr Dimple Kasana, NACO, India respectively.

The assessment of quality in a schematic way through an external agency using material of known but undisclosed results was called external quality assessment scheme (EQAS). This was considered a powerful tool that challenged the internal quality control measures being adopted by the laboratory. EQAS was a tool by which the entire testing process including the quality of results generated by a particular laboratory was assessed. External quality assessment scheme also compared the performance of different testing sites.

EQAS required a well-equipped, experienced laboratory at intermediate or central level to act as the organizing laboratory and a fairly reasonable number of laboratories as the participating laboratories. EQAS included submission of samples to participating laboratories; analysis by them and returning of the results to the EQA organizer who performed the statistical analysis and sent feedback to the participants to help them judge their individual performances.

To make available the results of the performance of individual laboratories to other laboratories or agencies, or to preserve anonymity, was a choice which would have to be made in each individual country according to the policy decided by health authorities.

4.4 Development of Plan of Action for Implementation of Quality System

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, 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 the implementation of a 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

5.1 To Participants

(1) The participants should strive to implement a quality system in their organizations and in other laboratories of their respective countries.

(2) The participants should develop standard operating procedures (SOP) for priority procedures, validate and use these in undertaking the procedure.

5.2 To Member Countries

(1) Member Countries should formulate a quality policy and implement it in all their laboratories.

(2) The procurement of the quality kits should be assured based upon the recommendations of a technical expert group.

(3) Member Countries should strengthen infrastructure and skills to produce and distribute internal quality control sera.

(4) Member Countries should impart training in quality aspects to their staff in laboratories as a priority.

5.3 To WHO

(1) WHO should support supply of internal quality control sera for HIV through regionally identified institutions for a period of two years.

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

6. CONCLUDING SESSION

The concluding session was chaired by Dr RS Paranjape. He thanked the organizers and the facilitators for making the Workshop a success and hoped the participants would be able to translate the knowledge gained in strengthening quality assurance practices in their own settings.

Annex 1

PROGRAMME

Day 1: Monday, 24 November 2003

0900 – 0930 hrs	Registration
0930 – 1000 hrs	Opening ceremony
1030 – 1100 hrs	Introduction of participants
1100 – 1230 hrs	Introductory lectures Laboratories in HIV Programme Principles and Practice of Quality Assurance
1330 – 1430 hrs	WHO strategies
1500 – 1530 hrs	Quality assurance for HIV/AIDS
1530 – 1630hrs	Country presentations

Day 2: Tuesday, 25 November 2003

0830 – 0900 hrs	Various tests: Rapid and ELISA based
0900 – 1000 hrs	Internal quality control measures
1030 – 1230 hrs	Demonstration
1330 – 1415 hrs	Principles and Practice-ELISA
1415 – 1630 hrs	Demonstration – ELISA

Day 3: Wednesday, 26 November 2003

0830 hrs	SOP writing
1000 hrs	Group work on SOP writing
1400 hrs	Rapid tests
1500 hrs	Demonstration of rapid tests and QA

Day 4, Thursday, 27 November 2003

0830 – 1000 hrs	Audit and error management
1030 – 1230 hrs	Internal quality assessment scheme

1330 – 1630 hrs	External quality assessment scheme Mechanism Role of organizer Role of participants Role of National Programme Manager

Day 5: Friday, 28 November 2003

0830 – 1000 hrs	Networking of labs: – At national level – At International level
1030 – 1230 hrs	Identification of constraints and formulation of action plan
1330 – 1630 hrs	Presentation of action Recommendations Valedictory

Annex 2

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