

Joint WHO – CDC Conference on Health Laboratory Quality Systems

**Lyon, France
9 - 11 April 2008**

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Abbreviations and acronyms

ACCSQ	ASEAN Consultative Committee for Standards and Quality
ADB	Asian Development Bank
AIDS	Acquired Immune Deficiency Syndrome
AMREF	African Medical & Research Foundation
AMTT	Association of Medical Technologists of Thailand
APLAC	Asia Pacific Laboratory Accreditation Cooperation
CDC	Centers for Disease Control and Prevention, Atlanta, USA
CLIA	Clinical Laboratory Improvement Act (USA)
CLSI	Clinical and Laboratory Standards Institute
COLABIOCLI	Cofederacion Latinoamericano Bioquimica Clinica (Latin American Biochemical Confederation)
CVN	Clinical Virology Network
DANIDA	Danish International Development Agency
DFID	Department for International Development (UK)
EA	European Cooperation for Accreditation
EQA	External Quality Assessment
EQAS	External Quality Assessment Scheme
EU	European Union
EPR	Epidemic and Pandemic Alert and Response
HIMS	Hospital Management Information System
HIV	Human immunodeficiency Virus
HPA	Health Protection Agency
IAAC	Inter-American Accreditation Cooperation
IAF	International Accreditation Forum
IDSR	Integrated Disease Surveillance and Response
IEC	International Electrotechnical Commission
IHR	International Health Regulations
ILAC	International Laboratory Accreditation Cooperation
ISO	International Standards Organization

JCDCMAS	Joint Committee for the coordination of technical assistance to Developing Countries in Metrology, Accreditation and Standardization
JDSC	Joint Developing Countries Support Committee
KIMMS	Key Incident Monitoring and Management Systems
LIMS	Laboratory Information Management System
LIS	Laboratory Information System
MDR-TB	Multidrug-Resistant Tuberculosis
MOH	Ministry of Health
MOHSW	Ministry of Health and Social Welfare
MOPH	Ministry of Public Health
MOU	Memorandum of Understanding
NATA	National Association of Testing Authorities, Australia
NHLS	National Health Laboratory Service
NIBSC	National Institute for Biological Standards and Control
NICD	National Institute for Communicable Diseases
NPHL	National Public Health Laboratory
PAC	Pacific Accreditation Cooperation
PAHO	Pan American Health Organization
PT	Proficiency Testing
QC	Quality Control
QM	Quality Management
QMS	Quality Management System
RCPA	Royal College of Pathologists, Australia
SADCA	South African Development Community Accreditation
SARS	Severe Acute Respiratory Syndrome
SEARO	South East Asian Regional Office (of WHO)
SOP	Standard Operating Procedure
TB	Tuberculosis
UK	United Kingdom of Great Britain and Northern Ireland
USA	United States of America
WHA	World Health Assembly
WHO	World Health Organization
ZINQAP	Zimbabwe National Quality Assurance Program

Summary

The World Health Organization (WHO) Lyon Office for National Epidemic Preparedness and Response and the US Centers for Disease Control and Prevention (CDC), Atlanta, USA, organized a joint Conference on Health Laboratory Quality Systems from 9 to 11 April 2008. The specific objectives were:

1. To review and discuss the quality systems suitable for health laboratories.
2. To discuss the development of laboratory quality systems within well-organized integrated national laboratory plans.
3. To share successful experiences and challenges of countries that have already made steps towards meeting the objectives.
4. To discuss other important issues relevant to the development of quality systems on a national basis.

The conference brought together over 200 health professionals from more than 70 countries and included laboratory professionals, senior government officers, academic institutions specialists, and staff from headquarters, regional and in-country offices of both CDC and WHO.

The conference included presentations on why quality systems were important, how to introduce such systems into resource-constrained countries, the value of integrating systems with existing disease programme laboratory networks and the challenges faced by those implementing such systems. In particular, an advocacy statement had been agreed upon, which was a standalone WHO – CDC joint document to be used by individual delegates when advocating for investment in laboratory quality with their governments.

Four breakout groups discussed how to develop national laboratory standards, external quality assessment (EQA), the advocacy statement, and integrated approaches to quality programmes. The groups made specific and general recommendations, which included the following:

For WHO

WHO should set up a resource and advisory group to assist Member States in the development of their national laboratory plans.

It is accepted that donor aid is essential but WHO should consider coordination to enable more efficient use of these valuable resources.

WHO should develop potential models of legislation and accreditation for adaptation and use in Member States.

For laboratory professionals

Laboratory professionals should use the advocacy document to convince ministries of health of the need for strategic development.

When implementing quality management systems, use should be made of the WHO/CDC/CLSI toolkit.

Laboratory professionals should provide the business rationale and evidence required for the investment in quality systems.

For ministries of health

There is a need to develop a fully integrated structure and referral system within which all health laboratories, including those involved in WHO technical programmes should operate. The objective is to develop a national laboratory organization, within the national health plan, which is responsive to the needs of patients and all users of the service.

The strategy for implementing quality management must include an examination of the potential constraints as listed in this report. A focal point within the ministry is essential, with a core advisory committee or group of experts, will legitimise the process. Those able to drive or act as champions of the programme should be engaged.

Quality management systems and quality standards should be introduced at all levels of the laboratories' organization.

The External Quality Assessment (EQA) is an essential tool and it should be coordinated at a national level. Other tools should be developed and used to measure success and progress.

National Reference Laboratories should seek to be accredited to internationally accepted standards, such as ISO 15189. Other laboratories will require a phased or staged approach to achieve appropriate accreditation.

1. Introduction

1.1 Objectives

The World Health Organization (WHO) Lyon Office for National Epidemic Preparedness and Response and the US Centers for Disease Control and Prevention (CDC), Atlanta, USA, organized a joint Conference on Health Laboratory Quality Systems from 9 to 11 April 2008. The specific objectives were:

1. To review and discuss the quality systems suitable for health laboratories
2. To discuss the development of laboratory quality systems within well-organized integrated national laboratory plans.
3. To share successful experiences and challenges of countries that have already made steps towards meeting the objectives.
4. To discuss other important issues relevant to the development of quality systems on a national basis.

The detailed agenda of the meeting is attached as Annex 3.

1.2 Participants and resource persons

There were over 200 participants at the Conference from all regions of the world. The list of participants is attached as Annex 4.1.

The WHO Lyon Office provided technical and operational support for the Conference.

1.3 Organization of the Conference

The Conference was held in Salle Ampère, Sofitel, Lyon, from 9 to 11 April 2008. The sessions were comprised of presentations and discussions, breakout group discussions and plenary discussions, which included the agreement to the text of an advocacy paper.

1.4 Welcome statements

Dr C. Mathiot introduced Madame S. Guillaume, Deputy Mayor of Lyon responsible for health and social services. After welcoming all participants, Ms Guillaume explained that the City of Lyon had a proud tradition of involvement in health care and supported quality standards for all. There is a significant health presence in Lyon, with 100,000 work positions in this field and a high involvement in a number of activities including vaccine production. Ms Guillaume added that well-equipped laboratories for the detection and treatment of disease were essential to good quality health care, and that there was also a tradition of support to and collaboration with WHO that entered a new stage in 2001 with the creation of the Office for National Epidemic and Preparedness and Response in Lyon. Ms Guillaume indicated that the agreement to host the Office was renewed in 2005 for a further five years. Finally, Ms Guillaume said that the Mayor of Lyon looked forward to welcoming all the participants to a reception in the City Hall of Lyon the following evening.

1.5 Introductory remarks

1.5.1 WHO – Dr G. Rodier (Director, IHR)

Dr Rodier said that the Conference had been in part stimulated by the need for all signatory countries to the International Health Regulations (2005) agreement to ensure that there was capacity to provide quality laboratory results to identify any agents and substances likely to cause public health emergencies of concern to the international community at large. Among the objectives was the reduction in the risk of the spread of diseases. There were three paradigm changes in the revised regulations:

- from **control of borders** to (also) **containment at source**,
- from **diseases list** to **all public health threats**, and
- from **preset measures** to **adapted responses**.

These measures entered into force on 15 June 2007 and all WHO Member States undertook to have action plans prepared by June 2009. There is a need to share the experience from the sophisticated countries with those from resource-limited countries. There needs to be cross-fertilisation of ideas and breaking of the isolation faced by many laboratories. Much was expected of this Conference.

1.5.2 CDC – Dr J. Ridderhof (Associate Director)

Dr Ridderhof explained that the drive towards generalized quality standards improvement in the USA occurred as a result of the 1988 Clinical Laboratory Improvement Amendments (CLIA) Program. The key features of the law included:

- standards based on complexity of testing, not on laboratory site,
- its application to virtually all clinical laboratories in the USA (approximately 180 000 vs the 13 000 previously regulated),
- including remedial actions in sanctions; and
- user fee funded

There were, therefore, universal standards expected of laboratories and universal implementation. Disease surveillance depended on the quality of laboratory results and laboratories were a part of the system.

During the period 2006 – 2008, WHO, CDC and CLSI collaborated with a laboratory quality management system initiative with the following objectives:

- to harmonize/develop an instructional training package/toolkit on implementing a laboratory quality system,
- to convene an international conference on laboratory quality (April 2008, Lyon); and
- to develop, publish and disseminate recommendations to governments advocating the need and allocation of resources to implement a quality system.

The package, which would be available towards the end of 2008, would consist of 12 individualized packages or modules that can be customized locally and include the following:

organization, personnel, equipment, purchasing and inventory, process control (QC & specimen management), information management, documents and records, occurrence management, assessment, process improvement, customer service and, facilities and safety.

In addition, it was hoped that an advocacy document could be agreed by the conference participants; this advocacy document would emphasize the need to work with the country laboratory infrastructure at all levels from the ministries of health, through national reference, provincial and district health centres.

2. Setting the stage: why quality systems are essential for good laboratory practices

Mr G. Fine (Executive Vice-President, CLSI)

It is important to clearly understand what laboratory services we are considering, why they are essential and where they fit in to the bigger health care picture. It is important to ensure that high quality services are developed and maintained using a quality systems approach. More resources and funding are becoming available worldwide for the **prevention** and **treatment** of infectious diseases. However there is a general lack of understanding that **diagnosis** is essential for their prevention and treatment. A common element in all infectious diseases is that all can and should be diagnosed and treatment monitored by **laboratory tests**. The diagnosis of infectious diseases starts with an accurate laboratory test.

There are many examples to support this. For example in Sub-Saharan Africa, the majority of the 12 million annual deaths are currently due to HIV/AIDS, malaria, TB, sexually transmitted diseases such as syphilis and gonorrhoea and other curable infectious diseases. What role does the laboratory have in such circumstances? There are good examples where the quality of supportive laboratory tests, even for these target diseases, has not been of the standard that it should have been. For example in Ghana, 40% of patients given a WHO-defined clinical diagnosis of malaria were confirmed to be having **bacterial sepsis** (not necessarily malaria). Other studies in, for example, Kenya (bacterial meningitis), Botswana (TB), Nigeria (typhoid), South Africa (HIV), Burkina Faso (HIV) and Tanzania (malaria) demonstrate the major limitations of basing diagnoses on clinical symptoms only. Reliable laboratory support services should have dramatically reduced the possibility of these misdiagnoses. Of the 32.2 million individuals living with HIV, only 10% are aware of their sero status. In a study in Tanzania, almost half of the 4 600 patients admitted to hospital with a diagnosis of malaria did **not** have a positive blood smear.

Poor quality laboratory services lead to:

- huge unnecessary expenditures in regions already plagued by resource-limitations,
- untold misery in human lives and suffering,
- inability to determine the true prevalence of disease; and
- perception that the laboratory services are unhelpful.

The result is that over-treatment is the norm. A prime example is the overuse of antibiotics for inappropriate clinical circumstances which leads to the emergence and predominance of resistant microorganisms. Examples include multi-drug resistant TB, overuse of chloroquine for malaria and overuse of broad spectrum antibiotics for non-specific bacterial or viral infections. Because reliable laboratory services are not available, misdiagnosis occurs resulting in:

- inadequate treatment,
- increased mortality; and
- inability to determine the true prevalence of diseases.

The challenge is to develop **affordable** and **sustainable quality** to support the diagnosis of infectious diseases and other medical conditions. For example, in Sub-Saharan Africa, WHO has designated essential laboratory services as malaria microscopic evaluation, haemoglobin, glucose and HIV. Ultimately, the goal has to be **better patient care**.

Furthermore, the IHR request all WHO Member States to develop the capacity to assess, detect and report to WHO any potential event of public health emergency of international concern through, among other criteria, **accurate and reliable laboratory results in a timely way**.

The critical importance of health laboratory quality in this process is now widely recognized and greater demands arise for implementing laboratory quality systems, including the development of national laboratory quality standards. Laboratories play an essential part in both the detection and prevention of diseases. This starts with doing the **right test, at the right place, at the right time** and achieving the **right result**.

The principles of high quality laboratory testing are the same anywhere in the world. It can, therefore, be standardized. Most laboratory errors are caused by systems and processes and not people. They are the areas where standards can help most. It does not matter how complex the environment is in which the quality management system is applied, the principles are the same. For example, the standards to be applied for simple point of care tests are the same as for the more complex CD4 tests to monitor HIV/AIDS therapy. A laboratory's quality management system (QMS) provides a framework for managing and monitoring quality standards in order to achieve organizational goals. The question is about which quality system should be implemented and built upon.

There are two systems in wide use: those of the International Standards Institute (ISO) and those of the Clinical and Laboratory Standards Institute (CLSI). Both are built on the same concepts but differ in the amount of specificity described. ISO is broader and CLSI has more specifics. **They are complementary and do not conflict.** However, for resource-constrained countries the requirements are for systems that are both comprehensive, simple to understand and scalable to meet local needs and settings. The 12 essential elements were described by Dr Ridderhof earlier. The choice of framework should be based on internationally recognized standards, simplicity, quality performance of the total process and detecting and reducing errors. However, the system will require political will to implement it, and the importance of laboratories must be recognized when resources are allocated.

A value of a QMS should be to achieve:

- accurate, precise and timely results,
- continuous process improvement,
- compliance with regulatory requirements,
- high productivity,
- employee and customer satisfaction,
- international accepted, local scalable and adaptable practices; and
- effective training and educational tools.

The organization of a quality programme requires building partnerships, planning, and organization. The scope of authority and responsibility of the quality coordinator and of others involved in the organization should be defined. Sufficient resources must be allocated to maintain the quality requirements. There are essential requirements for staff such as:

- an educational system,
- hiring, placement and supervisory policies,
- post descriptions; and,
- orientation, training and continuing education programmes and assessments.

There have to be appropriate policies for equipment, which will include selection, appropriate installation and calibration, maintenance, the requirement for routine calibration, troubleshooting and documentation review.

Policies for the supplies procurement must include the role of central stores, purchasing, customs and best price versus customer requirements, and delivery to the laboratory concerned.

Process control concerns all laboratory operations, including method evaluation and standard operating procedures (SOPs), specimen management, quality control and EQA. In addition, methods have to be found for controlling documents and records by adopting a uniform approach, systems for writing, approval and revision, and for storage retrieval and destruction.

Information management requires control of all incoming and outgoing information. Patient privacy and confidentiality must be protected and standardization of information captured. The provision of adequate and safe facilities and environments are essential.

It is important to ensure customer satisfaction by actively seeking information using surveys and focus groups whilst at the same time rewarding staff that provide a good service. QC and EQA are essential requirements and must include the pre- and post analytic phases as well as analytical process control, setting performance goals and instituting corrective measures.

In summary, laboratories are essential to the total health care system and are capable of being standardized on a global basis because quality systems can be applied in any environment providing they are scaled to the local environment. The WHO/CDC/CLSI harmonized laboratory quality systems package will be a great implementation aid.

Quality is a journey that must be taken in order to provide better health care.

3. How to institute integrated quality systems in the national laboratory systems

3.1 Expected legal and managerial role of the resource-limited governments and health care leadership

Dr N. Cabutti (COLABIOCLI)

The reality in Latin America is that there are segmented health systems with little official interest in laboratory quality because governments have other priorities. In addition, there is a lack of stimulus to improve quality. There are few controls or records of supplies procurement and the proportions of large and small laboratories are 10 and 70 per cent, respectively. There are major economic and structural differences between the laboratories. There is a lack of development in quality management processes and no national quality standards. There is automatic translation of international standards without appropriate modification to suit local circumstances.

Furthermore, there are major differences in the distribution of laboratories between the private, government and social security sectors. For example, the numbers of private, government and social security laboratories are: 5000/500/20 in Argentina, 4000/1000/3000 in Mexico, 450/18/18 in Guatemala, and 80/124/59 in Panama (see Table below). In some countries the actual numbers of laboratories in each group are not known; and in some countries the full information is not available.

Distribution of laboratories in main sectors in selected countries

Country	Private (%)	Government (%)	Social security (%)
Argentina	5000 (90.6)	500 (9.1)	20 (0.3)
Brazil	12000	?	?
Chile	700	250	?
Dominican Republic	468 (63.3)	207 (28.0)	64 (8.7)
Ecuador	3000 (90.1)	300 (9.0)	30 (0.9)
Guatemala	450 (92.6)	18 (3.7)	18 (3.7)
Honduras	?	127	5
Mexico	4000 (50.0)	1000 (12.5)	3000 (37.5)
Panama	80 (30.4)	124 (47.2)	59 (22.4)
Paraguay	339 (95.5)	15 (4.2)	1 (0.3)
Uruguay	84	59	?
Venezuela	1500 (79.1)	328 (17.3)	68 (3.6)

Full information is not available from some countries

The strategy employed for quality improvement relied on:

- improvement of legal issues including authorization and licensing,
- implementation of EQA programmes in all countries; and
- the establishment of a quality culture.

Fifteen countries now have a licensing process and, at the time of writing, five do not. Twelve countries now have functioning EQA schemes. Three countries have accreditation systems based on national standards and four have systems based on the ISO 15189 standard. There are difficulties in the application of the ISO 15189 which relate to management and technical requirements. However, the COLABIOCLI/PAHO strategy is to support countries prepare their laboratories for the achievement of international standards requirement by:

- legislation for licensing,
- implementation of quality control,
- establishment of national EQAS,
- audit mechanisms of implementation,
- continuing education process for staff,
- fulfilment of biosafety standards; and
- infrastructure for equipment maintenance.

Tools currently in use include publications on subjects such as distance learning (2005), equipment maintenance (2005), bio safety manual (2005) and guidance on achieving accreditation (2002).

There are, in addition, two further major considerations: ethics and bioethics. Guidance documents exist for clinical laboratories that include ethical principles, collaboration, patient rights, internal procedures and confidentiality. For clinical research, there is guidance on ethics, people vulnerability, conflict of interests, informed consent, research on children and confidentiality.

The strategies adopted have produced successes:

- only three countries without licensing laws,
- only five countries without EQAS,
- all countries have tutors in Quality Management,
- there is integration of government, social security and private sub-systems; and
- audits for accreditation have commenced.

The conclusion is that quality improvement and quality management can be achieved with strategic alliances between PAHO/WHO, COLABIOCLI and national ministries of health.

3.2 Challenges inherent in establishing full implementation of quality standards: the use of “staging” to meet local requirements

Dr R. Robertson, General Manager, NATA

There are difficulties in applying full accreditation standards and it is possible that much can be learned from the experiences of Australia and Thailand. Are there basic steps that can be taken?

There are particular difficulties with the type of language used and such documents assume:

- you understand “standards speak”,
- your situation is that represented by the standard,
- you have available access to relevant resources and supporting infrastructure; and
- the fact that accreditation expects full implementation of all parts of the standard.

What is there to learn from the two countries under consideration? There are differences in the two approaches used.

In Australia, the international and national standards were used, there was active collaboration between the accreditation and professional bodies, a peer process was adopted for assessment, a comprehensive EQAS was provided by the professional bodies and there is emphasis on **education** and **not compliance**.

In Thailand, the Ministry of Public Health and associated agencies were drivers, there is regular and coordinated training in laboratory management systems, comprehensive provision of EQAS, national standards which can be applied in any order and be staged, and an accreditation body that provides review and registration at each stage.

There are some basic steps that can be followed. Preparation and knowledge are required and professional body and government support appear to be key features. It is also important to investigate and understand the environment in which the national laboratory system operates. Study the experiences of those countries that have faced similar constraints.

It is important to develop national standards and supporting documents to suit local needs. When implementing them, identify standards that allow early achievement and encourage the need for ethics and professionalism. Establishment of a framework to enable review of implementation is important and give laboratories something to aim for by providing a staged approach. Providing opportunities for networking and mentoring provides a two-way effect of support.

There are other important additional features that should be addressed which include access to EQA, relevant training, opportunities to share experiences of success and failure, regular reviews to assess outcomes and to enable training needs to be identified and new policy directions to be set. Where necessary, areas of improvement of the national standards can be identified and acted upon.

Other issues for consideration will include:

- the diagnostic needs and best methods for delivery,

- the local infrastructure and geography,
- pre-analytical issues including collection and transportation of samples, expansion of the WHO laboratory networks,
- educational support systems and professional bodies; and
- laboratory biosafety and impact on the community.

3.3 Organizational challenges and national laboratory policies in combining vertical quality systems for an integrated quality system approach

Dr J. Ridderhof (US CDC)

Major challenges face those intending to improve the quality of their laboratory services. Among the difficulties is the perceived need to integrate networks that already exist. Mostly, these consist of the service delivery to the “target” diseases of Malaria, TB and HIV/AIDS. WHO already has networks for these target diseases, to which the polio laboratory network has to be added.

The global disease control programmes with laboratory initiatives include:

- Polio,
- Epidemic and Pandemic Alert Response (EPR),
- Stop TB Partnership Global Laboratory Initiative,
- HIV/AIDS Programme/HIV collaborative,
- Integrated Disease Surveillance and Response (IDSR),
- Vaccine Preventable Diseases; and
- Roll Back Malaria partnership.
- HIV/AIDS Programme/HIV collaborative,
- Integrated Disease Surveillance and Response (IDSR),
- Vaccine Preventable Diseases; and
- Roll Back Malaria partnership.

In addition, there are other initiatives that place a strain on the laboratory structures. For instance, less than 5% of MDRTB is detected using current technologies. As a result, there is an urgent need to scale-up the TB laboratory network and make use of different testing strategies including the use of liquid culture media, LED-based fluorescence microscopy and line probe assay molecular screening for MDRTB. All have to be integrated into existing structures and there is a need to not only do this within country settings but also between countries to ensure an effective global network. It is inevitable that such efforts compete for resources with existing generalized laboratory strengthening. However there is a need to embrace the technical programmes because they already have introduced the concepts of quality systems. There are

cross-cutting streams common to the structures required to produce an integrated service delivery. These streams include:

- staff training/retention,
- strengthen laboratory capacity,
- linked referral services,
- logistics and commodities management,
- facility and equipment management; and
- quality assurance.

The global programmes for TB, HIV, Malaria, Vaccine preventable diseases and EPR require a common structure comprised of national institutes, provincial laboratories, district laboratories and health centres. The lack of an integrated structure has led to specific problems at a district level, which appear to be: too many forms, too many bosses, different definitions, conflicting priorities, no feedback, and duplication of work. There is a need to ensure integration of the service at all levels and across all diseases in order to make the most efficient use of resources. There is also a need to ensure that national reference laboratories are accredited to international standards and that provincial, district and health centre laboratories are accredited within the country. Why are laboratory quality management and accreditation important? Primarily because they:

- assure reliability and accuracy of all tests which enhances the credibility of the laboratory,
- can be applied to individual and networks of laboratories,
- provide an organized framework for a strong network,
- facilitate and document laboratories' ability to meet IHR requirements,
- apply to all services,
- help staff morale and provide enrichment; and
- provide evidence of certification or accreditation valued by organizations and health programmes purchasing services and funding laboratories.

As already described there are internationally recognized standards to which all can aspire. The common components of these include: personnel, test method validation, quality assurance, equipment calibration and maintenance, EQA, document management including SOPs, information management and safety and facilities.

There are examples of integrated quality systems that have a focus on EQA in Zimbabwe and South Africa. In the former the ZINQAP not only provides an EQA service but also makes on-site visits to participating laboratories, runs workshops to rectify non-conformities, and collaborates with partners to produce national laboratory standards. In South Africa, the features of these programmes include:

- national quality assurance/EQA units,
- laboratory auditors trained in ISO-based standards,
- PT based EQA for TB and HIV extending to provincial and district laboratories; and

- interest in rechecking AFB smears.

There is a model to integrate the TB and HIV programmes, which would include promoting national QA units, combine scarce resources, general strengthening. Implementation at peripheral laboratories though will require strong intermediate/provincial laboratories, integrated on-site supervision, the provision of QA samples by national centres and some rechecking of AFB smears. It seems self evident that there is a need to formulate national policies and strategic laboratory plans based on a generic framework of linkages between laboratories at all levels of the service. Eight key interventions have been identified:

- strengthening laboratory management at all levels,
- strengthening infrastructure and support systems,
- human capacity development,
- establishing a national laboratory referral network,
- establishing a national QA programme,
- developing a comprehensive monitoring system including LIMS,
- the coordination of government and partner supported activities; and
- mobilizing resources to finance the strategic plan.

There are critical steps to be taken, which include: not assuming models from developed countries, defining priorities, determining who makes policy and plans, determining what defines development in terms of law, financial leverage, culture, best practices, politics and following existing standards.

There are critical partners in policy development and all should be involved. In addition, it is important to harness the expertise of professional associations, medical and laboratory scientists/leaders, nurses and midwives, hospital authorities and clients. This will require the setting of objectives with specific timed aims. For example: “Reverse the declining case detection rate and aim to increase to 70% by 2008”. This might require the provision of equipment, maintenance, provision of reagents and staff training. Start and finish dates would be set, and the responsible partner would be identified.

As mentioned previously by Glen Fine, there is already a set of modules for laboratory quality management system, which was developed as a result of partnership between WHO, CDC and CLSI, that will provide many of the necessary training packages. The next critical steps will include:

- developing a framework for integration supported by all global disease programmes,
- promoting a vision of integrated national laboratory systems that support the specific requirements of public health programmes,
- accrediting national reference laboratories to international standards,
- including all partners in strategic planning and policy development that include integrated quality systems,
- considering practical approaches for key testing; and
- accrediting other laboratories within countries to their own integrated national standards.

4. Successes and challenges in implementing quality standards

4.1 Caribbean countries

Ms V. Wilson (CAREC)

Ms Wilson described the objective of the programme, which was to strengthen the medical laboratory services in 23 countries in the Caribbean. The project was funded by the EU and implemented by the Caribbean Epidemiology Centre (PAHO/WHO), commencing in 2002 and ending in 2007. The vision for the outcome was:

- laboratory operations in accordance with agreed standards,
- laboratory monitoring accomplished through national registration and licensing,
- laboratories accredited to international standards,
- laboratory personnel trained to output high quality services, sustained training of laboratory and quality managers,
- creative continuing education mechanisms,
- strong networks of laboratory staff and key laboratory stakeholders,
- laboratory networks and referral systems supported by LIMS; and
- strong policy–level support for the laboratory sector.

Evaluations conducted in 2003 showed that there were some particular challenges, which included the loss of experienced staff, shortages of equipment and supplies, deteriorating physical facilities, inadequate planning, technological and administrative infrastructures, weak laboratory management and operational systems, no regulation and limited government commitment and the absence of national or regional standards. For example, more than 21 countries had no strategic health plan, more than 68% of countries had no laboratory regulation, more than 71% had no staff training programme, fewer than 75% had no assigned responsibility for quality management and 92% had no safety programme.

Specific project strategies were adopted that included a focus on governance mechanisms and the formation of national laboratory advisory committees, creating strategic alliances and partnerships, inclusive and participative approach to decision making. (For example, 2 000 stakeholders were engaged in the project's decision making process). Empowering staff and stakeholders and encouraging ownership of the change process was a key feature as was belief in sustainability. Identifying champions to advocate and promote quality operations in laboratories, training institutions and support services were key features of the project. Key strategic alliances were made, which included staff from the private as well as the public sectors, engagement with MOH staff, hospital administrators and health care providers, curriculum coordinators, the Caribbean and international standards bureau, EQA providers and biomedical and procurement professionals.

There have been major achievements, including:

- ISO 15189 was adopted by the region,
- the Caribbean laboratory accreditation system was established,
- model legislation for licensing of medical laboratories and practitioners,
- one harmonized educational curriculum based on a revised regional competency profile,
- fifty-four laboratory and quality managers trained to obtain the postgraduate certificates from the Michener Institute,
- laboratory staff trained in quality management and ISO 15189,
- distance education situation analysis and materials; and
- a cross-institutional model for distance–education delivery.

Progress was measured and is quantified in the Table below:

Process/Policy Improvements		
	2003	2006
QA coordination	35%	67%
QA manual	20%	70%
QC programme	20%	45%
HR development policy	10%	30%
EQA	25%	60%
Monitor error	35%	50%
Budgets	25%	50%
Legislation	6%	26%

Clinician surveys in six countries demonstrated that there had been improvements in turnaround time, accessibility, accuracy, and communication. Stakeholder comments indicated that a quality culture had been imbued, that training had become infectious, that laboratories had broken ground for others to follow, the road map is set and “the project has been a great success” was stated by a Minister of Health. A further comment indicated that the real results would be seen in a few years because “changing people’s behaviour takes time”.

There have been major capacity building outcomes, networks have been developed, there are private/public partnerships and there are common goals for improvement. There are plans for further development and many stakeholders are committed to the cause and there are changes in policy within and external to the laboratories. There were lessons to be learned but the countries that obtained the maximum benefit had established national advisory committees, developed

strategic plans, had developed systems for monitoring, had active support from MOHs and had wide stakeholder involvement. They also made maximum use of resources and had identified supporters with a personal commitment who were proactive leaders and champions of the project.

What is required is sustainability. There needs to be an endorsement by ministers of health who will adopt and enforce legislation for licensing, provide resources and ensure that the national laboratory advisory committees continue to implement the strategic plans. In addition, there will be continuing activities on a regional basis to ensure that there are continuing curriculum updates, distance education and accreditation mechanisms.

In summary, Ms Wilson said that the strategy and the criteria used to define quality were vital to make the intervention sustainable. The measuring of success should be defined. Perhaps most important of all is facilitating and sustaining behavioural change.

4.2 A Malaysian perspective

Dr K. B. Chua (NPHL/MOH)

Dr Chua explained that in Malaysia there was a Department of Standards with two main functions: the development of Malaysian standards, and the accreditation of conformity assessment bodies. The main functions of the department were to obtain national standardization and recommend standards for approval, and promote cooperation in standardization within the country and internationally. The accreditation activity was involved in conformity assessment, which included testing, calibration inspection and certification of products and systems. It maintained a register of accredited organizations and represented Malaysia internationally. The organization was involved internationally with ISO, IEC, ACCSQ, APLAC, ILAC, PAC and the IAF.

Health laboratories in Malaysia include conventional diagnostic laboratories, molecular diagnostics, health care related analytical laboratories and auxiliary medical diagnostics such as neurology, radiology and audiometry, etc. The main attributes required were capability, capacity and quality, communication and information management and biosafety/biosecurity. The challenges to the implementation of the ISO15189 standard were the high financial burdens, the demands on human resources, the practicality for all diagnostic laboratories and the regulatory process. The key points were documentation, traceability and fitness for purpose. The integrated approach to quality standardization commenced in 1999 with a food laboratory and biochemical screening for hypothyroidism. To this have been added laboratories for TB, bacteriology, diagnostic serology, cytology, a national TB reference laboratory, virology and a diagnostic molecular biology unit. The current organigram demonstrates that there is now an interrelationship between the diagnostic hospital laboratories, medical research, vaccine laboratories, diagnostic public health laboratories and the diagnostic veterinary laboratories.

4.3 The United Republic of Tanzania

Dr C. Massambu (Diagnostic services, MOH and Social Welfare)

The Republic of Tanzania has a population of about 40 million and life expectancies of 51 and 54 years for men and women respectively. Under the MOHSW there was an organizational structure which consisted of a national reference and public health laboratory, referral/zonal laboratories, regional laboratories, district laboratories and dispensaries and health centre laboratories. The organization was successful in that it had a unit for dealing with laboratory services. However, in Dr Massambu's view, this meant that there was sometimes less recognition and a bias towards government and clinical laboratory services.

The laboratory staff are distributed according to need; for example pathologists were found at central and zonal levels but not at district and health centres which were staffed by laboratory assistants whose education was to certificate level only. Laboratory scientists with a first degree would be found at central and zonal levels but not elsewhere. Laboratory technicians and technologists would staff the zonal and regional laboratories. There was an inadequate human resource, and training environments did not resemble working environments. There were also constant changes in technology and emerging diseases.

The equipment distribution showed that the health centre and district laboratories relied on manual techniques whereas the regional, zonal and central laboratories with medium to high volume throughputs relied on semi/automated equipment. Equipment distribution was dependent on set criteria of volume and maintenance was carried out through service contracts to private vendors. The planned distribution of equipment included the use of ELISA, RNA PCR, DNA PCR and flow cytometry technologies. This policy had the advantage of a high degree of harmonization and changes were being made towards the use of automated equipment with ongoing training of biomedical engineers to provide the maintenance. However, significant challenges included changing technologies, too few biomedical engineers, a lack of planned preventive maintenance, a lack of spare parts. A further problem was that some donated equipment was not in the national standard list and not according to the operational plans, some was not registered whilst some donated equipments were second hand.

The purchasing and procurement act of 2004 had harmonized the equipment and supplies purchases into standard lists. There was an operational plan for the national laboratory to support HIV/AIDS care with an inventory requirement for supplies. However, there was open competitive bidding and the use of generic names. There were significant challenges including inadequate knowledge of the materials, no regular updating of the register or list of equipment. There was also an increasing interest by business men in medical supplies without knowledge of technology or ethics. There was irregular supply of reagents and supplies. There is also dependency on donor support.

Some SOPs had been developed for microbiology, haematology, clinical chemistry, parasitology and histopathology. There was an established sample transportation system for HIV early infant diagnosis and CD4 counts. There was also an established EQAS for CD4, ELISA and HIV rapid testing. However, there was a poor infrastructure, inadequate funding and human resource, a lack of planned preventive maintenance of equipment. A major difficulty was the inadequate training of laboratory personnel commencing at undergraduate level.

In terms of information management, there were paper-based systems in all regions with the exception of two zonal and two regional laboratories where pilot electronic systems were in place. These were part of an HMIS supported by DANIDA to capture health statistics and track

resources. Current challenges included inadequate information management, lack of computer knowledge, poor infrastructure (electricity, roads, telephone etc.). There was also an increased workload on laboratory staff.

Despite the fact that there is a national health policy and an operational plan for HIV/AIDS, national standard guidelines for laboratory services, a safety and waste management manual and a laboratory strategic plan for 2008 - 2012 significant problems remain. Problems with the control of documents and records remain. Many are not used, old documents are not updated and there is poor record keeping and writing. Although occurrence management done in some laboratories documentation is poor, there are delays in responding to non-conformity and a lack of established functional SOPs and standardized reporting system.

Although assessments are done and there is supportive supervision with development partners and HIV care treatment partners, it is irregular. There is inadequate knowledge of quality management and no benchmarking system. There are examples of process improvements, such as staff being trained to perform CD4 counts, haematology and clinical chemistry. Quality assurance committees have been formed at national, zonal, regional and district laboratories, an accreditation process has been launched in five zonal laboratories and there is a laboratory mentorship programme. Significant challenges remain because of inadequate knowledge and funds, inadequate human resources and a weak infrastructure. Motivation is low and there are no incentives; this situation is aggravated by an increased workload and inadequate remuneration for staff.

Customer awareness seminars have been conducted in some laboratories. Satisfaction is being monitored by introducing opinion boxes. In other laboratories, a “desk” has been created to receive and respond to customer complaints. Nevertheless, there is no established mechanism to determine customers' needs and satisfaction. There is no biosafety containment level 3 facility in the country and few at level 2. Most laboratories suffer from inadequate space and ventilation. Challenges included the need to update knowledge on laboratory design and the need to improve safety and biosecurity.

Dr Massambu concluded that, although there had been some success in implementing quality systems, it had been mostly due to the technical and financial support from development partners. The ten biggest challenges are:

- the human resource crisis,
- changing technology,
- increased workload due to the increasing burden of disease and emerging diseases,
- donor dependency,
- poor infrastructure,
- inadequate funds and financial management skills,
- lack of motivation and incentives,
- inadequate knowledge of quality system management; and
- the need to change the attitude and mindset in all stakeholders?

4.4 Thailand

Dr P. Silva (Bureau of Laboratory Quality and Standards, MOPH)

Dr Silva's opening remarks indicated that the challenges originally faced had been that there were many laboratories with a wide variation in sizes and varying workloads. A large budget had been spent. However, there was a limited resource with no clear policy. There had been a need to improve motivation and sustain improvements. Objectives had been set which required high output, and that there were improvements that were sustainable and measurable. These changes had to be accepted by all parties and be easy to implement. In addition, they had to be flexible, suit the local organization and structure, had to be achieved with a small budget and required high participation rates. Although there were international standards, particularly ISO 17025 (2005) and ISI 15189 (2003), it had been decided to develop and implement national standards.

There was a national focal point for laboratories, and national standards were drafted and consensus built by peer review. After ratification by national authorities, an implementing agency had been identified which had trained the participating institutes, facilitated the adoption of the standards and monitored and evaluated the process. This was also supported by the local professional body (AMTT) and WHO and CDC.

The process was linked to the accreditation of hospital quality improvement and made use of the international standard (the red book) with the national standards version (the blue book). The sections of the national standards mirrored those of the international standard. There were 10 implementation stages:

- appointment of a steering committee which included all stakeholders,
- identification of the quality standards,
- establishment of the development checklists and scoring system,
- establishing the implementation approach for self evaluation and development,
- coordination within the regions,
- each region to be budgeted separately,
- signing of project agreements,
- budget transfers and progress reports submitted twice a year,
- appraisal of the evaluations; and
- results analysis and adjustment of the plan for the following year.

The strategies for implementation involved establishing partnerships, identifying stakeholders, delegation of responsibilities and the preparation of a work plan with a timeframe. The process also involved an evaluation tool and the assignment of the expected score depending on the level of the laboratory. A systematic development/improvement process was instituted. There was an expectation that each laboratory would perform a self evaluation that could be confirmed by external evaluation. There were 100 individual standards to be assessed and laboratories were expected to indicate full or partial compliance, non-compliance or where not applicable. This

type of evaluation enables laboratories to assess their own progress and groups of laboratories to be regularly evaluated.

Some important lessons had been learnt. Simple systems are easy to implement, a step-wise approach can be used, a comprehensive checklist is vital, voluntary participation makes a good start and that it was important to recognise that different laboratories are at differing levels of quality development. Implementation is more rapid in medium sized hospital laboratories and there are critical factors that influence quality development including training in practical skills. National standards facilitate progress towards meeting accreditation to ISO standards, the use of EQAS is an additional benefit, there had to be flexibility and it is important to have a positive approach.

Dr Silva posed some challenges for the audience: **why** do we have to do this, **when** will we do it, **where** will we start, **whose responsibility** is it, and **how** will we implement.

5. How to reduce pre- and post analytical errors?

5.1 A reminder and analysis in detail of errors incurred during non-analytic phases

Dr I. Gardner (RCPA)

Dr Gardner opened his presentation by reminding the audience that 60-70% of medical decisions are made with the help of laboratory results. Results were produced for patient benefit and there was a request-test-report cycle that began with and ended with the patient, of which the analytical phase was but one. He posed the question: where is it most likely to go wrong? The three main parts of the diagnostic process are the pre-analytical phase, which was influenced by external factors such as the patient, doctor, courier etc., the analytical phase with a focus on the laboratory, and the post-analytical phase where there is a focus on reports, LIMS, couriers and records. The main processes consisted of the pre analytical phases and were:

- patient information including identity, accuracy of patient records and whether the patient was a regular attendee or a single attendance,
- the request which needed to be clear and unambiguous where a doctors handwriting and understanding of the relevant test are important,
- collection of a sufficient volume of the right specimen in the right way and to ensure that any special conditions have been met,
- specimen labelling with mandatory patient identifiers and use of barcodes,
- transportation at the right temperature and at the right time with due regard for infectious specimens,
- selection of the correct specimen type e.g. the need for plasma or serum, and comments about problems including haemolysis or lipaemia etc.

The analytical phases included all the activities taking place within the laboratory, including the selection of the best methods and quality control, EQA, etc. It is the area where the laboratory can achieve the highest level of quality. The post-analytical phase however comprised areas over which the laboratory had some control and other areas that were more problematic. These were:

- the LIMS,
- machine interfaces,
- manual transcription and validation of results,
- correct doctor identification, courier delivery of results and correct filing in patient notes; and
- action on the results to ensure correct interpretation, relevant follow-up tests ordered and counselling of the patient.

So where is laboratory analysis most likely to go wrong? There is a method of measuring incidents involving the pre- and post analytical phases which is designed to identify and benchmark incidents. Recording of such data is a quality system requirement and whilst there are no mandated forms of data recording, there are some broad guidelines. This leads to some inconsistency in how incidents are recorded, which makes comparisons difficult. Dr Gardner pointed out that the ability to benchmark against similar organizations is valuable and can identify areas for improvement. EQA is a valuable tool in measuring some incidents. The RCPA is developing a programme for measurement which will complement existing analytical monitoring called **Key Incident Monitoring and Management Systems**. The Australian government is funding a pilot scheme for 2007/8 which should be fully available in 2009.

In highly functional laboratories the analytical process is normally good and the pre- and post analytical errors account for most errors. Sometimes such errors are outside the control of the laboratory. The advantages of monitoring non-analytical errors were that it enabled identification of major sources of error and indicated where intervention was necessary. It also stimulates the introduction of quality improvements and enables the monitoring of the effectiveness of the intervention.

Dr Gardner pointed out that errors will occur; they cannot be eliminated completely however the frequency of their occurrence can be reduced. While there is no accepted frequency, monitoring will enable benchmarking to take place so that comparisons with like laboratories may be made. Whilst analytical quality is important non-analytical errors can affect the whole process. A technically correct result on the wrong sample is of no value to the patient. A good quality system requires the monitoring of all errors. Dr Gardner stressed that there would be significant analytical errors until laboratories operate fully under ISO guidelines and quality systems. There would, however, still be pre- and post-analytical errors that need to be addressed. Therefore, it is equally important for these laboratories to be aware of where these are occurring.

Dr Gardner concluded that pre- and post analytical errors accounted for the majority of errors in well-functioning laboratories. Every laboratory is different and each laboratory must monitor its own error rate and compare itself with similar laboratories. Although good quality is expensive, poor quality costs much more.

6. Breakout group discussions

Participants were divided into four working groups and given specific tasks:

- how to develop national laboratory policies and standards to support quality systems,
- EQA and development of monitoring tools,
- advocacy for setting and implementing national quality standards; and
- integrated approaches for quality programmes.

The results, reports, conclusions and recommendations from the groups were presented in a plenary session and are summarised in section 9.

7. Strategic frameworks for instituting a global partnership among all

7.1 CDC's activities and its presence as a resource

Dr R. Martin (CDC)

Dr Martin reviewed CDC involvement in international activities, which comprised the investigation and surveillance of a wide range of infectious diseases and the growth of their resistance to anti-microbial agents. Its investigation and surveillance included non-communicable diseases and injury, tobacco use, toxic substances and occupational health. In addition it provided reference laboratory services. It had been involved with CLIA 67 and 88 regulations. It had developed proficiency testing programmes, standards, had world class laboratory facilities and carried out health systems research. CDC's global health strategy covered:

- public health surveillance and response,
- public health infrastructure and capacity building,
- disease and injury prevention and control,
- applied research for effective health policies; and
- exchange of information and lessons learnt.

CDC had divisions that were responsible for specific diseases including HIV/AIDS and TB. Its policy was also to integrate with other programmes and to publish technical information, develop community surveillance frameworks and support and document best practises. Although under the direction of a single director, CDC had integrated its efforts, had a focus on

public health, strengthened its regional networks for rapid detection of emerging infections. It also engaged with many partners including MOHs, multilateral organizations such as WHO, global non-government organizations such as the Red Cross and philanthropic agencies including the UN Foundation and the Gates Foundation. It is important to note that detection of new viruses will occur where they originate and not in the US, and that it was, therefore, crucial to have a global pathogen surveillance system. A number of factors were required in order to respond and this included the assistance of laboratories.

CDC is able to provide assistance including advocacy, direct technical assistance, materials, QA, a network of laboratories, training and collaboration, facilities design, safety recommendations, management and LIMS and further advice on testing algorithms. It also had many laboratory partners world-wide with whom it worked. These partnerships had led to the formulation of guidelines which included IHR and EQA of TB smear microscopy. Finally Dr Martin identified the following future considerations:

- an integrated approach to CDC programmes in countries,
- development of national strategic plans,
- provision of long-term support to QMS training and accreditation,
- support for national laboratory quality systems,
- establishment of national laboratory quality standards; and
- the implementation of quality management systems.

7.2 Expected advisory function of WHO and other partners

Dr R. Robertson (ILAC)

In her opening remarks Dr Robertson gave a short background to the activities of ILAC. In her view collaboration with WHO could help to raise the standards of diagnostic testing. ILAC is the international authority on accreditation with affiliated organizations throughout the world. It actively cooperates with other relevant international bodies and is involved in:

- developing laboratory accreditation practises and procedures,
- promoting laboratory accreditation as a trade facilitation tool,
- assisting developing accreditation systems; and
- recognizing competent test and calibration facilities around the globe.

ILAC was established initially to promote communication and provide peer evaluation. There were 59 signatories representing 46 economies. In all 30 000 laboratories and 5 000 bodies have been accredited. ILAC is structured in such a way that it was governed by a general assembly and a series of committees. A fundamental premise was the use of MOUs between the various bodies that ensured that a laboratory accredited by one partner had equivalent recognition by other partners.

A new strategic and business plan had set new directions for ILAC that enabled it to collaborate with WHO, with whom it shared common goals. Factors that affect a laboratory's performance have already been discussed and ILAC can help with the achievement of these goals by

providing a mechanism to sustain an approach to raising standards as an ongoing activity, by following a holistic approach and by progressively introducing standards and accreditation. ILAC can also support standards–raising through its JDSC and JCDCMAS committees by providing assistance with wider infrastructure development and by building opportunities for personnel. Dr Robertson looked forward to collaborating with WHO in the future.

7.3 Technical support from WHO

Dr R. Bhatia (WHO/SEARO)

Dr Bhatia opened his remarks by reminding participants that WHO is a United Nations specialized agency for health. It has 193 Member States, six regional offices coordinated by the HQ offices in Geneva and Lyon and 147 country offices. Its overall goal is the attainment of health by all peoples to the highest possible level. It works with MOHs to promote consensus, policies and practices both internationally and at country level. The highest level policy setting bodies are the World health Assembly (WHA) and in the regions the regional committees.

Policy directions had been set by the WHA in 1974 and 2005; and, for example, by the SEARO Regional Committee in 1971, 1972, 1973 and 1996.

Quality is attained in the core functions by:

1. articulating consistent ethical and evidence-based policy and advocacy positions,
2. managing information by assessing trends and comparing performance; setting the agenda for, and stimulating research and development,
3. catalyzing change through technical and policy support in ways that stimulate cooperation and action and help to build sustainable national and inter-country capacity,
4. negotiating and sustaining national and global partnerships,
5. setting, validating, monitoring and pursuing the proper implementation of norms and standards; and
6. stimulating the development and testing of new technologies, tools and guidelines.

WHO recognizes the importance of laboratories in the prevention of communicable and non-communicable diseases, for monitoring treatment, promotion of health and research directed at improving the quality of life. Laboratories are also critical for achieving the millennium development goals because they are essential components of the public health infrastructure.

The major issues confronting quality in laboratories include lack of awareness, a low priority at national level, inadequate expertise and knowledge of technical staff, poor networks, weak logistics for NEQAS, weak regulatory frameworks and sustainability. The support provided by WHO is aimed to address all of these issues. WHO does have a large number of publications aimed at addressing some of them. Tools have been developed to enable laboratory assessments to be made. Inter-country meetings are held to exchange information and training courses and workshops are held. For example, three cohorts of trainees have been held on capacity building using the WHO/CDC/CLSI training package. There are also major global networks of laboratories in specific fields including rubella, polio eradication, influenza surveillance, salmonella surveillance network, yellow fever and TB that are associated with reference, EQA and accreditation. Each regional office is also to a greater or lesser extent involved with the management of EQA programmes. Some of the regional offices have a specific focus; for

example PAHO has a network for dengue with a series of collaborating centres and reference laboratories. In the African Region there is an EQA scheme now in 45 countries and three consignments per year have been sent to all participants since 2002. There is good evidence, for example EQA for CD4 counts that such distributions help in the quality improvement process.

Dr Bhatia also described the important activity of kit evaluations that WHO carries out in order to achieve pre-qualification. It is able to purchase test kits at advantageous prices on behalf of more than 50 States; some 15 million test kits have been purchased for priority diseases.

Biosafety is of major importance and WHO has held workshops for information exchange, it gives advice on regulations for safe transport, runs training courses and provides technical support. It is also able to mobilize resources from, for example, the World Bank, DFID, ADB, the global fund and CDC. Strengthening quality as an integral part of a national laboratory system is a priority and there are global networks that support countries whose efforts are coordinated by WHO/HQ in Geneva.

In his final remarks Dr Bhatia posed the question: **What is Quality?** In his view it is about science and philosophy. **Quality is consistency and happiness.**

8. Breakout group presentations and discussions (plenary)

Group 3: Advocacy for setting and implementing national quality standards

Rapporteur: Professor C. Heuck

One objective of the Conference was to give delegates an agreed statement and recommendation, to be endorsed by all Conference participants, to be used in advocating to governments. A draft was prepared prior to the meeting, circulated for comment to WHO, CDC and an expert group. Modifications were made in the light of comments and presented to the group for discussion. Extensive discussion took place and further modifications made, which were put to the plenary session for further comment, discussion and modification. The agreed statement is in Annex 1.

The objective is that this statement can be used as a stand-alone in its own right and used by delegates when advocating the introduction of quality systems into their laboratories. It encapsulates all the main recommendations coming out of the Conference. The possibility of publication was discussed and delegates thought that it might merit publication in a scientific journal. It was agreed that the joint sponsors of the Conference investigate this possibility. It was also suggested that a more detailed and technical document could be produced based on the original statement.

Group 1: How to develop national laboratory policies and statements to support quality systems

Rapporteur: Mr G. Fine

During discussions it became clear that there are already good examples of projects being conducted to strengthen laboratory capacity in resource-constrained countries. Therefore, a careful search will reveal that there is no need to re-invent the wheel. Strong policy level support is required. **Champions are required within the political structure and the MOH** (be mindful that MOH officials have broad mandates of which laboratories are but one). There is often less understanding of laboratory issues than is wished. International organizations can and should help. It is important to **measure results**. (For example the % of the population that knows its HIV status). Remember that **what gets watched gets fixed!**

Specific recommendations:

1. Each country should have a national public health laboratory that has identified competencies based on minimal appropriate internationally recognized standards (for example ISO 17025 and 15189, CLSI etc.) and includes all phases of the quality cycle from pre-analytical through to, and including, the post-analytical phase that also

complies with IHR 2005 regulations and requirements. (A reasonable timeframe to be determined by WHO).

2. Develop model legislation (perhaps developed by WHO?) for the national use of international laboratory standards. There should be national regulations.
3. There should be accountability for the results. There needs to be a mixture of carrot and stick approaches with the use of rewards and recognition, and punitive actions that might include loss of work, loss of laboratory accreditation and laboratory closure. Such actions have to be taken with the use of undisputable evidence.
4. Introduce accreditation and use international standards to give credibility (WHO to take the lead to raise standards without the necessity of accreditation). Use a phased approach, an example being that of the approach used in Thailand, so that regional, district and/or local levels use a scaled down nationally based accreditation or “certificate of compliance” (consider the use of national councils representing all key stakeholders). Select an accreditor who is willing to build in scalability and flexibility into their scheme.
5. Tackle the difficult problem of human resources and use laboratory expertise as a driver. Focus on schools of laboratory training and of undergraduate and postgraduate training. Ensure that quality and quantity of the programmes are up to date. Attitude and culture changes may be required. Everyone wishes to be listened to, so include stakeholders. Train staff at all levels and all environments; problems often lead to inspiration.
6. Provide appropriate levels of funding. Use existing financial evidence on the need for quality (Royal college of Pathologists, EDMA). A business case should be made to show that there are wasted resources on treating wrong or misdiagnosed diseases. Strengthen the services so that they have the ability to show the prevalence of disease and the evidence of decline over time so that donor funding can be attracted. Heavy reliance on donor support in resource-constrained countries is a reality for the foreseeable future so develop solid plans to attract major funding and fit it into the national plan and directed where it is needed. Show demonstrable results that funding is well spent so that revenue streams are maintained. Make a business case for development and implementation for laboratory improvements based on a quality system.

Group 2: External Quality Assessment (EQA) and development of monitoring tools

Rapporteur: Dr M. Noble

During the general discussion it became clear that providers of EQA are in a unique position. Although participation in EQA is anonymous, it is inevitable that organizers do know the identity of their participants. However, unless there are agreed arrangements to the contrary, performance information is not divulged to third parties. Whilst they might be the first point of call for a laboratory requiring assistance, they do not see themselves as directly involved in any regulatory activity. They are primarily involved in education although evidence from the scheme may be used as evidence of performance.

The most significant outcome of the introduction of quality measures is the engagement of clinicians and government with laboratory staff.

Specific recommendations:

1. EQA must fit the needs of the local situation; blends of national, local and vertical programmes are appropriate.
2. Transportation costs and complexity are major impediments. WHO and other organizations must work with ICAO and other agencies to have exemptions for transporting quality materials.
3. The process of accreditation of EQA providers should be examined to look for barriers that hinder widespread compliance.
4. The use of internal quality indicators and confidential release of performance information can be beneficial to advocate for capacity building and should be considered by all.

Laboratories need to be aware that they have three customers: the patient, the clinician and the public health sector.

After the general discussion it was further recommended that all national reference laboratories participate in international EQA schemes.

Group 4: Integrated approaches for quality programmes

Rapporteur: Dr J. Ridderhof

During the discussion it became clear that there is a need to develop the message, but that there are significant challenges and obstacles, such as planning requirements, a need for advocacy and the organizational components required. Advocating for integrated approaches for quality programmes would be aided by the statement agreed during the earlier discussion. In addition, considerable information had become available during the Conference that was useful to promote collective actions. However, perhaps the difficulty of convincing donors to specific diseases could not be over-estimated and much discussion would be required with them.

The major discussion points and specific recommendations made were as follows:

1. To develop and change the message that there is a need to develop a systems approach, with a focus on quality systems and standards to achieve the common goals of quality patient care and public health programmes. All programmes gain through a shared approach.
2. There are particular challenges and obstacles to be overcome. Resources are allocated through disease-specific programmes, and, at national level, people and institutions are managed by separate programmes. Public laboratory systems do not intersect with the private sector.
3. Quality system planning should be part of a larger national laboratory system that is managed by the MOH which will coordinate the contributions of donors and programmes including all disease specific programmes, clinical services and stakeholders. Strategic planning provides an opportunity to combine programme resources for an integrated system.

4. Countries should develop an advocacy plan and tools to solicit programme support for integrated laboratory strengthening. Advocacy must include a business rationale and evidence for investing in systems. Also the case are strengthening laboratory leadership and management to integrate public health programmes and patient care.
5. There are organizational components to be addressed that include the fact that the global framework of disease programmes is required to support quality systems and organizational changes. The MOH should have a strong national director of national laboratory systems. The director should ensure that programme resources are combined.
6. to strengthen core functions and that there is a disease-specific national reference system.
7. A national quality system organization must develop national policies that support and mandate the system. There will be requirements for a national steering committee that is inclusive of all programmes and that can guide implementation. EQA functions should be combined or integrated. There must be guidance on biosafety and ethics, and there must be programmes for education and training at all levels.

9. Conclusions and recommendations

9.1 Conclusions

There was general agreement that the meeting had provided the opportunity to discuss the changes required to improve the quality of laboratory services in developing countries and discuss ways in which quality systems might be introduced. It is accepted that laboratories form an important part of the health systems of all countries, which exist to provide good quality services to their respective populations. Good quality laboratory results were required to ensure that patients were investigated appropriately and received the correct treatment. It is accepted that the introduction of such programmes require significant investment but this is small when compared to the economic consequences of poor quality. There is also significant misery for patients and their families if they suffer the consequences of poor laboratory performance which may include an incorrect diagnosis or inappropriate treatment. Delegates now had an opportunity with the knowledge provided and the agreement of an advocacy document (see section 9 and Annex 1) to help in convincing governments of the need to invest appropriately.

Major success stories from developing countries had been described during the Conference and several examples presented ways for producing and implementing the standards that needed to be introduced. A major message from the meeting was that there was **no need to re-invent the wheel**. Learn and adapt from countries with a successful plan that have a similar culture, political system and economic status etc. The tools already exist to enable progress to be made.

The first stumbling block of convincing ministries of health to commit to the programmes of improvement had to be overcome. Political will and leadership at the highest level is required and the “advocacy paper” is intended to help with this process. Any programme of change had to be fully inclusive and involve all partners, donors and professional laboratory workers at all levels of the service. The potential role of support from clinical colleagues must not be ignored; it is they who have to make use of the services and from whom much useful advice may be obtained. Above all, the process must include methods of measuring success and other changes. EQA is but one major measurement tool that must be developed, employed and interpreted progressively at all levels. Whilst many of the standards for implementation were related to the analytical process it was very important that due attention was paid to the pre- and post analytical processes which were also of vital importance. Such non-analytical errors will ruin any good work that has gone in to solving the analytical problems.

9.2 Recommendations

These main recommendations are a combination of those made by consensus in the main body of the meeting and those made by the breakout groups and include those for WHO, laboratory professionals and ministries of health. These are in addition to those made by the specific breakout groups.

For WHO

WHO should set up a resource and advisory group to assist Member countries in the development of their national laboratory plans.

It is accepted that donor aid is essential but WHO should consider coordination to enable more efficient use of these valuable resources.

WHO should develop potential models of legislation and accreditation for adaptation and use in Member States.

For laboratory professionals

Laboratory professionals should use the advocacy document to convince ministries of health of the need for strategic development.

When implementing quality management systems, use should be made of the WHO/CDC/CLSI toolkit.

Laboratory professionals should provide the business rationale and evidence required for the investment in quality systems.

For ministries of health

There is a need to develop a fully integrated structure and referral system within which all health laboratories, including those involved in WHO technical programmes should operate. The objective is to develop a national laboratory organization, within the national health plan, that is responsive to the needs of patients and all users of the service.

The strategy for implementing quality management must include an examination of the potential constraints as listed in this report. A focal point within the ministry is essential, with a core advisory committee or group of experts, which will legitimise the process. Those able to drive or act as champions of the programme should be engaged.

Quality Management Systems and quality standards should be introduced at all levels of the laboratories organization.

External Quality Assessment (EQA) is an essential tool and it should be coordinated at a national level. Other tools should be developed and used to measure success and progress.

National Reference Laboratories should seek to be accredited by international bodies to internationally accepted standards. Other laboratories will require a phased or staged approach to achieve appropriate accreditation.

10. Closing remarks

10.1 Rapporteurs

Dr D. Browning & Dr J. Zwetyenga

Dr Browning summarized some of the main conclusions and recommendations. Laboratories are a major part of the health systems, which were themselves attracting investment and attention from WHO. Up to 70% of clinical decisions are made with the support of laboratories, and therefore, it is imperative to have good quality. At the present time our “customers” lacked confidence in our results and remedial action is required. Quality management is required by all laboratories irrespective of levels and range of activity. National reference laboratories should aspire to be accredited to international standards whilst others within countries should be accredited to national standards. Structures should be integrated but the investment need not always be large. Remember no result is better than a poor quality one.

The quality management training toolkit developed as a result of collaboration between WHO, CDC and CLSI was extremely valuable, could be modified for use in all countries and had 12 specific elements.

There are serious manpower difficulties which have to be rectified; undergraduate training curricula require modification and there are serious problems of staff migration, retention, motivation and satisfaction. Above all behavioural change is required.

Specific recommendations have been recorded from the breakout groups and will be included as will the main recommendations from the Conference.

10.2 Delegates

Dr R. Amini (Iran (Islamic Republic of))

On behalf of all delegates Dr Rana Amini thanked WHO and CDC for organizing the Conference which had come at an appropriate time. Delegates had had the opportunity to discuss the changes that needed to be made in order to meet the expectations of users of laboratory services. The question had been posed: what is the answer? Many questions had been answered and she thanked those who had made presentations and for the discussions that had taken place. Delegates now faced the challenge of what they should take from the Conference and how they should commence the implementation of what had been learned.

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Annex 1

Joint WHO-CDC statement: Laboratory quality systems in the 21st century

As we move into the 21st century, diseases of public health importance continue to be a significant global threat. Widespread epidemics could cost millions of lives, and many countries are still struggling with a longstanding battle against rampant infectious diseases. In addition, chronic diseases, which in the past have been primarily of concern in wealthier countries, are now affecting other populations.

In order to deal effectively with the detection, treatment and prevention of these global threats to the health of the public, it is essential that accurate and reliable health laboratory testing be available in every country. Early detection and management of disease outbreaks can only be accomplished if responsive laboratory systems are in place. Many therapeutic decisions rely heavily on data from health laboratories. Prevention of infectious and noncommunicable diseases requires accurate diagnostic information. The critical importance of high-quality health laboratory services is now widely recognized.

Given the vital role that laboratories play in every aspect of health services, it is imperative that countries undertake the necessary measures for support and improvement. A laboratory quality system that engenders trust and confidence in laboratory services is essential. The ultimate goal is to ensure the provision of accurate, reliable and timely laboratory test results that are indispensable to all health activities and to support international health security. Cost and social benefits also result from high-quality laboratory services.

To ensure that health laboratories, irrespective of their location, can meet international requirements, laboratory systems in all countries will require strong political support and the means to institute measures for improvement and compliance.

Recommendations:

Organize national structures to support a country-wide laboratory quality system

National structures capable of supporting a quality system for laboratories at country level will require the following measures.

- The placement of skilled laboratory scientists/managers with sufficient authority in leadership positions in the ministries of health;
- Creation of a national laboratory quality office and appointment of a quality officer with authority and responsibility for oversight of national laboratory quality programmes;
- The allocation of adequate financial resources to ensure compliance with national quality programmes.

Establish national laboratory quality standards

International efforts are under way to develop health laboratory standards that help to ensure quality. These efforts should be supported as follows:

- Each country should establish its own set of standards according to country-specific needs based on internationally agreed standards.
- National laboratory standards need to take into account local factors, including any pertinent regulations, organization of the country's laboratory system(s), and resource constraints.
- It is recommended that countries with limited resources consider taking a staged approach, where principal requirements for all are stated in the national laboratory standards as a minimum requirement while more advanced and national reference laboratories are encouraged to aim at meeting internationally accepted standards such as ISO 15189.

Implement major laboratory quality system programmes

Many activities associated with quality assurance must be carried out by local laboratories, but assistance and oversight will be required at the national level. The following activities should be planned at a national level, with help and input from laboratories throughout the country, to:

- establish and revise national quality standards;
- establish strategy, aims and measures of progress;
- ensure that laboratory facilities and infrastructure are adequate and properly maintained for all testing being performed;
- ensure safety in all health laboratory facilities to protect workers within the laboratory, visitors to the facility and the general public at large;
- establish long-range plans for ensuring adequate and sustainable numbers of properly trained personnel for conducting laboratory operations;
- apply appropriate quality systems to all parts of laboratory management and operations, including the procurement process for supplies and equipment;
- develop national resources for ensuring internal quality control and for external quality assessment;
- develop a process for monitoring laboratory performance improvement;
- encourage the development of a structured advisory network for laboratories.

The governments of Member States led by ministries of health are urged to involve all stakeholders and interested parties in order to achieve these objectives.

Annex 2

Conclusions and recommendations of the working groups

Group 1: How to develop national laboratory policies and standards to support quality systems

Prior to the general discussion two presentations were made by Dr V. Bevan, and Dr C. Mwangi

1. Ms Bevan's presentation was on the contributions of the UK Health Protection Agency towards quality systems in UK laboratories. She began her presentation by emphasizing that the HPA was "dedicated to protecting people's health". It was involved in assuring quality and described the standards necessary which included QA, a service culture that focused on the user of the service, met accreditation standards and had a quality manual and other specified standards. SOPs were key as were the use of standard methods. At present, there are 75 bacteriology methods, 36 virology and 37 for food, water, dairy and environmental assays. There specifications given for culture media and 41 guidance notes. All were developed in conjunction with national health service bacteriologists. Testing strategies were set, as were the minimum acceptable standards for front line and confirmatory testing. The standard methods gave comprehensive information on all theoretical and technical matters and contained literature reviews and references. The objectives were to help accreditation and to have information on existing best practices. There is guidance on pre-analytical sampling and to help users make informed decisions. Some quality control reagents were supplied to assist laboratories with their IQC; future reagents included molecular quality control materials for, among others, chlamydia. International collaborative work was undertaken with NIBSC and CVN for more molecular standards. All these efforts towards standardization helped to ensure consistent high quality services by individual and groups of laboratories.

2. In her presentation, Dr Mwangi described the contribution that the Central Public Health Laboratory, Republic of Tanzania, has made introduced her remarks by pointing out that the laboratory services in Zambia had commenced in 1897 when Dr Robert Koch had established a government laboratory in Dar es Salaam. Many changes had taken place since. In 1961 the original laboratory had grown to become the Central Pathology Laboratory (CPL) which functioned as a reference and public health laboratory. Its original functions included the distribution of equipment and supplies, the provision of support to the school of medical technology, training technicians and writing SOPs. As health care developed, the CPL gradually became a laboratory for the national hospital and lost its role in giving oversight or supervision to other laboratories. This eliminated support to the periphery and reduced policy formulation and its regulatory role. In 1972, the laboratory services were aligned with new government administration structures. Laboratories became managed by health centre and regional development directorates. Referral laboratories were managed separately by central government. In 1991, the laboratory services were further organized to establish better managerial systems, coordination and improvement of the structure. The changes were expected to promote training of staff, standardize equipment, promote local production of all supplies and establish and enforce an ethical code for all laboratory health professionals. The result

was an organization split into specialist and consultant laboratories headed by a pathologist at regional, district, health centre and dispensary levels. The types of equipment, staffing and range of tests for each level were specified. More recently private laboratories have been regulated and health technologists registered. These changes did not result in the desired outcomes.

In 2002, a further assessment of the laboratory services, capacity and organization was conducted. The analysis found that there were many problems, including poor training, lack of QA and loss of public health laboratory functions. The investigation recommended a centralized model for service delivery and the creation of a national health laboratory system. This recommendation was not followed up. In 2003, the laboratory standard guidelines were reviewed to keep pace with changing demands. They were to:

- set an management organizational structure, have in place central administration and management, set the roles for and functions for diagnostics and define committees as the needs arise;
- set minimum standards (according to WHO/CDC/ CLSI guideline modules);
- provide guidance on equipment , maintenance, supplies and a specimen referral system;
- set minimum personnel requirements, skills, training , and job descriptions were written; and
- standardize methods and develop performance assessment systems developed.

The public health laboratory network in Tanzania now consists of a tiered system of six referral hospital laboratories, 23 regional and 133 district laboratories. Although an attempt had been made in 1986 to establish an NEQAS at national and regional levels the schemes were fragmented and, in 1998, they were revised.

With the help of CDC Tanzania, the MOH created a plan of action in support of the HIV/AIDS care and treatment programme. Recently, the MOH has released a QA framework to provide guidance on sustainable implementation of quality laboratory services by instituting a programme of quality improvement. It promotes monitoring and evaluation, provides tools and sample documents. There are national and zonal advisory committees. The quality assurance framework was fully endorsed and is being implemented through a phased work plan. A road map to quality has been produced with the assistance of CLSI. Phase 1 of the plan required a GAP analysis and the development of a quality plan. Implementation has taken place with the use of technical groups and selecting key areas for immediate attention.

Significant challenges remain, which include the fact that laboratory services span two ministries, there are inadequate capacities in the laboratory team and more than 20 partners are offering support. Guidelines require review: there is an inadequate number of trained staff, there are infrastructure needs, there is no national QA programme, there is no public health laboratory, there is a need to scale up the operation but there are financial constraints. The LIS requires standardization and information mechanisms are required. There are no systems for equipment maintenance.

Nevertheless there are success factors, which include coordination and consultation, donor coordination and laboratory partner's coordination. There is political will; there are guidance documents and partner support. Finally, Dr Mwangi pointed out that success depended on: collaboration, coordination, communication, commitment and continuity.

A lively and participative discussion followed which resulted in a number of good options for individual country representatives to take part and for internationally focused organizations to consider. In addition to recommendations on the need for strategic planning, there were six main recommendations. It was agreed that the strategic planning for laboratories had to be integrated into the overall health plan and that all major stakeholders should be involved. Developing consensus was important as was making the goals and timelines realistic. Identifying champions to drive the programme was vital. There are two main approaches; bottom up and top down, neither are perfect. There is already considerable information on planning and implementation available, including that from similar environments so we do not re-invent the wheel. Rather, we should:

- define the difference between strategic planning (three years plus timescale) and operational planning (1-2 years);
- design quality systems so that there is a high probability of early success to build confidence and develop a core group of experts in key areas;
- be realistic based on the political realities of capability, capacity and quality;
- clarify the roles of public health laboratories, hospital and private laboratories and ensure that all are integrated into the whole system;
- educate stakeholders to understand that quality is key.

WHO should set up a resource and advisory group to assist countries in advocating on behalf of quality systems to be implemented by WHO regional offices. There are many donors with differing goals but donor funds should be used in accordance with the country national plan and be coupled with government support and accountability.

Strong policy level support is required. Champions are required within the political structure and the MOH. We must also be mindful that MOH officials have broad mandates of which laboratories are but one. There is often less understanding of laboratory issues than is wished. International organizations can and should help. It is important to measure results. (For example the % of the population that knows its HIV status). We need to remember that what gets watched gets fixed!

Specific recommendations:

1. Each country should have a national public health laboratory that has identified competencies based on minimal appropriate internationally recognized standards (for example ISO 17025 and 15189, CLSI etc.) and includes all phases of the quality cycle from pre-analytical through to, and including, the post-analytical phase that comply with IHR 2005 regulations and core capacity requirements (a reasonable timeframe to be determined by WHO).
2. Develop model legislation (perhaps developed by WHO?) for the national use of international laboratory standards. There should be national regulations.
3. Be accountable for the results. There needs to be a combination of carrot and stick approaches with the use of rewards and recognition, and punitive actions that might include loss of job, loss of laboratory accreditation and laboratory closure. Such actions have to be taken with the use of undisputable driven evidence.
4. Introduce accreditation and use of international standards to give credibility (WHO to take the lead to raise standards without the necessity of accreditation?). Use a phased approach, an example being that of the approach used in Thailand, so that regional, district and/or local levels use a scaled down nationally based accreditation or

“certificate of compliance” (use of national councils representing all key stakeholders to be considered). Selection of an accreditor that is willing to build in scalability and flexibility into their scheme.

5. Tackle the difficult problem of human resources and use laboratory expertise as a driver. Focus on laboratory training schools of and on undergraduate and postgraduate training. Ensure that the quality of the programmes is up to date. Attitude and changes in culture may be required. Everyone wishes to be listened to so include stakeholders. Train staff at all levels and in all environments. Problems often lead to inspiration.
6. Ensure provision of appropriate levels of funding. Use existing financial evidence on the need for quality (Royal College of Pathologists, EDMA). A business case should be made to show that resources are being wasted on treating wrong or misdiagnosed diseases. Strengthen the services so that they have the ability to show the prevalence of disease and the evidence of decline over time so that donor funding can be attracted. Heavy reliance on donor support in resource-constrained countries is a reality for the foreseeable future therefore solid plans must be developed to attract major funding and fit into the national plan and directed where it is needed. Show demonstrable results that funding is well spent so that revenue streams are maintained. Make a business case for development and implementation for laboratory improvements based on a quality system.

Group 2: EQA and development of monitoring tools

Prior to the general discussion three presentations were made by Dr R. Amini, Dr J. Carter, and Mr J. Elliot

1. Dr Amini described the reasons for performing EQA. The main reason in her view was the need to establish the point of failure in the analytical and correct it. This is important for the laboratory as well as policy makers. There are key points when designing an EQAS, which include identification of priority areas, the spectrum of tests, laboratory capability, reproducibility, programme continuity, costs and cost effectiveness. There are international providers who provide high quality services which save time and trouble and who have a wide spectrum of tests at a fixed timescale and with data analysis. However, they are costly, there are shipment problems, they are not designed to address the specific needs of each laboratory and may not be able to detect the problem areas.

The answer has to be to carry out a situation analysis and assess cost effectiveness. It is important to know the number of laboratories in a country, the spectrum of tests and the number of laboratories that perform them, to prioritize the aims and goals for improvement, to know the budget and the shipment costs.

The goals are to verify the quality of results obtained at all levels of the service, to detect problems and evaluate kits and reagents, give assistance to solve problems, to stimulate and maintain good performance and to ensure the performance of national health programmes and to help verify the epidemic preparedness. The spectrum of disciplines and numbers of analyses are very wide. Dr Amini's experience led her to the conclusion that mixed materials should be used and the choice based on needs. The materials should always be analysed centrally so that the quality control materials themselves are controlled. It is wise to run a pilot trial before the introduction of a national scheme. Customer satisfaction was important.

2. Dr Carter described the East African Regional External quality Assessment Scheme (EA-REQAS). This is a pilot programme underway involving laboratories in Kenya, Tanzania, Uganda, and Zanzibar. It involved scheme development, organization at a regional level and national coordination, the use of reference laboratories, participating laboratories and a method of providing support by supervisors to enable remedial action. It is currently in a pilot phase and involves 200 laboratories in nine districts/countries and laboratories at all levels of the services.

There was a set of criteria for the selection of tests, including clinical importance, public health importance, those performed at a primary level using techniques of accepted accuracy, where materials could be preserved and using materials that were stable at warm temperatures. The range of tests and techniques reflect the priority of the countries, e.g. haemoglobin for anaemia, thick blood film for malaria and trypanosomes, and sputum for TB, to name a few.

The survey material is prepared by selected reference laboratories and SOPs for their preparation have been prepared; MOUs have been signed with each. There are reference laboratories in each of the countries. In the first year, eight tests were surveyed and in the second year a second set of tests were surveyed, including plus the two worst from the previous distributions. Tasks have been assigned to the national and regional coordinating centres which include preparation of materials, purchasing of supplementary supplies, organizing the delivery of the material, further QA checks, repackaging and preparation of instruction sheets. In addition, payments have to be made to the reference laboratories.

The advantages of local material preparation include:

- regional participation and scheme ownership;
- local pathology (parasitology);
- increased variety of material;
- use of existing transport systems;
- reduced costs ;
- capacity of reference laboratories; and
- regional cooperation.

This approach also generated great enthusiasm, however some disadvantages and problems do occur with locally produced materials, such as delays in preparation and submission, communication and payments to centres in different locations, the variability in the quality of the preparations and the fact that it is very manpower intensive.

3. Mr Elliot indicated that of the 12 essentials in the quality system suggested by the WHO/CDC/CLSI collaboration each was amenable to being monitored and quality indicators were used for all. The methods employed to monitor quality included IQC, participation in EQA, internal audits and external audits (peer review audits). The difficulty was about where to begin. Many of the drivers were the need to achieve accreditation. Besides, implementing quality is a journey. There were advantages such as introducing a quality system that lead to quality improvements, improved staff training, better relationships between laboratory and clinical staff, gaining international recognition, the subsequent improvements in patient care and subsequent cost savings. There were also some perceived disadvantages such as the apparent costs of getting there and the additional challenges for laboratories in resource-constrained countries. It is possible to set quality indicators. They are:

- turnaround times;
- continuing staff education (professional development programmes);
- regular meetings between laboratory and clinical staff;
- adherence to equipment maintenance schedules;
- stock inventory and procurement systems in place;
- continual monitoring of IQC and EQA results and taking corrective action; and
- monitoring of compliments and complaints.

Documents and records are central to an effective quality system and the production of SOPs is a good place to start.

During the discussion that followed, it was concluded that there are advantages and disadvantages to international and local EQA programmes and both have their challenges. Transport is a serious difficulty locally and particularly internationally where customs officers had difficulty in recognizing the importance of quality materials. In some countries, the ambient temperatures presented particular problems. EQA samples can be a safety problem for some end users. Some reference and research laboratories may not benefit from EQA because of their particular needs.

EQA providers see their role as primarily an educational one and methods of grading and assessment are part of the education process. Quality improvement activities that are based on external agencies are difficult to sustain when those agencies leave. Political and financial support is essential. Motivation, training and empowerment are powerful drivers of laboratory quality. EQA enables the evaluation of kits, reagents and equipment and provide assistance in decision making for policy makers. The most important useful approach to the introduction of quality measures is the bringing together of the laboratory with the clinician and government.

Specific recommendations:

1. EQA must fit the needs of the local situation; blends of national, local and vertical programmes are appropriate.
2. The costs and complexity of transportation are major impediments. WHO and other organizations must work with ICAO and other agencies to have exemptions for transporting quality materials.
3. The process of accreditation of EQA providers should be examined to look for barriers that hinder widespread compliance.
4. The use of internal quality indicators and confidential release of performance information can be beneficial to advocate for capacity building and should be considered by all.

The discussion closed with the reflection that laboratories need to be aware that they have 3 customers: the patient, the clinician and the public health.

Group 3: Advocacy for setting and implementing national quality standards

One objective of the Conference was to give delegates an agreed statement and recommendation from the Conference for them to use, as a stand alone document, to be used in advocacy to governments. A draft was prepared prior to the meeting, circulated for comment to WHO, CDC and an expert group, modified in the light of comment and presented to the group for discussion. Extensive discussion took place and further modifications made which were put to the plenary session for further comment, discussion and modification. The agreed statement is in annex 1

Group 4: Integrated approaches for quality programmes

Prior to commencing the discussion the group heard three presentations from Dr Y. Issabre, Dr J-M Gabastou and Dr S. Van Beers

1. Dr Issabre described the quality implementation project in Mali, which was a collaboration and partnership agreement with the Mérieux Foundation, the EU, the MoH Mali and with technical support from WHO Lyon. The overall objectives were to strengthen the capacities of the medical laboratories network and standardize laboratory practices. There were specific objectives, including the regular maintenance of laboratory equipment, training for staff, monitoring activities, setting up QA and to set up a centralized system for stock management and purchase.

In Mali, the laboratory network is organized into three levels: at the central or national level there are reference laboratories, focal points for integrated disease surveillance and specialized private and public laboratories for reference activities for all specialities. At the intermediate or regional level are the regional hospital laboratories and at peripheral and operational level will be found the health reference centres and community health centres.

In 2005, an assessment showed that quality systems were not in place. There was weak involvement by laboratory technicians, infrequent use of IQC, equipment checks rarely performed, poor equipment maintenance and with the exception of the national TB programme, almost no external evaluation.

During a workshop held in 2006 a national plan for QA was formed. The objectives were to ensure the adoption of a national quality policy, training staff in QA, implementation of QA, the setting up of a programme for EQA and monitoring the results of these activities. There were specific planned activities which included the implementation of EQA in 38 laboratories, supervision of laboratories and the setting up of a QA steering committee to coordinate the programme.

Training of trainers was carried out and network stakeholders trained at regional level; further training of directors and health managers and laboratory staff was conducted. Standardized diagnostic methods for priority diseases were introduced in order to improve performance. An EQA unit was formed in the national institute of research and public health. A capacity assessment of laboratories ability to participate in the EQAS was undertaken. Training in supervision of quality was performed.

The project has been coordinated by a steering committee which includes staff from the MOH and reference laboratories and a representative from Mérieux Mali Foundation. Its

mandate is to adopt and circulate guides for good execution of analyses, training coordination, support to the EQA scheme, supervision of the EQA unit, to coordinate the supervision of network laboratories and to provide access to accreditation bodies.

Initial achievements include the use of SOPs, capacity strengthening of the national EQA unit, strengthening the capacity of the equipment and reagents procurement unit, validation of the QA plan by stakeholders. A capacity assessment of the network of laboratories participating in the EQA schemes for malaria, TB, HIV and meningitis. In addition, two biologists have been trained in Johannesburg to further strengthen the EQA unit.

In conclusion, Dr Issabre believed that further achievements in network building and monitoring included:

- provision of 73 laboratories with equipment for environmental and analytical activities, consumables, reagents and stains;
- monthly supervision of in-country laboratories;
- organization of continuous education sessions; and
- the analysis of quarterly reports from the regional network in order to provide an evaluation of biological analyses framework and take corrective action where necessary.

To date the activities have cost a total of €745,425.

2. Dr J-M Gabastou stated that safety awareness was particularly important and was part of the quality assurance activity. Examples of the need for awareness included the dangers posed by, for example, anthrax, West Nile virus, SARS, avian influenza and the potential for an influenza pandemic. There were many other potential threats scattered throughout the world.

The IHR agreement in 2005 pointed to the laboratory response required during an outbreak. A key message was that laboratory services are essential to identify and confirm outbreaks and optimum working conditions required, including communication, specimen collection and transport, resources, biorisk management, trained staff, infrastructure, functioning equipment, appropriate reagents and reliable results. Unfortunately, this capacity cannot be “switched on” just for outbreak investigation. In 2005, the WHA asked Member States to follow WHO guidance and review laboratory safety, implement safety programmes, enhance compliance, mobilize resources and encourage the development of training programmes and competency standards.

The role of WHO is to actively support other programmes and partners, and to update guidelines. There is already much information available, including the WHO Laboratory Biosafety Manual, 3rd edition, 2004. From a global perspective, the question that needed to be asked was: do the laboratories meet appropriate internationally recognized standards? Further considerations included efficient use of resources, minimum risk to patient, the level of patient satisfaction and what the impact on health was. There are key elements in the quality system covering policy, process, monitoring tools and sustainability. In quality systems the issues of quality, biosafety and ethics overlapped. In addition, there was need to consider how biological materials were to be transported safely and there are international agreements for this. In conclusion, Dr Gabastou said that there was no escaping the fact that biosafety is an essential component of a quality system and that an integrated approach was required.

3. Dr Van Beers began her remarks with a quote “Quality costs money; No quality costs a fortune”. Quality can only be assured by a well-defined quality system aimed at ensuring consistency, reproducibility, traceability and efficacy of the products and services. There were several levels of quality implementation and a systematic approach is required. This starts with user requirements through the examination process and user satisfaction or dissatisfaction. There were resource needs and these were required by all laboratories including those for TB, HIV and malaria. Support systems were also required and these overlapped between the diseases. The quality improvement systems also overlapped. It is therefore logical to integrate the systems and embrace all diseases simultaneously. There are essential factors in quality management according to ISO 15189 that apply to all laboratories. Identified problems in quality systems show that 23% are process related and 77% are structure related. The various elements of ISO 15189 define essential elements in the quality management system for medical laboratories to meet service delivery and patient care goals. However, these standards are highly resource demanding and are not suited to every level of laboratory; resource-constrained countries need to develop their own minimum standards depending on the size and degree of sophistication.

However, is one standard applicable for all irrespective of the level and environment? Perhaps different levels of quality implementation are required. The model in Thailand offers one approach that can be adopted. In some industrialized countries, including the USA, there is recognition that laboratory requirements can be defined for differing categories of test. These situations offer the opportunity for a staged approach. Public health programmes, disease control programme and clinical service laboratories share the same quality goals and should therefore join forces in improving overall quality. It is important for all to share the vision.

In the discussion that followed, specific recommendations were made concerning the need to develop the message, challenges and obstacles, planning requirements, the need for advocacy and the organizational components required.

Specific recommendations:

1. Devise the message that there is a need to develop a systems approach, with a focus on quality systems and standards to achieve the common goals of quality patient care and public health programmes. Programmes gain through a shared approach.
2. There are particular challenges and obstacles to be overcome. Resources are allocated through disease-specific programmes and at national level people and institutions are managed by separate programmes. Public laboratory systems do not intersect with the private sector.
3. Quality system planning should be part of a larger national laboratory system that is managed by the MOH which will coordinate the contributions of donors and programmes including all disease specific programmes, clinical services and stakeholders. Strategic planning provides an opportunity to combine programme resources for an integrated system.
4. Countries should develop an advocacy plan and tools to solicit programme support for integrated laboratory strengthening. Advocacy must include business rationale and evidence for investing in systems and strengthening laboratory leadership and management to integrate public health programmes and patient care.
5. There are organizational components to be addressed that include the fact that the global framework of disease programmes is required to support quality systems and organizational changes. The MOH should have a strong national director of national

laboratory systems. The director should ensure that programme resources are combined to strengthen core functions and that there is a disease-specific national reference system.

6. A national quality system organization must develop national policies that supports and mandates the system. There will be requirements for a national steering committee that is inclusive of all programmes and that can guide implementation. EQA functions should be combined or integrated. There must be guidance on biosafety and ethics, and there must be programmes for education and training at all levels.

Annex 3

Agenda

Wednesday 9 April 2008

08:00 – 09:00	Registration at Sofitel	
09:00– 09:40	Welcome and opening remarks	
	Overview and goals of meeting	C. Mathiot (WHO Lyon)
	Opening by local representative	S. Guillaume (Deputy Mayor, health & social services)
	Introductory remarks WHO	G. Rodier (Director, IHR) J. Ridderhof (Associate Director)
	Introductory remarks CDC	
09:40 – 10:40	Setting the stage: why quality systems are essential for good laboratory practices	Chair: K. B. Chua (NPHL, Malaysia)
	Background and overview of the quality systems - Laboratory as an integral part of the entire continuum of healthcare	G. Fine (CLSI)
	Whose quality system to use?	
	Common elements of all health laboratory quality systems	
10:40	Break	
11:10 – 12:30	How to institutionalize integrated quality systems in the national laboratory system	N. Cabutti (COLABIOCLI)
	Expected legal and managerial role of the resource-limited governments and health care leadership	
	Challenges inherent in establishing full implementation of quality standards – scalability to meet local requirements	R. Robertson (NATA)
	Organizational challenges and national laboratory policies in combining vertical quality systems for an integrated quality system approach	J. Ridderhof (CDC)
12:30 – 14:00	Lunch	
14:00 – 16:40	Successes and challenges in implementing quality standards	Chair: J. Carter (AMREF, Kenya)
	Caribbean countries	V. Wilson (CAREC)
	China	P. Mingting (NCCL)
	United Republic of Tanzania (the)	C. Massambu (MoH)
15:45 – 16:00	Break	
	Thailand	P. Silva (MoH)

16:40 – 17:15	Wrap-up session – Discussion and Recommendations	
17:15 – 18:00	How to reduce pre- and post-analytical errors? A reminder and analysis in detail of errors incurred during non-analytic phases	I. Gardner (RCPA)
18:00	End of day one	

Thursday 10 April 2008

09:00 – 10:30	Breakout discussions	
	Group 1: How to develop national laboratory policies and standards to support quality systems? Quality system essentials utilizing the international standards; practical “hands-on” session	K. Klugman (Chair) G. Fine (moderator) F. Fuchs (moderator) C. Mwangi (moderator) P. Silva moderator
	Group 2: External Quality Assessment (EQA) and development of monitoring tools Discussions on the necessity of international/regional/national EQAs How to monitor the progress of quality systems implementation? To seek and propose monitoring tools, or “quality indicator”, useful for assessing the achievement objectively	M. Noble (Chair) R. Amini (moderator) J. Carter (moderator) J. Elliot (moderator) V. Fensham (moderator) M. Niedrig (moderator)
	Group 3: Advocacy for setting and implementing national quality standards To discuss and amend the draft advocacy paper aiming at the unanimous adoption by all the participants	Y. Ipuge (Chair) C. Collins (moderator) J. Elliot (moderator) C. Heuck (moderator) J. James (moderator)
	Group 4: Integrated approaches for quality programmes How can we address the challenge of integrating vertical quality programmes for TB, HIV, IDSR, and others? Brief introduction of biosafety in total quality management as a cross-cutting, common standard approach	J. Hughes (Chair) S. Beers (moderator) J.M. Gabastou (moderator) J. Ridderhof (moderator)
10:30 – 11:00	Break	
11: 00 – 12:30	Breakout discussions - Groups 1, 2, 3 and 4 (continued)	
12:30 – 14:00	Lunch	
14:00 – 17:00	Plenary session: presentations by breakout groups and discussions Group 3	Chair: S. Al Busaidy (C PHL, Oman)

Group 1

Break

Group 2

Group 4

Discussions

17: 00 – 18:30 **End of day two and Reception, City Hall, Lyon**

Friday 11 April 2008

09:00 – 11:00 **Strategic framework for instituting a global partnership among all** **Chair: K. Stinshoff**

Developing a global partnership of international organisations/partners to assist the national authorities, industry and other stakeholders

- CDC activities and its presence as a resource R. Martin (CDC)
- Expected advisory function of WHO and other partners R. Robertson (ILAC)
- Technical support from WHO R. Bhatia (WHO/SEARO)

11:00 – 11:20 **Break**

11:20 – 11:50 **Discussion: How to facilitate active involvement of normative and accreditation bodies as well as industry, academic/research institutions, NGOs and WHO collaborating centres?**

11:50 – 12:20 **Conclusions and recommendations**

Wrap-up Discussion
Endorsement of the Advocacy paper

Conclusions and recommendations

12:20 – 12:30 Closing remarks Dr R. Amini (Participants' representative)

12:30 **Close of Conference**

Annex 4.1

List of participants

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Mr David Featherstone, Expanded Programme on Immunization, Immunization, Vaccines and Biologicals, Family and Community Health

Dr Pascal Haefliger, Evidence and Policy on Emerging Environmental Health Issues, Public Health and the Environment, Health Security and Environment

Dr Jean Joly, Research for Neglected Priorities, Quality Assured Diagnostics, Special Programme for Research and Training in Tropical Diseases, Information Evidence and Research

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Annex 4.2

Composition of breakout working groups

Working Group 1	Working Group 2	Working Group 3	Working Group 4
How to develop national laboratory policies and standards to support quality systems?	External Quality Assessment (EQA) and development of monitoring tools	Advocacy for setting and implementing national quality standards	Integrated approaches for quality programmes
ANON Adoh BALL John BEVAN Valerie (moderator) BHATIA Rajesh BONCY Jacques DALTON Tracy DIAZ François ELANGO Varalakshmi ELSHAFIE Sittana ESHETE Yohanens FINE Glen (moderator) FUCHS Florence (moderator) FURTUNESCU A. GLAVIN HAEFLIGER Pascal HAYRAPETYAN Armen HO Thi Minh Ly IMNADZE Paata KABRANE Yamina KALASNIKOVA Tatiana KARAPETYAN Sergey KASYMBEKOVA Kaliya KHURELBAATAR Nyamdavaa KLUGMAN Keith (Chair) LEE Evan MAKOKHA Ernest MANCILLA Manuel MANGWANYA Douglas MASSAMBU Charles MOHSIN Thoraya MWANGI Christina (moderator) NICOLAS Pierre OJWIYA Amato ONOJA Ali PELLEGRINO Marcelo PEREZ GONZALEZ Mercedes ROBERTSON Regina SANDS Anita SILVA Panadda (moderator) STARKE Angela SUKATI Hosea TIMPERI Ralph VERNET Guy WILLIAMS M WIN THEIN Win YESMAGAMBETOVA Aizhan YOUSSEF Mohammad	ABESAMIS Criselda ADECHEBOU Ramato AMINI Rana (moderator) BAIG Badr BERNDT Anne BOND Kyle CABUTTI Norberto CARTER Jane (moderator) CHALERMCHAN Wilai CHARPENTIER Jean-François COGNAT Sebastien COLLOMBEL Christian DRAGOESCU Antoaneta ELLIOT John (moderator) FENSHAM Vivian (moderator) FERNANDES Paula FRANCISCO Moisés GARDNER Ian GHADIOK Gayatri GILPIN Christopher GUDETO Gudeta Tibesso HAN Lu HELLER Silke JAMES Vivienne KASYMBEKOVA Kaliya KUO Linda LECULIER Christophe LEMIUS Jacques MARTIN Robert MC ALISTER David MC KINNEY Barbara MENDIS Upul NIEDRIG Matthias (moderator) NOBLE Michael (Chair) OKUI Scholastica PARAMASIVAN C.N. PECA GOMES Maria Adelina PIMENTEL Guillermo PROSENC Katarina RAOUL Hervé RASOLONAVALONA Tiana RAZNAKOLONA Lala ROACH Coline SAKANDE Jean SCHEUTZ Flemming TORDO Noël UDO Stella URASSA Willy VINCENT Véronique WILLIAMS Maxfield ZELLER Hervé	ALBETKOVA Adilya BILE Edi BUI Thu Hien BURKE Eileen CABUTTI Norberto CHU May COLLINS Carlyn (moderator) DAYAL-DRAGER Renu DE LOS ANGELES Valera DEOM André ELLIOT John (moderator) GERMAIN Marc Anthony GUMA Gaspard HEUCK Claus (moderator) HOTZ Mark IPUGE Yahya (Chair) JAMES John (moderator) KALASHNIKOVA Tatyana KINIGI Juvent KINKESE Juliana KOJIMA Kazunobu KUEHL Debra KURANE Ichiro LECULIER Christophe MADISON Bereneice MAKHANDA Sibongile MENDIS Upul MUKANKWIRO Therese NDIHOKUBWAYO Jean-Bosco OKOYE Mac Paul PALADIN Julia PROSENC Katarina SAFADEL Nooshafarin SHOTT Joseph SHRIVASTAVA Ritu STINSHOFF Klaus WHITE Jenny WILSON Valerie WONGRAKPANICH Amorn ZEICHHARDT Heinz ZELLER Hervé	ABEBE Almaz AGUILAR Blasina AL-BUSAIDI Suleiman ALTHOFF Mario César BEERS Stella (moderator) BOAZ Iga BOEHM Emmanuelle BONNIER Michel BUADROMO Eka CHANDRASEKARAN Sujatha CHUA Kaw Bing DIARRA Seydou DUBOIS Philippe GABASTOU Jean-Marc (moderator) GALGALO Tura HADDADIN Aktham HERNANDEZ RIVAS Lucia HUGHES James (Chair) ISHTAIEH Issa JOLY Jean KARLSMOSE Susanne KUKLEV Vasily LAFOURCADE Berthe-Marie MASAMHA Jessina MENG Ling MOTSWALEDI Modisa MWAMBA Fales OXENFORD Christopher PIERSON Antoine PREVISIANI Nicoletta RASOANAIVO Nivo Hanitra RIDDERHOF John (moderator) SMITH Nadine SOKHENG Chuop SUTEHALL Gordon SZOMOR Katalin VAN WAKU Diane WALKUP Ruth YANG Chen-Fu ZULUMWAMBA Fales