Laboratory accreditation
WHO global perspective

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Laboratory Quality and Management Strengthening
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WHO core functions

1. Providing leadership on matters critical to health and engaging in partnerships where joint action is needed;
2. Shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge;
3. Setting norms and standards, and promoting and monitoring their implementation;
4. Articulating ethical and evidence-based policy options;
5. Providing technical support, catalysing change, and building sustainable institutional capacity;
6. Monitoring the health situation and assessing health trends.
2 strategic approaches towards accreditation

1. WHO accreditation

2. WHO support to Quality Management Systems towards accreditation
WHO accreditation

- System in place only for laboratories members of WHO Vaccine-Preventable Diseases networks (polio, measles, rubella, +/- YF and JE) and HIV drug resistance genotyping

- Started before development of ISO 15189

- VPD: WHO short-term need of reliable lab-based surveillance data for disease eradication or elimination

- WHO provides the standard, Proficiency-testing, +/- equipment, reagents and staff costs
Global Lab Network for Polio Eradication

N = 145 laboratories (2005)

The designation employed and the presentation of material on this map do not imply the expression of any opinion whatsoever on the part of the secretariat of the World Health Organisation concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.
Advantages

• For countries:
  – achievement of a high level of quality at minimal cost
  – international recognition
  – high confidence in laboratory results
  – Accreditation of these few laboratories can highlight the actual lack of quality in many other laboratories (or other units in the same laboratories, such as the bacteriology units vs. virology units) and raise awareness on laboratory quality

• For WHO: high confidence in laboratory results
WHO accreditation

Challenges:

- For countries:
  - Quality improvement of a small number of laboratories, usually at central level, and for a limited number of diagnostic tests
  - Problematic sustainability
  - In cases where other donor funding is not available, high financial dependence on WHO

- For WHO
  - Funding and human resources
  - Absence of formally recognized WHO supranational laboratories or formal networks for many laboratory tests (e.g. biochemistry, malaria, HIV) that could be mobilized to conduct accreditation visits.
  - Credibility as an accreditation body (e.g. WHO is not accredited to ISO 17011, WHO is not signatory of ILAC Mutual Recognition Arrangement)
  - Technical and management requirements of WHO standards and accreditation vis-à-vis existing accreditation schemes using internationally recognized ISO standards (ISO 17025 or ISO 15189).
WHO support to Quality Management Systems towards accreditation

- Advocacy and information sharing
- Technical guidance (guidelines, manuals...)
- Technical assistance (at country and/or institutional level): assessment, training...
- Proficiency-testing
- Quality of reagents (pre-qualification schemes)
WHO support to Quality Management Systems towards accreditation: advocacy
WHO support to Quality Management Systems towards accreditation: publications

Quality Assurance in Health Laboratory Services: A Status Report

Accreditation of Health Laboratories in the Countries of the SEA Region

Report of a Regional Consultation
Bangkok, Thailand, 6-10 October 2003

WHO Project: ICP BCT 001

World Health Organization
Regional Office for South-East Asia
New Delhi
February 2004
WHO support to Quality Management Systems towards accreditation: publications

- Quality Systems for Medical Laboratories
  Guidelines for Implementation and Monitoring

- Basics of Quality Assurance for Intermediate and Peripheral Laboratories
  Second edition
WHO support to Quality Management Systems towards accreditation: publications
WHO support to Quality Management Systems towards accreditation: publications
WHO support to Quality Management Systems towards accreditation: *publications*

- **Guidelines for Establishment of Accreditation of Health Laboratories**
- **Quality Standards in Health Laboratories**
  - Implementation in Thailand: A Novel Approach
  - *Mayura Kusum* and *Panadda Silva***

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WHO support to Quality Management Systems towards accreditation: publications
WHO support to Quality Management Systems towards accreditation: publications
WHO support to Quality Management Systems towards accreditation: *advocacy*

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.
WHO support to Quality Management Systems towards accreditation: *publications*

Best practice for developing standards for infectious disease laboratories in Europe

Laboratory Quality Standards and their Implementation
WHO support to Quality Management Systems towards accreditation: *training*
WHO support to Quality Management Systems towards accreditation: proficiency-testing

- Polio PT (RIVM, Netherlands)
- Measles and rubella PT (VIDRL, Australia)
- HIV, Hep B, Hep C PT (NRL, Australia)
- Global Foodborne Infections Network EQA (National Food Institute, Denmark)
- Tuberculosis DST EQA (Antwerp, Belgium)
- Haematology and Clinical chemistry (UKNEQAS)
- Microbiology EQA scheme for Africa (NICD, South Africa)
- Microbiology EQA scheme for Eastern Mediterranean Region (CPHL, Oman)
- Support to National EQA schemes
- ...

International Health Regulations
WHO support to Quality Management Systems towards accreditation: *pre-qualifications of diagnostics*

**WHO Prequalification of Diagnostics Programme**

The WHO prequalification of diagnostics programme aims to increase access to affordable diagnostic technologies of assured quality that are appropriate for use in resource limited settings. The programme provides Member States, UN agencies and other partners with technical information and advice on the quality of currently available HIV/AIDS, malaria and hepatitis B and C test kits and technologies.

Prequalification of diagnostics is a prerequisite for UN procurement ensuring that public monies are spent in a cost effective manner, on quality diagnostics.

Overview of prequalification of diagnostics

- [Overview document](#)
- [pdf, 196kb](#)
WHO support to Quality Management Systems towards accreditation: conclusion

- WHO is not a medical or clinical laboratory accreditation body even if specific WHO laboratory accreditation schemes have been established to serve disease specific surveillance activities.

- WHO recognizes ISO 15189 as the gold standard for medical laboratories.

- WHO encourages a stepwise implementation of ISO 15189 for advanced/central level laboratories, while national regulations should ensure that basic quality requirements are met in all clinical laboratories.
WHO support to Quality Management Systems towards accreditation: conclusion

- WHO works closely with partners and MoHs to support regional or national strategies to improve quality in a stepwise process through:
  - Advocacy and strategic planning activities with MoHs and partners
  - Technical assistance at country level to develop appropriate quality systems through national laboratory policy, regulatory and licensure mechanisms
  - Development of tools (implementation guidelines, assessment checklists…)
  - Workforce development (curricula or training materials development, training sessions organization…)