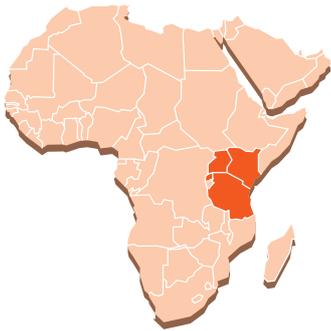


LABORATORY SERVICES

AT THE DISTRICT LEVEL



Laboratory services are essential to health care delivery. They address both preventive and curative activities, i.e. patient diagnosis, and the selection of drugs for treatment. They are also an indispensable tool in the surveillance and control of diseases, since improved disease recognition will improve the accuracy of statistical reporting, and thus effective national health planning.

In countries with limited resources, even rural health facilities can manage the most common diseases and those with outbreak potential by carrying out simple laboratory tests.

Regrettably, a lack of adequate diagnostic laboratory services leads to unnecessary, inappropriate or wrong treatment. This results in longer hospitalization and/or recovery time. The monetary repercussions of this are wide ranging, both from the national and the personal perspective.

The underlying causes of a faulty diagnosis are many. One reason is a general shortage of skilled staff. Other reasons include substandard infrastructure and facilities, and obsolete laboratory procedures due to lack of awareness of current advances.

Similarly, modern equipment is ineffective unless staff are trained to use it, the reagents are affordable and it is properly maintained.

QUALITY MANAGEMENT

Without a quality management programme, the likelihood of a faulty laboratory result – due to a clerical or technical error – is much greater. In addition, poor biosafety procedures may cause hazards to both laboratory staff and the community at large.

Another serious impediment to effective laboratory services is the lack of sustained financing. Annual government funding is often insufficient to meet all running costs. Although user fees have been introduced for clinical and laboratory services at some levels of health care, uncertainties over levels of funding prevent proper planning. Conversely, opportunities for more cost-effective running of laboratory services may not be fully investigated.

AN EAST AFRICAN INITIATIVE

One project which is aiming to overcome these problems involves three countries in East Africa, namely Kenya, Uganda and United Republic of Tanzania.

Based on a review of their laboratory services at district level, they drew up comprehensive National Laboratory Policy Guidelines that address the administrative structure, essential tests, techniques, equipment, facilities, staffing, supply systems and training needs.

In each country, a national quality assurance advisory body has been established, as well as a legal framework to regulate both laboratory premises and laboratory staff. A standard list of essential laboratory procedures is supported by generic standard operating procedures for use in district health services in all four countries.

Key to effective laboratory services are qualified staff. Training on new laboratory tests and updating skills, including record keeping, good laboratory practice, maintenance of equipment and biosafety are envisaged.

Monitoring laboratory performance is another important component, which includes the training of laboratory inspectors and external quality assessment of the essential laboratory tests.

The harmonized approach taken by these countries will facilitate the collection of meaningful data that can be used to monitor the burden of diseases in the region.

The project has already had a great impact on the quality of laboratory services and has allowed the countries to achieve goals that would have been difficult to achieve individually.

Strengthening of laboratory services merits support as it ensures safe and adequate patient care worldwide.



BASIC OPERATIONAL FRAMEWORK

The WHO Department of Essential Health Technologies assists countries to achieve a safe and reliable level of health services in a variety of health technologies through its Basic Operational Frameworks. Below is a summary of the requirements for countries to attain this level of health service for laboratory services at the district level, and the products and services that WHO can make available to support this goal¹.

With the scaling up of interventions against the major diseases of poverty – HIV/AIDS, TB and malaria – the need for diagnostic and laboratory services has never been greater. These technologies play a critical role in surveillance, prevention efforts, diagnoses and the monitoring of treatment. Scaling-up implies that health services are able to deliver essential laboratory and diagnostic support nationwide. However, major challenges need to be faced at country level, including weak national systems, rudimentary procurement and supply systems, disparity between urban and rural areas, lack of infrastructure and human resources, the variable quality of laboratory performance, and equipment that is either inappropriate or ill-maintained.

In addition, scarce resources are often used to buy "high-tech" laboratory equipment that is never used, either because staff are unable to operate it, or due to lack of affordable reagents or spare parts. Conversely, obsolete and less reliable techniques can still be seen, resulting in substandard patient care.

¹ *The Basic Operational Framework for Laboratory Services at the District Level can be found on the Internet at www.who.int/eht*

Policy

TO BE IN PLACE IN COUNTRIES

Tools for benchmarking laboratory and diagnostic services will have to be developed. National policies and guidelines related to laboratory and diagnostics services may have to be reviewed in light of these tools. Road maps for planning, implementation and evaluation of national systems will be developed. Important activities include:

- Government commitment to laboratory and diagnostic support services.
- Development of a national plan
- Registration, regulation /accreditation of laboratory services and staff
- Capital and resources for a national reference laboratory
- Establish laboratory networks for monitoring major diseases
- Professional associations
- Ensure minimum laboratory infrastructure at national and district level (at least one central laboratory).

WHO PRODUCTS AND SERVICES TO SUPPORT POLICY REQUIREMENTS

- Essential requirements for laboratory technology
- Policy guidelines for diagnostic support for monitoring HIV/AIDS ARV therapy
- National diagnostic testing guidelines

Quality and safety

TO BE IN PLACE IN COUNTRIES

National systems need to identify the diagnostic reagents, technologies and equipment that are appropriate for their country. Basic laboratory procedures and testing strategies for specific markers need to be validated and standardized at national level. Quality systems are vital at each level of laboratory services, including mechanisms to monitor the performance of laboratory and diagnostic services. Key elements are:

- Mechanisms to assess and validate diagnostic reagents and procedures
- National Regulatory Authority
- National Reference Laboratories
- National guidelines on basic laboratory procedures and testing strategies
- Quality systems, including standard operating procedures
- Regular measurement of laboratory performance against international standards

WHO PRODUCTS AND SERVICES TO SUPPORT QUALITY AND SAFETY REQUIREMENTS

- Assessing the quality of diagnostic technologies and laboratory procedures
- Standard procedures for laboratories
- Quality management guidelines
- Support to external quality assessment schemes for different laboratory disciplines

Access

TO BE IN PLACE IN COUNTRIES

Access to high quality diagnostic and laboratory procedures and equipment is increased through bulk procurement. Technology transfer and use of local products should be encouraged. Key elements are:

- National selection and validation procedures for diagnostics and equipment
- Standardized national procurement mechanism
- Streamlined procurement and distribution channels
- Negotiated prices through WHO and partner institutions
- Procurement Committee including all key players
- Reduced tax levies on imports of diagnostic reagents and equipment

WHO PRODUCTS AND SERVICES TO SUPPORT ACCESS REQUIREMENTS

- Guidelines for procurement and supply management systems for commodities, including donations and technology transfer
- Essential equipment list for laboratories and diagnostic support
- Bulk procurement at reduced costs

Use

TO BE IN PLACE IN COUNTRIES

Insufficient and high turnover of skilled staff is a reality in many countries. Also national curricula for educational degrees related to laboratory and health care services may not be adapted to the rapid evolution in diagnostic technologies. Hence there is a continuous need for additional training. Key elements are:

- Training of medical and technical staff, including biosafety procedures
- Clinical use of essential laboratory tests
- Appropriate use of laboratory technologies and equipment, including maintenance and quality assurance

WHO PRODUCTS AND SERVICES IN SUPPORT OF USE REQUIREMENTS

- Training of medical and technical laboratory staff in basic procedures
- Training in good laboratory practice and biosafety