WHO's laboratory programme

C. Heuck

The dependence of modern medicine on laboratory services has increased enormously during the last 50 years. Rapid developments in this field present a challenge for standard setting and quality control.

There has been a WHO programme on health laboratory technology since the Organization itself was founded. Today, more than 400,000 clinical laboratories are estimated to provide their services for the diagnosis and monitoring of diseases worldwide. Their activities consist primarily of examining specimens of human origin to establish or confirm the diagnosis of a disorder, monitor the development of a disease, and provide information for public health care through screening by means of microscopy and biochemical analysis.

Rapid development

These services have undergone profound changes. In the 1950s only a small number of analytes were investigated to confirm the diagnosis of clinically manifest diseases. Since then, biochemical research and technical development have opened up new ways for conducting investigations, and today it is not uncommon for laboratories to determine more than 1000 diagnostic indicators during their daily routine. About 1000 genes of the human genome have been identified, and a number of them are the determinants of hereditary disease. Laboratory performance has improved to such an extent that certain diagnostic indicators, including infective agents, can be detected at concentrations of only a few molecules in a specimen, and well before the clinical manifestation of the disease in a patient.

The amount of information provided by laboratories has increased to such an extent that medical professionals themselves find it increasingly difficult to interpret correctly. This, together with the increasingly specialized knowledge needed for the appropriate use of modern laboratory equipment, has led to significant change in the status of laboratories. Originally an auxiliary service, they are now seen as an essential independent entity of the health care system with advisory, controlling and monitoring functions, which include legal and ethical responsibility.

An essential element for the successful work of clinical laboratories is reproducibility and comparability of results. The founders of WHO saw standardization as a fundamental element of health care, and put this into the Constitution. The Health Laboratory Technology unit (LAB) was accordingly given responsibility for promoting the standardization of laboratory measurement and laboratory quality assurance, and supporting countries in the establishment of laboratory services ap-
propriate to their own needs, including the transfer of technology. To fulfil these responsibilities the great differences between countries with regard to their health problems and health infrastructure must be taken into account.

In 1974 the World Health Assembly, representing all the Member States of the Organization, asked the Director-General "to intensify the work of WHO in the coordination of the development of standards for chemical and biological diagnostic materials and their use with special emphasis on quality control". In 1976, LAB established the first International External Quality Assessment Scheme (IEQAS) in clinical chemistry, in collaboration with a WHO Collaborating Centre in Birmingham, United Kingdom. The purpose was to assist countries in developing their own national schemes for laboratory standardization and quality assurance. Subsequently, additional external quality assessment schemes were established by LAB for blood coagulation, blood group serology, haematology, immunology, microbiology and parasitology. Today, all the main disciplines of laboratory services are covered by an IEQAS. Other disciplines still need to be covered but they are more difficult to standardize and control.

The concept of quality assurance, with its complementary elements of external quality assessment and internal quality control, has been accepted worldwide. Today, 262 laboratories from 113 countries are participating in the WHO IEQAS. A survey in 1996 showed that at least 58 countries have established their own surveillance system, and at least 99 institutions are organizing more than 264 national external quality assessment schemes in the different laboratory disciplines.

Regional activities

The particular needs of laboratory services in developing countries have been a subject of particular concern at the regional level since the 1980s. The Eastern Mediterranean Regional Office completed a plan of action for improving health laboratory services in 1988. As a result, a number of countries in that Region have started producing their own reagents, established mechanisms for equipment maintenance, and set up national systems for laboratory quality assurance.

The Regional Office for the Americas, in collaboration with several nongovernmental organizations, has supported the implementation of national quality assurance programmes in the Caribbean and Latin America. The Regional Office for South-East Asia officially adopted a plan of action for quality assurance in laboratory practice in 1996. The Regional Office for Africa is helping to establish quality assurance procedures for laboratory services and has made a plan of action for the French, Portuguese and Spanish-speaking countries of the Region. The Western Pacific Region has established regional quality assurance programmes in microbiology.

These activities are complemented by intercountry training courses and workshops on laboratory management, local reagent production, maintenance of equipment and good diagnostic practice. A series of technical documents and publications have been issued in a number of languages, describing basic requirements for laboratory services in specific disciplines.
Current needs

The complexity and efficiency of modern laboratory technology are increasing rapidly. Only a few years ago it was unthinkable to diagnose a disease by a laboratory investigation that today can be carried out by less experienced personnel with minimal effort and equipment and in unfavourable working conditions. However, the production of such test systems requires high technical skills and is in many cases expensive. Nearly all modern laboratory technology is produced in industrialized countries, and other countries using it rely on importation.

The present situation gives rise to two major concerns. First, the complexity of the technology now in use challenges the existing structures and mechanisms for standard setting in laboratory medicine. In 1997 the World Health Assembly drew attention to the rapid growth occurring in the field of biologicals, including those used for the diagnosis of diseases, and the challenge this posed for assuring the “quality of biological products moving into international commerce”. Second, the high cost of modern laboratory technology impedes its transfer to countries that need it. This partially explains the relatively slow evolution of laboratory services in most of the developing countries. WHO’s activities for facilitating the exchange of information on technology production for laboratory services in developing countries are needed today more than ever.

In the current situation, rapid development increases the difficulty of ascertaining whether an optimal and legal choice of diagnosis and treatment technology is made. Standardized measurement and good laboratory practice are essential for the harmonization and control of laboratory technology. An increasing number of countries are attempting to achieve these by means of government regulations.