

Report on the

**Regional meeting of directors of public
health laboratories in Member States of the
Eastern Mediterranean Region**

Cairo, Egypt
3–6 June 2002

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1. INTRODUCTION

The WHO Regional Office for the Eastern Mediterranean organized a meeting of directors of public health laboratories in Cairo, Egypt, from 3 to 6 June 2002. The objectives of the meeting were to:

- discuss laboratory diagnosis for noncommunicable diseases;
- review the progress in the development of laboratory services; and
- review the progress of the implementation of previous recommendations.

The meeting was inaugurated by Dr Hussein A. Gezairy, WHO Regional Director for the Eastern Mediterranean. Dr Gezairy said that the development of health laboratory services in countries of the Region was based on national and regional plans which were formulated by the directors of health laboratory services, and subsequently amended during biennial meetings. He emphasized the role of governments as stewards in performing regulatory functions and in ensuring full technical supervision and legislative support for quality laboratory performance.

The agenda, programme and list of participants are included as Annexes 1, 2 and 3, respectively.

2. TECHNICAL PRESENTATIONS

2.1 A brief overview of noncommunicable diseases in the Region

The Eastern Mediterranean Region is a classic example of countries in the midst of an epidemiological transition characterized by increasing rates of obesity, growing prevalence of hypertension and diabetes, high rates of smoking and elevated rates of consanguineous marriage, which is associated with a high risk of genetic disorders. Cardiovascular diseases in the Region impose the highest morbidity burden among all other noncommunicable diseases. The main reason for this is an ageing population, high incidence of hyperlipid anaemia, high rates of smoking and changing nutritional and behavioural habits. Recent data show that the regional incidence of cancer is soaring and diabetes is reaching pandemic in member countries of the Gulf Cooperation Council (GCC). Problems facing implementation of noncommunicable disease programmes include: lack of surveillance and analysis of risk factors and lack of harmonization and monitoring surveillance methodology.

3. COUNTRY PRESENTATIONS

3.1 Bahrain

Public health services are distributed all over the country and are run by different organizations, such as the Ministry of Health and the Bahrain Defence Force Hospital. The public health laboratory comprises three main sections, these sections include: communicable disease, food and water microbiology and food and water chemistry. The Salmaniya Medical Complex provides services to inpatients, outpatients, private clinics and hospitals in the

country. The Salmaniya laboratory performs almost all specialized and non-specialized laboratory investigations.

3.2 Cyprus

There are sixteen laboratories functioning under the Ministry of Health. Eight of them are specialized laboratories and eight are medical laboratories. The services offered by them include screening for thalassaemia heterozygotes and prenatal diagnosis of thalassaemia, leukaemia and tumour typing, polymerase chain reaction (PCR), histochemistry and a variety of radioimmunoassay determinations. Within the private sector, there are 150 laboratories, 147 of which are routine health laboratories, performing a great variety of simple and complicated tests. Three of these are very specialized laboratories. One is a molecular biology laboratory situated in the Cyprus Institute of Neurology and Genetics, which deals mostly with research work on congenitally inherited diseases. The other two deal with human leukocyte antigen (HLA) typing. One is in the renal transplantation unit dealing with kidney donors and recipients and the other performs HLA typing on all prospective bone marrow donors.

3.3 Djibouti

Laboratory services are provided through a network consisting of nine peripheral laboratories, eight intermediate laboratories, four of which are district laboratories and five central laboratories. In addition, there is a laboratory in the French army hospital and two private laboratories. There are efforts to develop a national laboratory service which will be supervised by the primary health department. There is no specific budget for laboratory services and there are no local suppliers for laboratory materials.

3.4 Egypt

A national quality assurance programme was developed in 1995 supported in the initial phase by WHO. The data obtained from the laboratories in the programme are analysed statistically, and the mean, standard deviation and coefficient of variation are calculated. The programme is confidential and conducted in clinical chemistry and haematology specialties for investigations related to noncommunicable diseases. The programme has improved the quality of performance in Ministry of Health and Population (MOHP) laboratories. Last year, the programme was extended to involve laboratories in health insurance hospitals and teaching hospitals. The programme will be extended to cover private laboratories, initially on a voluntary basis. Medical health care is made available to all Egyptian citizens through a progressive network of health care facilities in which a patient may receive treatment or other health services, or to be referred to a higher level facility as the need arises.

3.5 Islamic Republic of Iran

Laboratories are categorized into four levels: peripheral, intermediate, regional and central. WHO regulations qualify each category. Due to the improved capabilities of the laboratories, as well as increased needs, laboratories are performing to a much higher standard. The Ministry of Health and Medical Education has a management policy in terms of equipment, reagents and locally and imported kits. Although the general policy is to support local manufacturers, these manufacturers have to be initially approved with regard to the quality of their final product. To achieve this result, all kits and reagents have to be evaluated and approved for mass production by reference laboratories.

3.6 Jordan

Health laboratory services in Jordan are provided by different sectors: the Ministry of Health: Royal Military Medical Services; the United Nations Relief and Works Agency for Palestine Refugees in the Near East (UNRWA); the university hospitals; charity societies; and the private sector.

The Laboratory Directorate supervises all ministry laboratories and licenses private laboratories. With the help of a licensing and administrative committee, the laboratory director is responsible for setting up standards in health laboratories. Each level of laboratory is instructed to follow a referral system and to submit a monthly report to the laboratory directorate and to the centre of information in the Ministry of Health. The laboratory directorate is also responsible for planning the annual budget for all Ministry of Health laboratories. Due to financial constraints, the allocated budget is far below the actual needs for both equipment and reagents.

The Minister of Health nominated a national quality control committee in June in 2001 in order to implement laboratory quality control on a national scale. The committee, including laboratory specialists from the Ministry, military medical services and universities and the private sector, has set up a comprehensive plan of action. Implementation of the quality control scheme will start in the near future by organizing workshops for all laboratory directors in the public and private sectors to explain the concept and the importance of implementing internal quality control followed by performing national external quality assessment in different laboratory disciplines. Through WHO support in 2000–2001 more than 120 laboratory technicians were trained on laboratory quality control in different laboratory aspects. In addition, 10 laboratories still participate in the external quality assurance system in biochemistry organized by the WHO collaborating centre in Tehran.

3.7 Lebanon

The health laboratory services provided by the Ministry of Public Health consist of: a central public health laboratory, one regional laboratory and 14 public hospitals with diagnostic laboratories. There are good national regulations covering the opening and operation of private clinical laboratories. Their implementation, however, requires considerable improvement. Private laboratories are approved by ministerial decree. Only

medical doctors or pharmacists specialized in laboratory medicine are licensed to operate clinical laboratories and are registered with the Ministry of Health. The national regulations also govern other conditions and requirements to run a medical laboratory, including premises and equipment.

3.8 Morocco

The reference laboratory services in the Institut National d'Hygiène develop activities connected to the noncommunicable diseases and supervise them in all public health laboratory services. Available information before 1990 indicated the prevalence of endemic goitre in multiple points of the country. In 1991, a high prevalence of goitre was confirmed in 65% of school-age children. The Ministry of Health identified the problem at national level and developed a national programme in 1993. The strategy of this programme includes supplementation of oil iodized in the form of oral capsules and fortification of salt. The choice of the vehicle was dictated by the fact that the salt is consumed by all the sectors of society. This strategy was supported by a statutory measure which made it compulsory to market iodized salt.

3.9 Oman

Following a regional meeting of managers of health laboratory services held in Muscat in 2000, only licensed personnel are allowed to work in laboratories and there are no restrictions as to the types of test which the private laboratories may carry out. A review and update was proposed to cover the auditing of these laboratories. Regarding storage and retrieval of laboratory data, the Ministry of Health has already established a computerized patient file system to include all the information pertaining to each individual patient in terms of history, laboratory results, medication and appointments within all ministry institutions in primary, secondary and tertiary care facilities. The central public health laboratory is well established and continuously strengthening facilities for the laboratory diagnosis of viral infections and other emerging and re-emerging diseases.

Currently, Oman is participating in many international quality assurance programmes. Noncommunicable diseases are becoming a major public health problem in Oman. Facilities for the laboratory diagnosis of these diseases are available throughout the country at the primary, secondary and tertiary care levels of health institutions. The recent establishment of a cytogenetic laboratory at the central health laboratories has complemented these facilities. Implementation of quality systems for the laboratory diagnosis of these diseases is in progress.

3.10 Palestine

In 1993, the Ministry of Health embarked on programmes aimed at developing health services. There are two bodies for the laboratories, one is in the Gaza Strip and the other in the West Bank, each with an organizational network. Laboratories in Palestine are run by governmental and nongovernmental organizations, UNRWA, the military and the private sector.

The directorate of laboratories and blood banks is responsible for medical laboratories and the public health laboratory. There is a number of staff working in these laboratories but they lack access to the continuing education programme, which is dependent on international coordination or donors.

3.11 Saudi Arabia

Health laboratory services are provided by the Ministry of Health, the military, the National Guard, security forces and the private sector. The director of regional reference laboratories reports to the Directorate of Health Affairs in their regions but technically they refer to the Assistant Deputy Minister for Laboratories and Blood Banks. The Assistant Deputy is responsible for overall implementation of the policies and framework of the strategic planning of the Ministry of Health.

The national committee for laboratory quality assurance established in 1996 is responsible for the monitoring and evaluation of laboratory services and quality assurance coordinators were designated in 11 regions. They have adopted a WHO programme for laboratory biosafety and have distributed programme guidelines to all laboratories. A quality management department was established as the general directorate of laboratories and blood banks headed by a consultant in laboratory medicine and health administration. The internal quality control programmes are monitored within the laboratories by the staff of the quality management department at the general directorate of laboratories and blood banks.

3.12 Sudan

There is an organized network of health laboratories in Sudan at Federal and State levels. The national health laboratory and the regional laboratories and some state central laboratories act as reference diagnostic laboratories and also provide public health laboratory services for food, water and environmental control. They also provide training for all laboratory personnel and participate in the national quality assurance programme. There is a national general directorate of laboratories and transfusion services responsible for the technical supervision of all laboratories, setting standards and specifications for all laboratories and training laboratory staff.

There are two technical committees on laboratory quality assurance. The quality assurance advisory committee is responsible for formulating national policies and plans for quality assurance in laboratories. It is also involved in the designing and evaluation of external quality control schemes for laboratories. The committee has representatives from all major health providers in Sudan: the Ministry of Health, the Armed Forces, police medical services, universities, nongovernmental organizations and the private sector, in addition to the national establishment for specifications and metrology. Another committee is responsible for advising on specifications and need assessment for equipment and supplies.

4. CONCLUSIONS

The private laboratory sector is rapidly expanding in the majority of countries in the Region. This development underlines the responsibility of the Ministry of Health and the central public health laboratories for setting standards for laboratory services and technology; licensing laboratory professionals and laboratory services; importing and conducting pre-marketing surveillance of laboratory equipment, reagents and consumables; coordinating with the Ministry of Education in the development of curricula for laboratory personnel and career development, coordinating with the Ministry of Social Affairs on the development of salaries in the public sector (an important factor limiting the improvement of the public health laboratory sector); coordinating and supervising the public health laboratory network; establishing mechanisms for the monitoring of performance of laboratories both in the public and private sector; and developing strategies to improve disease surveillance in the future. The development of laboratory technology is rapidly advancing and laboratory services will gradually gain managerial autonomy with their increasing technical knowledge.

Although some countries reduced import tax on medical diagnostic devices, diagnostic reagents and kits, other countries are still charging high taxes that are prohibitive for the development of laboratory services. Training, shortage of reagents and equipment maintenance are widely recognized as major problems.

The participants reviewed the extent to which they had been able to comply with the recommendations and plan of action agreed at the meeting held in Muscat, Oman, June 2000.

- Governments of 12 countries allocated a separate regular budget for health laboratory services. However, in many of these countries the budget is not under the control of the director of laboratory services.
- Ten countries were able to ensure that the majority of their staff had job descriptions. The remuneration of the staff in the public sector remains a difficulty. Most countries reported that the salaries did not allow a reasonable standard of living. As a result, many laboratory workers must have additional sources of income to support their families. Such a situation is detrimental for the improvement of the public health laboratory sector.
- Fourteen countries established task forces to assess the training needs of their staff. Much more training is required to improve professional manpower capability.
- Only nine countries were able to verify the standards and use legislation to ensure the quality of their reagents by providing statements of compliance with internationally-validated standards. Most locally-manufactured reagents and stains are not quality controlled. Twelve countries defined criteria to ensure that vendors of equipment met the requirements for the provision of training, operational manuals, spare parts, servicing and maintenance support. However, only five countries implemented a pre-market surveillance programme for diagnostic reagents and devices.
- Computer-based laboratory information systems are used by seven countries only. The systems are almost exclusively used at the central level, with one exception.

- Twelve countries implemented the requirements of quality assurance principles at all levels. Further investment is required to establish in national external quality assessment schemes in all disciplines.
- Sixteen countries have legislation on the minimum quality requirements of clinical laboratories. However, some criteria are out of date or have not been implemented. Moreover, the legislative measures are not fully applied in some countries.
- The upgrading of microbiological laboratory services is ongoing and 15 countries have reported improvements.
- Eighteen countries nominated laboratories to collect data on antimicrobial susceptibility, however, not all this information has been available to the Regional Office which is in the process of updating its information.
- Eighteen laboratories established laboratory-based disease surveillance in collaboration with national epidemiological programmes.
- Only 11 countries introduced laboratory safety policies and this is an area of continued concern.
- National professional societies exist in 12 countries, some of which have exclusive experts in laboratory medicine, whereas others cover the entire field of medicine.
- Fourteen countries organized national workshops and training courses on topics related to individual laboratory disciplines, or on laboratory quality assurance or laboratory safety. No courses were held on local reagent production.

5. RECOMMENDATIONS

To Member States

1. Allocate an independent regular budget to the national public health laboratory network.
2. Reduce import taxes on test kits, reagents and medical diagnostic equipment and consumables to a minimum to relieve the burden of costs and ensure that the limited budgets allocated to laboratories are used effectively.
3. Establish, by decree, a formal system for the pre-marketing surveillance of test kits and diagnostic reagents so that only locally-verified kits and reagents are considered for purchase in the country.
4. Formulate or update and implement regulations defining the quality criteria for the licensing of laboratory professionals and services. These regulations should apply to all sectors of health laboratory care.
5. Establish regulations on laboratory waste disposal and increase efforts in their implementation.
6. Increase efforts in the implementation of laboratory programmes, including internal quality control and national external quality assessment, and their extension to all major laboratory disciplines.

7. Continue to upgrade microbiology services and so enable WHO antimicrobial drug resistance surveillance to be carried out across the Region to ensure a timely response to emerging and re-emerging diseases.
8. Organize courses and workshops in laboratory management, with an emphasis on the application of principles in quality assurance, laboratory safety, local reagent production, preventive equipment maintenance and the use of laboratory services.
9. Improve coordination between the various ministries involved in water and food safety.

To Central Public Health Laboratories

10. Use computerized laboratory information systems which are essential and the most effective tools in the management of laboratory networks. WHO should facilitate the provision of suitable software and training.
11. Managers of public health laboratory services should continue to implement the following actions to improve the management of laboratory networks:
 - implement standard operating procedures for all laboratory disciplines to be used by all laboratories of the network;
 - set clear priorities for the responsibilities of laboratories at each level;
 - establish accountability of laboratories at each level;
 - establish close communication by holding meetings at regular intervals with professionals working at the intermediate and peripheral levels of the network.
12. Support national professional societies to improve the exchange of scientific and technical information at country and regional levels. This will encourage national authorities to better recognize the importance of laboratory services.
13. Initiate surveillance of noncommunicable diseases in collaboration with national epidemiology/noncommunicable disease divisions.

To WHO

14. Provide guidance on the core roles and functions of central public health laboratories.
15. Continue to expand the external quality assessment scheme in histopathology to laboratories of all countries in the Region.
16. Hold meetings with the directors of public health laboratories of Member States in the Region biennially.

Annex 1

AGENDA

1. Inauguration
2. Election of officers and adoption of agenda
3. Objectives of the meeting
4. Noncommunicable diseases, a regional overview
5. Role of surveillance of anaemia in the health of mothers and children
6. Public health laboratory diagnosis of lipoprotein disorders
7. Quality assurance in laboratory diagnosis and screening of diseases of DM
8. Osteoporosis: an increasing threat to society
9. Environmental factors and noncommunicable diseases
10. Recommendations
11. Plan of action
12. Closing session

Annex 2

PROGRAMME

Monday, 3 June 2002

- 08:30–09:00 Registration
- 09:00–10:00 Inaugural session
- Regional Director's address
- Election of officers and adoption of agenda
- 10:30–11:00 Objectives of the meeting, *Dr N. Metwalli*
- 11:00–12:00 Noncommunicable diseases: a regional overview, *Dr O. Khatib*
- 12:00–13:00 Role of surveillance of anaemias in the health of mother and children,
Dr M. El Saify
- 14:00–16:30 Country presentations

Tuesday 4, June 2002

- 09:00–09:30 Rapporteur's summary of previous day
- 09:30–10:30 Public health laboratory diagnosis
- 11:00–12:00 Osteoporosis: an increasing threat to society, *Dr N. Gowhar*
- 12:00–16:00 Country presentations

Wednesday 5, June 2002

- 09:00–09:30 Rapporteur's summary of previous day
- 09:30–10:00 Environmental factors and noncommunicable diseases, *Dr H. Abouzaid*
- 10:30–16:00 Country presentations

Thursday 6, June 2002

- 09:00–09:30 Rapporteur's summary of previous day

09:30–10:00	Malignant lymphoid disorder, <i>Dr N, Mokhtar</i>
10:00–11:00	Discussions of recommendations and plan of action
11:30–12:30	Adoption of revised plan of action
	Recommendations
12:30–13:00	Closing session

Annex 3

LIST OF PARTICIPANTS

BAHRAIN

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Dr Derek Yach, Executive Director Noncommunicable Diseases and Mental Health,
WHO/HQ

Dr Zuhair Hallaj, Acting WHO Representative, WHO/EMRO

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