

Health Laboratory Technology

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WHO WORKING GROUP ON APPROPRIATE TECHNOLOGY IN HEALTH LABORATORIES

London, 2-5 October 1979

1. INTRODUCTION

A Working Group on Appropriate Technology in Health Laboratories was convened by the WHO Regional Office for Europe in collaboration with the Government of the United Kingdom, in London from 2 to 5 October 1979.

The purpose of the meeting was to review the organization of health laboratory services in Europe and to discuss the roles and basic requirements of laboratories at local, regional and central levels. It was attended by temporary advisers and observers from nine countries, who had relevant experience of a spectrum of disciplines – clinical biochemistry, haematology and blood banking, microbiology, histopathology, immunology and food and environmental hygiene (see Annex II for list of participants).

Professor Ö. Ouchterlony was elected Chairman of the Working Group and Dr S.S. Brown, Rapporteur. Dr A.H. Wahba acted as Secretary.

The Group was welcomed by Dr R.M. Oliver, Head, Division of Medical-Scientific Services of the United Kingdom Department of Health and Social Security. He pointed out that there are three distinct uses to which laboratory tests are applied:

- differential diagnosis of disease, and monitoring of its progress and the results of therapy;
- screening for endemic disease in a defined population;
- clinical research.

He stressed that it was essential to define the technology appropriate to these three purposes, and to differing levels of health care. The Group should consider the best strategies for making choices of technology within recognized economic constraints; for simplifying rather than complicating diagnostic equipment and so reducing dependence on highly skilled staff or on scarce technical support services. It was also important to recognize that modern diagnostic facilities can be used to screen large populations, but that this can lead to imbalance between discovered conditions and the capability of therapeutic resources to cope with them.

On behalf of the WHO Regional Director, Dr A.H. Wahba, Regional Officer for Appropriate Technology for Health, thanked the United Kingdom Department of Health and Social Security for hosting the Group. He explained that the meeting was a sequel to three others which had been concerned with aspects of the rational organization and development of laboratory services in health care, namely: the organization and methodology of cytology laboratories (Moscow, 1976); food control laboratories (Copenhagen, 1977); and the role of the hospital laboratory in public health (Stockholm, 1978).

He noted that the past two decades have witnessed many important advances in the clinical laboratory sciences, with a corresponding increase in the workloads of health laboratories. New techniques and costly apparatus have been, and continue to be, introduced — often without proper assessment of their cost-benefit. Indiscriminate application of the full range of health laboratory technology currently available is not possible, even for the more affluent countries of the European Region. There is, therefore, an urgent need to determine the degree of inappropriate use of laboratory investigations and to seek to ensure the optimal use of laboratory technology as it develops and is applied in practice.

This thesis does not imply an artificial restriction on the growth of the clinical laboratory sciences. Rather it supposes the development of investigations which are really appropriate, in terms of both their technology and their scope and cost. Rational means of selecting or designing such investigations and implementing them to suit particular circumstances have yet to be worked out.

Short papers were then presented on the concept of laboratory technology for health care and its practical application

in the various disciplines; on the operation of health laboratories, with special reference to the primary or first levels of health care; and on the interactions of the laboratory with hospital staff, suppliers of reagents and equipment, and the community at large.

For discussion purposes, it was accepted that "appropriate" technology means technology that is not only scientifically sound but also acceptable to users, providers and decision makers alike, is simple in design and execution, fits within local cultures, and can be adapted and further developed locally at low cost. It was further accepted that primary or first-level health care refers to "essential health care made universally accessible to all individuals in a community through full participation of its members, by means that are acceptable to them and at a cost the community and the country can afford" (1).

In many parts of the world, primary health care is the direct responsibility of a health worker, without laboratory facilities, serving a population of a few thousand. In most of Europe, however, the first level of health care is represented by community health centres, or by district, regional or provincial hospitals, all of which have simple or more elaborate laboratory facilities.

2. GENERAL CHARACTERISTICS OF HEALTH LABORATORY OPERATIONS

2.1 Workload and the quality of performance

At present, about 500 substances are routinely determined in approximately 65 000 European health laboratories, using a wide variety of assay principles and techniques. The total number of analyses carried out corresponds to about 10 per inhabitant per year.

The calibre of performance of many of these analyses varies — sometimes substantially — as shown by European national, regional and local quality control surveys both in clinical chemistry (2) and haematology (3): quality control programmes

for the other clinical laboratory sciences are less well developed (4). Better comparability of results is important in order to:

- reduce the frequency of misdiagnosis of patients or of poor decisions about necessary therapy;
- minimize costly repetition of laboratory investigations;
- facilitate the execution of national or international research projects in different fields of health care, particularly those requiring epidemiological studies.

The general performance of methodologies and instrumentation will only improve if efforts within Europe are better coordinated by way of exchanging experiences of the clinical relevance of new tests, quality control procedures, reports of instrument evaluations, etc. There are strong arguments for encouraging laboratories to reduce the range and number of tests which they perform, so as to improve the overall reliability of results. In some disciplines, this would have the added benefit of lessening the turn-around time. For laboratories at the primary or first levels of health care in developing countries, lists of recommended basic tests in clinical biochemistry, haematology and microbiology have been drawn up (5), as summarized in Annex I.

2.2 Organization

Management and communications systems are important components of appropriate technology in the health laboratory. Such systems vary in size, structure, scope and function according to the organizational and clinical settings, but in all cases they should be capable of responding speedily and constructively to new developments in science, medicine and technology and to governmental and social pressures. The following paragraphs outline an efficient organizational structure for a large laboratory, but the general principles are applicable to all sizes of laboratory.

2.2.1 Management

In general, management techniques are most effective when staff work together as a team whose members are deployed at

discrete levels of responsibility. Thus the laboratory director is concerned with overall functions and policies, with liaison with clinicians and administrators, and with forward planning; the more senior medical, scientific and technical staff are together responsible for the efficient day-to-day operation of defined areas of the laboratory's work; junior staff and trainees perform circumscribed tasks according to well-defined protocols – their work patterns are fixed and little decision making is involved; ancillary staff may or may not have formal training or qualifications, and their tasks may be quite repetitive, but nevertheless they can make important contributions to the smooth running of the whole laboratory.

In addition to fulfilling internal and external professional responsibilities, the laboratory director must exercise management skills in developing harmonious relationships with his or her own staff and with the staffs of other hospital departments which provide the laboratory with, or share, facilities; maintaining satisfactory on-going liaison with users of the laboratory, who may be clinicians in the same or neighbouring hospitals, family or works physicians, or other clinical laboratories serviced on a local, regional or national basis; accounting for the laboratory's activities to appropriate hospital authorities or government departments of health, and thereby negotiating satisfactory budgetary and general planning.

Staff at a lower tier of responsibility should be delegated to effect liaison with nursing and clinical staff, as necessary, in the selection, reporting, interpretation and follow-up of tests; to recruit and deploy junior staff and regulate their training and working in a safe and cost-effective manner; to select and organize the testing, implementation and monitoring of appropriate laboratory techniques; to ensure a productive flow of work through the laboratory during both normal and unsocial hours; to attend to the ordering of supplies and the maintenance and renewal of equipment within defined budgets; to keep summary records of workloads, relevant analytical factors, and patient data.

2.2.2 Communications

In most laboratories, distinct two-way channels of communication can be identified between members of laboratory

staff, through operational rotas, work sheets, protocols, progress reports, requisitions, etc.; between the laboratory and its stores, and the suppliers of goods and services, by means of orders, quotations, contracts and services; between the laboratory and the responsible hospital or other administrative authorities, in terms of periodic reports and budgets; between the laboratory and members of the public, such as students and their tutors, potential trainees, and representatives of the mass media, often in the context of visits and personal meetings; and above all between the laboratory and its users, by way of specimens, test requests and reports, general enquiries, and bills.

In providing a service to clinical staff, laboratories require appropriate and correctly labelled specimens, dispatched in the proper containers and arriving at the right place at the right time. The clinic or ward nurses will be involved in, and often be responsible for, the collection and dispatch of specimens. This is a small but important aspect of the nurse's work, but because of varying shift patterns and staff turnover rates there is no guarantee that the same staff will be on duty often enough to become familiar with any but the most common investigations.

Liaison between the nurse and the laboratory needs to be simple, effective and bi-directional. Nurses need accurate information about:

- the conduct of particular tests;
- the conditions under which specimens should be collected;
- the dispatch and transport of specimens;
- special requirements or hazards.

Such information can usefully be made available to all staff in the form of a handbook prepared after consultation between clinicians, laboratory staff and nurses.

3. SPECIAL FEATURES OF THE CLINICAL LABORATORY SCIENCES

3.1 Clinical biochemistry

In a typical clinical biochemistry laboratory, about 30% of working time is devoted to processing specimens; about 50% to analytical work; and the remainder to clerical, organizational and developmental activities. Equipment is available to speed each of these stages, but while simple devices may reduce the effort at low cost, the gain in efficiency from the use of complex apparatus is often outweighed by the cost of capital investment. Such equipment should, in principle, improve the quality of the service rendered to physicians, and hence to patients, but only if the technology is well chosen.

All biochemical analyses should be directly concerned with the disease of the patient or the problem being studied. Specimen size should be minimal, and sampling and storage conditions optimal. The analytical procedures should fulfil appropriate criteria, including economy, reliability and speed. The reporting format should include comprehensive information on the system and component being analysed, the quantity, numerical result, unit and appropriate reference interval.

Until 20 or so years ago, biochemistry tests were generally performed by the physician in the clinic or at the bedside, and this was an inherently self-limiting and cost-conscious approach. In more recent years, the complexities of tests have led to centralization, but it can be predicted that this trend will be largely reversed with new developments in instrumentation, and that bedside techniques of analysis will once again become important.

3.2 Haematology and blood transfusion

Clinical biochemistry and haematology are related disciplines, and have many aspects of day-to-day laboratory operation in common. Nevertheless there are significant differences in approach, notably the fact that a major component of diagnostic haematology is microscopic morphology, which requires different skills from those needed for biochemical analysis.

Thus, in some European countries the two disciplines are practised in one department; in others haematology is an independent laboratory entity or it may be associated with a blood transfusion service.

Efficient deployment of technical staff in haematology laboratories, especially at the primary or first levels of health care, will be greatly assisted by the development of specialized training programmes (6), to cover a fundamental curriculum and utilizing set laboratory procedures.

Basic diagnostic haematology tests and blood coagulation studies require relatively simple general-purpose apparatus together with equipment for microscopy. Much more elaborate techniques and facilities are necessary for large workloads of routine haematology and for specialized cytochemical and serological examinations. For this reason it may be appropriate to conduct these investigations in blood transfusion laboratories which offer a service on a regional or provincial basis. The high cost of equipping such centres with the necessary cold stores, safety cabinets, microscopes and other equipment can thus be justified.

3.3 Microbiology

The diagnostic microbiology laboratory may be involved in one or more of the following activities – bacteriology, mycology, virology or parasitology, any or all of which may be concerned with epidemiological and public health investigations, as well as clinical problems. Laboratory staff thus have wide-ranging responsibilities. Technical work at the bench and standards of performance must be monitored by appropriate internal and external surveillance. There must be close cooperation with the users of the laboratory in the determination of appropriate indications and procedures for collecting and dispatching specimens, and in the input of necessary clinical data to the laboratory.

It is essential that the laboratory is not encumbered with a repertoire of routine tests which includes unnecessary investigations; nor ought it to be pressured into performing assays which should properly be entrusted to referral laboratories.

So far as bacteriology is concerned, isolation remains the major item of routine work. In spite of the recent development of more reliable culture materials, this laboratory activity has

not yet undergone the kind of transformation which has been observed in clinical biochemistry or haematology, or even in the field of serology.

While total automation is not possible in the bacteriology laboratory, different aspects of bacteriological testing can be mechanized or simplified, depending on local needs. Thus staining can be partially automated, but few laboratories have a sufficient workload to justify this approach. Sensitivity testing can also be facilitated by automation, but agar diffusion remains the most widely used method. The fundamental rule is that of not exceeding real needs and so generating unnecessary expenditure.

3.4 Immunology

Although the discipline of immunology arose from the study of protective factors in infectious disease, it has since gained major impetus from the identification of autoimmune disorders and the pragmatic reality of organ transplantation. The compass of the clinical immunology laboratory includes those investigations in which cells or molecules of immunological importance are analysed or quantitated (7). It does not lay claim to other work in which immunologic methodology is used to answer nonimmunologic questions, e.g., hormone radioimmunoassay. Clinical immunology is well established in some European countries as a separate specialty. In the United Kingdom, there are training and accreditation programmes and most areas have some form of routine service. Currently, the main areas of clinical importance are autoimmune and heteroimmune diseases, immunodeficiency and lymphoproliferative disorders, transplantation and therapeutic aspects.

The appropriate delivery of clinical immunology expertise and investigation can frequently reduce the time, inconvenience and discomfort experienced by patients suffering from a variety of undiagnosed disorders. In some circumstances, it may offer information of prognostic or therapeutic value. The provision of a comprehensive immunology service is particularly valuable when this is organized in conjunction with outpatient assessment and screening, e.g., for immunodeficiency. Although some of the potentially more straightforward tests (such as immunoglobulin quantitation and autoantibody detection)

can be performed at a district level, there is much to be gained from locating such a service in association with a major conurbation (8).

The pooling of resources and expertise which stems from this arrangement is especially important in a discipline which is developing so rapidly and which still requires considerable validation and development of its methods. Other implications of this degree of centralization are the needs for efficient facilities for specimen transport and report distribution, for increased participation in staff training programmes, and for enhancement of the laboratory department's consultative function.

The usefulness and credibility of a service can only be fully realized when a satisfactory dialogue has been established between the clinician and immunopathologist, in which both sides are willing to learn from and educate the other concerning their respective needs and problems.

With further advances in our knowledge of immunological mechanisms and their role in disease, it is likely that immunology will have much more to say about prophylaxis, in addition to diagnosis, prognosis and management. As the 1980s unfold, the most "appropriate technology" may become preventative, emulating the great strides made in other areas, e.g. smallpox immunization and eradication, and the prevention of rhesus haemolytic disease.

3.5 Histopathology

A basic service in histopathology may be provided relatively simply in terms of equipment and staffing. However, although the provision of a basic service in histopathology may be desirable, there is a minimum workload below which the laboratory will not function efficiently, at both the medical and the technical levels. In these circumstances, the nature of histopathology lends itself to centralization, with one laboratory serving the needs of a number of small hospitals by means of a messenger service. Even in hospitals with a sufficiently large workload to support a histopathology service, there may be particular areas of expertise which need the support of a specialized referral laboratory; in this way, types of material which are received only occasionally may be examined with maximum benefit to the patient. If such

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referral laboratories are to function efficiently, they should receive special funding so that they perform this task as a duty, and not merely as a means of informal contact between pathologists.

The standards of histopathology are chiefly set by those larger laboratories — often associated with universities — where routine diagnostic work and research projects are complementary activities, and where supporting staff and high-technology equipment are more readily available. Pathologists trained in large laboratories will expect to apply techniques learned there in their own laboratories which, by contrast, may be quite small in size. In introducing such techniques to small laboratories, it must be ascertained that they are of clinical importance and are not purely “laboratory-led” examinations. On the one hand, they must be shown to be cost-effective; on the other, the introduction of a limited range of techniques must not lead to a conflict between the scientific and professional aspirations of clinicians and pathologists, and the laboratory resources which are accessible. This aspect of appropriateness of technology is particularly important in histopathology.

3.6 Food hygiene

Although great progress has been made in the control of communicable disease, foodborne illness is increasingly important on account of microbiological or chemical contamination. Often, no definite cause can be found in many recognized outbreaks of food poisoning, and until a cause can be identified preventive measures cannot be taken. Intensive laboratory and epidemiological investigations, therefore, should be instituted as rapidly and effectively as possible. The laboratory’s role is to detect and identify the causative agent at an early stage of the outbreak. It is clear that food science and technology are expanding and that international trade in food is continually increasing. There is a need for parallel improvements in laboratory resources in this area.

The Group agreed that the staffing and range of facilities of food hygiene laboratories must be determined largely by local circumstances. The laboratory’s task is to support foodstuff inspectors, and to do this it must provide at least basic microbiological, parasitological and chemical services. The laboratory

in the front line may be supported by progressively more specialized services at regional or central level. In all cases, staff should be encouraged to develop methods and techniques which are appropriate to local circumstances, but central laboratories should offer manuals of basic methodology, and do their best to ensure that standards are maintained by proper training, refresher courses, quality control programmes and collaborative studies.

Laboratories should be able to report and interpret their findings in an intelligible way to the consumer, to local authorities and to enforcement agencies, which may not themselves have staff with the appropriate scientific background.

Central laboratories should coordinate the activities of laboratories in the front line by encouraging participation in national surveillance programmes, and by defining objectives for local programmes of work.

3.7 Role of industry

Industry endeavours to meet the reasonable demands of health laboratories by providing good reagents and practical measurement systems at acceptable cost. Industry can achieve these ends by applying technological quality control procedures at all stages, from the raw materials to the final products and from item to item. Industry is often closely involved in the development and refining of new methods of investigation. To this end industry and health laboratories should use a common terminology, as well as sound methodologies.

Industry has recognized that it is important to increase its service to laboratories in two particular ways:

- by supplying better information on the proper use and maintenance of measurement apparatus and on the correct use of reagents; and
- by providing reliable data on the limitations, in respect of precision as well as specificity, of the results of tests conducted under given conditions.

Laboratories can help to maintain a viable industry, with healthy and fair competition, through rational evaluation,

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- by providing reliable data on the limitations, in respect of precision as well as specificity, of the results of tests conducted under given conditions.

Laboratories can help to maintain a viable industry, with healthy and fair competition, through rational evaluation,

selection and utilization of commercial products, and by active cooperation in research and development.

4. CONCLUSIONS AND RECOMMENDATIONS

4.1 The laboratory's contribution to health care

The best long-term interests of patients and of the community at large should be carefully considered in planning, organizing and implementing appropriate laboratory services. In the past, patient and community interests have tended to take second place to those of clinical and laboratory staff.

The community, the laboratory professions, health authorities and industry together make an important contribution to the delivery of health care. Maximum effectiveness requires a good flow of information between all of these partners about their distinctive responsibilities and about the scope, limitations, logic and economics of laboratory techniques. At the same time, rapid developments in the clinical sciences demand constant reassessment of these factors, with a programme of continuing education or in-service training for all concerned. Positive efforts must be made to develop and apply common terminology and units so as to avoid communication barriers.

4.2 Cost-consciousness

A keen awareness of the costs and potential benefits of individual tests is essential, both for those who request and those who provide laboratory services. Properly chosen tests performed at the first level of health care may avoid the need for more expensive investigations performed at a higher level. The medical and laboratory professions and health authorities jointly should encourage cost-consciousness and gather and disseminate reliable information about the benefits and cost-effectiveness of laboratory tests. Tests which have outlived their usefulness should be identified and positively discouraged.

4.3 Choice and use of laboratory tests

Judicious selection of tests at the first level of health care, so as to avoid unnecessary or overspecialized investigations, is most likely to be achieved by an experienced clinician who has a broadly based up-to-date knowledge of the principal laboratory disciplines, and a good rapport with laboratory staff. Low-cost simple tests which can be performed by the clinician himself are to be encouraged, provided that they are relevant and intrinsically reliable.

It is important to achieve an understanding of the ways in which clinicians actually use or discard laboratory findings in making diagnostic or therapeutic decisions. The principles underlying this kind of decision making should be actively taught to trainee physicians, to discourage them from ordering superfluous tests.

Clinicians, and also nursing and ancillary staff whose work interacts with that of the health care laboratory, need to know about the contributions of pre-analytical and post-analytical factors to assuring meaningful laboratory results.

4.4 Choice and use of appropriate technology

Decisions as to the most appropriate technology for a health laboratory must take account of the immediate clinical setting, and the local, regional and national organization of health care. The centralization of some investigations may offer certain advantages, depending on analytical factors and on the importance of speed in returning a result. Hospital or health authorities need to consult clinical and laboratory staff in making decisions about rationalization or centralization of tests.

Reagent kits may be appropriate for small laboratories or for uncommon tests. However, their quality must be assured, preferably by independent evaluation, and the manufacturer's product information should be reliable, and adequate for the particular need. Whether or not reagent kits are used, laboratory procedures should be clearly documented and proper records kept. Maximum advantage should be taken of intra- and inter-laboratory quality control techniques so as to enhance staff motivation and job satisfaction.

Manufacturers also have a responsibility to supply users with informative manuals of instruction for the installation and efficient use of equipment. At the same time, laboratory staff should set high standards of operation and routine maintenance, so as to avoid unnecessary calls on service engineers.

4.5 Interaction with industry

The laboratory professions should seek to stimulate industry to produce innovative and cost-effective reagents and apparatus, especially those appropriate for basic investigations at the first level of health care. Complex automated instruments should only be designed and made in order to fulfil an agreed need; realistic estimates of the costs of day-to-day operation and of periodic servicing are mandatory.

For its part, industry should promulgate balanced factual information about new products, and inform the professions about the economics and risks of research and development into health laboratory techniques. Wasteful duplication of reagent or instrument evaluations should be avoided; instead, appropriate protocols which are acceptable on an international basis should be developed, so as to effectively test ergonomic as well as functional and analytical factors.

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Annex I

PRIMARY-LEVEL HOSPITAL LABORATORY TESTS

It is recommended that the following basic tests be carried out by the primary-level hospital laboratory. Other supplementary tests may also be performed at this level if they are in accordance with priority health needs and technical facilities and if resources are available.

Clinical chemistry

Blood:

- Glucose
- Urea
- Total proteins
- Albumin
- Bilirubin (total)
- Alkaline phosphatase

Urine: Physical examination and

- Protein
- Glucose
- Ketones
- Bilirubin
- Urobilinogen
- Blood
- Pregnancy test
- Sediment for cells and casts

Stools:

- Occult blood

Cerebrospinal fluid:

Total protein
Globulin
Glucose

Water:

Chlorine
Nitrate

Haematology

Haemoglobin
Cell morphology, including differential white cell count
White cell count
Packed cell volume and calculation of MCHC
Erythrocyte sedimentation rate
Reticulocyte count
Bleeding time
Clotting time

Microbiology

Blood:

Parasites

Skin:

Parasites
Fungi

Skin and nasal mucosa:

M. leprae

Sputum:

M. tuberculosis

Pus and exudates:

Bacteria

Cerebrospinal fluid:

Cell count

Bacteria

Parasites

Stools:

Ova and parasites

Urine:

Bacteria

Parasites

Vaginal swabs:

Trichomonas

Monilia

Candida

Bacterial culture and antibiotic susceptibility testing should be performed at this level whenever possible.

Annex II

LIST OF PARTICIPANTS

Temporary advisers

- Dr A. Bouguermouh
Pasteur Institute, Algiers, Algeria
- Dr S.S. Brown
Clinical Research Centre, Harrow, United Kingdom
(*Rapporteur*)
- Miss M.O. Clark
Scottish Home and Health Department, Edinburgh,
United Kingdom
- Mr N.B. Coupe
Denley Instruments Ltd, Billingshurst, Sussex, United
Kingdom
- Professor G. de Felip
Higher Institute of Health, Rome, Italy
- Dr Maria Dobрева
Institute of Hygiene and Occupational Health, Sofia,
Bulgaria
- Professor M. Hjelm
Hospital for Sick Children, Great Ormond Street, Lon-
don, United Kingdom
- Professor G. Horejsi
Institute of Haematology and Blood Transfusion, Prague,
Czechoslovakia
- Dr A.R. Leblanc
Department of Quality Control for Biomedical Tests,
Paris, France

Mr M. Ménard
Gilford Europe S.A., Evry, France

Professor V.V. Menshikov
All-Union Scientific Methodical Centre for Laboratory
Research, Moscow, USSR

Dr H.A. Olesen
State Hospital, Copenhagen, Denmark

Professor O. Öuchterlony
Institute of Medical Microbiology, Gothenburg, Sweden
(*Chairman*)

Dr W.G. Reeves
Queen's Medical Centre, Nottingham, United Kingdom

Dr G. Slavin
Northwick Park Hospital and Clinical Research Centre,
Harrow, United Kingdom

Representatives of Other Organizations

International Association of Medical Laboratory Technologists

Mr P.J. Basterfield
Royal United Hospital, Bath, United Kingdom

Mr J.L. James
Royal Victoria Hospital, Bournemouth, United Kingdom

Mr G.C. Pascoe
Executive Director, International Association of Medical
Laboratory Technologists, London, United Kingdom

Observers

Dr E.M. Woodward
Clinical Research Centre, Harrow, United Kingdom

World Health Organization

Regional Office for Europe

Dr A.H.W. Wahba

Regional Officer for Appropriate Technology for Health
(*Secretary*)

Headquarters

Dr W. Ferreira

Chief, Health Laboratory Technology