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**PLANNING, ORGANIZATION
AND ADMINISTRATION OF A
NATIONAL HEALTH LABORATORY
SERVICE**

**Third Report
of the Expert Committee
on Health Laboratory Services**

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EXPERT COMMITTEE ON HEALTH LABORATORY SERVICES

Geneva, 6-13 November 1961

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PLANNING, ORGANIZATION AND ADMINISTRATION OF A NATIONAL HEALTH LABORATORY SERVICE

Third Report of the Expert Committee on Health Laboratory Services

1. INTRODUCTION

The Expert Committee on Health Laboratory Services met in Geneva from 6 to 13 November 1961.

The meeting was opened by Dr M. G. Candau, Director-General of the World Health Organization. In his opening address Dr Candau stated that the objective of the Committee was to provide judicious recommendations for the establishment or strengthening of national health laboratory services in developing countries. Reference was made to earlier reports of the Committee on Health Laboratory Methods,¹ which had dealt with public health laboratory services and hospital laboratory services and the collaboration and co-ordination that should exist between them, and, in developing countries, had recommended their unification in view of economic factors and the training of personnel. The present report would be particularly concerned with practical methods of applying earlier recommendations to the special circumstances of developing countries.

The Director-General mentioned the great importance of planning for the difficult steps of development from the technical, operational and economic points of view. All factors must be clearly defined in accordance with the needs and health problems of the country concerned, and taken into account in the preparation of long-term programmes of development and assistance.

There should be emphasis on efficiency, which depends on a multiplicity of conditions that can only be fulfilled satisfactorily if all laboratories are organized in a well-administered system as an integral part of the

¹ *Wld Hlth Org. techn. Rep. Ser.*, 1957, 128; 1959, 161.

national health service. It is necessary to have in mind not only the present situation but also the future, and to visualize the changing problems which health authorities will have to face when the emphasis shifts to preventing diseases now almost exclusively in the province of curative medicine. A well-organized and flexible laboratory service can be adapted more easily and quickly to new types of activities.

Dr C. H. Yen was elected Chairman, Professor K. Raška, Vice-Chairman, and Dr R. Turner, Rapporteur.

2. GENERAL CONSIDERATIONS

With the recognition of the important role played by a health laboratory service in the fields of curative and preventive medicine, the need to consider the organization or reorganization of an integrated health laboratory service, particularly within a developing country, becomes apparent. This need, and the several aspects of planning, organization and administrative problems involved, have been the subject of study by several committees and study groups sponsored by WHO (the Expert Committee on Health Laboratory Methods,¹ the Expert Committee on Public Health Administration,² the Advisory Group on Public Health Laboratory Services, WHO Regional Office for Europe (held in Moscow, 14-19 October 1957), and the Seminar on Health Laboratory Services, WHO Regional Office for the Western Pacific (held in Manila, 5-16 December 1960).

While planning, organization and administration of a national health laboratory service may vary from country to country (depending on factors such as national administrative patterns, availability of health personnel and facilities, major health needs, size and population of the country, etc.), there are certain aspects of planning and organization which deserve attention. Some of the important ones are as follows :

- (1) The need to consider an integrated national health laboratory service as an integral part of the national health service.
- (2) The provision of health laboratories varying from the simple to the highly complex, depending on the national health needs.
- (3) The desirability of combining the functions of a public health and hospital laboratory into a single laboratory at appropriate levels in order to minimize the cost and better to utilize trained personnel.
- (4) The establishment of specialized laboratories and reference laboratories for a country or countries.

¹ *Wld Hlth Org. techn. Rep. Ser.*, 1957, 128 ; 1959, 161.

² *Wld Hlth Org. techn. Rep. Ser.*, 1952, 55 ; 1954, 83 ; 1961, 215.

(5) The desirability of integrating the health laboratories of a country under a single administrative and technical system for proper direction, supervision, operation, and maintenance of standards, and of establishing a division or department for health laboratory services within the national Ministry of Health.

(6) The need to establish a national advisory body on health laboratory services, which can advise the director of this service on matters of policy, standards and legislation.

(7) Problems involved in providing sufficient numbers of trained laboratory workers of all categories and more comprehensive legislation on qualifications and standards required of laboratory personnel.

(8) The eliciting of better appreciation and utilization of health laboratory services by medical and public health workers.

(9) The need to improve co-ordination between rural (local), district, provincial and national health laboratories at different levels, and between the health laboratory services as a whole and other governmental services, such as industrial, agricultural, veterinary, water supplies, education, etc.

(10) The establishing of more international and bilateral collaboration in the field of laboratory services.

Although the remarks and recommendations made in this report are primarily guide-lines for developing countries, many should be considered, and perhaps adopted, by developed countries wishing to improve their health laboratory organization.

3. DEFINITION OF A HEALTH LABORATORY SERVICE

The health laboratory service groups all the laboratories used in both preventive and curative medicine: public health laboratories, hospital laboratories and other laboratories which in some way deal with the health of the people of a country, whether considered individually or collectively.

3.1 Review of trends in development of health laboratory services

In many developed countries health laboratory services have grown rapidly since the beginning of this century but in a haphazard fashion. Thus, pathological laboratory services were often developed primarily to meet the teaching and research needs of medical schools and the clinical needs of hospitals. These services were therefore largely designed to serve the needs of curative medicine. Other laboratories were independently developed by authorities charged with public health duties, such as municipalities, and were designed to carry out public health functions such as the

microbiological control of water supplies, dairy and food products, as well as investigations for the exact laboratory diagnosis of many infectious diseases. Other agencies, public or private, undertook the manufacture of biological agents for the control and treatment of infectious diseases, e.g., vaccines, toxoids and antisera. Thus a number of independent and unco-ordinated agencies concerned with various aspects of health laboratory work were established. Gradually in many of these countries these agencies were organized by central authorities in two main systems: namely, a hospital laboratory service and a public health laboratory service. These services have met with a varying degree of success. In certain countries today they are very well established and adequately meet all the health laboratory needs of the country. These services have often been uneconomic owing to lack of co-ordination, wasteful duplication of effort, and failure to make the best use of resources. They have also sometimes left dangerous gaps in their activities.

In other countries such a dual system has not developed. In these, hospital and university laboratories were first established, and then public health functions were gradually added to them. This type of service has often failed to prove satisfactory, as frequently the necessary extra facilities and trained staff required for such additional duties were not adequately provided, with the result that public health needs were often sacrificed.

These varying experiences of the developed countries, chiefly over the past decade, have clearly indicated that in most instances considerable benefit may accrue from welding health laboratory services into a single national health laboratory service operating on a wide and well co-ordinated front to cover adequately, economically and efficiently all the laboratory needs of both curative and preventive medicine. In recent years in certain countries such comprehensive systems have been developed and have met with success.

Developing countries may thus benefit from the experience of developed countries in the recent past. It is therefore advocated that, in developing countries where there are no established health laboratory services or where such services exist only in rudimentary form, a single national co-ordinated laboratory service gradually be established.

The main advantages of such a system may be briefly summarized as follows:

- (1) Uniformity of techniques, training and administration.
- (2) Reliability of results and comparability of data with consequent reliable knowledge of health and disease patterns and trends.
- (3) Economy in the use of scientific personnel and material, and the employment of all resources to the best advantage.
- (4) Better control of the quality of the work in all its aspects, both from a state and from a private point of view.

(5) Complete coverage, in a balanced form, of all the various laboratory needs of the country with minimal duplication of efforts or the danger of gaps.

3.2 Scope and functions of a health laboratory service

Below are broadly outlined the main functions of a co-ordinated national health laboratory service, designed to meet the needs of both preventive and curative medicine, such as may be in operation today in a well-developed country. This may serve to illustrate the general aim of a plan for the establishment of such a service in a developing country. These services are listed according to the main disciplines of applied pathology and associated sciences.

3.2.1 *Microbiological services*

These services cover the fields of bacteriology, virology, mycology, parasitology and relevant serology as applied to :

- (1) diagnose established infectious diseases,
- (2) control treatment,
- (3) indicate when a patient is free of infection and therefore no longer a danger to others,
- (4) detect carriers, who are so important in the spread of many infectious diseases,
- (5) ascertain the precise nature of infective agents circulating in a community, and
- (6) ascertain the extent of immunity to a particular agent in a community, etc.

3.2.2 *Entomological service*

This service is required for the detection and exact identification of arthropod vectors of disease, and for the study of the distribution of various infective agents in such vectors, with the aim of determining the best type of campaign to adopt for their control and eradication.

3.2.3 *Pathological anatomical services*

These services are required for the performance of routine autopsies, for the scientific evaluation of clinical work, for research purposes, and for the provision of a diagnostic histological service. Another important and relatively new diagnostic advance in the field of histology is that of exfoliative cytology.

3.2.4 *Haematological and blood transfusion services*

3.2.4.1 *Haematological service.* This service makes provision for the performance of all types of haematological tests.

3.2.4.2 *Blood transfusion laboratory service.* This service is required for all laboratory investigations in connexion with transfusion, and for the preparation and control of human blood products.

3.2.5 *Chemical service*

3.2.5.1 *Chemical pathological service.* This is required for the diagnosis, assessment and control of treatment of many diseases.

3.2.5.2 *Other chemical services.* These are required for a variety of purposes—e.g., the control of environment, drugs, etc.

3.2.6 *Biophysical service*

This service is required for the detection of radioactivity and ionizing radiations, for the control of isotopes as used for diagnosis, therapy and research, and for the investigation and control of the environment.

3.2.7 *Hygiene laboratory services*

Hygiene laboratory services (microbiological, chemical, physical and physiological) are required for health sanitation—i.e., the control of water supplies, dairy products and environment in respect of the prevention and control of air pollution, industrial hazards, etc. In many countries these services are often carried out by other agencies, but usually the over-all responsibility is vested in the health authorities.

3.2.8 *Physiological and nutritional laboratory services*

In many countries there is a special laboratory service to investigate dietetic deficiencies and to determine the nutritional value of various foodstuffs in common usage. This information may be used by the authorities to advocate balanced diets.

3.2.9 *Production laboratory*

Services for the production of various biological preparations for the prevention and treatment of disease, i.e., for the manufacture of vaccines, toxoids, antisera; and/or for the production of standardized antigens and diagnostic antisera, are often important functions of a national health laboratory service.

3.2.10 *Control of quality of pharmaceutical preparations*

An important function of many health laboratories is a chemical and pharmacological service for the control of quality of pharmaceutical preparations to ascertain whether drugs used in the country comply with the national requirements.

In some countries a chemical analytical service which undertakes toxicological investigations for forensic purposes is associated with the health laboratory services.

3.2.11 *Control laboratory for biological products*

A control service for the biological and chemical testing of human blood products, vaccines, toxoids and therapeutic antisera used for prophylaxis and treatment in humans, with the aim of ensuring that these and other biological products, including diagnostic agents used in vivo in man, comply with the national requirements for purity, safety and potency, is an important function of many health laboratory services. In some countries there is also a service for the appropriate control of diagnostic agents—e.g., antigens and diagnostic antisera used in vitro.

3.2.12 *Forensic service*

Though the provision of a forensic medical service is primarily a responsibility of the Department of Justice, in some countries for purposes of economy and efficiency this service may be incorporated in the national health laboratory service. Thus the service for medico-legal autopsies may be associated with the pathological anatomical service, various medical laboratory examinations may be performed in collaboration with the appropriate technical sections, and toxicological analyses may be undertaken by the chemical division responsible for the analysis of drugs.

3.2.13 *Epidemiology services*

These services are important from a public health point of view, and are concerned with :

- (1) collecting and evaluating epidemiological data (notification of infectious diseases, results of microbiological investigations), and dissemination of epidemiological information to the health service ;
- (2) epidemiological investigation in the field, and the control of epidemics and carriers, and detection and charting of the spread of infectious disease in place and time ;
- (3) study of changing patterns of infectious diseases, the spread of etiological agents and the immunological responses thereto in the human and animal population ;

(4) organization of controlled field trials for the evaluation of different prophylactic measures ;

(5) the application of epidemiological methods to the study of non-infectious diseases in close collaboration with other disciplines of medicine.

Epidemiological services are differently organized in different countries —e.g., as independent services, as services closely associated with the laboratory service, or integrated into the laboratory service under the form of a hygienic-epidemiological service.

3.2.14 *Teaching and training*

A teaching and training programme for personnel employed in the service and for other health personnel is a necessary part of an integrated health laboratory service.

3.2.15 *Research*

A programme for research, particularly into health problems directly associated with the work of the laboratories and of health importance to the country, is an important activity of fully developed national health laboratory services.

4. THE PLANNING OF A NATIONAL HEALTH LABORATORY SERVICE

4.1 *Preliminary survey*

A national health laboratory service is essential for an efficient health service, both curative and preventive. As the laboratory service is an integral part of the national health service it should be gradually developed in balanced proportion to the whole ; a sense of perspective must always be maintained.

The planning of such a service for a developing country should be undertaken by an expert (or experts) with a high level of technical and administrative experience in the organization and functioning of a laboratory service. He may be invited by the government concerned, or requested through the assistance of international or bilateral agencies. His first task should be to survey the needs and evaluate the resources as they relate to the health laboratory services, and to study the factors which may affect the establishment of a long-term programme and influence the determination of priorities. Particular consideration should be given to the following points :

- (1) Cultural background of the population and educational facilities
- (2) Economic and technical level of the country and its rate of development
- (3) Geographical and climatic conditions
- (4) Transportation and communication facilities
- (5) Number and distribution of the population
- (6) Territorial organization and administrative system of the country
- (7) Major health problems of the country
- (8) Existing health services
 - (a) Organization of the Ministry of Health
 - (b) Types and distribution of health services
 - (c) Number and distribution of hospitals (number of beds), governmental and private
 - (d) Number and distribution of medical officers (local and foreign):
 - (i) government employees working in curative and preventive medicine
 - (ii) private practitioners
 - (e) Number of students studying medicine
 - (f) National health plan
- (9) Available laboratory resources
 - (a) Health laboratories :
 - (i) organization of the laboratory service
 - (ii) number, types and distribution of laboratories and services rendered
 - (iii) premises, equipment, methods
 - (iv) number and distribution of scientific and technical laboratory personnel
 - (v) training facilities
 - (vi) number of undergraduate and post-graduate students undergoing training in sciences related to laboratory activities
 - (b) Other laboratories in relation to the health service :
 - (i) attached to other governmental services
 - (ii) private laboratories
 - (c) Technical facilities :
 - (i) water, gas, electricity
 - (ii) repair facilities
 - (iii) availability of technical material

Adequate information on all these points is indispensable not only for the preparation of a sound programme but also for further evaluation.

4.2 Development of the plan

Analysis of the information obtained by the survey will provide a basis for estimating the health laboratory needs of the country and permit the formulation of sound recommendations. A national plan for the development of a national health laboratory service can then be worked out in consultation with the "national body" responsible for health planning and co-ordination.

This plan should follow the well-tried orthodox design of a pyramidal structure with laboratories of different grades at different levels and becoming fewer in number as the complexity and extent of the services they render increases. Such a plan should allow both vertical and horizontal co-operation within the laboratory service as well as with the clinical and public health services at all levels, and with other government departments or agencies which are connected with human health problems—e.g., the veterinary services, the sanitary engineering services, etc. This plan will also allow for effective administrative control in both technical and purely administrative matters.

In this pyramidal structure the less complicated and also most urgently required laboratory investigations will be decentralized to the maximum degree practicable, while the less urgent and more complicated will be centralized to a varying degree.

This plan, when fully developed, should provide for

- (1) A central or national laboratory which will be the technical headquarters of the system. In some instances, depending upon the administrative pattern of the country, the central laboratory will also be the administrative headquarters.
- (2) Intermediate laboratories, which may be of two types:
 - (a) state, provincial or regional laboratories, the title depending upon the constitution of the country, and
 - (b) district, county or municipal laboratories.
- (3) Laboratory side-rooms situated at the far periphery.

In certain countries, largely depending on their geographical size, density of population and constitution, it may be necessary to provide only one type of intermediate laboratory, whereas in others larger parent regional and smaller satellite district laboratories will be required.

5. ORGANIZATION OF A NATIONAL HEALTH LABORATORY SERVICE

5.1 Location, operation and technical integration, scope of work

5.1.1 *Location*

In public health work it may not be important where a laboratory is situated provided that it is in a main centre, is readily accessible, and is closely linked to the department of public health. It is essential, however, for clinicopathological work that a laboratory should be situated either within or immediately adjacent to the main hospital that it serves. This is necessary because the hospital pathologist should co-operate closely with the clinicians, and is often an active member of the diagnostic team. It is only by working in association with the clinicians that a pathologist can be a true consultant in clinical pathology, and exert that moderating influence which is often so necessary to prevent the demands for inessential and wasteful tests which cripple a developing laboratory.

5.1.2 *Central or national laboratory*

5.1.2.1 *Site.* In developing countries the central or national laboratory may first develop as a regional laboratory, in which case it will be best situated close to the main hospital of the national capital.

5.1.2.2 *Administrative functions.* The central laboratory should house the director of the national health laboratory service and his administrative staff, and accommodate the administrative headquarters of the service. There is sometimes a tendency to house the director not in a laboratory but in the general headquarters of the national health service. The duties of the director may be mainly administrative and therefore it may appear administratively convenient to house him there. His interests should, however, be directed chiefly towards his own service, and it is most desirable that he be kept in continued contact with its everyday practical problems, particularly if it is in a stage of rapid development. If he is away from a laboratory he may slowly lose contact with its technical needs, and this in time may act to the detriment of the service.

If it is possible, without detriment to his administrative responsibilities, the director should undertake the supervision of active laboratory work at least in a limited field.

The director as a member of the health ministry should also maintain close liaison with the director of the health service or equivalent officer so that he may develop his laboratory service in accordance with official

policy, and advise the health directorate on the progress, needs and aspirations of his service. This he may do by maintaining frequent working contact with the director of health services and by serving on its national planning council.

Later it may become desirable to convert this post into two separate posts, namely: (1) a director of the national health laboratory service, (2) a director of the central laboratory.

If epidemiology is developed as a part of the public health department, and not of the laboratory services, it is nevertheless desirable that the office of the epidemiologist be situated in the central laboratory. This will readily permit the very necessary and constant co-operation between the epidemiological and laboratory staff, and should greatly help to encourage a public health outlook in the laboratory service, and to direct the attention of the medical officers to the field as well as to the hospital.

A library for the laboratory service should be established at the central laboratory, from which should emanate a periodic information service to the peripheral laboratories.

5.1.2.3 *Technical functions.* The work of a national health laboratory service falls into two main branches, namely: (1) a public health branch, the main work of which in the initial stages will be in the microbiological field; and (2) a hospital branch, the main work of which will be in clinical pathology.

At the earliest stage possible in the development of the central laboratory, these primary divisions of work should be made. Suitably qualified medical officers should be appointed as chiefs, each of whom should be responsible in administrative matters to the director (who should co-ordinate and balance the work of the divisions), but should be in independent charge of the technical work of his division. Each of these primary divisions should, in time, be further divided into sub-divisions and sections, each under the control of a suitably qualified professional officer assisted by appropriately qualified and graded technical personnel. Thus the work of the microbiological division may be organized into sub-divisions or sections in bacteriology, virology, mycology, parasitology and entomology, whilst under the division of clinical pathology will be sub-divisions or sections in haematology, chemical pathology and anatomical pathology. The question whether these entities should be classified or sub-divided into sections will depend upon their size and functional relationship to each other. Thus, under microbiology may be a sub-division of bacteriology, which may include a section on mycology, etc.

Allied divisions for more specialized work of the service (e.g., chemistry, hygiene, blood transfusion, etc.), may also be established at the central laboratory so as to form a laboratory complex. These allied divisions

should be under their own technical chiefs, who will be responsible to the director.

Each primary division, when sufficiently developed, should act as a reference laboratory in its respective disciplines to the laboratory service as a whole.

The central laboratory should also be the parent organization of the service and should supply the peripheral laboratories with such prepared reagents as they may require.

Provision should be made at the central laboratory for transport and mobile equipment for field studies.

5.1.3 *Regional laboratories*

A regional laboratory may be regarded as a subcentral laboratory which serves a large administrative region, e.g., a state or a province, and should be located close to the main hospital of the state or provincial capital. It will be responsible for the hospital work of the regional hospital and the public health work of the region.

Each regional laboratory should, in time, be divided into the two primary functional divisions each with its own officer in charge, who should preferably be a medical officer. Each division should also be divided into appropriate functional sections suitably staffed.

In technical matters the primary divisions of the regional laboratory should subscribe to the technical policies of the central laboratory.

Each regional laboratory should attempt to be as complete in its technical routine services as is possible, and should only refer to the central laboratory those more specialized investigations which it cannot undertake. It should also use the central laboratory as required for consultative and reference work.

Certain of the allied divisions at the central laboratory may be represented at the regional level by suitable sub-divisions or sections—e.g., chemistry, hygiene, blood transfusion, etc.

Regional laboratories should act as parent laboratories to the district laboratories in their regions. They should thus undertake the more specialized types of investigation which are referred to them by their district laboratories. The officers in charge at the regional laboratories should also act as consultants to those at the district level. The regional laboratories may also supply the district laboratories with such special reagents as the latter may require.

The director of the regional laboratory should visit the district laboratories from time to time for inspection and supervisory purposes.

Finally, it may be found necessary to provide the regional laboratories with suitable transport and mobile equipment for field work.

5.1.4 *District laboratories*

These laboratories should be established close to the hospitals of different towns in the region, excepting the capital.

Their main functions should be to provide a clinical pathology service to the hospitals to which they are attached, and to undertake all the public health laboratory work of the district that they can satisfactorily do. At best these district laboratories may be staffed by only one medical officer, who would have to undertake both public health and hospital investigations. The work undertaken by a district laboratory should therefore be of a relatively simple nature, and the more complex forms of investigation should be referred to the regional laboratory.

The district laboratory should rely on its parent regional laboratory for its supplies.

The officer in charge of a district laboratory should be in technical control of the laboratory side-rooms of his district. He should visit each side-room at frequent intervals both for supervisory and for consultative purposes.

5.1.5 *Laboratory side-rooms*

These are very simple laboratories, probably consisting of only a single room, and staffed by one trained technician assisted by auxiliaries; they should be regarded as outposts of district laboratories. The facilities will be very limited, and such laboratories should be expected to undertake only the simplest tests—e.g., blood counts, examination of blood smears for malaria parasites, of sputum for acid-fast organisms, urinalyses, etc.

These side-rooms should also act as collecting points for various specimens required to be sent on to a district or regional laboratory, according to such rules as may be prescribed by the service.

5.1.6 *Reference laboratories*

Reference laboratories are those which specialize in a limited aspect of laboratory work. The functions of a reference laboratory are as follows:

- (1) it is a centre to which other laboratories may refer specimens for elaborate investigation in its special field;
- (2) it renders consultation services in its specialty to other laboratories;
- (3) it may be a centre for the preparation and standardization of diagnostic reagents required in this field;
- (4) it serves as a training centre for personnel and specialized methodology;
- (5) it is a research centre in its field;

(6) it is the agency which communicates with similar international centres.

A reference laboratory should be established only when a fully trained expert in the particular field concerned is available. Although it may often be convenient to situate it at the central laboratory, this is not essential; a reference laboratory for a particular subject could be developed at a peripheral laboratory, or even at a separate organization such as a medical school or a veterinary laboratory.

5.1.7 *Laboratory animals*

It is essential that early in the development of a health laboratory service adequate facilities be provided for breeding and maintaining laboratory animals fit for laboratory use. This section should be located at or near the central laboratory, and should be attached to it. It may be at the regional laboratory in cases where this fulfils the functions of a central laboratory. It should supply the animals required by subordinate laboratories, and advise in the management, feeding and use of these animals.

Each animal-producing unit should be under the direction of a qualified person trained in up-to-date methods of animal husbandry. This person could be a trained veterinarian, or a graduate in one of the animal sciences, who should be responsible to the director of the central laboratory. He should be assisted by an adequate staff of technicians and laboratory aides. He should also be responsible for training technicians in animal care.

6. ADMINISTRATION OF A NATIONAL HEALTH LABORATORY SERVICE

6.1 General remarks

The administration of a national health laboratory service must vary according to the governmental constitution of each country. Thus in some countries the organization, control and financing of a health service is vested in a central authority, whereas in a federation of states, each state may be financially independent and entirely responsible for its own health services. Other countries vary between these two extremes as regards their degrees of decentralization of governmental authority.

In those countries in which health is a central governmental responsibility, a scheme for a national health service and its effective administration may be readily implemented. In a federation of states, however, in which each state is autonomous on health matters, appropriate legislation and administrative measures may have to be taken to co-ordinate health

services and to share certain types of health work. Two main plans for the administration of co-ordinated national health services, including health laboratory services, may therefore have to be devised to suit the needs of different countries; modifications of these plans may also be required for countries whose constitutions fall between these extremes.

6.2 Plan of administration of a national health laboratory service in a country with a centralized government controlling all health services

6.2.1 Direction

In such a country the Minister holding the portfolio for health will be responsible for deciding on the policy of the national health service, on finding the necessary funds to develop and maintain that service, and in persuading the central legislative body to pass legislation for the effective organization and administration of health matters.

The executive officer to the Minister will be the director of the national health service, or his administrative equivalent (e.g., vice-minister, etc.). He will also act as official adviser to the Minister on all health matters, including the laboratory services, and will be responsible for framing the budget of the health service. The director of health laboratory services will be the executive officer of this service, and will be responsible for its organization and maintenance to the director. One of his important tasks will be to prepare the annual budget of his service within the limits of the funds allocated. He will advise the national health directorate not only on all the needs, present and future, of his own service but also on any legislation required for its efficient operation.

6.2.2 Functions of director of national health laboratory service

The director of the laboratory service, whilst responsible for the administration of the whole service, should as soon as is feasible delegate technical responsibility to the chiefs of the various divisions in their respective fields. He should devise his administration on the basis that it is a technical service, and consequently his administrative organization should be geared to meet adequately the technical needs of the service within the framework of the national health service.

The director of the service should be assisted by an administrative division under his immediate control. This division should have a senior and suitably trained administrative officer to whom the director should delegate the control of all administrative matters that do not require his personal attention. This administrative staff should comprise, besides the senior administrative officer, an accountant, a stores and supplies officer, and such other clerical and secretarial staff as may be required.

6.2.3 *Advisory committee*

A committee should be appointed to advise the director of laboratory services on :

- (1) the scope, organization and development of the service, on the priorities to be given to various classes of work, and on development schemes ;
- (2) the staffing, qualifications and grading of the various posts in the laboratory services, and the licensing and control of all health laboratories outside the health service ;
- (3) the authorization of scales of technical non-expendable equipment and consumable stores required by the various laboratories in the service, and the procurement of such supplies ;
- (4) the planning and location of new accommodation required by the service ;
- (5) the co-ordination of the laboratory service within itself, with other departments of the national health service, and with relevant outside agencies, governmental and non-governmental ;
- (6) the formulation of contracts for technical services into which the laboratory service may wish to enter with other institutions, e.g., universities and private laboratories ;
- (7) the nature and scope of research programmes to be authorized and carried out ;
- (8) the organization of special training programmes for professional and technical staff ;
- (9) such other matters pertaining to the service on which the director may require advice.

A particularly important function of this committee should be to make practical recommendations for the promotion of efficiency and economy, and for keeping a reasonable balance between the various divisions and sub-divisions, especially between the public health and hospital work with due reference to the basic needs of the country.

It is suggested that the committee should consist of : (1) the director of the service, who should be the chairman and who should be responsible for the agenda of the meetings ; (2) suitable representatives from the departments of public health, hospital, laboratory and veterinary services ; (3) suitable representatives from medical schools and national research councils, if they exist in the country.

The committee should be kept as small as possible for working purposes, but should have a balanced representation. The director should also have the power to co-opt any suitable person to the committee to help to deal with any special problem.

The functions of this committee should be purely advisory and not executive.

Sub-committees of suitable officers may also be appointed to deal with technical problems—e.g., a sub-committee for hygiene, and another for hospital service.

6.2.4 *Administration at lower levels*

6.2.4.1 *Regional laboratory.* Each regional laboratory should have a medical officer in charge.

Instructions for all administrative matters pertaining to the laboratory service should be transmitted from above to the officer in charge of the regional laboratory, and he should be provided with such subordinate administrative staff as is necessary for him to perform his duties adequately. Technical instructions should emanate from the chiefs of the divisions at the central laboratory, and should be transmitted through the director to the medical officer in charge of the regional laboratory.

At this level it may be desirable to establish a regional advisory committee.

6.2.4.2 *District laboratory.* The district laboratories should be under the control of the regional laboratories, and technical and administrative instructions to the officer in charge of a district laboratory should be transmitted from the officer in charge of the regional laboratory.

At the district laboratory level there may be a small local advisory committee.

6.2.4.3 *Laboratory side-rooms.* Laboratory side-rooms should be under the direct administrative and technical control of the officer in charge of the district laboratory, though immediate disciplinary control of the technician of the side-room may be vested in the officer in charge of the clinic or health centre to which the side-room is attached.

6.2.5 *Lines of communication*

The lines of communication upwards and downwards on all administrative and technical matters are thus clearly defined, and at all levels, except the lowest, there should be suitable advisory committees to co-ordinate the public health and hospital laboratory work.

Provision for official communication on administrative and technical matters should also be made at appropriate levels and through the proper channels with the local public health authorities, the hospital authorities, and other government departments and non-governmental institutions or agencies directly concerned with health matters—e.g., universities, industrial laboratories and private concerns. In short, suitable administrative

provision must be made in the health laboratory service for co-ordination and collaboration in health matters at four distinct levels, namely :

- (1) within the laboratory service itself ;
- (2) between the laboratory service and the other departments of the national health service ;
- (3) between the laboratory service and other governmental and non-governmental agencies concerned with health matters ;
- (4) finally, with international agencies and other countries.

It should be a very firm rule that official communications between the health laboratory service and agencies outside the country be conducted only through the director of the service.

The administrative machinery of the service and the correct channels for communication within and without the service should be known to all officers of the service as far as their responsibilities are concerned, and clear instructions on these matters should be printed in pamphlet form.

6.3 Plan of administration of a national health laboratory service in a country with a federal type of government

6.3.1 General remarks

In countries where the constitution provides for a federation of states of which each is autonomous in health matters, the organization and administration of a health laboratory service is somewhat more complicated. In such countries, there will, however, be a central government including a ministry of health, probably divided into a number of functional units, one of which should deal with health laboratory services. The functions of such a central health ministry must be largely to provide consultative and advisory services to the various state health departments. Co-ordination and collaboration between these state health departments on all health matters, including laboratory services, must therefore be channelled through the central ministry of health, chiefly on a basis of voluntary co-operation.

The importance of close co-ordination and collaboration on a national scale in all health matters—the employment (as far as possible) of uniform administrative and technical methods, the advantage of central buying in bulk of equipment and stores, and of sharing in common many health services—will be clearly evident to the various states.

6.3.2 Central advisory council

A central advisory council to the central ministry of health in which all the states are suitably represented should be set up, together with advisory

sub-committees of the officials concerned in more limited and specialized fields, such as health laboratory services. By this machinery, the ministry may successfully persuade each of the states to co-ordinate its health services, including their health laboratory services, so that they form virtually a national health service. By this means uniformity may be obtained between the states on :

(1) programmes for the teaching and training of laboratory personnel, both professional and technical ; examination systems and the awarding of certificates of competency ;

(2) the grading of all posts within the services, conditions of service, including qualifications required for various grades of posts, and scales of pay for these posts ;

(3) the licensing and methods of control of private laboratories, and the framing of legislation in health matters ;

(4) the organization and administration of a laboratory system and of the technical methods to be employed by, and the equipment to be used in, these services ; and

(5) all other matters in which they share common health problems.

6.3.3 *Administration at a state level*

Arrangements may also be made between the various state laboratory services to utilize the laboratory section of the central health ministry to undertake on behalf of the individual states the buying of all laboratory equipment and stores, and providing for a maintenance and repair agency.

The central ministry may also undertake to maintain a farm for the breeding and supply of experimental animals to the various laboratories.

The central ministry may undertake the important function of providing an information service on laboratory technical matters.

The states may agree to the provision by the central ministry of certain laboratory services that are most economically and efficiently carried out centrally—e.g., a national institute of hygiene, a production laboratory for the preparation of vaccines and antisera, a laboratory for the control of certain pharmaceutical and biological products.

It may also prove most effective for reference laboratories to be centralized and under the direct control of the ministry, as far as is practicable.

Finally, all official communications and other business between state health services and international agencies and government departments of other countries are best effected through a central ministry of health.

In order to pay for the work undertaken by the central ministry, the states should proportionately bear the costs. Each state, being financially independent, will organize, develop, control and finance its own health

services, including its own laboratory service. Therefore, presumably each state will develop a health laboratory service organized on the lines indicated for a country with a central government. Each state will appoint its own personnel and be responsible for all the costs of the service; for appointment of key personnel, the advice of the central laboratory may be made available to state governments.

6.4 Collaboration with other laboratories

6.4.1 Collaboration of health laboratory services with veterinary services

Since many infectious diseases, especially viral, affect both man and animals, and since the disciplines, particularly in the laboratory, of medicine and veterinary sciences are similar, it is obviously of great importance from the purely health and economical point of view that close collaboration and co-ordination should be fostered between the health laboratory and the veterinary services. This may readily be obtained in three ways, namely:

- (1) appointing a veterinarian to the advisory committee of the laboratory services;
- (2) making provision for suitable channels of communication at all levels in the laboratory service with the local veterinary service;
- (3) arranging for laboratory units of the veterinary services to be attached to or, when indicated, to be integrated with health laboratories.

6.4.2 Co-operation with other governmental and non-governmental agencies

It is most desirable that co-operation should be developed by the health laboratory service with other services in the country which are concerned with associated health problems, e.g., sanitary engineering, industrial and agricultural laboratories, etc.

6.4.3 Co-operation with university laboratories

Teaching is the primary function of universities. Universities are often tempted to take on routine services on behalf of the health service which may ultimately overburden them and be detrimental to their interests.

It is, however, necessary that a medical school readily obtain all the material it reasonably needs for its teaching and research programmes, and it is also most desirable that the university should be autonomous in its own teaching hospital. The laboratory services required by the teaching hospitals of a medical school should thus be provided entirely by the university. It is, however, only just and fair that, if the hospital is part of the health service, the university should be paid for the services rendered.

Universities may still play a valuable role in a national health service by providing reference laboratories, consultative service, and research facilities, and by training personnel.

6.4.4 *Co-operation with private laboratories*

With the exception of a few specially endowed private foundations, private laboratories are commercial enterprises. As a general rule it may be stated that, as far as routine investigatory services are concerned, a national health laboratory service should be self-sufficient but at times may have to make use of private laboratories for this type of work. Care should be taken in the drawing-up of contracts with such private laboratories to ensure that they have the necessary facilities satisfactorily to undertake the work, and that they employ approved methods.

In countries in an early stage of development certain biologicals—e.g., vaccines, therapeutic sera, etc.—may have to be imported from private organizations abroad. The health laboratory service should ensure that these products comply with acceptable minimum standards of purity, safety and potency.

6.5 **Laboratory personnel**

It is the human element in the service that is the determining factor of the quality of the work. Mere physical facilities cannot replace a good laboratory staff: it cannot be overemphasized that the worth of the service depends primarily on staff quality.

6.5.1 *Categories needed*

The categories discussed below are those which, in the opinion of the Committee, should ultimately be found in health laboratory services. Some developing countries may have difficulty in recruiting personnel because of lack of suitably trained candidates. Those countries therefore should plan ahead and select promising men and women for training to fill the positions needed, as well as to provide a constant supply of the various categories. It is realized that this will be a long process in countries which do not possess the necessary universities and training centres. In such cases, personnel from other countries will have to be recruited until they can be adequately replaced by local people. This, the Committee feels, is vital and requires careful planning. In addition, countries must establish attractive working conditions to allow recruitment of workers of the highest quality available. The Committee strongly feels that all staff should be employed on a full-time basis, and that part-time employment is detrimental to the morale of the personnel, the quality of the work performed, and development of the service.

(1) *Scientific*

(a) *Medical graduates*

(i) *Laboratory director*

The Committee feels that the director of the health laboratory service and of the central laboratory should be medically qualified, with at least five years' laboratory experience and/or specialized training in laboratory work. The director should be ultimately responsible for the over-all administration of his service and must not under any circumstances allow his lay administrative staff to assume his role.

(ii) *Other medical staff*

These are heads of the various sections and should be specialized in their respective fields. They are classified into various grades according to experience and performance.

(b) *Science graduates*

These are graduates with at least a bachelor of science degree in laboratory science or another appropriate biological science, such as : medical technology, bacteriology, parasitology, biochemistry, pharmacy, physics, etc. They are classified into various grades according to experience and/or training and performance, and may become heads of sections in the central laboratory according to their specialty. When a sufficient number of medically qualified persons is not available, science graduates with experience, particularly medical technologists, will of necessity be entrusted with subordinate laboratories.

(2) *Technical*

(a) *Laboratory technicians*

This category includes the bulk of the technical staff, and is composed of individuals who have completed high school and had a minimum of two years of theoretical and practical training in the various phases of health laboratory work.

(b) *Laboratory assistants*

This category includes individuals who have not necessarily completed high school but have passed through formal training, whether in a course or in a programmed apprenticeship, covering both theoretical and practical aspects of the general field but at a lower level than that of the course for the full qualification of laboratory technician. It is divided into two groups :

- (i) Those individuals whose training has taken them through all the main phases of health laboratory work, and who have also acquired the necessary skills for performing simple laboratory tests.

(ii) Those individuals who have been trained in only one aspect of health laboratory work to perform a single specified duty, such as the examination of blood smears in a malaria eradication campaign, etc.

(c) *Laboratory attendants (aides)*

This category includes unskilled members of the laboratory.

Any individual in the above-mentioned categories who shows improvement and initiative should be given the chance for promotion and advancement either by allowing him to take courses, or on the basis of adequate experience and performance. The categories listed under (1) (a) and (b) and (2) (a) are considered professional, whereas the remainder are considered auxiliary.¹

(3) *Administrative*

This category includes the administrative officer, accountant, stores and supply officers, librarian and secretarial staff. In general, the higher the educational background the better. The Committee recommends that this group should receive an adequate period of training in a laboratory service so that they may familiarize themselves with the special requirements of their work.

6.5.2 *Training of laboratory personnel*

Every central and regional laboratory should establish a training programme for technicians to ensure a constant supply. As pointed out earlier, candidates should have finished secondary education. Where conditions of a country do not permit the recruitment of candidates with secondary education, persons with lower educational achievements could be accepted but would have to be given special courses in arithmetic, elementary chemistry, biology and physics, in addition to the regular courses of microbiology, haematology, etc. The minimum period of training is two years for high school graduates, and more for the others.

Science and medical graduates have to be sent abroad for training if facilities do not exist in the country. These should be utilized in setting up technician-training programmes upon their return.

The Committee is of the opinion that technician training can best be done locally, and that laboratory directors should spare no efforts for developing such programmes. If this is not practicable, candidates should be sent to a neighbouring country wherever conditions are more likely to be similar to those in their own.

The Committee also recommends that each country set up minimum requirements and a certifying body for laboratory technicians. Technicians

¹ *Wld Hlth Org. techn. Rep. Ser.*, 1961, 212.

should if possible be rotated from section to section within the same laboratory and between laboratories to keep them in touch with the various techniques and to provide for more consistency in methods of work.

It is also recommended that serious consideration be given to the establishment of a centre in a well-functioning laboratory for the training of laboratory tutors. These should be senior technicians and technologists with several years of experience, and with an inclination and ability to teach. Several neighbouring countries could pool their resources and establish a centre used by all.

6.6 Methodology

Uniform technical methods of as simple a nature as possible and of proved reliability should be adopted throughout the country. This will simplify training, promote economy and efficiency, allow the use of standardized equipment, and render the results of investigations comparable.

6.7 Laboratory supplies and equipment

6.7.1 Standardization

It should be endeavoured as much as possible to use the same type of supplies and equipment. This allows for greater economy and easier standardization of methods. As far as possible equipment which is sturdy, and easy to repair and maintain should be used in preference to the more sophisticated and complicated instruments. At the beginning equipment should be purchased to meet the service needs of the laboratory; only later may special research equipment be considered.

6.7.2 Storage, maintenance and distribution

A main store for supplies and equipment is essential for the efficient and economical operation of the service. It should be responsible for the purchases of the whole service, and should be located at the central or, where geographic conditions warrant it, at the regional laboratories under the control of the laboratory director. Here, issues of supplies and equipment are made and standard solutions and controls are prepared for distribution to the branch laboratories. However, this should not mean that if a district laboratory has the ability to prepare its solutions it should not do so.

All repair work should be sent to the central laboratory, which is responsible for seeing that the job is promptly and efficiently done, and which will replace items out of commission. Such a function requires adequate attention to detail; the storekeeper, in consultation with the laboratory director, prepares a list of the projected needs of supplies and

equipment to keep the service running smoothly. Each service should formulate its own rules and regulations for indenting for supplies.

6.8 Collection and shipment of specimens

A laboratory examination can be only as reliable as the specimen submitted. A satisfactory specimen is one that has been collected properly at the right time and reaches the laboratory in a condition essentially identical to its condition at the time of collection. Health laboratory services should therefore prepare a description of the services available from the laboratories and instructions for proper collection and shipment of specimens, and should distribute this information for the guidance of clinicians and health workers. It is generally advisable for the laboratory to furnish the proper containers and to insist that these be used in submitting specimens. The specimens should reach the laboratory as rapidly as possible, and, if sent through the mail, specimens should be packaged so as to satisfy the prevailing postal regulations. The specimens should be accompanied by a request form furnished by the laboratory services, which should be properly completed to indicate clearly the type of examination requested, to provide pertinent information for identification of the specimen, and to assist the laboratory in processing the specimen in such a manner as to obtain the greatest amount of information.

6.9 Forms and records

A record of the nature of the examination and the results obtained must be kept on every specimen reaching the laboratory. The types of forms and records used are best determined by the heads of the laboratories in each country, but they should be uniform throughout the health laboratory service, and should provide for the collection of pertinent information necessary for epidemiological purposes and the proper administration of the laboratory service. Preference should be given to forms and records which require the least clerical work. In order to reduce errors they should be so designed as to require minimum transcription of data.

All reports should be filed and should not be discarded for at least five years.

6.10 Evaluation

6.10.1 Evaluation of health laboratory services

Although accurate evaluation of laboratory services is extremely difficult, perhaps the most effective approach to continuing evaluation is the prepara-

tion of an "activity report" on a monthly and annual basis. The exact format and content should be adjusted to the needs of the administration. It should, however, provide the following information :

- (1) Unusual problems encountered
- (2) Additions to or deletions of services offered
- (3) Changes in physical facilities
- (4) Addition of new equipment
- (5) Equipment, non-functional
- (6) Total personnel on duty, by category
- (7) Training provided to the staff
- (8) Number of specimens received, by category
- (9) Number of tests performed on specimens
- (10) Results of examinations (for epidemiological purposes and for assistance in evaluation of technical proficiency of the laboratory)
- (11) Special problems investigated

Such reports forwarded through channels to the director of the health services will provide continuing information on the status, performance, and growth of laboratories in the service individually and collectively. These reports should be supplemented by periodic visits to peripheral laboratories by personnel of the central laboratory and, when indicated, by personnel from the regional laboratories.

6.10.2 *Technical evaluation of methods and procedures*

Visits to the peripheral laboratories by members of the technical staff of the central or regional laboratories are one of the most effective approaches to the appraisal of the technical proficiency. During such visits available facilities should be reviewed and information obtained regarding space, equipment, personnel (including training and experience), as well as the technical procedures in use, with particular attention to the degree of adherence to approved methods. Such visits are particularly effective if the review includes the processing in the laboratory of accurately quantitative and identified specimens prepared in the central laboratory and furnished by the reviewer. In a developing laboratory service such visits and evaluation specimens may be difficult to arrange ; nevertheless, if at all possible this type of control should be undertaken, otherwise reliance on the monthly and other reports alone will be necessary.

If the results of the examinations performed are included in the reports, additional clues will be provided when they are analysed in relation to available epidemiological information and the findings in other laboratories.

The central and regional laboratories should keep records of the specimens referred to them by the peripheral laboratories. Review of these records will provide further clues to the technical proficiency of the submitting laboratories.

The central laboratory should practice self-evaluation by developing a system of quality control based on the regular addition of known controls in the technical procedures, and by establishing and adhering to reasonable limits of reproductibility.

Full advantage should be taken of national and international reference centres to check their accuracy in the identification and typing of reagents and the standardization of biologicals and chemicals.

7. IMPLEMENTATION OF THE PLAN

In many countries in which there has been little development, preliminary surveys to be carried out by consultants will clearly indicate the problems which have to be faced. Thus it may be found that there are few or no medical or science graduates available, and that there are few persons who have received sufficient schooling to allow them to embark immediately upon courses of technical training. The position may be further aggravated by the fact that such medical graduates as there are available will be required for more urgent clinical needs, and that many of the science graduates and persons who have had a secondary-school education will be required for fields other than that of laboratory medicine.

It will thus be absolutely clear that the only way in which a health laboratory service may be initiated will be by seeking assistance from elsewhere. This assistance may be obtained by arrangement with an international agency or with a developed country.

Such assistance may take two forms :

(1) the training abroad of suitable carefully selected candidates in medicine and in the appropriate sciences, and, later, the post-graduate training of several of the medical graduates in laboratory medicine ;

(2) the establishment of an organized course in the country for the training of technical personnel. This course should be started by a laboratory adviser, assisted by a senior tutor in medical technology, both recruited from abroad ; it would probably be started at a small diagnostic laboratory attached to a suitable hospital, which may form the nucleus of a future central or regional laboratory. This will help to meet the demands of the clinicians, which will of necessity be mainly of a diagnostic nature. It will also serve to obtain the necessary teaching material. Before such a course is started, however, it may be necessary to make arrangements with the Ministry of Education for a number of suitable candidates for

employment in the health and other government services to be given a special preliminary secondary-school education in the basic sciences.

Naturally, such a training course will at first have to be in simple methods of microbiology for the diagnosis of the more prevalent and important infectious diseases associated with a few public health techniques, such as the examination of water, and simple clinical pathological procedures such as blood counts and urinalyses. It may well take over a year before such trainees may be regarded as competent in the limited techniques that they have been taught. From these laboratory assistants the best should be selected for further training to become fully qualified laboratory technicians, and a few of these should be trained as tutors so that the training scheme may be extended and, eventually, the health laboratory service may become capable of training its own technical personnel. Though it may be desirable for these trained laboratory assistants to remain at the central laboratory to gain further knowledge and technical competency and strengthen this service, no doubt the exigencies of circumstances may demand that many of them be posted to peripheral hospitals to undertake laboratory side-room work. A number may also be absorbed into special and important but limited public health projects—e.g., malaria eradication, control of tuberculosis, etc. Eventually, however, a science graduate who has received some appropriate training abroad in medical technology may be available to take over the operation of the central laboratory under the supervision of the international staff and slowly develop it further, but its activities will still no doubt be confined to simple microbiological and clinical pathological procedures, and possibly the time may become ripe to develop some of the laboratory side-rooms in the periphery to a further stage. Next, a medical graduate who has received some appropriate post-graduate training in health laboratory work may become available, and he may be made director of the service. After working for some time as counterpart to the adviser, he may eventually take over the service completely. At this stage the service may be sufficiently advanced to undertake some diagnostic blood chemistry and even a limited amount of histological work. Great difficulty is likely to be encountered in these early stages in developing the public health aspects of the work because of the pressing demands of the clinicians. One of the chief tasks of the adviser in the early stages will therefore be to stress the importance of the public health work in conjunction with hospital work, to initiate a simple section for the collection of epidemiological data, and to encourage the laboratory to undertake some investigations in connexion with sanitation. Eventually more science graduates, and a few medical graduates who have had post-graduate training in health laboratory work, will become available so that the primary divisions in the central laboratory may be established, and the regional laboratories may slowly progress from the side-room stage. More and more laboratory side-rooms will also be

created, and many of them will become foci for the setting-up of district laboratories.

A section on entomology may have fairly high priority in the development of the central laboratory, depending on whether arthropod-borne diseases are prevalent in the country or not, but the development of other allied divisions—e.g., a separate hygiene laboratory, a chemical laboratory, etc.—will probably have to be delayed for some years, and it may not be practicable in the immediately foreseeable future to contemplate such developments as a biological production and control laboratory.

It will thus be clear that the implementation of a simple health laboratory service in a developing country may be a very slow process extending over many years, and that in the early stages assistance from abroad will be most necessary. This assistance will have to be over a number of years and at appropriate intervals of time, evaluation of the progress achieved will be necessary so that the position may be reviewed to indicate the extent to which the assistance will still be required, and also to modify and extend the plan in the light of the experience gained.

It is important right from the start to visualize the ultimate goal of a comprehensive health laboratory service. Though advancement towards this goal may be very slow, particularly in the early stages of development, it is essential to keep that goal always in mind so that a systematized service is visualized and slowly developed, unhampered by ad hoc schemes based on temporary expediencies which, by becoming entrenched, may unduly interfere with the development of a properly co-ordinated service.

In other countries the problem will be simpler, as there will already be some health services in existence, medical graduates will be more readily available and, because of better schooling facilities, it will be easier to obtain candidates for training as technicians. Suitable university science graduates may also be easier to recruit.

In these countries, however, assistance from abroad obtained by bilateral agreement with a developed country or an international agency may still be most desirable in order to improve the organization of the existing services, extend them and better integrate them with the health services, as well as to start new projects. This assistance may be given through the appointment of consultants or the temporary employment of technical teams, as well as by the awarding of fellowships for study abroad.

In other countries again, medical services may be still more advanced, and various types of health laboratory services may be available. In these the main problem will be to co-ordinate the existing services and further develop them so that a comprehensive national health laboratory service may be created.

In the more developed countries it may sometimes be desirable to obtain consultants from abroad to advise on specialized problems and to initiate more advanced types of service.

In all countries at various stages of developing health laboratory services, suitable candidates should be awarded fellowships for study abroad to prepare them in specialized laboratory fields.

8. DEVELOPMENT OF RESEARCH IN A HEALTH LABORATORY SERVICE

The primary function of a health laboratory service in a developing country should be to render service. Problems will be encountered, however, which are peculiar to a particular country and to the conditions under which the laboratory services are operating ; to solve some of these problems a certain amount of research should therefore be encouraged. Research stimulates the interest and intellectual curiosity of the laboratory personnel, and provides a better basis for critical appraisal of the quality of laboratory work performed. The opportunity to engage in research is also highly effective in attracting and retaining competent laboratory workers.

Research should be geared and co-ordinated to the needs of the country ; in the early stages of laboratory development it should be of an applied nature, adapting methods to local needs and resources, and concerned with the collection and analysis of data relative to the prevalence, ecology and epidemiology of disease. Productive research today can be achieved only when conducted by properly trained and experienced personnel. Research should therefore be limited largely to the central and perhaps the regional laboratories which have reached a satisfactory stage of development. The spirit of research and the intellectual curiosity accompanying it should be extended to the peripheral laboratories by soliciting the collaboration of personnel in collecting data and applying new methods under the supervision of the research staff of the central or regional laboratory.

9. INTERNATIONAL COLLABORATION

Although it is the duty of each government to assume the responsibility of the organization and operation of its health services, it is evident that, for economical and technical reasons, many developing countries need the assistance available from various external sources which should be considered in the preparation of a plan. It is of the utmost importance that all this assistance be co-ordinated at the level of the Ministry of Health in order to secure its best utilization.

International, bilateral and multilateral agencies are the main sources of technical assistance for the establishment and implementation of a

programme for the organization or strengthening of a national health laboratory service. The available resources are usually used in the following way :

- (1) Provision of short-term consultants to assist in the technical and administrative planning.
- (2) Provision of laboratory advisers for the implementation of long-term programmes.
- (3) Provision of visiting professors to assist in the training of the scientific staff in post-graduate courses.
- (4) Provision of fellowships for undergraduate and post-graduate training and research.
- (5) Provision of laboratory equipment to facilitate the initiation of the service and the training of personnel.
- (6) The organization of training courses in methodology, usually for participants of several countries.
- (7) The organization of seminars to allow laboratory staff of different countries to exchange opinions and experience.
- (8) Provision of adequate means to permit countries to participate in international research programmes.
- (9) Provision of an information service on health and technical matters.

In order to facilitate the work of laboratories of all countries WHO, as the directing and co-ordinating authority in the field of international health, has set up the following technical services :

- (1) Production and distribution to national central laboratories of international standards and reference preparations for the assay of a large number of biological substances.¹
- (2) Distribution of authentic chemical substances for analytical purposes² to national laboratories for the control of pharmaceutical preparations.
- (3) Establishment of international reference laboratories with the purpose of promoting uniformity and consistency throughout the world in diagnosis and in the identification and nomenclature of cells, micro-organisms and pathological tissues.
- (4) Distribution of standard strains of insects and standard insecticides, including isotopically labelled insecticides.

¹ *Wld Hlth Org. techn. Rep. Ser.*, 1960, 187; 1961, 222.

² World Health Organization (1951-9) *Pharmacopoea Internationalis*, Suppl., Appendix 17, Geneva.

(5) Formulation and distribution of:

(a) recommended methods for hygiene laboratory services, such as for the measurement and analysis of drinking-water,¹ water pollution, air pollution,² and food; for special aspects of environmental analysis such as radichemical analysis;³ and for determining the levels of resistance in insects of medical importance;⁴

(b) specifications for the quality control of pharmaceutical preparations,⁵ specifications for pesticides and analytical methods and equipment;⁶

(c) international requirements describing precautions to be taken and tests to be performed in order to ensure the efficacy and safety of important biological preparations such as vaccines and sera.⁷

(6) Publication and distribution of technical documents and reports on various subjects in which laboratory methodology is outlined.

The director of a national health laboratory service should be fully aware of the existence of these international services, and should make himself acquainted with the means and value of obtaining this assistance.

International collaboration may also take the form of direct contact between central health laboratories of countries in the same region for reference activities, exchange of information and training facilities.

10. SUMMARY AND CONCLUSIONS

(1) Integration of all types of health laboratories at different levels into a single national health laboratory service is considered essential for developing countries.

(2) The national health laboratory service should be an integral part of the national health service.

(3) Within this laboratory service, individual laboratory units varying from the simple to the highly complex should be provided at (a) central (national), (b) provincial or state, (c) district (county or city) and (d) rural

¹ World Health Organization (1958) *International standards for drinking-water*, Geneva.

² *Wld Hlth Org. techn. Rep. Ser.*, 1958, 157.

³ *Wld Hlth Org. techn. Rep. Ser.*, 1959, 173 (FAO Atomic Energy Series No. 1).

⁴ *Wld Hlth Org. techn. Rep. Ser.*, 1960, 191.

⁵ World Health Organization (1951-9) *Pharmacopoea Internationalis*, vol. 1, 2, Suppl., Geneva.

⁶ World Health Organization (1961) *Specifications for pesticides...*, 2nd ed., Geneva.

⁷ *Wld Hlth Org. techn. Rep. Ser.*, 1959, 178.

(or peripheral) levels ; their number and distribution will depend on the national health needs and the organizational patterns for the national health service.

(4) Scope and functions of a health laboratory service are described. It is emphasized that the service should meet the needs of both preventive and curative medicine, and that it should be developed in an orderly and co-ordinated manner, progressing from the essential units to the more complex.

(5) In planning an integrated national health laboratory service it is extremely important to base the plan on a sound survey of the needs and potentialities of the country concerned.

(6) Organization and administration of a national health laboratory service has been considered in the light of marked differences in the size of country and the national administrative pattern.

(a) It is considered desirable in a smaller country, or where the national administration has the authority to assume such responsibilities, to integrate administrative and technical direction of laboratories of different grades at different levels so that a central direction emanating from the Ministry of Health is carried through the national health laboratory service to laboratories at the regional and local levels.

(b) It is also considered that in decentralized governments the technical direction should come from the central Ministry of Health through the national health laboratory service, and that the administrative direction could independently come from the appropriate health department or unit to which the laboratory is attached.

(c) In the latter case, provision should be made for advice from the central laboratory service to be available in the recruitment of key laboratory personnel.

(7) It may be desirable to establish a division or department within the central national health services to direct and co-ordinate the national health laboratory service.

(8) It may be desirable at the national level to have an advisory body composed of appropriate members to advise the director of the health laboratory services on matters of policy, standards and legislation.

Similar bodies may be established at the regional level to advise the regional laboratory director, depending upon the size of his area.

(9) It was considered desirable for developing countries to combine the functions of a public health and a hospital laboratory into a single laboratory service at appropriate levels in order to promote efficiency, adequacy and economy. Uniform techniques should be used throughout the laboratory services of the country.

(10) A central (national) laboratory may in time extend some of its services to become an aggregate of specialized laboratories.

(11) After a country has reached a certain state of development it may be useful to establish specialized and reference laboratories.

(12) Developing countries should provide for training of qualified health laboratory personnel, and for more comprehensive legislation on their qualifications.

(13) There is need to strengthen the co-ordination of services between the rural (local), district, provincial and national laboratories, and between the health laboratory service and other governmental and non-governmental agencies associated with health matters.

(14) There is need to promote more international, bilateral and multi-lateral collaboration in the field of laboratory services.

Annex

**SUGGESTED LIST OF LABORATORY EXAMINATIONS
AT DIFFERENT LEVELS**

Type of test	Level No. 1	Level No. 2	Level No. 3	Level No. 4
HAEMATOLOGY				
A. Cytology of blood and cerebrospinal fluid (CSF)				
1. Red and white cell count	+	+	+	+
2. Differential white cell count	+	+	+	+
3. Eosinophil, platelet and reticulocyte count	+	+	+	+
4. Bone-marrow cytology	-	-	(+)	+
B. General haematological tests				
1. Haemoglobin determinations	+	+	+	+
2. Packet cell volume	(+)	+	+	+
3. Sedimentation rate	+	+	+	+
4. Bleeding and clotting time	+	+	+	+
5. Plasma recalcification	-	+	+	+
6. Red cell fragility	-	+	+	+
7. Prothrombin time	-	+	+	+
C. Immuno-haematology				
1. ABO blood groups and cross-matching	(+)	+	+	+
2. Other blood-group factors	-	-	+	+
3. Principal Rh factors	-	+	+	+
4. Other Rh factors	-	-	+	+
5. Compatibility test (Coombs)	-	(+)	+	+

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Type of test	Level No. 1	Level No. 2	Level No. 3	Level No. 4
CLINICAL CHEMISTRY				
A. Urine analysis				
1. Physical examination, specific gravity, etc.	+	+	+	+
2. Microscopic examination of deposit	+	+	+	+
3. Albumin, qualitative and quantitative	+	+	+	+
4. Glucose, qualitative and quantitative	+	+	+	+
5. Pentoses	—	+	+	+
6. Acetone bodies	+	+	+	+
7. Bile pigments	+	+	+	+
8. Urobilin	+	+	+	+
9. Urobilinogen	+	+	+	+
10. 17-Ketosteroids, etc.	—	—	(+)	+
11. Urinary calculi	—	(+)	+	+
12. Pregnancy tests	—	(+)	+	+
13. Sperm examinations	(+)	+	+	+
B. Renal function tests				
1. Phenolsulfonphthalein test	—	(+)	+	+
2. Others — see blood chemistry				
C. Liver function tests				
1. Icteric index	—	(+)	+	+
2. Bilirubin in serum	—	(+)	+	+
3. Thymol turbidity test	—	(+)	+	+
4. Bromsulphalein test (BSP)	—	—	+	+
5. Phenol turbidity test (Kunkel)	—	—	+	+
6. Zinc turbidity test (Kunkel)	—	—	+	+
7. Cephalin-cholesterol flocculation test (Hanger's test)	—	(+)	+	+
D. Gastric and duodenal fluids				
1. Occult blood	—	+	+	+
2. Total acidity and free HCl	—	(+)	+	+
3. Pancreatic enzymes (lipase, tryptic and amylase activity)	—	—	+	+

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Type of test	Type of material	Level No. 1	Level No. 2	Level No. 3	Level No. 4
E. Blood, CSF, urine					
1. Calcium	Serum, urine	—	(+)	+	+
2. Chloride	Serum, CSF, urine	—	(+)	+	+
3. Cholesterol—total	Serum	—	(+)	+	+
4. Cholesterol—free	Serum	—	—	+	+
5. Cholesterol—ester	Serum	—	—	+	+
6. Creatinine	Serum	—	(+)	+	+
7. Creatine	Serum	—	—	+	+
8. Glucose	Serum, CSF	(+)	(+)	+	+
9. Phosphorus	Serum	—	(+)	+	+
10. Proteins—total	Serum, CSF	—	(+)	+	+
11. Urea nitrogen	Serum	—	(+)	+	+
12. Uric acid	Serum, urine	—	(+)	+	+
13. Globulin	Serum, CSF	—	(+)	+	+
14. Alkaline phosphatase	Serum	—	—	+	+
15. Acid phosphatase	Serum	—	—	+	+
16. Amino acid nitrogen	Serum	—	—	(+)	+
17. CO ₂ capacity	Blood, serum, plasma	—	—	(+)	+
18. Glucose and insuline tolerance test	Serum	—	—	(+)	+
19. pH, blood and plasma	Serum, plasma	—	—	(+)	+
20. Non-protein nitrogen	Serum	—	—	(+)	+
21. Bromides	Serum	—	—	—	+
22. Magnesium	Serum	—	—	—	+
23. Potassium	Serum	—	—	—	+
24. Sodium	Serum	—	—	—	+
25. Protein-bound iodine	Serum	—	—	(+)	+
26. Salicylates	Serum	—	—	—	+
27. Sulfonamides	Serum	—	—	(+)	+
28. Copper	Serum	—	—	—	+
29. Thiocyanates	Serum	—	—	—	+
30. Iron	Serum	—	—	—	+
31. Transaminase (glutamic oxaloacetic and glutamic pyruvic)	Serum	—	—	(+)	+
32. Other enzymatic tests		—	—	—	+

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Type of test	Type of material	Level No. 1	Level No. 2	Level No. 3	Level No. 4
F. Clinical toxicological tests					
1. Gases	Blood	C	C	(+)	+
2. Inorganic poisons	Blood	C	C	(+)	+
3. Volatile poisons	Blood	C	C	(+)	+
4. Alkaloidal and other non-volatile organic poisons	Blood	C	C	(+)	+
G. Medicolegal examinations					
1. Immuno-serological tests	Blood	C	C	(+)	+
2. Special tests		C	C	C	+
Procedures or specimen	Disease or organism	Level No. 1	Level No. 2	Level No. 3	Level No. 4
		F.P.	F.P., M.P.	F.P., M.P., R.C.	F.P., M.P., R.C.
HISTOPATHOLOGICAL EXAMINATIONS					
Autopsy, biopsy, tissue	Bacteria	C	C	P	Cf, R
	Rabies, yellow fever	C	C	P	Cf, R
	Subcutaneous and systematic mycoses	C	C	P	Cf, R
	Clinical and medicolegal cases	C	C	P	Cf, R
General histopathological techniques	Embedding and routine stains	C	C	+	+
	Embedding, differential and special stains	C	C	C	+

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Procedures or specimen	Disease or organism	Level No. 1	Level No. 2	Level No. 3	Level No. 4
		F.P.	F.P., M.P.	F.P., M.P., R.C.	F.P., M.P., R.C.
BACTERIOLOGICAL EXAMINATIONS					
A. Stained smears					
1. Nasopharynx and throat	Diphtheria, Vincent's angina	+	+	+	+
2. Sputum	Tuberculosis and pneumonia	+	+	+	+
3. CSF	Tuberculosis and meningitis	+	+	+	+
4. Gastric washings	Tuberculosis	(+)	+	+	+
5. Urethra and vagina	Gonorrhoea	(+)	+	+	+
6. Wounds	Clostridia	(+)	+	+	+
B. Cultures					
1. Nasopharynx and throat	Diphtheria, cocci etc.	C	P	Cf	Cf, R
2. Sputum	Tuberculosis, cocci, etc.	C	P	Cf	Cf, R
3. CSF	Tuberculosis, cocci, etc.	C	P	Cf	Cf, R
4. Exudates	Bacteria infections	C	P	Cf	Cf, R
5. Blood	Enterics, brucella, streptococci	C	P	Cf	Cf, R
	Leptospira, tularensis	C	C	P	Cf, R
6. Gastric washing	Tuberculosis	C	P	Cf	Cf, R
7. Urethra and vagina	Gonorrhoea and others	C	P	Cf	Cf, R
8. Faeces	Enterics	C	P	Cf	Cf, R
9. Urine	Tuberculosis and other bacterial infections	C	P	Cf	Cf, R
10. Anaerobic culture techniques	Clostridial infection and food poisoning	C	P	Cf	Cf, R
C. Antibiotic sensitivity tests					
1. Non-acid-fast micro-organisms		—	(+)	+	+
2. Mycobacterium		—	—	(+)	+
D. Pathogenicity tests					
Laboratory animal inoculations	Various organisms	—	(+)	+	+

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Procedures or specimen	Disease or organism	Level No. 1	Level No. 2	Level No. 3	Level No. 4	
		F.P.	F.P., M.P.	F.P., M.P., R.C.	F.P., M.P., R.C.	
E. Serological tests						
1. Agglutinations, precipitations, flocculations and other related tests	Enterics (Widal)	C	(+)	+	+	
	Enterics (culture)	—	P	Cf	Cf, R	
	Brucella (Widal)	C	(+)	+	+	
	Streptococci, pneumococci	—	P	Cf	Cf, R	
	Tularensis	C	C	(+)	+	
	Leptospira	C	C	(+)	+	
	Rickettsia (Weil-Felix)	C	(+)	+	+	
	Mononucleosis	C	C	(+)	+	
	Cold agglutinins	C	C	+	+	
	'Phage typing	—	—	(+)	+	
	2. Complement-fixation tests	Syphilis (VDRL or Kahn)	C	+	+	+
		Syphilis	C	(+)	+	+
		Leptospira	C	C	(+)	+
<i>Malleomyces mallei</i> (glanders)		C	C	C	+	
Histoplasmosis		C	C	C	+	
VIROLOGICAL EXAMINATIONS						
A. Complement-fixation tests	Rickettsia, and virus	C	C	P	Cf, R	
B. Isolation	(Tissue culture, egg and animal inoculations)	C	C	(+)	+	
C. Identification	(Neutralization, haemagglutination)	C	C	(+)	+	
MYCOLOGICAL EXAMINATIONS						
A. Wood's light examination	Dermatophytes	(+)	+	+	+	
B. Wet mounts	1. Hair	Piedra	(+)	+	+	
	2. Hair, skin, nails (KOH)	Dermatophytes	(+)	+	+	

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Procedures or specimen	Disease or organism	Level No. 1	Level No. 2	Level No. 3	Level No. 4
		F.P.	F.P., M.P.	F.P., M.P., R.C.	F.P., M.P., R.C.
MYCOLOGICAL EXAMINATIONS (continued)					
3. Skin	Chromoblastomycosis	(+)	+	+	+
4. Sputum	Rhinosporidiosis	(+)	+	+	+
5. Bronchial washings	Yeasts, mycelium, granules	(+)	+	+	+
6. Pus	Yeasts, mycelium, granules	(+)	+	+	+
7. Spinal fluid (India ink)	Yeasts, mycelium, granules	(+)	+	+	+
C. Stained smears					
1. Sputum (Gram and acid-fast)	Yeasts, <i>Actinomyces</i>	+	+	+	+
2. Mucus membrane scrapings (Gram & Wright stain)	Yeasts, <i>Histoplasma capsulatum</i>	+	+	+	+
3. Blood (Wright or Giemsa stain)	<i>Histoplasma capsulatum</i>	+	+	+	+
4. Bronchial washings	Yeasts, <i>Actinomyces</i>	C	(+)	+	+
D. Cultures					
1. All clinical material — inoculation of media	All pathogenic fungi	C	P	+	+
2. Identification of isolates		—	P	+	+
E. Biochemical tests for identification of fungus cultures					
	Dermatophytes, yeasts, <i>Actinomyces</i>	—	—	+	+
F. Pathogenicity tests					
Identification of fungus cultures	<i>Cryptococcus neoformans</i> , <i>Actinomyces</i>	—	—	+	+
G. Skin tests					
	Histoplasmosis	—	—	(+)	+

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		F.P.	F.P., M.P.	F.P., M.P., R.C.	F.P., M.P., R.C.
PARASITOLOGICAL EXAMINATIONS					
A. Wet mounts					
1. Faeces	Protozoa, helminths	+	+	+	+
2. Urine	Schistosomes	+	+	+	+
3. Sputum	<i>Paragonimus</i>	(+)	+	+	+
4. Blood	Microfilariae	(+)	+	+	+
5. Rectal biopsy or aspirates	Amoebae, schistosomes	+	+	+	+
B. Stained thin and thick blood film					
	Malaria, filariasis, relapsing fever, <i>Leishmania</i>	+	+	+	+
C. Stained faecal smears and rectal aspirates					
	Amoebae, schistosomes	-	(+)	+	+
D. Concentration					
1. Faeces	Protozoa (cysts), helminths (eggs, larvae)	-	+	+	+
2. Blood	Microfilariae	-	+	+	+
E. Egg counts on intestinal helminths					
	Estimation of worm load	-	-	+	+
F. Direct examination of arthropods, snails, etc.					
	Identification of vectors, intermediate host, etc.	-	-	(+)	+
G. Immuno-diagnostic					
1. Complement fixation tests	Schistosomes, <i>Paragonimus</i> , <i>Echinococcus</i> , <i>Leishmania</i> , filaria	-	-	-	+
2. Haemagglutinations	Echinococcosis	-	-	-	+
3. Bentonite flocculation	<i>Trichinella</i>	-	-	-	+
4. Dye test	<i>Toxoplasma</i>	-	-	-	(+)

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Procedures	Type of specimen	Level No. 1	Level No. 2	Level No. 3	Level No. 4
HYGIENE LABORATORY SERVICES					
A. Bacteriological	Water, milk, dairy and food	—	(+)	+	+
	Air	—	C	C	
B. Chemical	Water, milk, dairy and food	—	C	+	+
	Air, sewage	—	C	C	+
C. Biological	Sewage, industrial waste	—	C	C	+
D. Radiological	Water, food	—	C	Gross radio-activity	Chemical separation, specific nucleotide determinations, etc.
CONTROL OF PHARMACEUTICALS AND BIOLOGICALS					
A. Chemical	Drugs, biologicals, etc.	—	—	—	+
B. Biological	Drugs, biologicals, etc.	—	—	—	+
C. Microbiological	Drugs, vitamins, biologicals, etc.	—	—	+	+
Production of :	Type	Level No. 1	Level No. 2	Level No. 3	Level No. 4
A. Therapeutic sera	Diphtheria, tetanus etc.	—	—	—	+
B. Vaccines and toxoids	TAB, cholera, rabies, smallpox; tetanus and diphtheria toxoids, and others	—	—	—	+
C. Diagnostic antigens	Bacterial suspensions, etc.	—	—	+	+
D. Diagnostic sera	<i>Salmonella, Shigella</i> , etc.	—	—	—	+

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