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WORLD HEALTH ORGANIZATION

TECHNICAL REPORT SERIES

No. 161

HOSPITAL LABORATORY SERVICES

Second Report of the Expert Committee on Health Laboratory Methods

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WORLD HEALTH ORGANIZATION

PALAIS DES NATIONS

GENEVA

1959

EXPERT COMMITTEE ON HEALTH LABORATORY METHODS

Geneva, 27 October - 1 November 1958

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This report was originally issued as mimeographed document WHO/HLM/35.

HOSPITAL LABORATORY SERVICES

Second Report of the Expert Committee on Health Laboratory Methods *

1. INTRODUCTION

An Expert Committee on Health Laboratory Methods met in Geneva from 27 October to 1 November 1958.

The session was opened by Dr P. Dorolle, Deputy Director-General of the World Health Organization. In his opening address Dr Dorolle, after briefly explaining the status and functions of expert committees, said that he would not elaborate upon the agenda but that he would like to speak from a general point of view on the particular item under which would be discussed the relationship between public health laboratories and hospital laboratories and which constituted a link between a meeting of an Expert Committee on Health Laboratory Methods held in 1956 and this one. Various factors, such as the stage of development, the pattern of life, and social conditions, determined the extent and form of this relationship in the different countries. Any recommendations made by this Expert Committee on the problem would be of great value to the various health authorities, but in making them the Committee should bear in mind that WHO is concerned not only with the more favoured countries but also, and in fact mainly, with countries where a great deal remains to be done in the field of health.

Dr George Z. Williams was elected Chairman, Professor J. Horejsi Vice-Chairman, and Professor J. F. Murray Rapporteur. The draft agenda was discussed and adopted.

2. DEFINITION AND PHILOSOPHY

Hospital laboratories provide those clinical laboratory services which apply the knowledge and techniques of basic sciences to diagnosis, prognosis, treatment, and prevention of disease. It is generally accepted that

* The Executive Board, at its twenty-third session, adopted the following resolution :
The Executive Board

1. NOTES the second report of the Expert Committee on Health Laboratory Methods;
2. THANKS the members of the Committee for their work ; and
3. AUTHORIZES the publication of the report.

(Resolution EB23.R23, *Off. Rec. Wld Hlth Org.*, 1959, 91)

such laboratories provide services in the fields of morphological pathology, chemical pathology, microbiology, and haematology.

In most medical communities this is accepted as the hospital practice of pathology and it is in this broad sense that the term "pathology" is used by this Committee.¹

The hospital laboratory and its highly trained medical and scientific staff bridge the gap between the rapidly advancing front of science and the care of the sick and maintenance of health. To best accomplish their primary mission the pathology team must direct every effort to the best interests of the patient. Experience indicates that a medically trained scientist must be in charge of the hospital laboratory if the most effective laboratory service is to be provided.

The laboratory is sometimes used as an automatic device for the analysis of specimens without regard to the clinical situation or to the clinical importance of results. Unfortunately, this way of working is characteristic of many routine laboratories, tends to occur in centralized and technically specialized laboratories, and is the rule when a medically trained person is not in control.

The laboratories should, however, be organized to function as an integrated part of the practice of medicine in both the scientific and medical aspects. This is more a question of the personal attitude of the responsible head of the laboratory and of the medical training of its staff than of the local and administrative position of the laboratory. This type of work is highly desirable and may be promoted through daily discussions between the laboratory heads and the clinicians with regard to individual patients. With the advance of medical science, the clinical laboratory progressively becomes more important as the basic source of analytical information concerning the patient. But provision of technical analyses alone is insufficient. The pathologist is not only the medical biologist, chemist, and mathematician of the hospital; he must also fill the important role of a consulting colleague to the patient-care physician by correlating the total picture of pathology with the clinical picture, and provide all possible help in solving difficult clinical problems by application of his laboratory facilities. Only the medically trained and thus clinically oriented scientist (usually the pathologist) can adequately fulfil this role.

However, in the large laboratories of medical centres, university hospitals, and institutions, no one person is sufficiently expert to keep abreast

¹ In some countries it has become customary to use the term "pathology" in a limited sense, viz., the field of morbid anatomy and histopathology. The Committee prefers to use the term in its broadest sense, i.e., the study of the changes resulting from disease. By the designation "pathologist" is meant the medically trained scientist who has specialized in the field of pathology or one of its component scientific disciplines such as bacteriology or biochemistry; another term is "clinical pathologist". The equivalent terms in French are "médecin biologiste" and "biologiste clinicien".

of all the required fields of medical science. Therefore pathologists, clinical biochemists, microbiologists, and sometimes physicists, must co-operate as teams to meet the needs of modern medicine.

Thus the mission of the hospital laboratory includes :

1. Provision of comprehensive, accurate analytical test results.
2. Collaborative consultation with the clinicians regarding the most useful application of scientific procedures to patient care.
3. Training of professional and technical staff.
4. Research.
5. Adaptation to laboratory medicine of useful advances in basic science.

3. DEVELOPMENT OF HOSPITAL LABORATORIES

Historically the hospital laboratories have developed mainly from four sources : pathological anatomy ; biochemistry ; non-clinical departments of universities and medical schools ; and clinical departments.

Generally, the first laboratory service given by the hospitals was in pathological anatomy, and in some countries this science still seems to dominate the laboratory service, the different specialties being found under this heading, but individual clinical interests and initiative have sometimes played an important role in the development of hospital laboratories. In other countries, although the first laboratories were for pathological anatomy, modern development has been directed by medical graduates who have specialized in biochemistry or some other discipline and who have accepted total responsibility for all laboratory procedures. The Committee notes that, in some countries, biochemists may be non-medical graduates in chemistry ; in others, this responsibility may be carried by graduates in pharmacy.

The non-clinical departments of medical schools have had a definite influence on the scientific and technical development of laboratory procedures. In many cases these departments provide a part of the routine hospital laboratory service.

The stimulating influence of clinical departments on laboratory work cannot be over-estimated ; it has in many instances dominated the evolution of hospital laboratories. New laboratory procedures often initiated by the clinician were later established in the hospital laboratory. The current adoption of more complicated methods has necessitated the opposite procedure ; the clinician now presents his problems to the pathologist who seeks a solution by the application of new or established methods.

4. REVIEW OF EXISTING HOSPITAL LABORATORY SERVICES

Within the scope of this document it is not practicable to review hospital laboratory services in all countries. The following summary, based on information received from 22 countries, deals with the subject only in broad outline.¹

4.1 Authorities responsible for hospital laboratory services

The authorities responsible for the provision of hospital laboratory services vary from one part of the world to another. In some countries not only the hospital laboratory services but also those related to public health are the responsibility of a department of the Ministry of Health in the central government. In other countries each hospital is responsible for the provision of its own laboratory services. Every gradation of responsibility between these two extremes is to be found somewhere in the world, so that it may be said that hospital laboratory services may be the responsibility of central, provincial, district or municipal governments, of hospital boards, of universities, or of research organizations.

4.2 Organization of hospital laboratory services

The organization of hospital laboratories varies and, indeed, must vary according to the circumstances in which the work is performed.

The diseases prevalent in a country will have an effect upon the type of hospital laboratory work. The important epidemic diseases no longer represent a major problem in countries advanced in public health, and in these long-lived populations, other categories of illness have emerged, viz., the metabolic, malignant neoplastic, and degenerative diseases. In others, where health protection is minimal, the acute problems are those associated with malnutrition, parasitic and infectious epidemic diseases.

The geographical conditions of a country, its political and administrative organization, and the distribution of its population also definitely influence the organization of its hospital laboratories. In countries where the population is concentrated in crowded areas, within easy reach of well-equipped laboratories, centralization of hospital laboratory work ensures uniformity and high scientific and medical efficiency, but in others many hospitals are still dependent on postal pathology services.

¹ A list of the countries on which information was available is to be found on page 30.

4.3 Organization of laboratory service in different types of hospitals

The type of hospital influences the quantitative and qualitative aspects of hospital work. The grading of hospitals proposed in the First Report of the Expert Committee on Organization of Medical Care¹ has been followed in the present report.

The regional hospital is located in the chief town of a region and may work in collaboration with a medical school. It offers a high standard of service in all branches of general medicine, general surgery and midwifery, to meet the needs of the local inhabitants; it is fully equipped with highly specialized departments such as neurosurgery, plastic surgery, cardiothoracic surgery, radiotherapy, diagnostic specialized laboratories, etc.

The intermediate hospital is responsible for a smaller area. In addition to general medicine, paediatrics, surgery and maternity departments, it has a number of specialized departments, for example, departments of otorhinolaryngology, ophthalmology, radiology and pathology. An X-ray department and a diagnostic laboratory under well-qualified specialists are indispensable.

The local hospital provides general medicine, surgery and obstetrics for the day-to-day needs of a small localized group. The number of beds varies from a hundred to less than a dozen.

In vast countries with large populations which are almost devoid of medical care and health control the grading may be different. The "regional" hospitals will be situated in the capital or other large cities of the state, and the "intermediate" hospitals will be in large towns. "Local" hospitals will be in smaller towns at the distant periphery, and in these countries, a variation of this type of hospital, the "rural" hospital, functions as the community health centre. Characteristically, such a centre is served by a single medical officer who meets the needs of both preventive and curative medicine.

The regional hospital usually has the best laboratory service, with a tendency towards independent clinical laboratories, each pursuing a different laboratory discipline and each under the direction of a medical or non-medical scientist. In other instances, it is preferred to keep all the clinical laboratories as part of one organization under the supervision of a senior pathologist. On the other hand, the desire of some clinicians to operate their own laboratories has influenced the organization of hospital laboratories.

Much work in the field of applied physiology is carried out in clinical departments, but only a very few countries have organized these services into a specific laboratory unit.

¹ *Wld Hlth Org. techn. Rep. Ser.*, 1957, **122**, 17

Various organizational combinations of different specialties of laboratory work within a hospital have developed for traditional, administrative or economic reasons. Only to a small degree do they seem to be founded on a systematic scientific basis. Almost every combination has been tried at some time or another. Only in countries in which laboratory services fall under a unified organization or control is there complete integration between different types of laboratories.

The intermediate hospital may not include the specialized sections, and often the pathologist will possess wide experience in several or all branches of pathology. Thus the concept of clinical pathology as encompassing and integrating all the laboratory specialties has been widely accepted.

The local hospital has the least developed laboratory organization. Not infrequently, it is under the supervision of an interested clinician. Daily control is, however, usually exercised by a senior technician. In the "rural" type local hospital laboratory services are seldom available.

4.4 The staffing of hospital laboratories

The staffing of hospital laboratories depends on quite as many, and on the whole the same, factors as those governing their general organization.

4.4.1 Professional staff

The professional staff is mainly composed of medical graduates. There are, however, cogent reasons why, in some countries, there is a tendency to replace them with non-medical graduates. A shortage of medical graduates with the necessary additional training, and the rapidly expanding specialization of laboratory work are factors leading to the employment of non-medically trained scientists with a more comprehensive knowledge of technical and scientific problems than that normally possessed by medically trained men.

4.4.2 Technical staff

The technical staff is variously composed of personnel who may have received their initial training in special schools for laboratory technicians followed by an apprenticeship in hospital laboratories, and of those who have university degrees in science. There are, however, always some of the staff who have practical experience of laboratory work acquired by apprenticeship; in some countries this is the main method of training technicians, even though practical experience may be supplemented by theoretical courses.

4.4.3 Auxiliary staff

In addition to the above classes of personnel there is an important auxiliary group of laboratory aides and animal attendants. In the larger laboratories there are also administrative and clerical staff.

4.5 Scope of hospital laboratory services

The scope of the services provided by a laboratory depends upon the work carried out in the hospital of which it is an integral part. It may vary from complex work connected with clinical research and teaching to routine service using only simple methods. These services thus involve a very wide range in medical and other sciences. On the other hand, the review discloses that valuable hospital care may be provided with the aid of a very restricted group of tests.

5. FUNCTIONS OF HOSPITAL LABORATORIES

5.1 Services to in-patients

In considering the functions of hospital laboratories the Committee recognizes that there are various stages of development which have been reached in different countries. The following list refers to the functions which the hospital laboratory services should provide in a country, and not necessarily to the divisions of any single laboratory. In countries with a more highly developed laboratory service the major laboratories distribute these functions among a group of integrated units but, in countries with less developed laboratories, this division of functions may not be possible. The following services are traditionally supplied by hospital laboratories.

5.1.1 *Morphological pathology*

- (i) Morbid anatomy
- (ii) Histopathology and histochemistry
- (iii) Exfoliative cytology

The provision of services in morbid anatomy and histopathology has long been a prime function of hospital laboratories. The Committee notes that, in many hospitals histochemistry is now a commonly used diagnostic method and though not generally available in all laboratories, exfoliative cytology is constantly expanding as a useful diagnostic procedure.

5.1.2 *Chemical pathology*

This broad category of chemical studies in the field of pathology always includes the customary determinations of carbohydrate, lipid, protein, and electrolyte constituents of blood, urine and other body fluids, and also of their metabolism. Certain groups of tests are directly related to organ functions. In the larger laboratories endocrine substances and enzyme reactions are determined. Another important group of tests measures levels of drugs and toxic substances.

5.1.3 *Microbiology*

- (i) Bacteriology
- (ii) Parasitology
- (iii) Mycology
- (iv) Virology
- (v) Immunology

The service of microbiology was first applied to hospital diagnostic work in the field of bacteriology. With the constant growth and subdivision of this field many large laboratories now contain specialized units dealing with the various subdivisions. In some instances, owing to local conditions one or more of these subdivisions, such as parasitology or virology, stand in their own right as independent departments. It seems probable that this expansion and subdivision of microbiology will be a continuing feature, but for the purpose of this report the various subdivisions have been included under the one discipline.

5.1.4 *Haematology*

By haematology the Committee means the study of the blood, the bone marrow, the reticulo-endothelial system, and those diseases associated with aberrations of their cytological constituents; the study of the physico-chemical features associated with haemorrhagic and other blood dyscrasias; immuno-haematology; and the laboratory procedures associated with blood transfusion.

In some countries the following additional fields are being developed as laboratory services.

5.1.5 *Medical biophysics*

The handling and administration of radioisotopes are not generally controlled by hospital laboratories but are the responsibility of special or radiotherapeutic departments. The increasing use of radioisotopes in diagnostic procedures, however, makes it necessary to include medical biophysics as one of the developing hospital laboratory services. Other special biophysical techniques are also being developed as diagnostic aids.

5.1.6 *Clinical physiology*

Complex tests of physiological function are carried out in many clinical departments but, in one or two countries, they have been concentrated in a department of clinical physiology. These investigations include electrocardiography; phonocardiography; heart function tests; heart catheterization; blood volume determinations; spirometry; ventilation analyses at rest and during exercise; determination of the diffusion capacity of the

lungs ; estimation of the basal metabolism ; blood gas analyses ; renal function tests ; renal vein catheterization ; and portal pressure determinations.

5.1.7 *Allergology*

In a few instances, laboratory tests for allergy are performed in the hospital laboratory, although generally they are considered clinical procedures.

5.2 Services to out-patients

A review of hospital laboratories throughout the world reveals that there are wide divergencies of practice in this regard. In some countries, the above-listed services are provided to out-patients as an integral part of medical care ; in others, out-patients are specifically excluded. The Committee is of the opinion that, where warranted by socio-economic conditions and compatible with the organization of the medical profession, out-patients should be served by the hospital laboratory, and that under certain circumstances home-care patients may be included in this service.

5.3 Training

In Section 8, the part played by the hospital laboratory in training professional, scientific, technical and auxiliary staff is discussed in considerable detail. The Committee believes that in addition to this clear-cut responsibility the hospital laboratories should participate in the training of ancillary personnel, such as nurses, midwives and social workers.

5.4 Research

Research does not often exist as an integral part of the daily work of the hospital laboratory even in the instances of those larger laboratories possessing scientifically trained staff, but it should be regarded as part of the function of every laboratory and essential to the development and maintenance of an adequate standard of laboratory practice. It is not always necessary for research to be applied to the solution of fundamental problems ; it can equally well be oriented to methodological, epidemiological, and patient problems.

More often laboratory results are used for studies considered as clinical research when close collaboration between the hospital laboratory and the clinical departments is of great importance. Although the scientific programme of the laboratory, as well as its daily routine work, should be concerned primarily with service to the clinical departments, this does not

mean that the laboratory research must be directed by the clinician, nor that the head of the laboratory should not undertake independent investigations.

No laboratory results should be used by the clinician for research purposes, except in collaboration with the pathologist, nor should the pathologist try to evaluate the clinical importance of results except in consultation with the clinician. This type of applied research may be the main scope of the scientific activity of the hospital laboratory.

In university centres, collaboration between the hospital laboratory and science departments is as important as collaboration between the laboratory and the clinical departments. Part of the task of the hospital laboratory is to adapt the progress of scientific research to its own daily work in service to clinicians.

6. RELATIONSHIP BETWEEN HOSPITAL AND PUBLIC HEALTH LABORATORIES

A consideration of the relationship between hospital and public health laboratories is rendered complex because there is much overlapping of function and, as a result, the laboratory services in most countries show greater or lesser degrees of integration between the two services.

It might be well, first of all, to consider the two services from a purely theoretical point of view and to seek to determine the extent to which theoretical considerations must be modified by practical experience.

6.1 Functions of public health and hospital laboratory services

It may be accepted as a basic fact that the prime purpose of a public health laboratory service is to safeguard the health of the community against infectious, epidemic, and occupational diseases, whilst that of a hospital laboratory is to restore and preserve the health of the individual.

6.1.1 *Public health laboratory services*

It is axiomatic that the provision of a pure public health laboratory service must rest with the governmental department or departments responsible for the health of the community. Depending upon the political structure of the country, this may be at the central, provincial, county, district, municipal, or local health level, and it may be the responsibility of one or more central governmental departments (Health, Agriculture, Education, Welfare, etc.) or of their counterparts in regional and local governments.

As to the organization of public health laboratories, the Committee refers to the first report of the Expert Committee on Health Laboratory Methods.¹

6.1.2 *Hospital diagnostic laboratory service*

Whereas public health laboratory services may be situated in any convenient centre on which the transport and postal services of the area converge, an adequate clinico-pathological diagnostic service must be associated with, and situated in, the hospitals. The largest, most highly developed, and most competent hospital laboratories will automatically become the consultant and reference centres to the smaller laboratories in their area.

Whereas the public health laboratory service, being the responsibility of a government department, will tend to be unified in its control and organization, hospital laboratories are much more likely to be responsible only to the hospitals which they serve and therefore to be much more diversified in their standards, techniques and organization.

6.2 **Overlapping of function between public health and hospital laboratory services**

The question may now be raised as to how far there is overlapping of function between two such laboratory services. The most obvious overlap occurs in the field of microbiology, including bacteriology, virology, mycology, and parasitology. In blood transfusion, too, there is overlapping when the public health service deals with this work. In the fields of haematology, chemical pathology, and morphological pathology there is seldom any real overlapping. Nonetheless, in some countries, because district hospital laboratories are inadequate or non-existent, public health laboratories offer a service in those fields on a postal basis. The less developed the community or hospital, the more probable it becomes that one laboratory will supply both services.

Complete integration can only exist if a governmental authority is responsible for both laboratory services or has delegated the responsibility to some other organization such as a medical research council.

In such a completely integrated system, the public health laboratory services would fall under the control of hospital pathologists and, in the larger university centres, might be a function of the university departments of microbiology, public health, or preventive medicine. Such a system, to function adequately, would require very close co-operation with municipal, county and other local government health services.

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

In actual practice there are few countries in which public health and hospital laboratory services are either completely separated or fully integrated.

Integration of the services is most easily achieved at the local level. In large urban centres, integration can also be readily achieved but, in such centres, the necessity for reference and consultant services to the surrounding local laboratories will require special facilities, e.g., animal accommodation which may not be easily provided even in large hospital laboratories. For this reason, it may be necessary to establish a special public health section of the laboratory service, but this requirement can be met if the service is associated with a university medical school. At the highest level, complete integration is not easily achieved unless a large complex of associated laboratories exists at some geographically convenient point. Such a complex would necessarily include a large and specialized clinicopathological diagnostic laboratory in which the department of microbiology would be sufficiently well equipped and developed to provide specialized units such as a salmonella and shigella reference laboratory, a staphylococcus phage-typing laboratory, a serological and *Treponema pallidum* immobilization reference unit, a mycological reference unit, a section of diagnostic virology, and so on. The complex would also, of necessity, include a serum production unit, a statistical and epidemiological division, and other specialized sections.

6.3 Advantages and disadvantages of integrated public health and hospital laboratory services

One of the major advantages of integration of the public health and hospital laboratory services is the elimination of overlapping functions. This applies particularly in the field of microbiology. Much duplication of accommodation and equipment can be avoided. With a central supply section providing consumable stores, reagents, stains and media, the saving in administrative costs is considerable. A unified laboratory system also eliminates competition for personnel and facilitates professional and technical training programmes to a degree which cannot be achieved when there are two parallel overlapping services.

Furthermore, the activities of all medical personnel concerned with the health of the community and of the individual make contact at a common point. Thus the clinicians, medical officers of health, and pathologists are constantly in touch through the laboratory, whereas, if two parallel laboratories perform the public health and hospital laboratory functions, the medical personnel responsible for the community health and those responsible for the sick may seldom have professional contact. An integrated service emphasizes the important preventive aspect of medicine. The pathologist, being responsible for the bacteriological services to the patient

and also to the community, has an opportunity of co-ordinating them and ensuring co-operation between the clinicians and the public health officers.

Thus a unified laboratory brings together the clinician concerned with cancer of the lung, the pathologist concerned with its diagnosis, and the public health administrator responsible for the control of potential environmental carcinogens; it ensures contact between the bacteriologist, the medical officer of health and the clinician in charge of the infectious diseases hospital; it facilitates the meeting of the surgeon, the bacteriologist, the epidemiologist, and the municipal medical officer, to all of whom the control of certain hospital hazards represents an internal integration of hospital laboratory and public health functions.¹

In highly developed countries with extensive hospital and laboratory services, much can be said in favour of two parallel services in which, by reason of specialized training, a higher degree of technical and professional proficiency may be attained.

The difference of emphasis, upon the health of the community on the one hand and upon that of the individual on the other, is sometimes advanced as a reason for the separation of the two services. It is maintained by the protagonists of this view that, when the two services are provided from the same laboratory, the pathologist is tempted, by reason of his medical training and clinical interest, to lose sight of the welfare of the community in his understandable concentration on the diagnostic problem of the individual hospital patient.

In less fully developed countries, in which trained professional and technical staff is at a premium and where dispersal of energies and personnel can only lead to a general lowering of standards, the advantages of integration outweigh the disadvantages. The only point at issue is that of deciding how far integration should go and whether it should stop at the local, the intermediate, or the regional level.

The question of a dual system of laboratories, or of a partially or completely integrated laboratory service, is therefore one which can only be decided in the light of the available personnel, the needs and degree of development of a country, its tradition, background and experience, its geographical and sociological features, and its medico-political pattern.

6.4 Existing co-operation and integration in representative countries

The most efficient integration of public health and hospital laboratory functions is found in the well-organized and closely-integrated systems of

¹ A typical example is cross-infection in modern hospital care which has arisen from indiscriminate use of antibiotics. Antibiotics have reduced mortality from infectious diseases and now protect surgical patients to an extent never before possible, but their abuse and misuse, resulting in resistant strains of bacteria, and a certain carelessness which has crept into daily hospital aseptic routine present a serious problem.

public health laboratories and stations with hospital laboratories in Czechoslovakia, Great Britain and the USSR. There is cross communication of scientific information, reference materials, consultation, technical assistance, and training at every level from local to regional and central, under careful direction, and based on a master plan. Under these circumstances few problems of co-operation exist.

On the other hand, the opposite extreme is illustrated by the situation in the United States of America where the complex heterogeneity of hospitals with a large proportion of private hospitals and private pathology laboratories under individual and independent control interferes with effective co-ordination of public health and hospital laboratory interests.

6.5 The need for close co-operation and integration of public health and hospital laboratories

Review of the existing conditions discloses some need for better co-operation in nearly all countries.

The Committee is impressed by the urgent need for a single system of laboratories to fulfil both hospital and public health laboratory functions in those countries where there is very little or no laboratory service and often no medical or sanitary service for vast dense populations of humanity. This situation is dramatically exemplified in India, Korea, and most of the Eastern Mediterranean nations. The lack of medical and technical staff, the paucity of supporting funds and the low economic status of the people in these areas, together with the existence of primitive epidemiological problems, acutely attest the need for a well-planned and closely-integrated system of laboratories to provide the simplest of public health and outpatient type diagnostic laboratory services. These can frequently be on a mobile basis. A plan and detailed specifications for such a system would be very helpful in establishing these services. Physicians and technical staff working under such conditions must be trained in both hospital and public health aspects of laboratory practice.

There should also be vertical integration to facilitate supply and directional assistance for the rural health units by intermediate (district) and regional (state—usually medical school) level laboratories. An added and important advantage of this system would be that it would provide an insight into public health problems for medical students and young physicians in training.

The development of such a system must start from the central or state level to provide guidance, facilities, and personnel for operation at the local (rural) level.

It is emphasized that in spite of the advanced state of public health and hospital practice of pathology in many nations there are still vast areas of the world where the above-described needs and approach are urgent.

There is another group of countries in which entirely different needs exist. Here hospital laboratories and central and state public health services are well developed but their efficient application to problems of the community at large is hampered by the absence of effective voluntary co-operation or integration. This situation requires intensified education and orientation of the medical student and young physician in resident training with regard to public health problems, epidemiological techniques and industrial and preventive medicine. Pathologists must learn the importance of public health application of their knowledge and methods.

Areas of public health effort in which the co-operation of the hospital laboratory will become increasingly important are chemical analyses related to patients exposed to industrial toxic hazards, water and air pollution, and nutritional epidemiology with reference to the study of geriatric conditions (atherosclerosis, etc.). Studies in cancer must be included. In the future, other equally important ways in which the hospital laboratory can contribute to the public health effort will surely emerge.

In considering the need for collaboration, it must be mentioned that to obtain the most effective integration in the interests of human communities, and to protect the medical and scientific integrity of the control of public health activities, medical personnel must be free from political and other external influences and control, and must be appointed and assessed solely on the basis of their professional and personal qualifications. Furthermore, the pathologists directing hospital laboratories must not permit their interest in public health problems to interfere with their services to the sick, or vice versa.

7. GENERAL REQUIREMENTS FOR THE ORGANIZATION OF HOSPITAL LABORATORIES

7.1 Factors which will influence the type, size and organization of hospital laboratories

7.1.1 Existing hospital laboratories

As a general rule, hospital laboratories are first developed in the major centres of population. In developing further services, existing laboratories are used as the centres in which personnel training and specialization of services are provided. From them the trained staff are delegated to peripheral hospitals to initiate new laboratories. Thus, the extent of existing services profoundly influences the speed at which expansion can take place. Before beginning any extension of hospital laboratory services, therefore, it is essential to make a complete survey of all existing hospitals and, in the light of the situation with respect to regional, intermediate and local

hospitals to decide upon a system of priorities for the establishment of further laboratories.

7.1.2 Local health and population conditions

The general health status of the population, the climatic zone of the country, the epidemiology, the age structure, density and distribution of the population, and its socio-economic circumstances will influence decisions as to the extent and siting of hospital laboratories. Cognizance will have to be taken of whether the population is increasing, static, or decreasing; whether it is mainly rural or urban, and whether an adequate public health system already exists or not. Not only will the immediate population have to be considered, but some thought will also have to be given to the health status and epidemiological problems of adjacent territories.

7.1.3 Extent of public health services

The extent of the public health services in a country, and particularly the extent of the public health laboratory services, will exercise a determining influence upon the development of hospital laboratories. At the same time, the overlapping functions of these two types of laboratories make it essential for them to work in the closest harmony and to be integrated as far as possible. This often depends as much upon the attitude and character of the personnel responsible for the two services as upon any other factor.

7.1.4 Available economic support

Hospital laboratory services can be provided only within the scope of the financial resources available to them. As it will probably be essential to establish some kind of priority with regard to development, expansion must proceed from the regional hospitals towards the periphery according to a predetermined plan.

7.2 Technical planning and organization

7.2.1 Premises, space and equipment

It appears to be a universal fault in planning hospital laboratories to underestimate the amount of space required for immediate use and for future expansion. In planning a hospital laboratory, adequate space must be allocated. No universal relationship seems to exist between the number of patients served or specimens handled and the space set aside for a laboratory, but the Committee is emphatic that, not only should the initial space be sufficient, but it should also make provision for future growth of the hospital, out-patient department, specialized clinics and population served,

as well as for evolution of the medical sciences leading to an increasing number of laboratory tests required by clinicians.

These recommendations are particularly applicable to the regional hospital in which the greatest increase of work, and perhaps teaching duties, may be expected to occur. In such hospitals, provision should be made, not only for the daily routine work of the laboratory, but also for research activities, library and staff facilities, and for teaching and demonstration rooms.

As a general principle, the hospital laboratory should be easily accessible to the clinical staff and be sited upon a main hospital traffic lane, not relegated to the basement or some remote part of the building. In planning laboratories, attention must be given to possible future physical expansion. For this reason it may not always be desirable to site the laboratory within the main hospital building. It may well be planned, however, as a wing or in a central block which connects ward blocks with out-patient and special clinic services. In smaller hospitals of the intermediate and local type the laboratory should be planned as an integral part of the main building but with due foresight to future expansion.

Under some circumstances and, as regional hospitals develop, it may be desirable to have, in addition to the central routine laboratory, one or more smaller laboratories closely adjacent to the out-patient or special clinic departments. In such circumstances the Committee is of the opinion that all laboratories in a hospital should be under the control of the hospital pathologist.

Not only will the size of a laboratory be related to the size of the hospital and the population which it serves, but the elaboration of equipment will also vary according to the nature and complexity of the hospital. Although the basic equipment is similar for all general hospital laboratories, careful thought must be given to the nature of the special equipment to be included in larger or specialized laboratories. In doing so, careful prior thought must be given to the design of the laboratory so that, in consultation with the architect, it will be suitable for the equipment to be installed and for the duties to be performed.

7.2.2 *Personnel*

The staff of hospital laboratories will be medical professional, non-medical professional, technical, and non-technical in nature. Availability of such personnel may well be a limiting factor in establishing a hospital laboratory service and, as the service grows, a shortage of such personnel may prove to be an embarrassment. Every effort should therefore be made in such a service to organize an adequate training programme and to establish working conditions which will attract workers of the highest quality to the service and allow of its necessary expansion. It is the opinion

of the Committee that all hospital laboratory staff should be employed on a full-time basis and be adequately remunerated. In particular, remuneration should be such as to ensure that the economic status of medical and technical laboratory personnel is equivalent to that of their colleagues in other fields of medicine.

The proportion of professional, non-medical graduate and technical staff varies considerably from one country to another, but the ratio should be such that the supervisory duties of the professional staff are in no way impeded. In small laboratories, where only one or two technical staff are employed, daily supervision of the laboratory should be vested in a clinical member of the staff but technical control should be exercised by a visiting pathologist. In such circumstances, and indeed in all laboratories, free use of the "check" system of specimens should be made.

The actual number of staff allocated to a laboratory should be related to the amount of work, but so far as the Committee is aware no exact mode of measuring work load has been devised. Several "unit" systems have been used in different countries, but the Committee is of the opinion that they are expensive, cumbersome, unscientific, and useless. It is believed that these systems give no more information than the simple mean number of tests carried out per unit time. Using this method of evaluating work load, care should be taken to ensure that it is not permitted to reach such a level as to interfere with efficiency and accuracy.

Occupational risks are always increased by excessive work load, and the risks in laboratories should not be neglected in such circumstances. In hospital laboratory work, the main hazards are connected with work on tubercle bacilli, enteric pathogens, and viruses. The questions of the occurrence and the mode of contraction of such infections have lately attracted great interest, and different ways of prevention have been discussed. The Committee considers the matter to be important and recommends that rules for laboratory hygiene and for the prevention of laboratory infections should be worked out on an international level.

7.2.3 *Budget*

The Committee is of the opinion that every hospital laboratory should work to an annual budget and that the budget should be related not only to the annual volume of routine work but also to the research activities of the staff. In reviewing the budget, authorities should ensure not only that new and necessary equipment is supplied and running costs met, but that there is adequate provision for the replacement of equipment before it has deteriorated to the stage where it acts as a brake, reducing the speed and efficiency of the laboratory.

The budget can be considered under the two main headings of installation and running costs. Installation costs will include those of construction,

fixtures, furniture and basic equipment. Running costs will cover the purchase of all expendable material, repairs, the provision of utilities, wages, salaries and insurance. These costs are usually met from one of three sources : indirectly from the government through a regional organization ; from a local administration ; or paid out of the income obtained for the work performed by the laboratory.

The depreciation in the value of the installations and equipment should be taken into account.

A five-year plan can be drawn up for the renewal and modernization of equipment, as well as a plan for the renovation of the premises, repairs, regular painting, etc.

7.3 Recommended organizational structure of hospital laboratories

The organizational structure of hospital laboratories should be based upon several important criteria : (1) desirability of providing the best service possible in the most economic way under the limitations of budget and space available ; (2) necessity for maintaining the scientific quality and reliability of all laboratory work ; (3) the great advantage of the closest liaison between the laboratory personnel carrying out the analyses and the physician in charge of the patient.

The following suggestions with regard to *minimal* standards of functional organization, space and personnel for the three categories of hospital laboratories previously discussed in this report are made with the full realization that there is an extremely wide variation in the numbers of beds, the scope of medical practice, and the out-patient responsibilities of hospitals in each of the categories. However, the Committee deems it necessary to provide suggestions for the average desirable organizational and structural facilities, with the knowledge that considerable modification will be necessary to adapt the suggestions to local conditions.

When a hospital laboratory is being planned, certain space and technical equipment should be provided for research activities. Any tendency of authorities to regard research as a task of secondary importance must be resisted. Scientific research must be regarded as an integral part of the daily work of the laboratory and as being of fundamental importance for the services given to the clinical departments. The working programme of the scientifically trained staff must be so planned as to permit of research activities. A certain amount of technical assistance must, within the regular budget of the laboratory, be provided for research activities. Scientific problems of a more extensive nature undertaken by the laboratory should be supported by some foundation for scientific research or by special funds. Such support should cover the cost of the technical staff required and of scientific instruments not available in the laboratory or not ordinarily used

for routine work. If the amount of time which a scientifically trained member of the staff can spare for research work within the ordinary working programme of the laboratory is not sufficient for the problem with which he is dealing it will be necessary to make funds available for increasing the staff. Routine work load should never be permitted to override research opportunities. Special research funds should not be used to procure or maintain premises or equipment already available to the laboratory, or for the purchase of chemicals or media normally used by the laboratory, even if consumption may be increased by the research work.

7.3.1 *The regional hospital laboratory*

This is the largest laboratory of the group, serving the largest number of hospital beds, usually 300 or more. It is normally located in one of the larger cities and very often functions as a reference laboratory. Not infrequently this laboratory will be a part of, or very closely associated with, the hospital of a medical school, in which case it has the opportunity to co-operate closely with laboratories of other types and can draw on the research facilities of the medical faculty.

7.3.1.1 *Functional organization*

In every case, it is deemed essential that the laboratory at this level should consist of more than the traditional specialized units of chemical pathology, haematology, microbiology, and morphological pathology. Whenever possible, and especially in the medical centres, it is highly desirable that supplementary specialized units, such as biophysics and virology, should be added. It may be possible, depending upon the clinical practice in the individual hospital or region, for other special laboratories to be included. It must be emphasized that at this level research is always an important function for which proper provision must be made. In addition, reference, consultation and training are important functions.

Another problem in a country such as India is that presented by the large number of out-patients attending hospitals. Even in the largest hospitals in such circumstances there is urgent need for simply equipped laboratories which could undertake large numbers of repetitive tests, such as haemoglobin estimations and blood film, faecal and sputum examinations, for out-patients. The more complex tests for out-patients in such hospitals would be referred to a fully equipped laboratory.

7.3.1.2 *Location*

Whenever possible, the laboratory should be sited centrally for easy access by the clinicians. At the same time it must be so situated that future physical expansion will not be impeded.

7.3.1.3 *Space*

In designing a regional hospital laboratory, care must be taken to provide space for those services which are not necessary in smaller hospitals. The usual space will be required for professional, administrative, and clerical staff; media and solution preparation rooms; autopsy facilities; several laboratory rooms for each discipline; washup, sterilization, and store rooms; research activities; and staff facilities. In addition, there must be space in such a laboratory for large refrigerator and incubator rooms; photographic unit; library; record room; teaching and demonstration laboratories; and conference rooms. Most regional laboratories will supply media, standard solutions, and other similar services to the intermediate hospitals. This will involve regional laboratories in a considerable amount of work connected with the storage and despatch of media, solutions, reagents, etc., and for this provision must be made.

7.3.1.4 *Personnel*

The size of the staff will necessarily depend upon the size of the laboratory department and its accommodation. In addition to the senior pathologist in charge of the laboratory there will be several other pathologists and probably non-medical graduates who are heads of sections. Junior pathologists and technical staff, together with an adequate administrative and clerical staff must be provided. In a large laboratory of this type, laboratory aides and animal attendants will be necessary and also staff to deal with preparation, storage, and despatch of media, solutions, reagents, etc. According to local circumstances the maintenance staff may be attached to the laboratory itself or to the hospital of which it forms a part. Responsibility for the public health work of the area will demand a proportionately larger staff.

7.3.2 *Intermediate hospital laboratories*

Usually these hospitals have from 100 to 300 beds, and their medical services are complete. There is a wide variation in their location and the scope of their functions, but in general the following minimum requirements may be stated. It is highly desirable to supplement these with more extensive laboratory services whenever possible, in order to give better support to the practice of medicine in the hospital.

7.3.2.1 *Functional organization*

Even the smallest hospitals of this category must be equipped to carry out the important procedures in chemical pathology, microbiology, and haematology. Services of morphological pathology may be referred to a central, regional, or other reference laboratory, but in the case of the larger

hospitals in this category adequate facilities for morphological pathology must be included. In the latter instance the size of the hospital and the relations of the hospital laboratory with the public health laboratories or the medical schools may facilitate the establishment of other laboratories such as biophysics.

7.3.2.2 *Location*

Whenever possible the laboratory units should be grouped under the supervision of a single pathologist in a central place in the hospital, and should be easily accessible to the patient-care physicians. Again it is important that the location shall not interfere with future physical expansion.

7.3.2.3 *Space*

In laboratories of this type, accommodation must be provided for the professional, technical and clerical staff; laboratories; washup; sterilization and store rooms; autopsy facilities; research; and staff facilities.

7.3.2.4 *Personnel*

In the intermediate type of hospital, the laboratory staff should include a senior pathologist and such assistant pathologists (medical or non-medical graduates) as are required. Technical, laboratory aide, and clerical staff should be in proportion to the volume of the work. The remarks made under section 7.3.1.3 (page 23) concerning extra space and personnel in regional hospital laboratories responsible for the public health work or central stores of an area are equally applicable to intermediate hospital laboratories.

As in the case of the regional hospital laboratories, the larger laboratories in this group will require facilities for preparation of their own bacteriological media and for chemical reagents. However, for the smaller hospitals these should be provided from centralized supplies or purchased as convenience and local conditions permit.

7.3.3 *Local hospital laboratories*

Hospitals in this category will usually have from 10 to 100 beds and will require laboratory service ranging from the minimal to that found in the smaller intermediate hospitals. In the local hospitals there is less need for a full range of laboratory tests and, in many instances, it may be possible for them to be staffed by technicians under the control of a clinician and of a visiting pathologist. In some countries, however, such as India, these small hospitals serve a large area and a vast population, so that, although the number of beds is small, the volume of out-patient laboratory

work is very large. In such instances, the laboratory will need to be relatively large and to be under the control of a full-time pathologist who will be assisted not only by technical staff but also by non-medical graduates who are competent to take charge of sections of the work.

In these same countries, a fourth type of laboratory is required. This could be called a primary health centre laboratory and could serve a group of villages. In each district there might be several such laboratories. These would be laboratories at the periphery where the medical officer in charge, assisted by a trained technician, could carry out simple side-room tests such as urine, blood, and faecal examinations. It is essential that such laboratories be vertically integrated with the nearest fully equipped local laboratory so that more complex tests could be referred to it when necessary.

The primary health centre laboratory need occupy only a single room and would require only a limited amount of bench space and equipment.

8. TRAINING AND QUALIFICATION OF HOSPITAL LABORATORY STAFF

In most countries four categories of laboratory personnel exist :

- (1) medical graduates ;
- (2) non-medical graduates ;
- (3) technicians (fully qualified) from whom a more or less long period of training is demanded ;
- (4) laboratory aides who are unqualified technicians trained mainly by apprenticeship in practical laboratory work.

In certain countries there exists a group of technical staff who obtain a bachelor's degree on qualification.

The time demanded for the qualification of medical graduates in the laboratory service varies in different countries according to local conditions, the mean period being four to five years. For non-medical graduates the time necessary for qualification is also very different, the average time being three years. A great variety of specialization exists in this category, e.g., biochemists, biologists, serologists, parasitologists, and so on.

The period of training of qualified technicians varies in different countries from one to five years. In some countries, training is mainly by apprenticeship ; in others from which information has been obtained special schools exist, in some of which education and practical training are comprehensive and the student obtains his training in the main disciplines of laboratory work. In other countries the education is specialized from the beginning.

Laboratory aides obtain their education mainly by apprenticeship. In some countries short courses are given to this category of laboratory personnel.

It is generally accepted that for the further development of a high scientific standard of laboratory work and for the appropriate function of laboratory diagnosis in respect of the demands of both in- and out-patient departments of the hospitals of all categories, facilities must be provided for the adequate training of all categories of laboratory workers, having regard to the functions which the laboratory has to fulfil.

For training and qualification the following general features are recommended.

1. *Medical graduates*

(a) The director of the laboratory should always have sufficiently long training in the main branches of clinical pathology. It is desirable that he also has some clinical experience. The length of time necessary for training will vary according to local conditions. In any case, the director of the laboratory should be experienced enough to be able to supervise the work of his staff and to be a consultant for clinicians and other laboratories of lower grade within the area of his competence. He should also be well enough trained to be able to plan, stimulate, and direct the research work of the laboratory. It is important that the director of a laboratory should have the same position as the directors of other clinical departments of the hospital from the point of view of administrative and economic status.

(b) Other medical graduates in the laboratory who are in charge of different sections should have a sufficiently comprehensive training in the special branch in which they actually work.

In some countries there still exists a great lack of qualified medical laboratory personnel. To meet the demands in this respect a shorter and intensive course in clinical pathology of one year's duration may be arranged, but as soon as possible more comprehensive training should be provided.

2. *Non-medical graduates*

It is most desirable to encourage the employment of non-medical graduates in the laboratories because they are usually both scientifically and technically very well trained. Their work is of great help to the pathologist who very often cannot go into the details of various highly specialized analytical procedures and who is not well instructed in how to handle complicated apparatus. They will, of course, never be interpreters of laboratory findings; this duty must always be undertaken by a qualified clinical pathologist.

The non-medical graduates obtain special qualification mainly during actual laboratory work. In certain circumstances they may be in charge of special sections of the laboratory, but they always stand under the leadership and responsibility of the director. The members of the Committee would emphasize that these non-medical graduates carrying senior administrative responsibility should always be equivalent to their medical colleagues both administratively and economically.

3. *Technicians*

The education and training of laboratory technicians should be both theoretical and practical. The length of training should be arranged according to local conditions. The education is concluded by examination and diploma. In some cases the education of the laboratory personnel can take place by practical training in recognized laboratories, usually district ones. It is also possible that in some countries the technicians can obtain a bachelor's degree. The committee is of the opinion that all attempts to give higher qualifications to the technical staff to meet the ever-growing demands of medical science should be welcomed.

The basic training should be polyvalent so as to enable the technician to work in any branch of laboratory work and also to be able to rotate in the laboratory. The technician works under the supervision of graduate personnel.

4. *Laboratory aides*

The laboratory aide has minimum qualifications and works under the supervision of a qualified technician. By practical experience and training, a laboratory aide may be enabled to obtain full qualification. The graduate staff, as well as qualified technicians, should give him any help necessary for his full qualification. It is desirable that, parallel with improvements in the training of technicians, this category should in the future be replaced by fully qualified personnel, as is already the case in some countries.

9. RECOMMENDATIONS

The brief investigations concerning the functions of hospital laboratories and their varied organizational structures which were possible during the present session of this Expert Committee on Health Laboratory Methods indicate the urgency for a more comprehensive study and more detailed recommendations in relation to the following items :

1. Preparation of a manual of plans and procedures for the building and organization of hospital laboratories. This should include model plans for laboratories in several sizes and types of hospitals.

2. Manual of recommended elementary health laboratory methods applicable to medical and public health practice in remote and undeveloped areas.

No single system of simple and useful laboratory tests for both elementary medical and public health methods exists. This problem requires developmental research to investigate the best procedures for testing blood, urine, stools, water, and food, and for the initiation of public health control methods under the primitive conditions that prevail in dense rural populations characterized by the absence of medical and sanitary services. This is an urgent problem in large sections of the world and deserves immediate attention.

3. Detailed plans and curricula for several types of training programmes for health laboratory technicians.

4. Suggested model for integrated functions and organization of hospital and public health services in a single system of laboratories for small nations and remote rural areas.

5. The need for international standardization of nomenclature and methods in laboratory work is strongly felt by the members of this Committee who would welcome any initiative which might be taken in the matter. There is a definite world-wide need for uniformity of laboratory language and a common purpose in accumulation of valuable demographic data related to changes of aging in healthy populations as well as epidemiological patterns of universal diseases such as many virus infections. Reliable and comparative information is impossible without standard methods.

In the view of this Committee, although all the recommendations made above for further study are important, item 1 is particularly urgent and such a manual would be of great use throughout the world.

10. SUMMARY AND CONCLUSIONS

1. A review of hospital laboratory services has shown that grave defects exist in many parts of the world. In some instances, these defects are due to the fact that such services, for various reasons, have not yet been completely organized. In others they are due to the existence of conflicting interests which have led to a complex heterogeneity of laboratories not always organized in the best interests of the community as a whole.

2. Every hospital, however small, should possess a laboratory within its own precincts and "postal pathology" should be used only when centralization ensures a higher standard.

3. In developing hospital laboratories in countries where no decentralized service exists, the initial steps must necessarily be taken in the major

centres of population where, in the largest hospitals, laboratory units with satisfactory facilities for the training of technical and auxiliary personnel should build up a corps of skilled laboratory workers which can be used, in turn, to establish laboratories in regional, intermediate, and finally local and "rural" hospitals.

4. In these centres complete diagnostic, research, training, reference and consultant facilities must be available.

5. In planning such a service, standard plans for accommodation and equipment in different types of hospital should be prepared.

6. The laboratories should, at all levels, not only provide diagnostic facilities but should also carry on research activities ranging from the most simple collaborative types in the smallest to the most complex in the major laboratories.

7. No general plan can be laid down within the scope of this report for the organizational control of such a service but it is believed that, as far as possible, hospital laboratories should operate within a unified system.

8. The hospital laboratory service and public health laboratory work should, at the local level, be completely integrated and similar integration should be carried to the highest possible level consistent with the public health and hospital organizations of the country. At the highest level, the two types of work may have to be performed in separate laboratories, but even so they should be closely linked and the staff be interchangeable.

9. Hospital laboratories should not only serve in-patients but should, whenever the socio-economic and medical organization of the country permit, also serve out-patients and such home care patients as is desirable.

10. To meet the best interests of clinicians and of pathologists, hospital laboratories should be sited in the hospital building on a main traffic lane and should not be relegated to the basement or some remote part of the building.

11. As far as possible every hospital laboratory should fall under the direct and immediate control of a full-time pathologist. Where there are insufficient pathologists available, effective control of the laboratory may be exercised by a non-medical graduate. Under all circumstances the ultimate responsibility should rest with a medically qualified person and the ultimate technical control with a pathologist.

12. Administrative authorities, in budgeting for hospital laboratory services, should recognize the importance of making provision for research activities and also for ensuring that the economic and personal status of the professional (medical and non-medical) and technical personnel is in every way equal to that of their colleagues in other fields of medicine.

Annex**LIST OF COUNTRIES AND TERRITORIES ON WHICH
INFORMATION WAS AVAILABLE REGARDING EXISTING
HOSPITAL LABORATORY SERVICES**

Belgian Congo	Japan
Belgium	Netherlands
Canada	New Zealand
Chile	Nigeria
China (Taiwan)	Sweden
Czechoslovakia	Turkey
France	Union of South Africa
Great Britain	Union of Soviet Socialist Republics
India	United Arab Republic (Egypt)
Israel	United States of America
Italy	Yugoslavia

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