Chemical Pathology or clinical biochemistry is the application of chemistry and its allied techniques for the elucidation of disease, diagnosis and often management in an individual patient and to the screening of apparently healthy populations for pre-clinical disease.\(^7\) With the rapid advances in biochemical knowledge, techniques and methodology, chemical pathology has been receiving increasing recognition (Fig. 1). The range and number of biochemical investigations available is increasing and with it the use of biochemical investigations in clinical practice has become a routine practice. With improvements in socio-economic conditions, the public is also becoming more conscious of the importance of health and laboratory investigations. The changing patterns of disease and the development of specialties in hospitals have also increased the demand for laboratory investigations in clinical biochemistry.

**DEVELOPMENT AND CURRENT STATUS**

The Institute for Medical Research (IMR) founded in 1900 had facilities for the scientific study of clinical medicine, and amongst the many divisions there was a Chemistry Division, for both organic and inorganic research. In 1906 the IMR began undertaking routine work for the medical services including the provision of chemical analysis and had on its staff a chemist and an assistant chemist. Up to the end of the 1920's the chemistry Division was involved in diagnosis, toxicological and routine chemical analysis and it also carried out work for the medical, police and other government departments, far from the original intention that the division should serve the research needs of the Institute\(^2\). The Department of Chemistry established in 1946, took over all the non-medical routine work, and the re-organised division became the Division of Biochemistry in the IMR.

Branch laboratories of the IMR established at Ipoh in 1929 and at Penang in 1954 served the laboratory needs of the general hospitals in these places. The pathology laboratories attached to the bigger general hospitals offered some biochemical tests. However the facilities were meagre prior to 1957. The General Hospital, Kuala Lumpur (GHKL) was served by the IMR since its founding in 1900. Around 1962, the GHKL began developing its own laboratory facilities and during this process, personnel, equipment and supplies were drawn mostly from the IMR. Today, the GHKL has fairly well equipped clinical biochemistry laboratories.

With the commissioning of the University Hospital (UHKL) in 1967, the Clinical Diagnostic Laboratories attached to it became one of the well equipped laboratories in Malaysia. The Chemical Pathology Section was able to offer the full range of biochemical tests\(^3\) comparable to those available in the developed countries at that time. In terms of laboratory investigations in relation to patient load the Chemical Pathology Section can be considered as one of the busiest in Malaysia (Fig. 2). This is in keeping with the philosophy of the Faculty of Medicine to provide high level laboratory support for teaching, patient care and research activities in the Medical Center.

In close proximity to the IMR and GHKL and juxtaposed between the two, the Medical Faculty of the Universiti Kebangsaan Malaysia (UKM) started developing its own clinical diagnostic laboratories in 1973 and has well equipped chemical pathology laboratories.

The facilities for laboratory investigations and the range of services available vary considerably in different parts of the country. In the Government services the laboratories are grouped into five levels according to their location and function. It is the function of the level IV and V laboratories to cater to the special requirements of hospitals.\(^4\)

With the decentralisation policy of the Ministry of Health with regard to laboratory facilities, minimal laboratory facilities have been developed and are available in many of the peripheral hospitals and health centers where routine and essential biochemical tests can be done. As a consequence, the Division of Biochemistry at the IMR which used to serve many of the hospitals is undertaking less and less of the simpler routine diagnostic tests today (Fig. 3). However it continues to provide diagnostic services, especially some of the specialised tests to hospitals and private...
practitioners in addition to its role as a reference center. It is also involved in (a) the training of biochemists and medical laboratory technologists recruited for service in the Government and (b) various research and development programmes.\(^5\)

Private Laboratories

The recognition of the usefulness of biochemical tests by private practitioners led to the starting of clinical laboratories in doctors' clinics especially in the group practices. This process was facilitated by the easy availability of 'kits' and simple instruments for measuring some common constituents in serum and urine. Many private laboratories also came into being, offering routine biochemical tests as well as other tests in clinical pathology to private doctors and the public. Whereas some of the laboratories have pathologist cover and are reasonably well equipped, others have mushroomed without any pathologist cover or proper facilities. Currently they are not subject to any accreditation and since some of them do not participate in any quality assurance programmes, their performance can be suspect and so detrimental to patient care services.

It is important that regulations be brought in for such laboratories to be open for inspection by accreditation authorities. By registering the laboratories the information regarding professional staff, tests performed, facilities available in the form of equipment will have to be provided in order to assess the work of the laboratory and its suitability to provide diagnostic services to the public. It is important that public interests be adequately safeguarded.

EQUIPMENT

The Clinical Biochemistry laboratories at the UHKL, GHKL, IMR and the Medical Faculty of UKM have a wide range of sophisticated analytical equipment including multi-channel continuous flow analysers as well as automated discrete analysers. The range of equipment in the other hospitals in the country varies considerably. The bigger hospitals do have automated equipment needed for routine analyses of glucose, electrolytes, bilirubin etc. The training of laboratory staff in the preventive and routine maintenance of equipment is being encouraged as this would minimise breakdowns as well as facilitate the rapid rectification of minor faults.\(^6\)

PERSONNEL

Three main categories of staff are found in the bigger laboratories attached to General Hospitals, i.e. the pathologist, the biochemists and the laboratory technologists/assistants. The different background and training of the various categories of personnel in a laboratory, gives them a different role in the day to day work of the laboratory and its administration.

(a) Pathologists

Most of the hospitals have only general pathologists. However, with the advances in medicine and laboratory specialities, it is no longer possible for the general pathologist to be an expert in all branches of laboratory medicine. This situation has led to the emergence of specialists in laboratory medicine in the developed countries and to a limited extent in Malaysia. It is only the Faculties of Medicine and the IMR that have posts of Chemical Pathologists. There are no established posts for Chemical Pathologists in any of the general hospitals in Malaysia. It is indeed unfortunate that even the biggest hospital in Malaysia has no provision for a Chemical Pathologist.\(^1\)

(b) Biochemists

The Biochemists play an useful role in the clinical biochemistry laboratory and some of the peripheral laboratories are at times under the supervision of biochemists. They have responsibility for the analytical procedures and quality control programmes. At present there are over 35 biochemists in the government service. All those recruited as biochemists in the government are given a short period of training in the IMR where they are familiarised with relevant medical knowledge, laboratory procedures in clinical biochemistry and some basic aspects of laboratory management before being posted to the peripheral laboratories.

(c) Medical Laboratory Technologists

Much of the day to day work of the laboratory depends on this category of staff. The training of good medical laboratory technologists takes between 3-5 years. Currently the medical faculties of the University of Malaya (UM) as well as UKM have facilities for in service training of medical laboratory technologists, whereas the IMR has a 3 year structured training programme for laboratory technologists for the health laboratory services in the country.
Training Programmes in Chemical Pathology

(a). **Master of Pathology (MPath) – University of Malaya**

All students in the MPath course do a 16 weeks intensive practical training program in Chemical Pathology. In addition there is a series of lectures/tutorials/seminars in the two year MPath course. There is also provision for specialising in Chemical Pathology in the second year of the course.

(b) **MBBS Course – University of Malaya**

During the second year of the Medical Course, students are given a series of lectures in Chemical Pathology. In the fourth year they have a 4 week posting in Clinical Pathology where the emphasis is on the practical training and interpretations of test results and the role of laboratory investigations in medical practice.

(c) **BSc. Degree – Biochemistry**

Four of the local Universities offer a degree course in Biochemistry. At the UM, students in the final year of the Honours course have a short posting in Clinical biochemistry to acquaint themselves with the working of the clinical biochemistry laboratory. In addition to those graduating locally, a significant number of students return after completing their studies overseas. Currently it is possible for those biochemists interested in furthering their education to pursue a course of research leading to the MSc. degree in the UM.

(d) **Courses for Medical Laboratory Technologists**

There are opportunities for medical laboratory technologists to have specialised training in clinical biochemistry at the Faculty of Medicine, UM, leading to the Advanced Certificate in Medical Laboratory Technology. Similar facilities are also available in the IMR.

Types of Services Provided

The investigations provided by Chemical Pathology laboratories may be grouped into three main categories:–

(a) **Routine Tests**

These tests contribute to the bulk of the workload in many laboratories and include determinations of blood urea, glucose, electrolytes, bilirubin and qualitative tests on urine. In the bigger laboratories these may also include liver function and renal function tests. In recent years facilities for carrying out these tests are gradually becoming available at most hospitals.

(b) **Special Tests**

These tests need special equipment, trained personnel and appropriate sample preparation. They are ideally performed after consultation between laboratory staff and clinicians. Examples of special tests include the feto-placental function tests, hormone assays and measurements of trace elements, vitamins, lipoproteins and iso-enzymes. As these tests are expensive and time consuming they are usually batched. Facilities for such special tests are usually available in the bigger hospital laboratories. The range of special tests offered varies from laboratory to laboratory. In addition to the clinical biochemistry laboratories some related biochemical investigations are also done by the nutrition and radiochemistry divisions in the IMR as well as in other departmental laboratories in medical institutions. Some special investigations especially toxicological in nature are also done by the Government Department of Chemistry.

(c) **Emergency Tests**

These are tests considered essential for the immediate management of the patient and are offered 24 hours a day. The range of tests offered may vary from hospital to hospital with the bigger hospitals having facilities to do a wider range of tests and restrictions being placed in the smaller laboratories. Some examples of emergency tests include blood glucose, electrolytes, blood gases, serum bilirubin, amylase and salicylates. The UHKL has a special laboratory (STAT Lab) for attending to emergency requests and special staff are assigned for such services. In the small hospitals some of the laboratory staff are on standby and are called on to do particular tests on request.

**Utilisation and Cost of Laboratory Services**

In recent years concern has been expressed over inappropriate utilisation of laboratory services at many meetings and this is particularly true in clinical biochemistry. Numerous factors
are known to act as constraints on the performance of laboratories as well as contribute to the rising utilisation of laboratory services. The cost of laboratory services has increased tremendously owing to the rise in cost of equipment, spares, consumables and maintenance services.

For more effective utilisation of the laboratory various educational measures are taken amongst which are:

1) Close communication and consultation between laboratory personnel and clinician on the (i) selection of laboratory tests and its subsequent interpretation; (ii) correlation of laboratory data with clinical findings for monitoring the usefulness of laboratory tests and in improving laboratory performance.

2) Periodical audit programmes to assess utilisation of laboratory services.

3) Instilling a greater awareness of the cost of diagnostic services on the consumers of the services.

4) Instructions on proper utilisation of the laboratory services to medical students and junior doctors.

LABORATORY PERFORMANCES

There is concern about the state of laboratory services in the country today both among the consumers of the service as well as the providers. The aim of most laboratories is to cater for an annual increase of 15 – 20% in workload as well as develop functionally by another 5%. The workload in chemical pathology laboratories have increased considerably over the years and this is illustrated in Fig. 4 with special reference to two major hospitals.

Amongst the various laboratory measures taken to cope with the rising utilisation and workload of laboratory services are:

(i) **Batching of tests:** Tests are done only after sufficient number of samples are accumulated or at certain intervals.

(ii) **Profiling:** A complete set of related tests are done on a single sample. The cost per test is reduced in terms of reagents and personnel time.

(iii) Automation and work simplification procedures in many areas of laboratory service and a process of updating of equipment is continually done for efficiency and improved performance.

QUALITY ASSURANCE PROGRAMMES

Doctors cannot make logical decisions either diagnostic or therapeutic unless the data that is generated by the laboratory is reliable. It is the aim of all laboratories and the expectations of the users that the service provided should be reliable, efficient, quick and fairly economical.

Quality Control programmes both internal and external are practised in laboratories in the developed countries. They help to maintain confidence in the laboratory services and also ensure the quality of results generated. Many of the bigger laboratories subscribe to international quality control programmes besides various internal Quality Control programmes.

LABORATORY DATA PROCESSING

None of the laboratories have centralised electronic data processing facilities at present. However, there are plans to introduce such facilities at the Medical faculties in the near future. The present system of reporting results entails manual transcription with its attendant possibilities for errors in addition to the delays in transmitting the results.

The availability of computer facilities would hopefully reduce the time interval between requests, analysis, results, and reports. Further such facilities would aid in highlighting useful information and so make interpretations easier for the laboratory and the clinicians. The provision of cumulative results with the storage and retrieval of laboratory data would be very much facilitated and this would augur well for medical audit and research. Other benefits that would accrue include the monitoring of laboratory performance and utilisation.

MEDICAL RESEARCH ACTIVITIES

Malaysia with its multiracial population offers tremendous opportunities for the study of socio-cultural, dietary and other influences on disease patterns and biochemical parameters. The facilities that are available can be considered as satisfactory, even though it may not be comparable in all laboratories and institutions.

The IMR was the only institution engaged in medical research in the early years. Today there are five universities and three medical faculties with modern facilities, trained personnel and adequate funding involved in various research programmes. It is possible that the interest of the laboratory staff cannot be sustained merely by routine work and problems related to methodology and evaluation.
boration with clinicians provides an opportunity for the laboratory staff to be involved in clinically oriented research activities.

ADMINISTRATION OF LABORATORIES

Currently there is no central organisational set up solely entrusted with the administration or management of the laboratory services in the country, and this affects their growth and development especially in the government sector. A separate division of laboratory services with its own budget and programmes would facilitate the proper development and modernisation of laboratory services in Malaysia.

CONCLUSION

In developing countries with limited resources too much dependence on the laboratory is to be discouraged. The pooling of resources by the major institutions both in terms of personnel and services would result in the availability of a wider range of tests and also economise laboratory expenditure and benefit patient care and related activities greatly. It has also to be recognised that an efficient laboratory service is an essential pre-requisite for any modern patient care service especially hospital based medical practice.

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Fig. 1. DISTRIBUTION of the workload in terms of tests performed in government laboratories (1981)
(\textit{e} includes serology, histopathology, cytology and autopsies)

Fig. 2. Average number of investigations in clinical biochemistry per patient (both in and out patients) at two major hospitals in Malaysia during the last 7 years.

Sources of Information for:

Fig. 1. Planning and Development Div., Ministry of Health, Malaysia. Clinical Pathology refers to simple tests done by polyclinics and outpatient laboratories.

Fig. 2. 1. Annual Reports of the University Hospital.

Fig. 3. Annual Report of the University Hospital 1982, Annual Report of the IMR, 1982, Planning and Development Div., Ministry of Health, Malaysia.

Fig. 4. Total number of investigations in clinical biochemistry over a period of 7 years in two major hospitals in Malaysia.

University Hospital (38%) GENERAL HOSPITAL (59%)