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ASPECTS ON LABORATORY TECHNOLOGY

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1. Introduction

During the last 30 years the practice of clinical laboratories has changed in several aspects. The development in technology is one of the most important causes for the changes. There are quantitative as well as qualitative changes and all disciplines of laboratory medicine have been influenced. Many more laboratory tests are requested and the laboratories can produce the results much faster, utilizing modern equipment. The repertoire of tests available for the clinicians have been multiplied during these 30 years. The development during the same period has increased both the accuracy and the reproducibility (precision) of the laboratory results and thereby giving them much greater value for the medical decisions.

Today the clinical laboratories play an important role in diagnostic work, in control of medical and surgical treatment and in prevention of diseases.

2. Technology changes in all laboratory disciplines

The development of technology has had its impact in laboratories of all kinds, in histology and cytology, in microbiology and immunology, in physiology and in blood-type serology, but perhaps more than anywhere else in the laboratories of clinical chemistry and haematology. The impact of technology and some of the problems it creates, therefore are more easily seen in the two last-mentioned disciplines.

3. Landmarks in the development of instruments and analytical principles

As landmarks in the technological development could be mentioned on the instrumental road: electric filter-photometers, flow cell photometers, spectrophotometers, continuous flow analysers, reaction rate analysers, mechanised diluters, computerized multitest analysers and particle counters, coagulation measuring devices, etc., etc. Different analytical principles and refined techniques have been introduced, leading to semi-micro and micro-methods. Utilizing immunochemistry and labelling with radioactive isotopes made it possible to determine vitamins, hormones, drugs, etc., which are present in the body fluids in very low concentrations.

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4. Centralization trend

The modern, sophisticated laboratory instruments with a high output of results are relatively expensive, and their use and maintenance often need specially trained staff, consequently we see attempts to use them for many specimens during the whole workday, and if possible at night, too. One result is a marked tendency to centralize laboratory work, both within the hospital and for a town or a region. We have faster and more correct laboratory results, but the distance between patient and clinician on one side and the laboratory staff on the other side has increased.

5. Collection, labelling, transport and storage of specimens

In all health laboratory work there are problems related to collection, labelling, transport and storage of specimens. Standardization in this field is important. For each of the different types of specimens, such as blood, serum, sputum, urine, stool, pus, tissue biopsy, etc., it is recommended to have a precise description giving details how to collect, type of container, how to label, temperature for storage, etc. The matter is complicated by the fact that some constituents, e.g. in serum and in urine, necessitate a very short time interval from collection to start of analytical procedure, other constituents remain unchanged for days or weeks. In some countries the rule is that personnel from the laboratory bleed both inpatients and outpatients; in other countries doctors and nurses perform this job. It is recommended that the head of the laboratory is responsible also for the correct "preparatory" part of the laboratory work. As an example: the use of several, different types of tubes for collection of blood might be a real safety risk at centrifugation and might give wrong results in some chemical analyses.

6. Sophisticated tests and kits

Some tests are seldomly requested and some tests need very sophisticated equipment, reagents and/or skill. In several countries such tests are performed in a few laboratories only. As a consequence the distance between the clinician and the laboratory worker is increased, a dialogue between them is difficult. In such cases strict rules for collection, labelling, preservation and transport of specimens are very important. Problems related to payment for this type of analytical work can be difficult to solve and a system to ensure that only specimens from relevant cases are analysed, can be necessary.

During recent years "kits" with all the reagents for several "difficult" or "sophisticated" analyses have been introduced. The industrial production of reagents, which are difficult to prepare in normal laboratories, can deliver the necessary tools for the performance and the control of the analytical procedure. "Sophisticated" analyses are hereby brought within the limits of smaller laboratories. The proper evaluation of kits and the comparison of kits from different manufacturers can be difficult for a single laboratory, especially when dealing with tests for rare, pathological conditions. This situation stresses the importance of good collaboration between laboratories on a regional, national and international level.

7. Instruments on-line with wards

The use of modern electronics presents the possibility of direct, "on-line" connexion from the laboratory instrument to a computerized patient-register and to the doctors and nurses in the wards. But there are risks connected with such a system, which omit the human factor as a "filter", when results leave the laboratory. The personal responsibility in laboratory work, handling specimens from patients, has its positive features, and they

shall not be forgotten. In this connexion could be mentioned the important problems related to patient-identification, specimen-identification, machine-readable labelling, proper transport and preservation, and also the duty of the laboratory staff to give immediate notice or "alarm" to ward or clinician, when a result is peculiar. Communication from clinician and ward to laboratory staff, e.g. when a patient receives drugs influencing the analytical result, is important and can be difficult in a very mechanized and computerized laboratory organization.

8. Urgent tests

The urgent tests, which should be performed without delay, present special problems in a large laboratory, where a rather rigid organization often is necessary. In some hospitals, a special "emergency laboratory" is established; if the tests here are performed with other methods than the usual routine methods of the laboratory, then an efficient quality control system is essential. Clinicians have difficulties in interpreting, if they receive consecutive results for the same constituent, measured in the same patient, with different accuracy and different precision.

9. Unrequested analytical results

The appearance and the use of multichannel analysers, producing 6, 12 or 24 different analytical results on each specimen, gave rise to debates on the utility of "unrequested" analyses. This debate continues and is related to the usual rules for establishment of "reference values"; to the clinician's ability to use unrequested results compared with requested; and to economic aspects.

10. Evaluation of equipment; laboratory management

Selection of the proper equipment and instruments for a given laboratory requires broad knowledge and experience. Many considerations must be included in the process of decision. Important background information is the likely workload, the need and the possibility for maintenance and for supply of spare parts. Another important aspect is the education and training of the staff-members, who shall use the instruments.

The head of a laboratory has as responsibility both the planning and the supervision of the daily work in the laboratory and the evaluation of future needs and the resources necessary to meet them. Problems related to recruiting of staff and to its continuous education, to safety rules, to data handling, to budgeting and many other parts of management are important, but in most countries given very little attention in the education and training of future heads of laboratories.

11. Bed-side tests and tests performed by patients

Two special lines in the technological development are (a) the bed-side methods and (b) the tests performed by the patients. The bed-side methods in clinical chemistry are especially related to measuring the respiratory function, the acid-base disturbances and the metabolic disorders in other emergency situations, e.g. in diabetic patients. For the patient's own monitoring of his or her situation the urine-investigation is the most important one. New equipment, which gives insulin continuously, controlled by instrumental measurement of the blood-glucose level, is on the experimental stage.

12. Need for international collaboration and research

One important task for the near future regarding laboratory technology is international collaboration about guidelines for the manufacturers' information about equipment. The Expert Panel on Instrumentation of the International Federation of Clinical Chemistry (IFCC) and the Commission on Automation of the International Union of Pure and Applied Chemistry (IUPAC) have recently published a set of papers which outlines decision criteria for the selection of analytical instrument (R. Haeckel et al., J. Automatic Chemistry 1980, 2, 22-33).

Another task is research to demonstrate which kind of analytical reliability is necessary when measuring different constituents in biological fluids in different medical situations. This problem cannot be solved just by asking the clinicians, what they think they need. Well-planned studies of intra-individual variations in health and disease are needed.

Another important problem, belonging to the sphere of education, was presented in a recent Editorial in "Annals of Clinical Biochemistry": "... the technology of clinical biochemistry and the ability to measure substances of biological interest now far outstrip the ability of clinicians to interpret and utilize the data for the benefit of individual patients". (1979, 16, 337).

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