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THE PLACE OF AUTOMATION IN HEALTH LABORATORY SERVICES

by

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I. Introduction

The activities of health laboratory services have been largely affected by the rapid progress in curative and preventive medicine. The volume of work was also affected by the evolution in the attitude of the community, demanding for more tests.

The first automated equipment was introduced to the market about fifteen years ago to enable the laboratories to cope with a large volume of work without a proportional increase in health manpower and cost of tests. In addition to the increasing out-put per technician, the introduction of automated equipment leads also to an improvement in precision and reliability of results.

At present, 60 to 80 % of health laboratory work is feasible for automation.

Blood counts, haemoglobin, haematocrit, blood groups and Rh factors can be determined by automation. MCV (Mean Corpuscular Volume), MCH (Mean Cell Haemoglobin) and also MCHC (Mean Cell Haemoglobin Concentration) can be automatically calculated. A complete haematological profile can be obtained in three minutes.

In Clinical Chemistry, a very large number of determinations, including proteins, carbohydrates, lipids, electrolytes, functional tests vitamins and enzymes can be carried out automatically. Radio-immuno-assays applied to hormones, such as adrenocorticotrophic and thyroid hormones are fully automated.

Automation has also been applied to microbiology, mainly in sero-immunology (VDRL test for syphilis, febrile tests, serology of toxoplasmosis, histoplasmosis, coccidioides, latex fixation test for rheumatological arthritis; C-reactive protein, anti-streptolysins, Trichinosis, Latex tests, Heterophilic antibodies, LE Cell).

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Partially automatic methods are also applied to toxicology, detection of heavy metals, gases and some insecticides in organic fluids. Salicylates, barbiturates and sulfonamides can also be determined by automation.

Automation has also been applied to mass health examinations such as :

- a) Screening for early identification of illness at an asymptomatic stage (e.g. early detection of cancer).
- b) Epidemiological survey to determine the health status of a population.
- c) Epidemiological surveillance to follow changes on health status of the community.

Concerning public health laboratory, automation has also been applied to the analysis of pharmaceutical preparations, drug control, water quality tests, food control, detection and quantification of air pollutants.

Research programmes have largely benefited from automatic devices. "In vivo" methods have been developed by the use of automatic machines to study the steps of carbohydrates metabolism in the blood circulation of the patient, effect of insulin, as well as the reaction of the organism to different drugs.

A wide range of semi-automated devices has also been applied in the laboratory work which permits varying degrees of automation and saves space, time and effort.

Automatic reagent and sample delivers and automatic diluters permit a greater precision and economy in glassware, costs, handling and washing. Spectrophotometers with a direct read-out or reaching concentration in any appropriate unit, with a flow-through cuvette, is another application of automatic equipment to manual methods. Such spectrophotometers eliminate errors of calculation and save time and glassware.

Many scientists are now preferring the use of the term "Mechanization" instead of automation because the mechanized analytical equipment applied to health laboratories so far do not include a regulating feed-back system.*

* Richterich and Greiner (Zeitschr. clin.Chem. hlin. Biochem., 8, 558 (1970) and 9, 187 (1971)).

Recommendations about the use of automated equipment in developing countries cannot be given in absolute terms because the factors that should be considered before a decision on the utilization of such equipment vary from country to country: transport system of samples, technical level of the staff, training facilities, availability of service for repair and maintenance, volume of work and financial possibilities. Another important point to be considered is the cost-benefit and cost-effectiveness relations. Therefore, only considering an average of these factors for certain types of laboratories could suggestions on use of automation be presented.

II. Types of automated equipment

Although it is not the purpose of this paper to present a detailed description of different types of automatic analytical equipment, we feel it is useful to give a short summary of the types of analyzers available at present.

- i) Continuous flow analyzers. All the steps of the tests (dialysis, incubation, extraction, filtration, decantation, etc.) except the final function are carried out in a system of channels. Their speed is limited to 40-100 tests per hour and the risk of contamination from the preceding sample is relatively high. This type of analyzer is the most commonly used at present. Multichannel systems (2-12) are available.
- ii) Discrete analyzers. The determination is carried out in a test tube imitating manual methods. The risk of contamination from the preceding sample is very low due to the isolation of the sample. Deproteinization has, very often, to be performed manually when using this type of equipment. 2-32 multichannel types are available.
- iii) Centrifugal analyzers. This type has recently been developed by Anderson at the Oak Ridge National Laboratory, USA. It depends on centrifugal force to mix samples and reagents. The version available at present includes complicated electronic controls.

Due to the large number of equipment released the market prices are decreasing. However, considering the initial cost and price of installation, prices are still higher in comparison with any other laboratory equipment and prohibitive to many laboratories.

III. Analysis of the main factors involved in the use of automation

a) Cost per unit of Manual and automated tests

These costs are composed of the working expenses (time of collection of samples, treatment of samples, cleaning and documentation). Cost of the material (reagents, chemicals, glassware, electricity) and the cost of the instruments including installation, maintenance and repairing. It could not be sensible to use a 12 - of 24-channel in a small laboratory per occasional tests. However, in a large laboratory it would be of great use. The equipment would work at full capacity saving time which should reasonably justify the price and running expenses of the equipment. To meet the needs of small hospitals and for the day-to-day routine analyses of medium-size hospitals, less expensive smaller equipment with flexibility to satisfy the particular needs would be feasible. Semi-automatic methods could be also satisfactory for laboratories with a limited workload which allow the use of existing laboratory equipment and involve less capital expenditure than the fully automated methods. Many of the semi-automatic devices are relatively simple and can be adapted to any laboratory, whereas fully automatic equipment are more complicated and the technicians need special training to deal with them.

b) Laboratory staff

It is essential that the laboratory workers receive adequate training in order to apply automation correctly and intelligently. It is imperative that at least one and preferably two technicians in the laboratory possess a very detailed knowledge of the apparatus. They have to understand the principle involved in the techniques and possess sufficient biochemical background. A technician with sufficient knowledge in functions of electronic apparatus to recognize disfunction, and capacity for remedying instrument problems as well as for maintaining equipment, should also be available. The quality of the performance depends greatly on the amount of care and skill with which the machine is operated. It has been predicted that automation will result in a decreasing of manpower in laboratories. This prediction has only partially been confirmed. Automation in health laboratories can free the technicians of routine work and they can be devoted to other activities.

c) Maintenance and repair of the equipment

The regular preventive or routine service should be normally carried out every six months and would include operational checks, cleaning and replacements of aged components. This routine service could be done by a technician having some knowledge in electronics. Most of the larger companies supplying automatic equipment produce good instruction manuals, with clear diagrams of circuits for routine maintenance and detection of misfunction. Some manufacturers also offer training courses on routine service, handling and repair of equipment, which the technicians can attend. These training courses are run in Europe and in the United States. If the laboratory has not any person trained to take care of the equipment and relies entirely on a manufacturer or his representative, two problems can arise :

- i) The cost involved could be high, mainly if the manufacturer has no technical staff in the country.
- ii) The time delay on repairing could be very long and the instrument may be non-operational for several months, mainly if the spare parts do not exist in the country.

Some faults cannot be repaired even by a highly trained technician. The assistance of an engineer should be required. In some areas, where this assistance cannot be supplied with a reasonable delay, a breakdown could result in serious problems mainly when the equipment is serving several hospitals which is often the case when a centralization justifies the capital committed in its acquisition.

d) Precision and reliability

Automation improves the patient care as more precise and reliable results can be obtained. Human errors are reduced from 8 to 1 %. However, accuracy of results depends greatly on the alertness and intelligence of the person dealing with the apparatus, of the characteristic of the equipment itself and methodology, as is the case when using any other apparatus. Automation is not a safeguard against errors. The detecting equipments incorporated in automatic machines are based on the same chemicals and photometric principles and they can introduce the same errors as those occurring when operated manually. By way of illustration the interference by phosphorus when determining calcium in biological specimens using a "cold" propane -air flame photometer occurs when operating manually or automatically.

e) Handling of data

Automation has greatly increased the out-put of health laboratories. Using automatic equipment, 2 technicians can perform in 2 to 3 hours the same volume of work as 4 to 5 technicians in 8 hours using manual methods. Perhaps more significant is the application of automation to micromethods to perform antibiotic sensitivity tests : automatic equipment enables the technician to perform several hundreds of sensitivity tests per day whilst by manual methods the number is limited to ten samples per day. A centralization of work to justify the high price of the equipment results in an even greater volume of findings. A clerical problem arises as many technicians are necessary to deal with the large volume of data. The accumulation of results which cannot be collected and distributed leads to the loss of great advantages of automation, such as the faster delivery of laboratory reports and the economical implication due to the reduction in time of hospitalization of patients. Some equipment such as Autochemist has a built-in computer which produces a printed record of all results. However, the computer makes the system more expensive and only a very large laboratory or a great centralization of work could justify consideration of the commitment of capital to buy an expensive system.

IV. Types of laboratories

In most countries there are three main types of laboratories in relation to their location and degree of technical development: central, intermediate and peripheral laboratories.

- i) Peripheral level. As the functions of these laboratories are normally restricted to the performance of very simple analytical procedures (e.g. haemoglobin determination, urine analysis) there seems to be no need for automated equipment at this level. To decrease the workload of the technical staff (normally only one or two laboratory assistants) the use of pre-prepared reagents for qualitative and semi-qualitative tests such as dip-sticks and test tapes could be suggested.
- ii) Intermediate level. For the reasons presented in section III (a, b, and c) and mainly to the fact that the number of tests carried out at this level is still small in relation to the potentialities of automation, we do not suggest the use of this equipment at the intermediate level. However, semi-automatic equipment can be used. These devices are easy to handle, inexpensive and require simple service for maintenance and repair.

- iii) Central level. The use of automatic equipment at this level could be suggested, provided that all conditions mentioned in III and mainly large volume of work or possibilities of centralization, availability of staff trained for automated analysis and adequate facilities for maintenance and repair are fulfilled and the cost-effectiveness study has shown its rentability both technically and economically.

V. Mass Health Examination (MHE)

There are reasons both for and against the use of automated equipment in MHE in public health projects.

No general recommendations can be given but the advantages and disadvantages can be summarized in a tabular form : *

ADVANTAGES AND DISADVANTAGES OF USING THE SAME AUTOMATED ANALYTICAL EQUIPMENT FOR A HOSPITAL AND MASS HEALTH EXAMINATION PROJECTS

For :

1. The number of analyses will be higher, which will give a better economical background for the investment.
2. It is sometimes easier to use funds for purchase of equipment for MHE projects than for hospitals.
3. MHE may give reference values that are important to have for clinical work. It is in such case an advantage if the methods are identical.

Against :

1. There may not be enough time for maintenance of the apparatus, which may increase the incidences of disturbances during the run of e.g. urgent determinations from a hospital.
2. There may be difficulties obtaining qualified personnel supervising the equipment at inconvenient times of the day.
3. If medical centres are organized for health surveillance, it is an advantage if the answers from the laboratory tests can be obtained before the individual has left the centres. That is not possible to arrange if urgent samples from a hospital have to be run at the same time.

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Report prepared by Dr C. H. de Verdier and Professor M. Rubin for WHO on Automation in Developing Countries.

The following points presented by Wasman, Hedstrand and Hood* have also to be considered:

- a) The time should in the main be gone for inventory population studies which do not end up with active steps for control. If there is a clearly demonstrable increased risk for future serious disease intervention should always be taken.
- b) The screening organization must be dimensioned with due regard to the capacity for work-up and continuous control.
- c) Deficient resources for further work-up and treatment of the conditions to be found should at the present time restrict screening to certain age groups where on treatment the yield can be expected to be good.
- d) Attempts to obtain a presymptomatic diagnosis is motivated when there is therapy available of proven or highly probable efficiency.
- e) After screening the information to and the initial handling of those subjects in which the primary screening has given definitely pathological or suspicious or borderline findings is a very important and rather delicate step. This is the one step that requires the most expense in time by highly qualified and experienced physicians.
- f) Mass surveys directed against certain organs or groups of diseases tend to grow in number and magnitude. This will probably create a chaotic situation for those subjects who will be called to a great number of projects and also eventually will be given different informations regarding to borderline findings. The aim must be a common organization for preventive medicine.

VI. Summary

Automation has been introduced to health laboratory services to cope with the steadily increasing demands for laboratory determinations and the shortage of personnel.

Automatic equipments have been applied to almost every field in routine laboratory work, public health, MHE, as well as to research studies.

The idea of incorporating automatic equipment to the laboratories is very attractive, but its acquisition has to be envisaged with a realistic sense. Studies of feasibility are highly desired before committing funds to purchase automatic equipment. Although prices of these equipments are decreasing, the initial cost and installation are still higher than any other laboratory apparatus and justify a careful analysis of all technical and

*Scand. J. clin. Lab. Invest. Supp. 118. 39 (1971)

economical aspects, including economic resources of the country, applicability of the equipment (routine laboratory work, public health, research), price of the equipment and cost of analyses per unit, variation in time of patient's hospitalization reduced by a rapid delivery of results, expenses involved for maintenance and repair of the equipment and availability of skilled manpower to deal with the apparatus.

These considerations are related to laboratories at central level, as it is suggested that automated equipment should not be used at intermediate and peripheral level.

In relation to MHS reasons for and against the use of this type of equipment are presented.