



INTERNATIONAL CONFERENCE ON CLINICAL LABORATORIES:
PRACTICE, MANAGEMENT AND USE

Brussels, Belgium, 25-28 November 1980

Agenda item IV.B



INDEXED

DEVELOPMENT OF NATIONAL PRODUCTION AND EVALUATION OF LABORATORY MATERIALS

by

Professor M. J. Krawczynski
Chairman of Laboratory Diagnostics
Medical Centre for Postgraduate Education,
Warsaw, Poland

Today, in each country there is only a limited possibility of carrying out all routine laboratory diagnostic investigations without having the national industry producing laboratory materials. Under this name we understand laboratory equipment, including laboratory apparatus, reagent kits of different kinds, diagnostic sera, control materials, as well as strip tests, etc. In other words all that is necessary to perform routine laboratory investigation for the possibly wide population in the country.

The technical development of laboratory diagnostic investigations is going in the direction of maximal simplification of laboratory test performance, with simultaneous decrease of their costs. The final result will mean an increase of the number of tests performed and of their availability for wider circles of the population.

However, these tasks cannot be achieved in countries where the industry producing laboratory materials does not exist or is only weakly developed. Such a situation is typical of the least developed countries as well as for the majority of developing countries.

National production of laboratory materials

The above-mentioned countries can cover their needs in laboratory materials only by their import from developed countries in which actually more than 80% of the world production is concentrated. In the majority of cases such a solution is not possible, because of limited financial means available in these countries for health services, including laboratory medicine. In such a situation only a limited number of tests can be performed and then only with laboratory material that can be totally or partially prepared by the laboratory workers themselves, and where there is no need for any special laboratory equipment; as a consequence the whole diagnostic process is delayed and less precise. The same concerns the monitoring of the diseases by using laboratory tests. In the majority of cases the diseases are not monitored at all by laboratory tests, which finally results in a decrease of the quality of health services in the country.

In developing countries and sometimes also in other more advanced countries, the import of laboratory materials is only rarely controlled by laboratory specialists and remains in the hands of administrative officers, who often make very fundamental mistakes, importing laboratory materials which are not very suitable or even unsuitable for the needs of diagnostic laboratories in the country. It is not the purpose of this paper to analyse the reasons

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leading to such mistakes, but the marketing activities of some producers in such circumstances should be stressed and disapproved. The results of such erroneous decisions is that the little money available is definitely lost for the diagnostic laboratories and the whole technical progress in laboratory medicine delayed.

The only way out is to solve the problem in these countries, to develop the national production of basic laboratory materials and to ensure the proper evaluation of these materials which must still be imported.

There are two possibilities to develop the national production:

- (a) introducing original new production technologies, or
- (b) on the basis of licences ("know-how") obtained from countries, having the experience in the production of laboratory materials.

In the majority of countries there are no technical and economical conditions to develop original technologies or there are only limited conditions concerning the most simple kinds of laboratory materials. In these countries the total or partial production of laboratory materials should be based mostly on the cooperation with developed countries. The producers from developed countries can build their own factories on the territory of the developing countries and produce themselves laboratory materials. In such a situation, the host country can usually get the necessary materials at considerably lower prices.

The other possibility is when the developing country, according to technical documentation, is going to produce laboratory materials on its own account. Very often it is not necessary to buy the licences for the newest technologies which generally are too sophisticated for the developing country and probably less useful than the older technologies, which in addition can be sold by the producer at more favourable financial conditions. It seems that WHO should even encourage the producers in advanced countries to sell to the developing countries at low prices, the technologies which are actually for them no longer interesting. We can suppose that many developing countries can solve this problem by way of a national production of laboratory materials in a relatively short time.

This concerns the simplest laboratory materials, e.g., simple robust photometer, blood gas analyser, dosimeters, automatic pipettes, reagent kits and strip tests, for the most often performed routine analyses, e.g., glucose, urea in blood, urine analysis including bacteriuria, etc., as well as different sera, disposable material of different kinds, e.g., test tubes, plastic pipette tips and control sera for quality control.

Another possibility is to develop the production of laboratory materials especially designated for developing countries. As examples of such equipment should be mentioned: monochromatic absorptiometer (MONA) with such advantages as low cost, digital read out in concentration units and very low current consumption from an integral battery. Another example is the swizzle stick system for blood sample collection and the separation of plasma. Both of the above-mentioned systems were tested by WHO with positive results.

The analytical systems based on solid-phase analysis (analytical multilayer films from Kodak and strip-test system "Seralyzer" from Ames-Miles) must also be taken into account. Because general practitioners are also highly interested in the development of such simplified systems, there are concrete perspectives to develop their serial production, which will guarantee the low prices of these materials and their availability.

In socialistic countries mainly original technologies are introduced in the production of laboratory materials. But the system of licences purchase is also not excluded. This concerns for example, the production of strip tests which are actually developed with the cooperation of world known producers, such as Ames-Miles and Behring-Mannheim. There exists also the possibility for the cooperation of several countries in the common production of laboratory materials, e.g. COMECON countries.

It must also be stressed that committees of laboratory standards, e.g., the newly founded European Committee for Clinical Laboratory Standards (ECCLS), have to play a very important role in supervising the production of laboratory materials and in elaboration of necessary standards, including special standards for developing countries.

Summarizing, it seems to be rather justified to suppose that in the near future in some developing countries, the national production of laboratory materials will be developed, contributing to intensify the activity of laboratory services.

Evaluation of laboratory materials

Today the evaluation of imported laboratory materials seems to have even more importance from a practical point of view than the development of national production, which is more a problem of the future.

The question on how to reasonably use the limited financial means to cover the basic needs of laboratory medicine and even to promote more or less intensive technical progress in this field is in many developing countries not easy to be answered.

Therefore, it seems to be desirable to elaborate with international cooperation maybe under the guidance of WHO, regulations concerning the evaluation and control of laboratory materials imported and also produced in each country; the existing committees of laboratory standards could actively help in the elaboration of such regulations.

In the last two years an officially approved system of laboratory materials evaluation was introduced in Poland by the order of the Ministry of Health and Social Welfare, 19 February 1979. The main task of this system is to ensure that only properly evaluated equipment, reagent kits, and other diagnostics can be used in routine laboratories in Poland. The evaluation is mainly directed towards the estimation of the practicability of laboratory materials in conditions which are typical for the majority of routine laboratories in the country.

The evaluation is performed by the Commission of Laboratory Equipment, Reagents and Diagnostics, which is an official organization of the Ministry of Health and cooperating on one side with other departments in the Ministry, such as the Department of Medical Technology and Department of Pharmacy, and on the other side with Expert Boards for Laboratory and Microbiological Diagnostics which are supervising the whole activity in these fields in the country.

The President of the Commission and eight members are nominated by the Ministry of Health for a period of four years; the President must be one of the members of the Country Expert Boards. The chemical and equipment industries as well as foreign trade agencies are represented in the Commission.

The Commission approves the laboratory equipment, e.g., clinical photometer, on the basis of opinion given by two reference laboratories after 3-6 months of routine use. The whole evaluation procedure is standardized and some fundamental questions must be answered, such as the need to buy special reagent kits to ensure the routine use of the equipment evaluated. The following final conclusions should be formulated:

"The equipment is suitable or not suitable for routine laboratory work and can or cannot be admitted to the use in routine laboratories in Poland." The final opinion is sent to the Ministry of Health and on this basis the approved equipment is registered on a special official list. Only the equipment being registered can be imported by foreign trade agencies. The same criteria are used for the laboratory equipment which is produced in the country. Only after the necessary criteria concerning the quality and practicability are fulfilled, can the equipment be used in routine laboratories. When it concerns the national production, the Commission begins to evaluate the equipment already on the earlier phases of the production, e.g., in the phase of prototype.

In a similar way the reagent kits and other diagnostics are evaluated by the Commission and registered by the Ministry of Health; this concerns, of course, diagnostics which are used only for "in vitro" investigations. The diagnostics used for "in vivo" are evaluated by the Drug Commission in a similar way as all the drugs.

Health authorities in Poland, introducing the above described system of evaluation and registration of laboratory materials, have in mind to eliminate either from import or from national production, all laboratory materials not suitable for use in routine laboratories in the present situation and which are often very expensive. In this way the limited financial means available for laboratory medicine can be properly and effectively used.

Summarizing, I should like to stress that the Polish system of laboratory material evaluation and registration can be considered as one of the first experiments with the aim of rationalizing and controlling the import and the national production of these materials, according to the needs and interest of the Health Service, which is guaranteed by the wide participation of laboratory specialists in the Commission.

Conclusions

The following conclusions can be formulated as the summary of the problems discussed above:

1. The development of national production of laboratory materials is the only realistic way to cover the material needs of laboratory medicine in developing countries.
2. The quickest way to realize this aim, is to buy the licences from developed countries, especially when it concerns simplified laboratory materials (equipment, diagnostics, etc.).
3. The introduction of original technologies developed in the country to the production of laboratory materials can also be useful.
4. To ensure the rational use of the limited financial means destined for laboratory diagnostics, the permanent evaluation system of imported and of home-made laboratory materials should be officially introduced.
5. WHO should encourage the authorities of all Member countries, to initiate or to continue the development of laboratory materials production according to the interest of all countries, as well as producers and users and to introduce especially in developing countries, as soon as possible, an efficient evaluation and control system of imported and home-made laboratory materials.

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