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COLLECTION AND USE OF DATA FOR HEALTH AUTHORITIES  
INCLUDING LEGAL CONSIDERATION

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Data originating from diagnostic laboratories which should be used by health authorities, can be classified as follows.

1. Data of general character informing health authorities about the actual situation of public health in the country, district, region, town, etc., epidemiological data, data concerning the activities of preventive and clinical medicine, etc. These data are one of the important factors used in the elaboration of a general health strategy and policy by health authorities.
2. Data concerning the organization and activity of diagnostic laboratories on different functional levels in the country. These data should be a factor determining the specific policies and strategy of health authorities towards the diagnostic laboratories in different aspects: legal, organization, personal and technical.

Health laboratory data

1. The collection of these data until now, is not based on any official regulations and has more or less sporadic character. Usually these data are included in the regular reports of health service officials sent to the health authorities representing different administrative levels; e.g. from regional medical centres to the district health authorities and finally to the Ministry of Health or other central health authorities. Part of these data can also be used in the reports sent by national governments to WHO. Only in emergency cases, such as the detection of dangerous infectious disease, can the data be sent direct from diagnostic laboratories to the local or even to the central health authorities.

In countries where the so-called Medical Diagnostic Centres (MDC) exist or will be soon organized, their main task will be the organization of regular prophylactic mass investigations on populations under the influence of different risk factors. The collection of the data should be under official government regulations, according to which the results of such prophylactic investigations based mainly on laboratory tests, should be analysed, properly interpreted and sent to the district and then the central health authorities. This should be done in the form of a complex report with final conclusions concerning the practical effects of the prophylactic actions tested.

MDC are or should be equipped with adequately programmed computers which will collect, select and collate the data and finally analyse them statistically.

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Such prophylactic actions, often performed by MDC with the collaboration of diagnostic laboratories in the regions which are of primary importance for the health activities of different countries as well as WHO, show that the MDCs will be one of the most important collectors of laboratory data in the near future and a very important link in the transmission of data from diagnostic laboratories to national health authorities and eventually to WHO.

This data also contains information concerning the present organization and the technical and personal situation in the individual diagnostic laboratory. According to local regulations, the head of the laboratory is usually obliged to inform his local health authorities, such as the director of the hospital or polyclinic, about all changes in the organizational structure of the laboratory, including both technical and staff aspects, as well as any change in the methodology used in the laboratory. These data are very important for local authorities and will be used in the planning of investments in the laboratory and in preparing its annual budget.

#### Systems of reporting of laboratory data

The collection of data concerning the activity of diagnostic laboratories in the majority of countries are until now yet regulated by health authorities. However, in many countries there exists primitive systems of data collection according to which only the number of patients investigated in the laboratory and the number of analyses performed are collected for health authorities. Eventually the mean number of analyses performed for one patient in the hospital or polyclinic as well as the mean number of analyses performed by one technician, are also determined. It is clear that such data do not provide sufficient basis for a deeper analysis of the laboratory activities.

But in some countries, e.g., Poland, a unified and objective system of statistics and data reporting in the field of diagnostic laboratories has been developed. Such a system gives the opportunity to perform a deep, precise and objective analysis of the actual situation of diagnostic laboratories, simultaneously at the level of the whole country as well as at hospital, polyclinic and regional medical centre levels.

It is commonly known that such analysis is especially difficult in diagnostic laboratories because:

1. There are big variances between different laboratories in relation to the technical difficulties and in the time spent in performing the laboratory methods, as well as in the increasing mechanization and automation of laboratory work which leads inevitably to the conclusion, that the proper analysis of diagnostic laboratory activity can not be based only on the number of analyses performed.
2. It is also necessary to know not only the productivity of laboratory staff, the efficiency of equipment used and the general organization of laboratory work, but also the requests for laboratory examinations from the hospital or polyclinic; this depends upon different and often not exactly precise factors, such as professional qualifications of physicians, traditional education, financial possibilities of the hospital or polyclinic and others. The need to be precise and define exactly such factors seems to be today or in the near future, one of the most urgent tasks of the health authorities especially when the multiphasic diagnostic strategy of different systemic diseases is to be introduced in the medical praxis.

The system of statistics and data reporting which will be considered below as an example, has been working in Poland since 1968 and has been evaluated for a relatively long time in routine laboratories.

The basic principle of this system is that all analyses performed in routine laboratories with the use of obligatory and standardized methods are arbitrarily divided into five groups depending approximately on the time spent on their performance. The first group consists of the simplest analyses which have the value of one unit, the second of three units, the third of seven units and the fourth and fifth consist of the most complicated analyses, for 15 and 30 units respectively.

In the laboratory each day the number of units obtained and the number of determinations performed are put in a special form. These data are then summarized after a certain period of time, e.g., monthly, yearly. The monthly and yearly reports also include additional data such as, number of hours worked, number of patients admitted, etc., which are necessary to perform a unified and objective analysis of laboratory activities.

Besides the above principles, it was very useful to introduce as a parameter of the objective analysis of laboratory activities, different coefficients which after a long experience appeared to be very useful for this purpose.

The following coefficients were introduced until now:

1. Coefficient of "paid productivity" (CPP) =  $U/pwh$ , which is the ratio of units (U) performed in the laboratory in the period of time to be reported to the "paid work hours" (pwh) of all professional laboratory staff; this coefficient provides information on the theoretical productivity of the whole professional staff excluding administrative.
2. Coefficient of "real productivity" (CRP) =  $U/owh$ , which is the ratio of all units (U) performed in the same period of time to the number of really worked hours (owh) and represents the mean number of units per hour.

The comparison of these two coefficients gives immediately the information about the degree of absence of laboratory personnel in the period controlled.

3. Coefficient of "laboratory results utilization" (CLU) which represents the ratio of the number of units (U) performed in the period being actually under control to the number of patients (p) treated in the polyclinic or the number of "bed-days" (bd) in the hospital:

$$CLU_p = U/p \quad \text{or} \quad CLU_h = U/bd$$

To make possible the comparison of this coefficient for hospitals of different bed structure it was necessary to introduce an auxiliary coefficient of "hospital bed profile" (hbp) and to calculate the corrected coefficient of laboratory results utilization from the following formula:

$$CLU_h/corr. = CLU_h/hbp$$

4. Coefficient of "test structure" (CTS) =  $U/AP$  represents the ratio of units (U) to the number of analyses performed (AP) in a given period of time. In laboratories where only the simplest examinations are performed (for 1 unit) this coefficient is low (about 1.0). The higher the CTS the higher is the percentage of more difficult and more complicated tests performed in the laboratory.

The optimal values (reference values) for each coefficient are established experimentally, e.g. the optimal value for CRP is about 10. However it must be also taken into account that the influence of automation and mechanization upon laboratory work efficiency by introducing to our system the necessary correcting factors to reduce the number of units performed according to the degree of automation in a given laboratory (mechanization, partial automation, full automation with EDP).

With the introduction of obligatory quality control procedures, it was necessary to introduce the new coefficient of self-control and methodical progress (CSC) which can inform the health authorities about the intensity of control action in a given laboratory and about the dynamics of methodical progress in this laboratory. This coefficient can be calculated from the formula:

$$CSC = d/e$$

where  $d$  represents the number of determinations performed in the laboratory (determination: each analysis performed in the laboratory not taking into account in which way the result of this analysis will be used) to the number of estimations  $e$  (estimation: laboratory analysis performed only for diagnostic or monitoring purpose, that is the final product of laboratory activity).

After our experience, the units for "emergency analyses" should be multiplied by the factor 2 or 3. These units as well as the number of emergency estimations should not be used for the calculation of the coefficients for the whole laboratory. However, they can serve for the analysis of "host laboratory" activity.

The system discussed above can be considered not only as a report system, but also as a tool to assist health authorities in defining policies for diagnostic laboratories. With the use of calculating and reporting of CSC, it will be possible to stimulate the introduction of new methods and systematic quality control into routine laboratories.

The data obtained using the reporting system discussed above are practical very condensed data concerning the activities of laboratory services in a given period of time and on the different organizational levels, especially useful and convenient for administrative health authorities. In other words the system itself especially the coefficients can be considered as a system of data collection and selection with the aim of preparing for the health authorities a simple and clear picture of diagnostic laboratory activities. However, to ensure the proper interpretation of data supplied by the system, some precautions and limitations should be taken into account.

1. The system is mostly suitable for the analysis of individual laboratory activity or even individual laboratory departments, e.g., department of haematology, department of clinical chemistry, department of bacteriology, because the optimal values of coefficients (reference values) can be different for each laboratory department.
2. The system allows to compare the activities of diagnostic laboratories belonging to the same methodical and functional group and of similar size. Therefore the system can be widely used for general analysis of laboratory activities in countries having an organized laboratory service. In such countries all diagnostic laboratories are divided into several groups according to their methodical programme and size. The system discussed allows to formulate general conclusions concerning the laboratory service activities of each group of laboratories in the range of the district, region and even of the whole country.
3. It is desirable that the detailed analysis of data should be performed by a senior administrative officer working in the laboratory service and only the final conclusions transmitted to the health authorities.

Following these suggestions it will be possible to use the above described system of data collection concerning the diagnostic laboratory activities as a very useful source of condensed information to elaborate the proper policies of health authorities for laboratory medicine.

It seems that this system can be quite easily introduced into different countries, even if they are very differentiated in the development of their laboratory medicine.

#### Legal aspects

The elaboration of legal regulations concerning the laboratory data collection for health authorities and their practical use by these authorities should be recommended by WHO for all countries. One of the propositions on how to solve this problem was discussed above. The above-mentioned reporting and analysis system has for many years been obligatory in Poland, but until now only on the level of a single laboratory. The development of this system and its widening on the district and country levels with use of computers are now under consideration by the County Expert Board and Ministry of Health and Social Welfare. The acceptance of our data collecting system by other countries and eventually by WHO needs firstly an experimental

study in several countries with different types of development of laboratory services. The results of the study should be discussed and assessed by a working group of experts or advisers designated by WHO.

The conditions in which the data of general character (results of laboratory investigations) should be collected for use by health authorities, are much more difficult for legal regulations, because as it was mentioned before they are usually included in the reports of different health service officers and in this way are in some degree legally regulated. Only the collection of data concerning prophylactic mass investigations performed by the organized network of Medical Diagnostic Centres can and should be, in each country, officially regulated by health authorities.

These regulations should give the precise kind of information which should be supplied from MDC to the local and central health authorities, such as:

- (1) the aim of prophylactic action;
- (2) the number of persons investigated and the characteristics of population investigated;
- (3) the tests performed;
- (4) the results of testing and their statistical analysis;
- (5) the evaluation of the whole action performed;
- (6) the practical conclusions summarizing this action.

The unification of such a data collection system can be very useful in the elaboration of a general strategy in the planning and conducting of different prophylactic actions, especially at country level.

In brief it should be stressed that the elaboration of legal regulated collection of laboratory data will increase the practical usefulness of whole laboratory work, not only from the diagnostic and monitoring point of view, but also as one of the most important factors determining the strategy of health authorities towards the basic problems of the health service as a whole and towards laboratory medicine.