



INTERNATIONAL CONFERENCE ON CLINICAL LABORATORIES:
PRACTICE, MANAGEMENT AND USE

Brussels, Belgium, 25-28 November 1980

Agenda item I.A.4



INDEXED

Diase, La B

ETHICAL CONSIDERATIONS:
INFORMATION FOR PUBLIC HEALTH AUTHORITIES AND UTILIZATION
OF TEST RESULTS BY THOSE AUTHORITIES

by

Professor A. Lafontaine, Director
and
Dr P. Bruaux, Medical Biologist
Institute of Hygiene and Epidemiology, Brussels, Belgium

I. ETHICAL AND DEONTOLOGICAL PROBLEMS

In clinical biology as in other fields of medicine there are many delicate ethical problems. We shall give a few examples, without claiming the list to be exhaustive. We would also draw attention to the important distinctions between ethics, deontology and medical law, fields which people tend all too often to regard as identical whereas sometimes they may be very different or even contradictory, ethics taking precedence over the other two.

1. Communication of results - medical confidentiality

The quality of the results of tests performed in a clinical biology laboratory is obviously of cardinal importance, but the quality of the transmission of these results to the clinician is equally important: the results must be transmitted in such a way that they are comprehensible to the clinician and can be interpreted by him. This highlights the importance of clinical training for the head of the laboratory: he must visualize the results of his analyses in relation to the clinical case and not just in purely technical terms.

In some cases the availability of the biologist and the speed at which the results are transmitted may be of the utmost importance; hence the need to man the services full time and to beware of excessive automation.

Moreover, in communicating the results the head of the laboratory must pay particular attention to medical confidentiality, by which he is bound just as much as the clinician. The patient is entitled to absolute health protection* and the laboratory must ensure that the individual results cannot come into the possession of unauthorized persons.

This raises the more general problem of the notification of certain diseases to the public health authorities: in principle, we feel it is really the clinician who is responsible for making this notification. The laboratory should perhaps share this responsibility in certain very severe cases, but in all cases such notification must fully respect the individual's right to medical confidentiality while effectively informing the responsible authorities, who must also observe medical confidentiality.

* I think this should read "absolute secrecy" - Translator.

The issue of this document does not constitute formal publication. It should not be reviewed, abstracted or quoted without the agreement of the World Health Organization. Authors alone are responsible for views expressed in signed articles.

Ce document ne constitue pas une publication. Il ne doit faire l'objet d'aucun compte rendu ou résumé ni d'aucune citation sans l'autorisation de l'Organisation Mondiale de la Santé. Les opinions exprimées dans les articles signés n'engagent que leurs auteurs.

2. Epidemiology and clinical biology

In the fields of preventive medicine, social medicine and epidemiological surveillance in general, the clinical biology laboratory has a particularly important role to play. The choice of tests to be performed for these purposes will obviously differ widely from the choice of tests for curative medicine. It will depend on the precise objective of the epidemiological study: screening for social diseases such as tuberculosis or venereal diseases, screening for various drug addictions, screening for alcoholism, determination of genetic defects, etc.

Here again, however, the interests of the individual from the moment of conception and his right to medical confidentiality must be observed.

On the other hand, if epidemiological surveys reveal abnormal test results for a given person (sometimes entirely unrelated to the purpose of the survey), the head of the laboratory must have sufficient clinical training to be able to see the possible pathological significance of these abnormal results and should inform the subject's own doctor or at least warn the subject to get in touch with his doctor. All this shows the importance and necessity of collaboration between the different branches of medicine: the clinical laboratory is part of a whole and must be integrated into medicine as harmoniously as possible.

3. Relations between the patient and the laboratory

The need for close collaboration between clinicians and laboratories, between epidemiologists and laboratories, and between school hygiene doctors or occupational health doctors and laboratories has already been stressed. The relationship between the patient and the laboratory also deserves to be taken into consideration and strengthened. All too often the patient is just an impersonal specimen number for the laboratory, whereas he wants - as is his right - to be listened to, to be informed about the tests he is to undergo and about the reason for these tests. It is therefore essential to have a physician present in the laboratory who, even if he is not himself in charge of the laboratory, can listen to the patient and get to know his concerns and anxieties. It is up to this same physician to explain things to the general practitioner and the specialist when they ask for advice on the technical possibility or impossibility of certain procedures. The role of this physician is to ensure the essential liaison with the clinician so as to follow the "clinical case" together with him, to interpret the test reports to him effectively, to consider with him the need for any additional tests, and to follow the progress of the case by adjusting therapy as required or by providing the moral support required in certain situations: "Better knowledge of the case can only improve the quality of care".

4. Ethical problems in clinical trials

Clinical trials of new therapeutic substances are absolutely necessary but present delicate ethical problems. The clinical biology laboratory often plays a very important role in this area. Obviously it is the clinician in charge of the trials who is responsible for their organization and who must take all necessary precautions before the study begins: information on the acute, sub-acute and chronic toxicity assessed in animals, on any teratogenic and carcinogenic effects, on the pharmacology, bio-availability, bio-transformation and metabolism of the substance under investigation, on the possible appearance of side effects, etc.

However, the head of the laboratory participating in the trial must also have access to all this information and participate fully in the organization of the study: he will be particularly careful to propose all tests which might lead to the early detection of side effects. The same problems arise with the introduction of new vaccines.

5. The dangers of certain tests

"Primum non nocere." This ancient principle of medicine is still relevant today and the doctor must weigh the pros and cons before deciding on a test which might endanger the health or even the life of the patient: for example, performing a dangerous biopsy or injecting a potentially toxic or irritant substance.

Under the pretext of advancing medical science or the absolute need for an accurate diagnosis (sometimes when there is no hope of therapy), the patient must not be subjected to tests which are inconsistent with his pathological status or are psychologically unacceptable to him.

In any case it must never be forgotten that the doctor/patient relationship is a relationship between two human beings, not between a scientist and a pathological state, and that the advantages and disadvantages must be weighed carefully. The depersonalization of medicine is one of the major causes of the criticisms - alas too often justified - that are levelled against modern medical science, and this might explain the ever more frequent recourse to alternative forms of medicine.

6. Reasons for the increase in the consumption of clinical biology procedures

There are many such causes and by no means all of them are associated with wrongful "overconsumption". They are essentially associated on the one hand with scientific and technical progress, with the improvement of our biological knowledge and therapeutic capacity, and on the other hand with a genuine "overconsumption" of biological procedures.

A. Progress in medical science, biology and technology

It is this progress, mainly technological progress, which is the main cause of the expansion of clinical biology tests and it is safe to say that much of the progress in medicine in recent decades was founded on the intensive use of tests.

We shall give just a few examples:

- In resuscitation and emergency medicine, the surveillance and efficacy of treatment depends on the rapid and frequently repeated measurement of a number of biochemical parameters such as electrolyte balance or acid-base balance.
- In endocrinology, recent progress has been governed by the possibility of measuring a wide range of specific hormones.
- In the field of immunological and blood diseases, progress is due to new techniques for the measurement of specific proteins.
- Methods of enzyme measurement have also led to improved knowledge of the diagnosis and treatment of infectious diseases.

B. Overconsumption of clinical biology procedures

The "overconsumption" of clinical biology procedures may be defined as the pointless or too frequent performance of a certain number of tests. The borderline between such overconsumption and the proper practice of clinical biology is of course very difficult to determine, but in some cases overconsumption is obvious and may be derived from several causes:

- (1) One of these causes is the excessive prescription of routine check-ups, which consist of a wide range of tests performed either on healthy subjects for the purpose of periodic examinations or on patients who have been questioned and examined too briefly.

There is no doubt that a large number of clinical biology tests can be useful and that some of them are necessary, whether in individual medicine (for diagnosis and therapy) or in preventive medicine (for screening or epidemiological control), but a choice has to be made in the light of the technical, human, social and economic possibilities.

From this point of view it would be helpful if the most prosperous nations would think more deeply about their practice of medicine and - though we do not wish to be cynical - if objective evaluations could be made of the real medical value of certain technologies.

The choice of tests may vary greatly according to the objectives of clinical biology, which themselves are extremely varied.

(a) Individual medicine

- For diagnostic purposes the choice of tests should essentially be based on a careful clinical examination in order to avoid very extensive "screenings" and "check-ups" which include a lot of pointless tests or which cannot lead to any practical conclusion or effective action.
- A certain number of basic tests ought to be selected, with a hierarchy or order of priorities wherever possible so that more detailed but case-oriented tests can be performed later. Clearly this presupposes constant collaboration between biologist, epidemiologist and clinician.
- For the purposes of therapeutic surveillance, it is generally easier to select which tests to perform but the frequency of testing must be fixed at reasonable intervals. Here again collaboration between the clinician and the biologist is essential, and contacts with other technologies or even other disciplines, particularly surgery, should not be forgotten.

(b) Preventive medicine, social medicine and epidemiological surveillance

In these fields the choices and the reasons for choice clearly differ very greatly from those in curative medicine, and more effective participation by clinical biology laboratories in these various branches of medical science would be desirable; it might be accompanied by a reduction in the number of tests for individual medicine.

The ethical problems this raises have already been dealt with under item 2.

(c) Medical research and epidemiological studies

These are very specific areas where the clinical biology laboratory can play a technological support role but may also be able to develop new initiatives.

In these areas it is not possible to justify direct or indirect financial support from the sickness and disability insurance agencies unless these agencies regard such research as useful for improving their activities or optimizing their expenditure.

In these fields in particular, ethics and deontology should constantly be borne in mind.

(2) Another major cause of overconsumption is associated with what is called "connexity", i.e. the performance, by physicians of a discipline other than clinical biology, of a certain number of tests for their own patients. Some of these specialists carry out a large and often routine list of biological tests for their patients. Even if their only intention is to ensure the quality of diagnosis or treatment, they can be criticized in some cases for not always making sufficient distinction between what is necessary, useful or superfluous, and for sometimes allowing themselves to be carried away by fashion or by out-and-out perfectionism.

(3) Nevertheless, the major and particularly dangerous source of overconsumption is the commercial exploitation of clinical biology. This kind of exploitation is very often engaged in by commercial companies whose major objective, admitted or not, is to make money. It is often aggravated by the existence of "fee-splitting", commission payments offered by the commercial laboratories in a wide variety of forms. Under present Belgian legislation this type of laboratory is perfectly legal and only a deontological body such as the Medical Council is equipped to take action against physicians who agree to work in laboratories that engage in such commercial practices. Legislative provisions are needed and are being drafted.

(4) Finally, it cannot be concealed that one of the major causes of overconsumption, in Belgium at least, is the vital need for some health care establishments to make good the losses incurred in many sectors of medical or allied hospital work. To do so, it is absolutely essential to see that the "profitable" sectors of medical work, including clinical biology, run at maximum capacity. This is indisputably an unhealthy situation and the public authorities ought to reconsider the allocation and utilization of funds and adjust them as precisely as possible to the objectives, so that hospital organizations (and sometimes research departments) are not compelled to seek resources for the survival of sectors recognized as essential through the organized exploitation of social security.

7. Ethical problems raised by the overconsumption of clinical biology procedures

Overconsumption, whether deliberate or otherwise, also raises many ethical problems. We have briefly analysed some of the most important causes of this overconsumption. Each of them ought to be overcome by ethical principles and deontological rules based on the proper practice of clinical biology.

(1) In principle, before tests are requested a careful clinical examination should always be performed to identify what biological tests are required. Test request forms designed in such a way that only a pencil mark is needed to request a whole range of tests should be banned, as it is essential to avoid inappropriate forms of prescription which might also open the door to the unacceptable divulging of information. Here the training of the prescribing physicians is particularly important: we shall return to this point later.

(2) As regards "connexity", strict deontological rules must be applied: in particular, extensive routine biological explorations and excessively frequent check-ups should be avoided or should be carried out only if genuinely justified.

(3) The commercial exploitation of clinical biology should be countered by deontological rules and by adequate legislation. In particular, the fee-splitting which is one of the bases for this commercial exploitation must be vigorously repressed.

(4) Among the causes of overconsumption, we have stressed the vital need for some hospital or even research establishments to encourage overconsumption so as to offset the losses made by certain sectors. Here again deontological measures are needed in order to make the medical biologist more independent of the management of the hospital establishment. At the same time, of course, solutions will have to be found for the sectors losing money, which are equally essential, so as to ensure that medical research has the necessary support and is not required to display the economic profitability which tends to be demanded of non-medical research.

8. Automation of clinical biology tests

The automation of clinical biology tests also presents specific problems:

(1) To some extent such automation may afford protection from technical human errors and make the results more reliable. However, it must be borne in mind that highly sophisticated automatic apparatus requires constant surveillance by highly qualified personnel. It also calls for the use of very reliable "standards", which often tend to be

trusted too blindly. This raises the problem of setting up a system for the control of these standards and of the reagent "kits" available on the market, the quality of which often leaves much to be desired. The problem of the precise identification of samples also deserves constant attention.

(2) Excessive automation presents undeniable dangers. There is no doubt, for example, that the presence of equipment performing dozens of different tests simultaneously on the same samples almost inevitably leads to overconsumption of tests. Here again, the introduction of a system for evaluating the equipment available on the market should be considered.

(3) Another aspect which should not be overlooked concerns the administrative convenience of equipment that may have advantages for the laboratory but is likely to lead to disturbing competition with non-automated laboratories and to have undesirable effects on the relationship between patient and laboratory and on scientific observation, not to mention the need to attain a critical minimum level of utilization to make such equipment an economic proposition. We unfortunately have to add another comment, that is that some heads of laboratories omit to verify and sign the results produced by this automatic equipment.

(4) Finally, automation has the drawback of squeezing out the small laboratories which may be geographically essential and are often called upon to cope with emergency situations. We should not forget that even in countries like Belgium there are less favoured regions, there are weekends and holiday periods, there are breakdowns in some sophisticated equipment, and in some cases there is the difficulty of obtaining the specific reagents demanded by these "robots".

9. Problems associated with "underconsumption" and "dysconsumption" of clinical biology tests

The "overconsumption" of clinical biology tests has been widely commented on in most countries in recent years. It certainly occurs in some cases, but that should not hide the fact that technical progress has led to a better approach and hence to better treatment of many pathological conditions. In some circumstances or in some countries or regions, there is also a definite "underconsumption" and "dysconsumption" of clinical biology procedures.

1. Underconsumption

It should be possible to perform a certain number of basic tests at the same time as laboratory examinations, even if these tests have no direct relationship to the current pathological condition. Obviously these basic tests should be selected extremely cautiously to avoid any "wrongful overconsumption".

For example, the measurement of the blood sugar level always appears to be useful during an analysis, even if the purpose of the analysis is not to detect diabetes: in epidemiological surveys it is always possible to discover a certain percentage of latent diabetes cases, which need to be taken into account either for the sake of the individual concerned or from the genetic viewpoint. Similarly, quantitative determination of gamma-glutamyltransferase could be useful for the detection of chronic alcoholism, which is often not admitted to. Excessive regulations could also lead to underconsumption, which might become open to criticism and even inadmissible. Finally, in some countries the available equipment and manpower are often insufficient to perform essential analyses: this should give food for thought to our over-consuming countries, and we might well devote part of our expenditure on luxuries to developing basic clinical biology in certain areas of the world.

2. Dysconsumption

There is no doubt that a certain number of tests which have remained in everyday practice have now been overtaken by more modern techniques. For example, should not the flocculation tests for examining liver function be replaced by more specific tests such as quantitative determination of transaminases or of gamma-glutamyltransferase? What is the use nowadays of the determination of cholesterol, and should it not give way to determination of HDL cholesterol?

10. Standards for the operation of clinical biology laboratories

The application of other measures, such as setting fairly rigorous standards for clinical biology laboratories, has been suggested in an attempt to improve the situation. These measures (standards for laboratory managers, for technical staff, for premises, for equipment, administrative standards, minimum range of tests, etc.) may be useful, but they should under no circumstances lead to the unwanted disappearance of the small and medium-sized laboratories of high quality, to the advantage of more organized and more mechanized establishments. This would bring with it the danger of creating de facto monopolies for a few over-equipped establishments and services. Another danger is that the result would be the opposite of the intended effect, since over-equipment and excessive automation almost inevitably lead to overconsumption, whether deliberate or otherwise, and ultimately to lower medical efficacy.

In our opinion such standards should be more a matter of principle: need for regular checks on the quality of the work of employees; need to ensure that the quality of equipment and documentation is maintained; need for geographical limitation of activities, tempered by the importance of keeping certain very specialized tests for the highly qualified laboratories; implementation of programmes of inter-laboratory comparisons and standardization.

II. RESPONSIBILITIES AND DUTIES RELATING TO THE USE OF LABORATORY TESTS FOR INFORMING THE PUBLIC HEALTH AUTHORITIES ABOUT NOTIFIABLE DISEASES

1. Responsibilities and duties of a medical nature

(a) Respect for the individual's interests

The first duty of the staff in charge of a testing laboratory is to fulfil their commitments towards the patient, including the observance of medical confidentiality, but they must also fulfil their commitments towards society, while always safeguarding the interests of the individual who has entrusted himself to the physician.

(b) Quality of tests

Next, the laboratory heads are responsible for the validity and quality of the test results they supply. This responsibility covers all stages of analysis from the precise identification of patients, the quality and correct labelling of samples, and the storage conditions for samples, up to the technical performance of the tests and the validation and interpretation of the results.

(c) Internal and external quality control

Internal quality control within each laboratory is of cardinal importance for ensuring the validity of the tests.

The way this internal control is organized obviously varies in the different disciplines of clinical biology and according to the size of the laboratory. To ensure the quality of the test results, voluntary or compulsory participation in external control programmes is also essential.

(d) Control of equipment, apparatus and the various products and reagents

As a corollary to these problems of external and internal control, it is important not to forget the regular control and maintenance of the equipment available to the laboratory. The quality of the various biological substances (whole blood, freeze-dried sera, reference antigens and antibodies, etc.) used by the laboratories as "standards" is of the utmost importance, as is the quality of the various reagents and kits supplied to the biologists for performing their tests. Better definition and better control of all such equipment and reagents should be introduced, but obviously this is beyond the means of the laboratory heads and action by the public authorities is essential.

(e) Genuine control over the communication of results to clinicians; an urgent problem

Moreover, the biologist is also responsible for communicating the results to the clinician; together with the latter, he must be able to interpret the results in the light of a given disease situation. He must also be able to give guidance as to what supplementary tests are required. The test results may very strongly influence any therapeutic decision (for example, a blood platelet rate below 15 000 per mm³) and obviously the biologist is legally responsible. He is also legally responsible for the rapid performance of the tests and communication of the results in special urgent cases.

2. Various responsibilities of a social and economic nature

These responsibilities rest not only with clinical biologists but also with a series of other groups: prescribing physicians, patients (check-ups!), legal requirements, hospital organizations, mutual benefit societies and even charitable organizations.

There is no doubt that the testing methods and techniques developed in recent years are important components of medical progress both from the diagnostic and therapeutic viewpoint and from the scientific viewpoint, and it would be a serious mistake not to make use of these modern methods when they are really necessary and useful for the patient or the community. It would also be wrong not to disseminate them as widely as possible, although their limitations must not be forgotten and the objective priorities must not be neglected. Nevertheless it must be recognized that clinical biology has its limits, in some countries financial, in other countries technological and human. It is therefore important to make a careful evaluation of the "cost/benefit" balance in each case and in general, in order to make a discerning choice of the tests most essential for the individual and the community, without neglecting the purely human aspects and the social aspects. It must not be forgotten either that clinical biology is not necessarily linked financially to a compulsory sickness and disability insurance system. It may well be asked if the present financial problems would have arisen if the sickness insurance system had remained completely free.

Another aspect of the problem which varies from country to country but is fairly widespread concerns the various commercial companies engaged in the manufacture of equipment and the production of reagents, and even in the organization of quality control. These companies can undoubtedly be very useful, but their privileges must not extend to exclusive rights, which are dangerous, or to the encouragement of overconsumption.

3. Responsibility for the compulsory notification of certain communicable or other diseases

The head of a laboratory, together with all his staff, is bound by medical confidentiality and he certainly cannot disclose the results of the tests performed to the public. The problem of what information laboratory heads should supply to the public health authorities is an ethical matter: both the interests of the individual (who is entitled to medical confidentiality) and the interests of the community (compulsory notification of certain communicable diseases such as venereal diseases, hepatitis, tuberculosis, etc.) must be taken into account. The question may arise as to whether it is the clinician or the laboratory which has confirmed a diagnosis that is responsible for notifying the public health authorities. In our opinion this is mainly the duty of the clinician, except in very serious cases where the need for speed is overriding.

This position is all the more justified because errors in identification may occur, because the laboratory may have received more than one sample from the same case, and because some diagnoses (for example, virological diagnoses) are based on changes in immunological findings. It must be added that it is valuable for the responsible authorities to obtain data which the clinician can supply but the laboratory cannot.

This problem of responsibility can be solved only by close collaboration between clinicians, biologists and public health authorities in respecting the interests of both the individual and society.