



INTERNATIONAL CONFERENCE ON CLINICAL LABORATORIES:
PRACTICE, MANAGEMENT AND USE

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CLINICAL LABORATORIES IN FRANCE

by

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I. THE CHANGING PATTERN OF EXPENDITURE ON CLINICAL ANALYSIS IN THE LAST TEN YEARS

The sum expended on clinical analysis by the different forms of French health insurance reached 2.5 thousand million French francs in 1978, an increase of 20% (500 million F.fr.) over the previous year's figure.

The cost of this category of insurance reimbursement has been growing at an average annual rate of 19.5% since 1969, with peaks, when reimbursement rates have gone up (+ 23% in 1971 and 1978, + 30% in 1975), against a steady background increase of not less than 12-15% a year.

This annual increase of nearly 20% in the reimbursement of fees for clinical tests carried out in private clinical laboratories is well above the inflation rate and its causes must be sought elsewhere.

The reimbursement of fees for laboratory tests nevertheless still represents the same proportion (3%) of total health insurance payments over the last decade, as all insurance benefits have gone up.

To give an idea of the situation, the total number of tests carried out by all private laboratories was 518.2 million B (where B is a theoretical unit representing one laboratory test on the official list) in 1969 and 2000 million B in 1978, an almost fourfold increase.

Several factors are involved in this increase in the number of tests:

- periodic amendments to the official list of tests by the inclusion of new tests whose employment has become common practice or is required to implement public health policies (e.g., introduction of the serodiagnosis of toxoplasmosis and rubella in 1975);
- increase in the number of tests ordered by physicians as a result inter alia of more information on biological matters reaching medical practitioners and the general public;
- increase in the number of clinical laboratories (400 to 500 a year until 1975, when a law was promulgated to regulate the profession);
- increase in the productivity of clinical laboratories as a result of the appearance on the market of automated equipment with a high output.

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II. REGULATION OF THE PROFESSION

The profession of director of a clinical laboratory has been regulated by the Law of 11 July 1975 on the basis of three main principles:

- higher qualifications to be required of directors and deputy directors of clinical laboratories;
- practice of the profession to the exclusion of others;
- quality control of tests.

1. A number of decrees to implement the Law were passed between 1975 and 1978 and set out:

(a) the qualifications required of directors and deputy directors of clinical laboratories, namely possession of four out of five of the specialized diplomas issued by universities in the fields of biochemistry, haematology, bacteriology/virology, immunology and parasitology. The diploma courses are followed on a part-time basis and the candidate must allow four, or in exceptional cases three, years to acquire his qualifications. In addition, if the director of a clinical laboratory wishes to perform histological and cytological tests, he must be in possession of the requisite diploma, which requires a course of study lasting three years;

(b) the conditions governing the temporary replacement of directors and deputy directors of clinical laboratories;

(c) minimum technical staffing requirements (proportion of directors and deputy directors to technicians, and proportion of technicians in relation to the total amount of work done by the laboratory) and the qualifications required of such technical staff (possession of one of a list of certificates or diplomas);

(d) minimum requirements regarding premises (which must be under a single roof) and equipment.

2. With regard to practice of the profession to the exclusion of others, it should be noted that it was previously usual in France for clinical laboratories to be run by medical practitioners, pharmacists or veterinary surgeons.

Before promulgation of the 1975 Law, some of these persons pursued both occupations and ran a medical practice or worked as a dispensing pharmacist as well as running a clinical laboratory. The 1975 Law made the running of a clinical laboratory a separate profession, distinct from that of physician, pharmacist or veterinary surgeon, and gave those practising both professions at the time the Law was promulgated a time-limit of eight years (to 1983) in which to decide between the two. Directors of clinical laboratories nevertheless continue to be subject to the authority of the regulatory councils of their specific professions; a special section of the Pharmacists' Council has been set up for the purpose and the Medical Council has the power to authorize the practice of clinical, histological and cytological analysis.

At present the number of medical practitioners running clinical laboratories represents one-third of all laboratory directors.

The recent changes in the medical curriculum and in the medical population makes it likely that this proportion will become more balanced in future.

3. The quality control of laboratory tests became compulsory this year.

It is carried out in the form of a comparison of test results given by different laboratories and is organized by the National Health Laboratory, which is a special department of the Ministry of Health and Social Security.

Responsibility for the technical aspects of the work is assumed by four scientific societies, which have each appointed a scientific director (who is the head of a clinical laboratory in a university teaching hospital) to look after technical application of quality control procedures in the following disciplines: biochemistry, haematology, bacteriology/virology, parasitology.

Each laboratory is charged a set fee of F.fr. 1300 for quality control, which has to be carried out at intervals of not more than three months or six months, depending on the discipline concerned.

Lastly, there are a number of regional associations soon to receive official authorization that will take responsibility for internal quality control in laboratories (every two or three days) with the voluntary collaboration of the director of the laboratory concerned.

4. A decree is now being prepared that will set out the conditions governing on-the-spot technical inspection of laboratories to supervise the proper conduct of clinical tests.

III. PROFESSIONAL ASSOCIATIONS

1. France has four professional associations representing directors of private clinical laboratories and three professional associations representing biologists in state hospitals. As a general rule, membership depends on the original professional qualifications of the laboratory directors (physicians, pharmacists), on the way the profession is practised (on its own or in combination with another medical or pharmaceutical occupation) or on the type of establishment where the work is done (university or non-university hospital).

These professional associations represent a large proportion of the profession. The medical biologists' association, for instance, has a membership of 1000, as has the association of full-time directors of clinical laboratories. The association of directors of clinical laboratories who are also pharmacists has 1500 members.

2. A national standing committee on clinical biology was established by the 1975 Law. It has been in session since November 1975 and meets each month. One-third of its membership is made up of representatives of the administration and the health insurance bodies, one-third of persons appointed because of their competence in the field, and one-third of representatives of the professional associations. All the professional associations mentioned earlier are represented on the committee, whose opinion is sought when legislation to implement the 1975 Law is being drafted and when inquiries are being made into the situation of individual laboratory directors in possible cases for exemption. The committee is chaired by a Councillor of State.

IV. FUTURE PROSPECTS

1. Number of laboratories

The principles of the 1975 Law as put into effect by the implementing legislation enacted in recent years have led to a spontaneous decline in the increase in clinical laboratories, whose number is tending not merely to remain stationary but even to fall.

In addition, the final date of 1983 set by the law for enforcement of practice of the profession to the exclusion of others has led to the spontaneous closure by their proprietors of a number of laboratories attached to pharmacies, which were principally engaged in forwarding specimens for testing to full-time laboratories.

There are at present about 4000 clinical laboratories in France, 1500 of them public ones. Approximately 700 of the 2500 private laboratories are attached to pharmacies. Some of these laboratories, which provide public health services in rural areas where it would not be economically feasible to set up full-time laboratories, will be allowed to continue operating after 1983, following re-examination of the local situation in each case, but the total number will probably be reduced to a third.

2. Quality of testing

Quality control among laboratories, as well as the almost universal introduction of quality control within each laboratory, will help to improve laboratory procedures by keeping staff better informed, as will a system of continuing training for directors of clinical laboratories. The involvement of the scientific societies will also help to improve assessment of the quality of test procedures, the consistency and quality of performance of test apparatus and the reliability of reagents. The higher qualifications required of the directors of clinical laboratories also give reason to believe that over the next ten years the proper performance of tests will no longer be called into question, so that the current practice of physicians asking for repeat tests as a check will no longer occur and the number of laboratory tests requested will not increase.

The technical inspection programme for clinical laboratories will check that clinical laboratories are performing properly and will provide for the removal of unsatisfactory laboratories from the active list.

3. Future trends in laboratory technology

As a result of the scientific and technological developments that have taken place in recent years, some tests now carried out appear to be obsolete, to duplicate information given by other, more specific tests or to be of little medical utility.

The periodical reviews of the official list of tests should in the next few years encourage practitioners not to prescribe tests that are not needed to establish a diagnosis or to supervise the course of treatment. These reviews should also have the effect of discouraging directors of clinical laboratories from buying expensive, over-sophisticated equipment without giving proper thought to the economic constraints associated with the health insurance budget and dissuading them from continually increasing the size of their laboratories.

Lastly, the performance of certain very specialized tests or very recently developed tests will be confined in future to laboratory directors of proven competence, who have the requisite equipment at their disposal.

CONCLUSION

These recent measures, which are now in the process of being implemented, should ensure over the next ten years that clinical laboratories will provide better service, that there will be no further increase in the reimbursements to be made in this field by the health insurance schemes and that the proportion these costs represent of all medical and para-medical services liable for reimbursement will be reduced.

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