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THE QUALITY CONTROL OF CLINICAL ANALYSIS
IN FRANCE AT THE PRESENT TIME

by

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I. The quality control of clinical analysis has been part of the practice of clinical pathology in France for about ten years now. The key dates may be considered to be the meeting on Prospective Human Biology at Pont-à-Mousson in October 1970 and the National Meeting on Biology at Lyons in November 1971.

I.(a) At national level the first practical step was taken by the French Society of Clinical Biology, which, in conjunction with the professional associations, introduced a scheme of inter-laboratory quality control in the field of biochemistry, under which the biologists were given the opportunity to take part in about 30 inter-laboratory exchanges between June 1972 and June 1979. Participation was voluntary, and between 1500 and 1600 laboratories were involved in this quality control exercise by early 1970.

Similar experiments have been carried out in the field of haematology since 1973 (22 inter-laboratory exchanges between 1973 and 1979) and in the field of microbiology (bacteriology and parasitology) since 1975 with the assistance of Etalonorme, the French Microbiological Society and the Society of Tropical Pathology.

I.(b) During the same period, regional quality control associations were set up that offered their members assistance in setting up intra-laboratory quality control schemes and organized inter-laboratory exchanges at more frequent intervals than those taking place at national level.

II. In July 1975, the Law amending the section of the Public Health Code dealing with clinical laboratories, Article L.761-14 in particular, made the quality control of clinical analysis compulsory. This Law also strengthened supervision of the administrative and technical aspects of clinical laboratories.

II.(a) On 7 December 1978, a decree on quality control was promulgated to specify the conditions governing implementation of Article L.761-14 of the Public Health Code.

The purpose of the compulsory quality control introduced by the decree is to assess the quality of the analyses carried out by each laboratory subject to control, taking into account the procedures, reagents and equipment used.

The decree envisages that such quality control will not only ensure the reliability and continuing improvement of clinical analysis in the broad interests of public health, but also help each laboratory to keep a check on the quality of its procedures and performance.

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It further provides that, without prejudice to the compulsory control procedure, the quality control of clinical analysis may be organized on a regional basis to assist laboratories on technical matters and foster permanent monitoring of their performance. Such optional quality control schemes are to be run by public institutions or private associations approved by the Minister of Public Health.

To sum up, the quality control of clinical analysis in France may be said to be based on two complementary programmes:

- (1) Compulsory quality control provided on an external basis at intervals, for each branch of analysis, of not more than three months. This scheme has been in force since August 1979 and is run by the National Health Laboratory with the technical assistance of approved institutions working under three-year contracts.
- (2) Optional quality control provided on an internal basis, although external control is also a possibility. This scheme provides permanent monitoring as opposed to the periodic monitoring provided by the first one.

II.(b) In practice, the organizational structure of the quality control scheme is as follows:

The National Health Laboratory is responsible for establishing and updating the list of laboratories. Each laboratory is given a code number to ensure anonymity during quality control procedures.

The Director-General of the National Health Laboratory, with the assistance of an advisory committee of 24 members, more than two-thirds of whom are biologists, initiates quality control and deals with the results. The performance of quality control procedures is entrusted to approved associations, working under three-year contracts. These associations are generally scientific societies specializing in one of the disciplines concerned.

The responsible scientists in these associations know the participating laboratories by their code numbers only; the National Health Laboratory is the sole body in a position to identify a laboratory from its code number.

Quality control is at present carried out for the following four disciplines:

- biochemistry
- haematology
- bacteriology and virology
- parasitology.

Taking all disciplines together, there will be 12 quality control operations in 1980.

III. To date six inter-laboratory exchanges have been held for the 4797 public and private laboratories subject to quality control, and these have in return paid a set fee to the State (currently F.fr. 1300).

III.(a) Four thousand four hundred and fifty two laboratories took part in two exchanges on biochemical tests, namely determinations of urea, creatinine, glucose, sodium, potassium, calcium, phosphates, uric acid, chlorides and proteins in blood.

Four thousand three hundred and seventy laboratories took part in two exchanges on haematological tests, namely red cell count, white cell count, haemoglobin, haematocrit, prothrombin test, activated cephalin test, blood grouping, detection of irregular agglutinins and determination of fibrinogen.

Three thousand eight hundred and fifty laboratories took part in a quality control operation on bacteriological tests, namely the identification of two microbial strains together with determination of their response to antibiotics in vivo and in vitro and the antistreptolysin O test.

Lastly, 3626 laboratories took part in a quality control operation on parasitological tests, namely the search for and identification of parasites in (a) a preserved stool specimen; and (b) a blood smear, and the identification of two strains of cultured fungus.

III.(b) It would be premature to draw any other than general conclusions from these first steps in quality control, but in view of the fact that the scheme covers all clinical laboratories, whether hospital or private, in France, the information that has been collected is of considerable interest.

This information is particularly important as regards the amount of automated equipment used in laboratories and the different types of reagents employed, for which quality control appears increasingly indispensable in view of their influence on the quality of clinical analysis.

From another standpoint, analysis of the results as a whole allows an assessment of the performance of French clinical laboratories to be made and perhaps compared with that for other countries that have applied similar schemes.

III.(c) Apart from the initial information gathered and the individual taking-stock it is hoped will follow from the preliminary results, account will need to be taken in the future of the way a laboratory reacts when a mistake occurs. A serious mistake will not be made twice unless the director of the laboratory concerned fails to realize his responsibilities.

However, whatever penalties may be envisaged, they cannot be applied unless quality control of clinical analysis and technical surveillance of the proper conduct of tests have both shown that tests have not been carried out in a satisfactory manner.

Apart from the administrative authorization required for the practice of clinical tests, which is subject to meeting a minimum of required conditions, the supervision of clinical laboratories in France thus operates at two levels:

- (1) statutory quality control of clinical analysis, which supervises laboratory operations by means of the dispatch of pretested specimens;
- (2) technical surveillance of the proper conduct of tests, which makes on-the-spot checks on the conditions under which tests are carried out in cases where the quality control of clinical analysis has repeatedly revealed deficiencies.

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