



INTERNATIONAL CONFERENCE ON CLINICAL LABORATORIES:  
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STRUCTURE OF CLINICAL BIOLOGY LABORATORIES IN BELGIUM

by

Professor A. Lafontaine, Director

and

Dr P. Bruaux, Medical Biologist,  
Institute of Hygiene and Epidemiology,  
Brussels, Belgium



INTRODUCTION

Clinical biology combines, sometimes arbitrarily, a number of the clinical methods which have proliferated in recent decades and have become basic factors in the progress of medicine, not only in the field of diagnosis and therapy but also in the field of preventive medicine and research.

Technology is developing in such a way, moreover, that there is a danger of the patient and the doctor being forgotten; perhaps it is time for the medical profession to remind itself of its basic mission and to hold fast to it in the interests of the individual and the community: to help them to safeguard their health (i.e. a state of complete physical, mental and social well-being) in conformity with human and medical ethics.

Medicine in Belgium is organized on a liberal system, and in principle every physician holding the diploma of "Doctor of Medicine, Surgery and Midwifery" is entitled to practise "the art of healing", including clinical biology. The various medical disciplines such as internal medicine, cardiology, pneumology, paediatrics, surgery, gastroenterology, otorhinolaryngology, urology, clinical biology, nuclear medicine, etc. are not yet governed in Belgium by postgraduate diplomas. In fact, however, these various specialties exist within the framework of the law on the compulsory Sickness and Disability Insurance, and there are boards of recognition, under the auspices of the Ministry of Public Health, which authorize physicians to carry out services honoured by the Insurance within the various medical disciplines, including clinical biology.

1. OUTLINE OF THE ORGANIZATION OF CLINICAL BIOLOGY LABORATORIES

Because of the liberal organizational system there are many types of laboratory in Belgium, some of which are only quite loosely related to clinical biology proper. At the national level there is a national public health institute, called the Institute of Hygiene and Epidemiology, which has the following functions:

- the study of scientific hygiene problems related to the prevention and correction of factors which could impair human health and well-being;

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- the epidemiological study of harmful factors and their mechanisms, and of ways of controlling these factors.

This Institute, which has a central laboratory and branches in each province of the country, is not a clinical biology laboratory and does not directly perform tests for in-patients or outpatients.

However, this national health institute is directly linked to clinical biology in many ways: for example, it is the national reference centre for microbiology (Salmonella, Shigella, meningococci) and for virology (influenza, hepatitis). It is also responsible for supervising the clinical biology laboratories and for organizing the external quality control of tests, a task it performs in collaboration with university departments.

The clinical biology laboratories are varied both in size and in their activities. Broadly speaking the following can be distinguished:

(a) University laboratories

These are laboratories attached to the teaching hospitals (within State universities or free universities). Besides their functions in the diagnosis and treatment of patients, these laboratories also have a teaching role (in the training of both physicians and allied health personnel) and a research function. These laboratories are also varied in their activities:

- each teaching hospital normally has a general laboratory performing tests for the majority of its inpatients;
- some specialized services (internal medicine, paediatrics, etc.) have smaller laboratories attached to their wards or outpatient departments;
- finally, there are a certain number of highly specialized laboratories which perform only a few tests or a few groups of tests: e.g. quantitative determination of medicaments and toxic substances, quantitative determination of certain hormones, nuclear medicine laboratories, immunology laboratories, etc.

Altogether 139 university laboratories have been listed in Belgium (out of a total list of 2200 laboratories).

(b) Hospital laboratories

These are laboratories attached to the various non-teaching hospitals, whether public or private. In general these laboratories cover the majority of the clinical biology disciplines: haematology, biochemistry, immuno-haematology, serology, microbiology, morbid anatomy, haemostatis and coagulation, etc.

(c) Clinical biology laboratories outside the hospitals

These are generally private laboratories performing clinical biology tests for patients who for the most part are not hospitalized. Normally these laboratories are run either by medical biologists or by pharmacist/biologists. They too cover the majority of the disciplines of clinical biology.

(d) Laboratories of clinical physicians (known in Belgium as "connexist" laboratories)

Many clinical physicians have laboratories attached to their consulting rooms, where they perform clinical biology tests (or have these tests performed) for their own patients. These physicians are either specialists in a discipline other than clinical biology or are general practitioners. Unlike the other laboratories, they generally perform only a limited proportion of the biological tests within a specific discipline, such as hormonology. They have the technical advantage of establishing a close link between the clinical observations and the biological data.

## 2. NUMBER AND DISTRIBUTION OF CLINICAL BIOLOGY LABORATORIES IN BELGIUM

In preparation for the introduction of compulsory external quality control in Belgium, a fairly accurate catalogue has been made of the number and distribution of these laboratories.

Altogether some 2200 laboratories have been listed; this figure may seem rather high, but it is important to stress that by no means all of them carry out all the clinical biology tests.

In short, these laboratories can be subdivided as follows:

- 20.9% are run by medical biologists
- 9.4% are run by pharmacist/biologists (fully recognized).

These first two groups are those which in principle cover the majority of the clinical biology disciplines.

- 2.1% are run by pharmacists who are recognized only for certain disciplines;
- 37% are run by "connexist" physicians, i.e. physicians specializing in a discipline other than clinical biology but carrying out technical procedures related to their specialty;
- 29.1% are run by general practitioners; these perform only a comparatively limited number of technical procedures;
- finally, 24 laboratories or 1.1% represent special cases, such as occupational medicine, military medicine, etc.

To illustrate the geographical distribution, Table 1 shows the distribution of all the laboratories throughout the nine provinces of Belgium, together with the number of laboratories per million inhabitants and per thousand physicians. Table 2 gives the corresponding distribution for hospital laboratories.

## 3. FIGURES FOR THE CONSUMPTION OF CLINICAL BIOLOGY PROCEDURES

These figures give some idea of the trend in the consumption of medical procedures and clinical biology procedures during the last 10 years. They are derived from information supplied to us by the Ministry of Social Security.

Table 3 shows the trend in total expenditure by the Sickness and Disability Insurance since 1970, together with the clinical biology expenditure, and presents the latter as a percentage of total expenditure by the Insurance. The base used for the indices is 1970 = 100.

It may be noted that clinical biology expenditure has increased much more sharply than general expenditure:

- It multiplied by a factor of 5.69 from 1970 to 1978, whereas total expenditure multiplied only by a factor of 3.78.
- Its share of total expenditure rose from 8.78% in 1970 to 13.2% in 1979. However, it should be noted that in 1979 the percentage did not increase any further, but actually fell slightly (13.2% compared with 13.87% in 1978).

Within the clinical biology procedures, we felt it would be interesting to record the trend in consumption for a recent technique of clinical biology, the diagnostic use of in vitro radioimmunoassays (RIA). Table 4 shows this trend from 1974 to 1979. It shows that expenditure on this discipline of clinical biology has advanced very sharply, which is quite understandable in view of the importance of the development of these techniques for the quantitative determination of hormones, for example, and for the evaluation of various serum proteins.

From 1974 to 1979, expenditure on RIAs was multiplied by a factor of 8.93, whereas expenditure on all clinical biology tests rose only by a factor of 2.62 and total expenditure by the Sickness and Disability Insurance rose by a factor of 2.04. Expenditure on radio-immunoassays, as a proportion of total clinical biology expenditure, rose from 3.26% in 1974 to 11.13% in 1979.

#### 4. LEGAL ASPECTS

Apart from the law on "the art of healing" (Royal Decree No. 78 of 10 November 1967 concerning the practice of the art of healing, the art of nursing, the paramedical professions and the medical commissions) establishing the general rules for the practice of the medical profession, and the law on the "conferment of academic degrees" (Regent's Decree of 31 December 1949 coordinating the laws on the conferment of academic degrees and the programme of university examinations) establishing the conditions for obtaining university diplomas, the legislation governing clinical biology laboratories is essentially derived from the law of 9 August 1963 instituting and organizing a compulsory insurance system for sickness and disability in Belgium. Essentially this law gives an entitlement to reimbursement of fees by the Sickness and Disability Insurance, not an authorization to perform a medical procedure.

As already stated, it is by virtue of this law of 9 August 1963 that the various specialist medical disciplines have legal existence in Belgium. As regards clinical biology, an ad hoc commission under the auspices of the Ministry of Public Health establishes the criteria for the recognition of physicians specializing in clinical biology.

A similar procedure is followed for pharmacists (and certain graduates in chemical sciences) in order to qualify them to perform clinical biology tests.

More recently a Royal Decree issued in application of the law of 9 August 1963 (Royal Decree of 10 November 1978) made official recognition compulsory for all laboratories performing clinical biological tests, whereas before that date only the persons performing such tests had to be recognized. The recognition of laboratories is based on criteria concerning the staff, premises, facilities, equipment, starting materials and scientific documentation needed to perform the services and to take the samples. External quality control of the tests has also been made compulsory by this Decree.

A Commission on Clinical Biology has been given the task of defining these criteria and proposing practical ways and means for performing external quality control; implementing decrees are currently being drafted.

Moreover, a law of 25 July 1938 created the Order of Physicians in Belgium (Royal Decree No. 79 of 10 November 1967 concerning the Order of Physicians). This Order is empowered to take disciplinary action in respect of physicians in the practice of their profession. In September 1979 the Council of the Order of Physicians made a statement on the problems of clinical biology laboratories and issued rules of conduct for physicians in the field of clinical biology. These rules were sent to all Belgian physicians and are intended for physicians requesting tests, for medical biologists, and for clinicians performing tests for their own patients.

In conclusion, it is pointed out that a bill on clinical biology laboratories is at present being discussed in Parliament. The main purpose of this bill is to avoid and prevent commercial practices in the field of clinical biology.

TABLE 1. GEOGRAPHICAL DISTRIBUTION OF LABORATORIES

All laboratories, including those run by clinicians  
(specialists and general practitioners)

(Situation on 8 February 1980)

| Province         | Number of laboratories | Number of laboratories per million inhabitants | Number of laboratories per thousand physicians |
|------------------|------------------------|--|--|
| Antwerp          | 346                    | 221  | 117  |
| Brabant          | 541                    | 243  | 69   |
| Western Flanders | 280                    | 262  | 143  |
| Eastern Flanders | 342                    | 259  | 132  |
| Hainaut          | 251                    | 138  | 90   |
| Liège            | 177                    | 177  | 62   |
| Limbourg         | 163                    | 231  | 163  |
| Luxembourg       | 33                     | 151  | 79   |
| Namur            | 69                     | 170  | 69   |
| Total            | 2 202                  | 226  | 94   |

TABLE 2. GEOGRAPHICAL DISTRIBUTION OF CLINICAL BIOLOGY LABORATORIES

Hospital laboratories - Total

(Situation on 8 February 1980)

| Province         | Number of laboratories | Number of laboratories per million inhabitants | Number of laboratories per thousand physicians |
|------------------|------------------------|--|--|
| Antwerp          | 86                     | 55   | 28   |
| Brabant          | 139                    | 62   | 18   |
| Western Flanders | 64                     | 60   | 33   |
| Eastern Flanders | 82                     | 62   | 32   |
| Hainaut          | 65                     | 50   | 24   |
| Liège            | 76                     | 76   | 27   |
| Limbourg         | 44                     | 62   | 44   |
| Luxembourg       | 13                     | 60   | 31   |
| Namur            | 15                     | 36   | 15   |
| Total            | 584                    | 61   | 25   |

TABLE 3. TREND IN CLINICAL BIOLOGY EXPENDITURE AS A PERCENTAGE OF TOTAL EXPENDITURE

|  | 1970     | 1971     | 1972     | 1973     | 1974     | 1975     | 1976     | 1977      | 1978      | 1979      |
|--|----------|----------|----------|----------|----------|----------|----------|-----------|-----------|-----------|
| Total expenditure by the Sickness and Disability Insurance (B.fr. x 1 million) | 34 324.0 | 38 071.9 | 44 446.0 | 52 658.5 | 63 741.4 | 80 110.7 | 95 350.8 | 105 687.0 | 117 892.6 | 129 750.0 |
| Index for growth of total expenditure  | 100      | 111      | 129      | 153      | 186      | 233      | 278      | 308       | 343       | 378       |
| Expenditure on clinical biology (B.fr. x 1 million)                            | 3 012.9  | 3 597.4  | 4 538.1  | 5 391.7  | 6 553.1  | 9 072.1  | 11 366.1 | 13 475.9  | 16 352.6  | 17 148    |
| (as percentage of total)   | (8.78%)  | (9.45%)  | (10.21%) | (10.24%) | (10.25%) | (11.32%) | (11.92%) | (12.75%)  | (13.87%)  | (13.2%)   |
| Index for growth of expenditure on clinical biology                            | 100      | 119      | 151      | 179      | 217      | 301      | 377      | 447       | 543       | 569       |

TABLE 4. GROWTH OF CONSUMPTION OF IN VITRO RADIOIMMUNOASSAYS (RIA)

|  | 1974  | 1975  | 1976  | 1977    | 1978    | 1979    |
|--|-------|-------|-------|---------|---------|---------|
| Expenditure on RIAs (B.fr. x 1 million)          | 213.9 | 559.4 | 905.2 | 1 300.7 | 1 697.4 | 1 910.0 |
| As percentage of expenditure on clinical biology | 3.26% | 6.16% | 7.96% | 9.65%   | 10.38%  | 11.13%  |
| Index for growth of RIAs                         | 100   | 261   | 423   | 608     | 793     | 893     |
| Index for growth of clinical biology             | 100   | 139   | 174   | 206     | 250     | 262     |
| Index for growth of total expenditure            | 100   | 125   | 149   | 166     | 184     | 204     |