LABORATORY MEDICINE SPECIALIZATION TEACHING AND TRAINING IN ITALY WITH A GLANCE TO SOME EUROPEAN AND NON-EUROPEAN COUNTRIES

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Abstract
The Italian Ministry of Education, University and Research has recently reformed the medical schools of specialization in accordance with a series of EC Directives. Four different curricula have been defined into the class of “Diagnostics and Laboratory Medicine”, respectively: Anatomic Pathology, Clinical Biochemistry, Clinical Pathology, and Microbiology & Virology. Each curriculum is based on a scheme of 300 credits, that includes formal educational activities and practical activities distributed on a five years’ period. The four curricula share a common course of either formal or practical activities. Main training and professional objectives are in favour of: a) the principles of appropriateness and of evidence based medicine, b) the acquisition of either on-the-bench experience and practice, or skills in organizing and managing the laboratory activities and personnel c) the understanding of data and phenomena relevant to the patients in a clinically oriented vision, d) the ability to translate research results into diagnostic advantages, e) the values of humanism and ethics.

When comparing the Italian curriculum with some European and non-European curricula in Laboratory Medicine, many similarities are apparent: above all, the medical pertinence of the profession is increasingly affirmed in favour of a consultancy role to be played by the specialist in Laboratory Medicine at the clinical level. Main conclusions: a) the education, skill and expertise required for laboratory specialists regard now a broad variety of issues, b) these embrace not only technical, scientific and organizational aspects, but even the ability to develop consultative capacities in different diagnostic areas, c) moreover the implicit translational aspects in the profession require the adoption of innovative and multifaceted curricula.

INTRODUCTION

In the early seventies no specialization and/or post-graduation were needed for obtaining a position in the Italian hospital laboratories. Such a condition of no-needed specialization lasted until the early nineties, when European Community started to issue directives (1,2) to the state members to adopt a system on a uniform basis of graduation and of post-graduation/specialization for all medical graduates. To be specialized became, over a few years, a prerequisite for practising the medical activity in a specific professional field. As a consequence the Italian National Health System was encouraged to demand applicants the ad hoc specialization, as a pre-requisite for a position. In hospital laboratories, where not only medical doctors but even biology and chemistry graduates (so called scientists) are employed, this fact caused for some years a diversity of positions. On one side specialized MDs, on the other side non-specialized, non-MD graduates, a condition able to generate some serious issues. In the following years this was mended by some laws by decree (3).
**Curricula in “Diagnostics and Laboratory Medicine” in Italy**

In 2005 a reform of the Italian Medical Schools of Specialization (4) has defined four different types of curricula into the class “Diagnostic and laboratory medicine”, respectively:

1. Anatomic Pathology, with admission open only to candidates with medical graduation;
2. Clinical Biochemistry, with admission open to candidates with medical graduation or alternatively in: Biology, Veterinary Medicine, Medical Biotechnology, Veterinary Biotechnology, Pharmaceutical Biotechnology, Pharmacy, Chemistry;
3. Clinical Pathology, with admission open to candidates as in point 2;
4. Microbiology and Virology, with admission open to candidates as in point 2.

The two curricula showing more similarity are Clinical Biochemistry and Clinical Pathology, and are to be dealt with in the following discussion.

All the curricula are based on a common scheme of 300 credits, which includes formal educational activities (up to 30% of credits) and practical activities (at least 70% of credits) distributed over a five years’ period.

Both formal and practical activities are specifically and precisely defined for each curriculum in terms of:

- disciplines contributing to the education of the trainees
- skills to be achieved by the trainees.

A. The common course

All the four curricula share a common course (s.c. “common trunk”) of either formal or practical activities, in order to fulfill the basic requirements needed for an education in Laboratory Medicine (LM). The common course (81 credits on the whole) is distributed all over the curricula five years, with the main dedication in the first three years.

Consequently each of the individual schools provides the common basis of educational and professional skills within the field of LM, which is therefore deemed to be a wider professional domain in the clinical-diagnostic area. This aspect appears substantially in accordance with parallel curricula in Laboratory Medicine of USA and some other European countries.

Main disciplines of the common course are: Clinical Biochemistry and Molecular Biology, General and Clinical Pathology, Anatomic Pathology, Surgical Pathology, General and Clinical Microbiology, Internal Medicine.

The common course appears able to do a liaison role throughout the curricula for:

- promoting multi-disciplinary learning;
- focusing on a comprehensive, clinically oriented view of the profession;
- allowing the trainee to acquire theoretical and practical knowledge more extensively than traditionally achieved in individual sectors.

In this way, every specialist in progress increases/improves her/his professional competences:

- by sharing the wider fields of knowledge that characterize the range of Laboratory Medicine disciplines;
- by being allowed to boost her/his skills to levels not more and not just limited to technical and analytical issues;
- by being entitled to do on a par with clinicians when interviewing and/or advising

B. General objectives of education in LM

Both educational training and professional education are addressed at:
developing special aptitudes to work in accordance with the principles of appropriateness and of evidence based medicine;

stimulating the overall ability of the trainee towards a critical approach to knowledge, through either the acquisition of the on-the-bench experience, or the ability to translate innovative research results;

understanding data and phenomena, by critical review of findings based on real or simulated cases;

paying attention to the values of humanism and ethics of the profession in Laboratory Medicine;

favouring patient’s treatment issues related to a holistic view of healthcare;

enhancing professional interactions;

paying attention to her/his own territorial and social context.

C. Specific objectives of education in LM

a) Curriculum in Clinical Biochemistry

Both educational training and professional education are addressed at:

acquiring theoretical scientific and professional knowledge of the biological and biochemical parameters, and relevant alterations observed/measured in samples, ex vivo and in vivo, in relation to either normal or pathophysiological states;

becoming familiar with the clinical biochemistry and pathology of nutrition and of physical activities at different levels of body organization, from single molecules to cells, tissues, organs, and the whole body both in man (and in animals);

gaining skills in the study of markers of changes that are at the basis of inherited and acquired genetic diseases;

gaining skills in organizing and managing the laboratory activities and personnel, from single sections to more complex units, in a certification/accreditation context;

acquiring knowledge and skills in laboratory processes and methods, particularly as regards:

* methods of molecular biology/pathology applied to clinical needs, molecular diagnostics and recombinant biotechnology for the diagnosis and evaluation of both disease susceptibility and prevention,

* use of innovative technologies for quantitative and qualitative analysis of the above parameters to levels of high sensitivity and specificity,

* use of methods and technologies for the evaluation of environmental pollutants and of xenobiotics, including additives and residues in food;

becoming able to apply and report the prescribed quality control procedures.

b) Curriculum in Clinical Pathology

Both educational training and professional education are addressed at:

acquiring theoretical scientific and professional knowledge in the field of diagnostic pathology and clinical laboratory methods in cytology; cytopathology, immunohematology, genetics and in the diagnostic application of molecular methodologies in human samples;

acquiring the necessary competence in diagnostic and clinical aspects of reproductive medicine and in laboratory medicine of the sea and of sports activities;
- gaining skills in the study of cellular pathology in oncology, immunology and in immunopathology, and in genetic pathology, at ultrastructural and molecular levels;
- acquiring knowledge and skills in laboratory processes and methods, particularly as regards:
  * diagnostics on human samples, related to issues of hygiene and preventive medicine,
  * diagnostics, control and prevention of human health in environmental, occupational medicine, community medicine, forensic medicine, thermal medicine and space medicine.

**RELEVANT LM CURRICULA IN SOME EUROPEAN AND NON-EUROPEAN COUNTRIES**

A summary comparison with curricula from some other countries, either European or non-European, seems now appropriate.

1. At first the “Summary of Graylyn Conference recommendations for Clinical Pathology (CP) training” in USA (5) is considered, that among others states:

   “After completing CP residency training, the resident should be capable of directing and managing clinical laboratory services and be able to:

   - serve as a consultant to physicians on cost-effective test strategies and interpretation of results;
   - select, evaluate, and apply laboratory instruments and procedures appropriate to the screening, diagnostic, and monitoring needs of clinical decision making;
   - plan, organize, staff, and direct laboratory resources;
   - use the techniques of medical informatics to acquire and manage data, translate data to clinically useful information, and communicate that information in support of patient care and educational programs;
   - play an influential role in medical staff and healthcare delivery activities that reach beyond the confines of the laboratory.”

2. In Canada, Medical Biochemistry and Clinical Biochemistry are based on two post-graduation training curricula:

   - **Medical Biochemists** whose training is regulated by the Royal College of Physicians and Surgeons of Canada (6). The requisites are: a) graduation from medical school, b) completion of the required internship (4/5 years).
   - **Clinical Biochemists** whose training is regulated by the more recently created Canadian Academy of Clinical Biochemistry (CACB), and is performed in several medical schools with courses of 2/3 years duration (7). The requisites are: a) PhD, b) some post-graduate research experience.

Details of both medical and clinical biochemist training programs reveal a difference in emphasis and duration rather than in course content, with medical trainees required to spend at least 1 of their 4 training years in clinical disciplines relevant to the practice of biochemistry.

3. **Chemical Pathology (also known as Clinical Biochemistry) in UK (8)**

Doctors in the speciality, obtained through an examination, have dual direct responsibilities:

- the provision of a reliable analytical service;
- the management of the (analytical) process (and the staff);

Moreover they have to manage and supervise:
assurance of quality and provision of guidance on the selection of tests and
assessment of the significance of the results (particularly with some of the less generally familiar tests);
in that both are considered the province of the chemical pathologist.

Not last:

- the clinical role, not only by advising on the management of patients with metabolic disturbances but by increasingly having direct responsibility for such patients in out-patient clinics and on the wards.

4. Final look at Biologie médicale in France that has been very recently reformed, with a decree deemed able to significantly modify the professional scenery in either public or private sectors. The access to the profession is open to both medical doctors and pharmacists.

Cardinal points of the reform are:

- the profession is medically oriented;
- the medical biologist has a full medical role in patient’s care, with the right of checking appropriateness in test prescription.

At the completion of the studies, the specialist should:

- be competent in the analytical and methodological fields, with knowledge in human metabolism, physiology and pathology;
- be able to discuss with clinicians, with a scientific based approach, as for the appropriateness of prescriptions and interpretation of results;
- take into account the medico-legal aspects of the profession and the framework of ethical standards needed to support patients.

Interestingly some common key words/phrases appear throughout the curricula from the different countries above considered, Italy included:

- trainees are either Medical graduates or “Scientists” graduates;
- professional perspective is clinically/medically oriented, holistic, with attention to humanism and ethics;
- educational propensity is oriented towards multidisciplinary learning
- abilities and competences to be developed encompass, among others, consultancy, appropriateness, translational issues;

skills should be gained in technical, analytical and staff management; together with the ability to play influential role in medical staff and healthcare.

**Organizational aspects of Italy’s main LM specialization courses: Articulation of training activities, time duration, tutoring and final examination**

For each trainee the School Council (i.e. the governing body) shall establish:

- the standard location(s), with reference to the specific activities to be performed, either formal instruction or practical training
- specific training programs, generally based on a semester term
the pace of knowledge acquisition, training and competence by gradually increasing the complexity, criticality, technological sophistication and responsibility to be attributed to the trainee: the latter identifies the increasing levels of autonomy the trainee is entitled to assume in laboratory activities.

- the criteria for evaluating either the progress of learning/training or the levels of achievement with respect to the objectives
- appropriate means for the registration and reporting of individual progression.

The School Council annually appoints tutors (staff structure), who are each assigned a set number of trainees, usually two but not more than three, and are charged to:

- play the vocational training activity in the field,
- participate in educational activities seminars, discussion of clinical cases, staff meetings, journal clubs, interdisciplinary meeting, etc.
- provide a detailed assessment on the activities carried out by the trainee during the vocational training.

For obtaining the diploma of specialization, the trainee must complete 300 credits on the whole, articulated in a full 5 years’ course.

During each year (about 60 credits) formal activities account for about 30% of the credits; training (on the bench) activities for the 70% of the remaining credits.

The final examination consists in the discussion of a thesis of specialization and takes into account the results of all evaluations resulting from the in itinere trials and judgments of the teachers-tutors.

**Number of Specialization Schools, Network Organization and Trainee Positions in Italy**

Presently there are:

- 8 Schools of specialization in Clinical Biochemistry
- 18 Schools of specialization in Clinical Pathology
- 19 Schools of specialization in Anatomic Pathology
- 9 Schools of specialization in Microbiology and Virology

Each school is part of a network of university hospital laboratories (possibly on a regional basis) and of major Health Service Hospitals that distinctly provide either formal or training activities.

Each trainee is selected on the basis of an entrance examination consisting of a series of multiple choice questions; after admission he/she signs an agreement for the whole course of specialization and is waged for during the whole course duration.

As for 2009, the following agreements have been drawn up:

- Clinical Biochemistry: 26
- Clinical Pathology: 55
- Anatomic Pathology: 59
- Microbiology and Virology: 29.

**Conclusions**
The education, skill and expertise required for laboratory professionals embrace now a variety of technical, scientific and organizational issues. Laboratory Medicine trainees are expected to learn and attain either technical or, more and more, consultative capacities in rather different diagnostic areas. Translating into practice some innovative findings coming from scientific research implies new and multifaceted curricula for medical laboratory specialists. All the above can be achieved from the beginning by planning the most appropriate means of instruction and training provided by the university courses, and through the continuous education by the scientific associations later on.

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