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The Medical Laboratory Scientist expert in the Transfusion field with post-basic training: training, higher competences and tasks in Italy and abroad

A. Stefanone (Pavia), G.A. Petrilli (Campobasso), A.G. Bianculli (Roma), A. Lombardi (Ascoli P.), D.F. Santarcangeli (Milano), A. Magaldi (Potenza), S.A. Distefano (Palermo), S. Stanziale (Padova).

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I. Introduction

The purpose of this work is to evaluate the usefulness of the professional figure of the Medical Laboratory Scientist (MLS) operating in the Transfusion field with post-basic training. This figure is not currently present in the Italian reality, even if foreseen by The National Collective Health Work Contract 2016- 2018, while it is present and mentioned in foreign literature (Australia, United Kingdom) with the name, Transfusion Practitioner.

The T.P. (Transfusion Practitioner) works in collaboration with the Medical Directors of the Immunohematology and Transfusion Medicine Service and deals with haemovigilance and prevention of transfusion risks, while promoting the safe and appropriate use of blood among colleagues, among clinicians and within laboratories. In this context, the role of the T.P. is to facilitate relationships with clinicians so as to have a more effective and safe performance towards patients.

1.1 The MLS expert abroad

The Medical Laboratory Scientist is a figure which is present in all the health communities of the world albeit with different names and with very different training paths. The diversity in the training path implies a variety of tasks attributable to this professional figure, however some of these tasks are universally recognized. In this regard, the MLS is generally responsible for ensuring the accuracy of the test result and collaborating with other professionals present in the analysis laboratory. Furthermore, this figure ensures that the pre-analytical, analytical (where most of the responsibilities lay) and post-analytical phases are carried out correctly. The MLS recognizes anomalies in the result of a test and when possible, corrects the incident factors to bring the test result as close as possible to the real result, performs validations, calibrations, quality control on the instruments and records the data obtained. The MLS also recognizes the factors that can lead to an error in the analytical result of a test (hemolysis, coagulation, icterus, etc.) determined by the pre-analytical phase. For example, the difficulty in performing a venous blood sampling, can cause a clot in the sample to be used for a blood count or hemolysis in the serum sample, destined for clinical chemistry, which will determine an unreliable and not validable test result. Or the conversation with the patient when performing the sampling, which can take on a very important aspect to be passed on to the laboratory for the correct interpretation of the analytical data (think of hormonal dosages for example). For this reason, in many countries around the world, the figure of MLS, who acts as a link between the pre-analytical and the analytical phase, is associated with the figure of the phlebotomists who draws blood samples, so that he can manage all the critical issues of this delicate initial phase. Generally, the MLS is responsible for the response time of the analytical data (TAT), which is of fundamental importance in the timely diagnosis of a pathology, so much so, that the American Clinical Laboratory Association ACLA, estimates that 70% of the decisions concerning the diagnosis and treatment of a patient are based on laboratory test results. In the United States and the UK, the senior MLT can take on significant management and decision-making roles in a clinical laboratory. In the USA this advanced figure can also assume the role of laboratory director, while in the UK he takes on the role of consultant clinical scientist. The clinical scientists; can intervene transversely from the execution of the diagnostic tests and indicate the therapeutic and rehabilitative treatments. Although this professional figure corresponds to 5% of the UK workforce, his work affects 80% of all diagnoses and clinical decisions.

In the USA the medical laboratory scientist is a generic term that identifies a professional schooled in many areas of a clinical laboratory, usually qualified with a single academic title. Other times, this basic academic title can be followed by additional training or extra academic titles which authorize him to perform complex analyzes in ultra-specialized fields of clinical biochemistry, hematology, coagulation, microbiology, toxicology, virology, parasitology, mycology, immunology, immunohematology, biobanks, histopathology, histocompatibility, cytology, genetics, cytogenetics, microscopy electronics and IVF. The specialized medical laboratory scientist is characterized by acronyms that identify his specialization: SBB (Specialist in Blood Banking) for the American Association of Blood Banks, SM (Specialist in Microbiology) for the American Society for Microbiology, SC (Specialist in Chemistry) for the American Association for

Clinical Chemistry, or SH (Specialist in Hematology) for the American Society for Clinical Pathology (ASCP). These additional names are useful for identifying one's own training, in the world of job hunting and in the allocation of wages. In summary, a laboratory technician specialized in biobanks will be called: MLS (ASCP) SBB; and so on. In the United States, a medical laboratory scientist (MLS), medical technologist (MLT), or a clinical laboratory scientist (CLS) generally has a degree in medical laboratory science, clinical laboratory science or medical technology. Other additional academic courses specialize him in the chosen biological science (clinical chemistry, microbiology, immunology, etc).

Both academic paths allow the MLS / MLT / CLS to obtain the certification from a national certification board (currently there are 3 certified boards: American Association of Bioanalysts (AAB), American Medical Technologists (AMT) and American Society for Clinical Pathology (ASCP) and be able to present themselves in to the working world with the specialization achieved. Most graduate programs for MLS are divisible into three different options:

- 1) 3 + 1 years, where in the last year the student undergoes a practical training by rotating in various sectors of the laboratories;
- 2) 2 + 2 years, where the student is subjected to 2 basic theoretical years and another 2 years of practice;
- 3) 4 + 1 years, with a 4-year basic training and one in a recognized hospital or clinical facility.

The student in the second phase of studies, the practical one, generally undergoes a training of 40 hours per week, up to 52 weeks. In the USA in 2018, an MLT medical laboratory technician had an average salary of \$ 51,219, while an MLS medical laboratory scientist of \$ 67,888. Another disadvantage for an MLT is that some American institutions prefer to hire only MLS. The MLT, in fact, must be supported by a laboratory MS Medical Scientist, despite having characteristics similar to the MLS. In the USA, moreover, it is estimated that in 2025 there will be a shortage of 98,000 medical laboratories.

As in all other health professions, a medical laboratory scientist can advance his career by incrementing his training and specializing through the achievement of additional qualifications: Master of Science, Master of Business Administration, Master of Health Administration and Doctor of medical laboratory science for managerial roles; PHD for the research sector and aspiring laboratory directors; Doctor of Medicine or Doctor of clinical laboratory Science, with this qualification, according to the American law, you can direct any laboratory.

Table I Average data of occupation and salary in the USA

MEDICAL LAB TECHNICIAN FAST FACTS	
Projected Jobs Created	22,900
Projected Job Growth	14%
Low Salary	\$29,640
Average Salary (Median)	\$51,770
High Salary	\$79,530
Entry-Level EDU	Associate's Degree (Technician) or Bachelor's Degree (Technologist)
<i>Sourced from BLS, June 2018</i>	

In the UK there are 2 figures employed in the laboratory: the Clinical Scientist and the Biomedical Scientist. The role of the Clinical Scientist is to promote the health of patients and to speak, for this purpose, with doctors, nurses and other health figures by giving advice and directing doctors in the diagnosis. The biomedical scientist, responsible for the analytical part and the laboratory data, receives an average salary of 48,798 pounds. In order to practice, both figures must be registered with the Health & Care Professions Council (HCPC) which has 200,000 professionals who graduated from accredited universities. Both figures have a practical postgraduate course, possible even in non-accredited universities.

In Australia, the medical laboratory scientist has an academic course of four years, after which he can obtain a professionalizing master degree. Degrees and master programs must be accredited with the Australian Institute of Medical Scientists (AIMS).

In New Zealand, a medical laboratory scientist, has graduated from a specific degree program recognized by the Medical Science Council of New Zealand. After graduating, they must work for six months under supervision and enroll in the Medical Science Counsel of New Zealand and obtain an annual enrollment certificate.

In Ghana, there are three professional figures in the laboratory: the medical laboratory scientist (MLS.D), a professional with a six- year degree and a PhD in medical laboratory science; the medical laboratory scientist (MLS) with an academic course of 4 years in medical laboratory science and the medical laboratory technician (MLT) with a 3 year diploma in medical laboratory science. The training program of all three figures includes a rotation of the students in the various laboratory sectors, under supervision.

2. The Italian National Collective Health Work Contract

In the world of work, knowing what the The National Collective Work Contract provides, is of fundamental importance, as it allows us to define the roles and functions that are covered. The National Collective Work Contract, includes the agreements stipulated between national union bodies and national employers associations. Basically they are agreements governed by private law but which, according to the law, have a predominance over individual agreements, unless the latter provide an improvement for the worker with less contractual power than the employer. The categories and qualifications in The National Collective Work Contract refer to the categories, which are divided into apprentices, workers, intermediates, clerks, professional and managerial staff and directors, although in some employment contracts there may be more specific categories. Then there are the qualifications, which describe the position of a specific professional profile and indicate which level of remuneration it belongs to. Some qualifications are general and common to all Italian National Contracts, others are more specific depending on the various sectors of reference.

2.1 Levels and tasks

Other fundamental points to understand how The National Collective Work Contract works are the levels and the tasks. The levels are considered parameters which have to be used in order to identify the remuneration due to each worker and the part of the legislation to be applied. For example, when analyzing the contractual institutions of the trial period, the notification in the event of dismissal or resignation, reference is always made to the provisions that vary according to the levels.

On the other hand, no reference is made to the levels or categories in the case of overtime, since the amount of the increases is valid for all workers. The tasks represent that set of rules, behaviors and duties that are the responsibility of the worker and that the employer, in turn, has the right to demand. In the private work sector, The National Collective Work Contract is stipulated by and among the workers representative organizations (trade unions) and employer associations (or a single employer). This contract establishes the discipline of individual employment relationships (defined as the regulatory part) and some aspects of their reciprocal relationships (the mandatory part). However, in the Italian public administration sector, the stakeholders are the union representatives of workers and the Agency for the negotiating representation of public administrations. The official database is kept by the National Council of Economy and Labor (known as CNEL in Italy).

2.2 The higher competences of the MLS according to the current National Collective Work Contract

After years of blocks, on May 21, 2018, the new National Collective Work Contract was signed for the staff of the healthcare sector, for the 2016-2018 three-year period. The most innovative part of the new agreement, as ARAN (Public Administration Bargaining Agency) defined it in its illustrative report, was represented by the new institution of functional assignments for all category D roles that replace the Organizational Position Assignments and coordination assignments, as clearly specified by Aran itself. The Institute of Organizational Positions was introduced by the The National Collective Work Contract of the health sector on 7/4/99, and has often represented not so much a tool to integrate the corporate

organizational model, but as a reward for senior employees of the Sector (cat. D), chosen by the same managers proposing the organizational positions, as they operate in important sectors within the Operating Unit, in order to incentivize and reward their autonomy of action and responsibility. The institute did not have to represent a career progression and once assigned to the chosen employee, it remained so until new organizational needs or a final negative evaluation.

The new functional positions, such as those of organizational positions to be used as replacements, must involve the carrying out of functions that provide for the direct assumption of high responsibilities, but the formulation of art. 14 specifies, not surprisingly, that these responsibilities must be "... additional and / or more complex than the specific attributions of the category and profile to which they belong (art. 14).

This new part in the description should specify that the functions covered by the functional assignment can never coincide with attributions to be considered already present in the candidate classification and, therefore, represent something new, additional, more complex and / or more responsibility. From the articles 13, 14, 15, 16 and 17 we note that the functional assignments can be an organization assignment, which is foreseen in a single typology, even if variously graded according to its complexity and in this grading the coordination function provided by the Law 43/2006 for the health role, it follows that the coordination functions alone are not attributable to either the social workers or the staff of the technical, professional and administrative roles.

In the system of organizational positions, coordination was different from the organizational position, so much so that in the event of conferment of an organizational position to the coordinator, the relative indemnities could accumulate (art. 11 clause 4, CCNL 20/9/01). As for the requirements, 5 years of experience in cat. D are required to fill this position. The master degree represents an element of enhancement for the purpose of assigning the more complex tasks. While for the sole coordination function, possession of a master in accordance with ex law 43/2006 and 3 years of seniority in cat. D and Ds was required.

The professional assignment represents the real novelty, as it is aimed at recognizing the clinical-assistance career; requires the possession of significant knowledge and high/complex and innovative professional skills. For health care personnel and social workers, two types of professional duties are envisaged:

- The position of professional specialist, reserved for those who possess the first level specialist master, referred to in art. 6 of the law n. 43/2006, according to the university didactic regulations defined by the Ministry of Health and the Ministry of the University, on the advice of the National Observatory for Health Professions, reconstituted at the MIUR (Italian Ministry of University and Research) with the interministerial decree of March 10, 2016 and after hearing the Regions.
- The position of expert professional, which requires having acquired advanced skills through complementary regional training courses and professional activities recognized by the regions. This denomination of EXPERT therefore no longer identifies the personnel classified in cat. Ds, who with the new National Collective Work Contract takes on the qualification of Senior, but precisely, a type of functional assignment which, as specified in the aforementioned act of address of the Sector Committee can be attributed to the professional already within the current system and that aims to enhance the skills acquired by healthcare professionals. Article 16, clause 9, with regard to health care personnel and social workers, specifies that the organization tasks of the OU (Operative Unit) to which they belong are higher than those of specialist and expert professional.

For the technical and administrative staff, the professional assignment is unique and involves the carrying out of highly professional and specialized functions related to enrollment in professional registers, where they exist. For this conferment it is necessary that one has five years of experience in this profile, cat. D and enrollment in professional registers, where they exist.

In conclusion, we can state that:

- the concept of advanced practice, and of advanced competences, includes both the acquisition and the implementation of specialized practices, intended as activities on specific professional sectors, and practice on large professional sectors for taking charge of complex professional problems;

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- the acquisition of advanced skills requires specific professional experience and pertinent training courses;
 - the core topics for the development of advanced competences are in most cases attributable to the following areas: clinical practice, leadership and management, education, research, consultation.

3. The MLS expert in the Transfusion field

As we just stated, the National Collective Work Contract of the Health sector signed on May 21 ,2018, introduced the roles of specialist and expert professional. The specialist must be in possession of the Specialistic 1st level Master, consequently this figure could coincide with the MLS operating in The Immunohematology and Transfusion Medicine Service, with post-basic training. In this regard, the National Observatory of Health Professions has produced a document containing a list of approximately ninety Masters divided into three groups by type of content, among which there is Technical procedures in the transfusion and Biobank, addressed to MLSs who intend to acquire advanced skills in this sector.

It is therefore considered necessary to trace an identikit of the MLS specialist operating in the Immunohematology and Transfusion Medicine Service, it not being a figure with functions mainly attributable to the coordination of the staff.

Based on the Anglo-Saxon literature related to this argument, the Transfusion Practitioner's activities may include:

- transfusion education to clinical colleagues;
- information regarding transfusions to patients and families;
- risk management: drafting, implementation, updating and monitoring of local policies and procedures;
- monitor and provide feedback regarding the observation of the guidelines on good practices and consequent verification of the applications carried out;
- management of transfusion accidents and related investigations;
- follow-up of haemovigilance and reporting of adverse events;
- risk prevention and corrective actions;
- management of the appropriate use of blood and collection of statistical data relating to its use;
- implementation of Patient Blood Management strategies.

All Transfusion Practitioner activities involve collaboration with other professional figures both within the Transfusion Service and in the wards. In referring to Anglo-Saxon literature and the role attributed to the T.P., an activity divided on two fronts could be identified, one relating to the relationship with the clinical wards/departments and one within the Transfusion Service.

In the clinical field, the activity of the specialist MLS could be:

- link between the Transfusion Service and the clinical-surgical areas;
- management of the correct application of procedures and protocols in case of doubts on the part of medical and nursing health personnel;

- supervision to maintain the traceability of the processes;
- detection of training needs of the personnel involved in the transfusion activity;
- audit organization;
- periodic reports with the wards.

Within the Transfusion service he could deal with:

- taking care of relationships and team activities with Medical Executives;
- collaborate in the drafting and revision of the guidelines;
- keep in contact epidemiologists and scientific societies;
- propose and test new methods in order to improve working activity;
- management of emergencies and critical issues in collaboration with the Head of the structure;
- attention to the activity inside the laboratory, listening to the problems highlighted by colleagues and organizing periodic meetings for comparison and resolution;
- collection and analysis of reported adverse reactions and highlighted non-conformities;
- collection of training needs and consequent participation in the organization of courses;
- management of tutor activities for new hired / trainees;
- participation in the assessment of the acquisition / maintenance of the skills of MLS colleagues.

The Ministerial Decree 745 of September 26, 1994 defines in this manner the profile of the MLS: carries out his work performance with technical-professional autonomy in direct collaboration with the graduated laboratory staff responsible for the various work in the laboratory, participates in the planning and organization of the work within the structure in which he operates. In the previous definition there are the terms autonomy and collaboration, that perfectly adapt to the role of the specialist MLS, understood as a figure capable of acting autonomously as a link between the Transfusion and the Ward, while carrying out his activity in close collaboration with colleagues and Medical Executives.

The role of the specialist MLS should mainly concern the safety of transfusions and the appropriateness in the management of the patient blood (PBM) within the healthcare facilities. Much of the work is to ensure that current clinical practices comply with national and international guidelines and standards. Again citing the foreign literature dedicated to the Transfusion Practitioner, the role of our MLS with post-basic training should contribute to improving transfusion activity by promoting good practices.

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