European Association for Professions in Biomedical Science

Transition to Bachelor of Science in Biomedical Science

Recommendations from the European Association for Professions in Biomedical Sciences Members

General Governing Body

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European Association for Professions in Biomedical Science
EPBS is an International Non-Profit Association (AISBL) registered under the Belgian law.
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Executive Summary

Health 2020 is the new European health policy framework. It aims to support action across government and society to: “significantly improve the health and well-being of populations, reduce health inequalities, strengthen public health and ensure people-centred health systems that are universal, equitable, sustainable and of high quality”.

It is critical that all health professionals have the knowledge, skills and competencies to support achievement of this goal.

Labour force mobility is believed to contribute to economic and social progress, a high level of employment, and to balanced and sustainable development. The EU Directives 2005-36 and 2013-55 enshrine this mobility for professionals while ensuring consistency of standards.

The European Association for Professionals in Biomedical Science is committed to these ideals and to creating the environment where mobility will flourish and knowledge, skills and competencies are comparable.

The EPBS policy on Education, approved in Oslo 2009 is that:

- ‘The minimum standard of education for Biomedical Scientists acceptable to EPBS is a Bachelor level or 1st cycle (180 -240 ECTS) under the Bologna Process

- Progress to higher level degrees of Masters and PhD is an integral part of the Education and Training of Biomedical Scientists ‘

This goal has been achieved in most, but not all, member countries.

This document has been prepared by the Working Group on Education to facilitate the transition to a BSc for all EPBS members.

It explores the 1st cycle of study examining the general education objectives of the BSc and the knowledge skills and competencies required of a Biomedical Scientist in modern healthcare.

To assist members, and course directors, a framework curriculum is suggested.
The report links the entry level BSc to the second objective of progress to higher education at Master level.

Implementing these recommendations will ensure that all members within EPBS will achieve the standard of Level 6 under the European Qualifications Framework. Failure to implement these recommendations will lead to a two tier system which is not in the best interests of patients, scientists nor governments.

70% of clinical decisions are based on the result of a diagnostic test. Patient safety demands that these tests are carried out appropriately by qualified competent staff with due regard to the pre analytical, analytical and post analytical factors influencing the test and its interpretation.

Finally we conclude that standardising the level of education of Biomedical Scientists to higher education is in the best interests of patients served by Biomedical Scientists, contributing to increase the efficacy and efficiency of the Health systems and the response level of the health care providers.

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1 Introduction

The development associated with health technology has enabled healthcare to evolve to prevention of the disease and its early detection through screening and monitoring. Simultaneously, advance methods of intervention for therapeutic purposes and clinical research have been applied.[1]

Cancer, cardiovascular and infectious disease, are today the major causes of morbidity and mortality in developed countries.[2] This underlines the need for integrated application of sophisticated methodologies of clinical-laboratory testing, able to detect morphological and physiological changes in the individual at an early stage, before the onset of the disease, allowing a preventive clinical intervention.

This, alone, highlights the need for proper education and training, where competent and regulated professionals present themselves as a key-partner in screening, diagnosis, prognosis, treatment, clinical research and monitoring individual, or group of individuals, in order to maintain current health standards.

Emerging trends in regulation and accountability dictate that all healthcare professionals have the necessary knowledge, skills and competencies to deliver safe patient care. For scientists in clinical laboratories this is particularly important where technological advances occur at a rapid pace. This requires a solid education and training with emphasis on basic and advanced science and technology which produces graduates who are versatile and dynamic, responsive to emerging knowledge and technology and who can incorporate their learning into the clinical laboratory and, in addition, undertake healthcare research.

The scientific and technological development, applied to healthcare, has marked the need to permanently rethink the organisation of knowledge. The new paradigm of clinical management in primary, secondary and tertiary care, imposes a requirement for greater adaptability of human resources, with greater operational capacity in the process of work organisation and clinical laboratory reasoning, with improvement in quality of patient care in terms of disease prevention, diagnosis and monitoring.

The European Union has a suite of Directives and Regulation which impact on education standards and mobility of professionals. The Directives on the Free Movement of Professionals of 2005[3] and 2013[4] coupled with the Bologna process[5] and the Qualifications Framework[6] have moved to align qualifications and support the mobility agenda. The most recent initiative is the ESCO[7]

project which aims to classify European Skills, Competences, Qualifications and Occupations, bridging the communication gap between employers and educators.

The movement to regulate professionals requires that we have consistent, accredited and regulated education and training providing the graduates with comparable and transparent knowledge skills and competencies to practice their chosen profession. Employers require confidence that regulated professionals moving between countries are of a comparable standard.

In anticipation of this evolution the EPBS published its policy on Education in 2009, [3] this policy states that

- *The minimum standard of education for Biomedical Scientists acceptable to EPBS is a Bachelor level or 1st cycle (180 -240 ECTS) under the Bologna Process*
- *Progress to higher level degrees of Masters and PhD is an integral part of the Education and Training of Biomedical Scientists*

This standard has been achieved in the majority of EPBS countries. There is an urgent and pressing need to ensure a consistent standard of education and training across Europe to protect patient safety and to facilitate the European ideals of mobility for professionals.

2 EPBS Working Group on Education

The Working Group on education was established and approved during the General Governing Body meeting of 2014 in Dublin, Ireland.

The aim of this Working Group is to bring together the stakeholders in member countries where the level of education of Biomedical Science/Biomedical Laboratory Sciences has not yet reached the consensus standard, the first level of Bologna with a minimum of 180 to 240 ECTS (3 to 4 years of education) with integrated supervised clinical training in all European countries.

The names and affiliations of this working group are listed in Appendix 1

The current need to reform the education of Biomedical Science/Biomedical Laboratory Science in Germany, Spain and Switzerland offers an opportunity, and a challenge, to rethink the composition of courses in the designated areas of healthcare technologies, particularly in relation to the evolution of science and clinical-laboratory technologies applied to healthcare and research, promoting increased international harmonisation, particularly in Europe. Graduates must have the knowledge, skills and competencies to enter this demanding profession, the skill set to progress to

masters' level, with the capacity to participate in research and critically review findings. As reported in the Journal of the International Federation of Clinical Chemistry and Laboratory Medicine journal; "*As the science of laboratory medicine became increasingly more complex, a breadth and depth of knowledge was required prior to beginning entry level work. This ultimately led to the utilization of the higher education system in the US*".[9]

Professions spanning a matrix of science, technology and innovations that are constantly evolving require education programmes that prepare the graduates for the mental adaptability necessary in this constantly changing environment. This is particularly important in the field of Biomedical Science/Biomedical Laboratory Science where knowledge of pathophysiology is constantly evolving and the diagnostic methods and their interpretations must keep pace to support the clinical-laboratory in, screening, diagnosis, prognosis and monitoring of therapy based on the study of biological samples from whole organs to sub cellular level and to aid epidemiological research

It is clear that to respond to these demands the Biomedical Science/Biomedical Laboratory Science education must be at a higher education level and need to reflect:

a) A common scientific base, particularly with regard to laboratory investigation and analysis of biological phenomena
b) A deep understanding of the scientific basis of disease and the principles of the methods for analysis of biological samples.
c) Integration of models for interpretation of data arising from all biological samples from organs to sub cellular proteins and molecules
d) An awareness of the national and international mobility and employability opportunities, focusing on educating graduates who are versatile, capable of adapting to the fast pace of change in healthcare both in its structure and service delivery while maintaining the skills to embrace knew knowledge and methods.
e) Greater alignment to international standards, facilitating the recognition of training and professional skills and enhancing the transnational nature of the profession with particular reference to standardisation in Europe

Changing the education of Biomedical Science/Biomedical Laboratory Science in Germany, Spain and Switzerland, to adopt the first Bologna cycle along with other European countries will facilitate the identification of areas of specialisation to occur in the second cycle (Master level). This will allow graduates to explore the full potential of their knowledge, with the ability to capture new concepts of scientific and technological basis, having a focus on analytical research with regard to investigation of structural phenomena, morphological, biological, biochemical, molecular and epidemiological using biological samples.

This proposal, by involving a vast and complex framework of knowledge, skills, competencies, and references, should be developed in levels 6, 7 and 8 of the European Qualifications Framework (EQF).

- Level 6 for obtaining transversal skills (1st cycle - undergraduate, 180/240 ECTS credits);
- Level 7 to obtain skills in specific areas (2nd cycle - master with 60/120 ECTS credits);
- Level 8 to obtain vocation skills to the design, research and develop a body of knowledge on this area of healthcare.[6]

The European Association for Professions in Biomedical Science (EPBS) recommends the first level of Bologna as minimum standard (180-240-ECTS; three to four years), of higher education, with supervised clinical training included[3]. Corresponding to the European Qualifications Framework, level 6.[6]

Aligning the education and training of the Biomedical Science/Biomedical Laboratory Science in these three countries, the rest of Europe, should confer professional qualifications and skills certification, which will permit acceptance of credentials by scientific and professional organisations within the EU Community and at internationally, e.g. :

- Cytopathology, which is an occupation regulated by the International Academy of Cytology - International Board of Cytopathology;
- The profession of "Biomedical Laboratory Scientists or Biomedical Scientists", recognized by European scientific societies such as the Institute of Biomedical Science (IBMS) or the Health & Care Professions Council (HCPC) in the United Kingdom;

- The profession of Medical Scientist recognized by the Academy of Medical Laboratory Scientists of Ireland;
- The profession Biomedical Scientist/Biomedical Laboratory Scientist represented at European level by the EPBS and at international level by the International Federation of Biomedical Laboratory Sciences (IFBLS).

The standardisation and harmonisation of education for Biomedical Scientists throughout Europe would permit the use of the designation "BIOMEDICAL SCIENCES" and " Biomedical Scientist" as the common European designation for this profession, replacing the current inadequate one "Medical/Biomedical Laboratory Technician" http://www.ec.europa.eu/internal_market/qualifications/regprof/index.cfm?fuseaction=profession.regProfs&profId=1480

This is in convergence with models inspired in other European reference countries, in congruence with the identity of the different fields of study, maintaining an international professional identity.[3]

The EPBS Working Group on Education presents the following guidelines for Biomedical Science/Biomedical Laboratory Science study cycles. In doing so it aims to contribute to the enrichment of the course content, enhancement of the clinical practice training and raising the professional profiles of higher health education schools. In addition it seeks to increase its social mission by promoting a line of harmonious vocational education and training with scientific rigour at its core, to provide better care and health services to the community.

3 The First Cycle of Studies in Biomedical Science/Biomedical Laboratory Science

3.1 Designation

Biomedical Science/Biomedical Laboratory Science is a scientific area inherent in clinical-laboratory research, in order to support the analytical study of biological samples with regard to structural phenomena, morphological, biological, microbiological, biochemical and molecular, for the understanding of normal body function, recognition of pathological conditions and epidemiology, in man and other living beings.[8, 10]

The study of Biomedical Science/Biomedical Laboratory Sciences requires solid knowledge in a broad range of life, traditional and medical sciences, that will serve to support the acquisition of knowledge to enable a critical and valid interpretation of experimental results, conducting research projects, code knowledge and undertake good laboratory practices, in order to understand the importance of the laboratory in health and disease. This must include consideration of all aspects of healthcare, including safety, social aspects and ethics.

The degree in Biomedical Science/Biomedical Laboratory Sciences is characterised by a series of skills and competencies that are developed during the process of teaching and learning, according to a multidisciplinary curriculum.

Graduate Biomedical Scientists/Biomedical Laboratory Scientists are uniquely placed to work in clinical laboratories and undertake original and translational research as a result of their knowledge skills and competence in analysing all biological samples. They are specifically trained in the rigorous scientific method where attention to detail is paramount. In addition they are trained to recognise and distinguish the abnormal and pathological from normal variation.

There are several approaches to the education of Biomedical Science/Biomedical Laboratory Sciences. In our review different academic backgrounds were identified, for example the access to the profession requires additional clinical practice, as in England institutions, in which a Bachelor of three years does not confer professional certification, this is only obtained after an assessed period of clinical practice of twelve to eighteen months. In other countries the solution was the inclusion of clinical practice in the initial training, as in Ireland and Portugal. The duration of training varies, from 210 ECTS (3 ½ years) in Finland, up to four years in Ireland, Portugal and Canada. Although the duration of education in USA is of four years, to apply for a certification in Medical Laboratory Science, the training period is of at least 6 months within a total of eight semesters.[9]

The necessary training education for access to vocational certification in Europe is often 240 ECTS, with a minimum of 210 ECTS, and the recommendation of EPBS 240 ECTS points, including clinical practice."

The *EPBS* in their *Education Policy Document* approved at the *General Governing Body meeting* in Oslo 2009 recommend *EPBS recommends that education programs for Biomedical Scientists should equip graduates to be employed as decision makers in clinical laboratories. The programs should prepare graduates to participate in leading and developing the clinical laboratory service ensuring patient safety, quality assurance and scientific rigor. The minimum standard of education for Biomedical Scientists acceptable to EPBS is a Bachelor level or 1st cycle under the Bologna Process. The standard envisaged is a minimum of 4 years of higher Education (240 ECTS) including supervised clinical practice. Clinical Placement - before being registered or licensed for independent practice as Biomedical Scientist, candidates should undergo a supervised and assessed clinical placement*".[8]

In 2012, IFBLS approves Guidelines Regarding Core Competence and Core Curriculum, which advises: "IFBLS policy is that the education level for a Biomedical Laboratory Scientist/Biomedical Scientist should at minimum be equivalent of Bachelor of Science (180-240 ECTS points)".[10]

The trend that we have witnessed since the publication of our policy is a move to Bachelors level education with curricula that focus on scientific innovation in technology and evidence based laboratory medicine in most, but not all, European Union countries

The need for standardisation is highlighted by the inclusion of this profession among those regulated under the Community Directive 2005/36/EC of the European Parliament and Council, related to the recognition of professional qualifications and facilitating the free movement of professionals within the European Union.[3]

In examining the curricula in European Reference States (Finland, Ireland, Norway, Portugal, Sweden, UK and others) the EPBS Education Policy Document and IFBLS *"Guidelines Regarding Core Competence and Core Curriculum"*, the following common scientific areas to all emerge:

- Anatomical Pathology / Histopathology
- Clinical and Laboratory Haematology;
- Clinical and Laboratory Immunology;
- Clinical and Laboratory Microbiology;
- Clinical Biochemistry;

- Cytopathology;
- Forensic Pathology
- Molecular Pathology
- Transfusion Science

The matrix of education and training proposed here, addresses in a coherent fashion, the requirements for the analytical study of the structural, morphological, biological, biochemical and molecular characteristics of biological samples and epidemiological studies. This is the first cycle or undergraduate education and training required for a Biomedical Scientist/Biomedical Laboratory Scientist.

Based on the different training models in Europe for the education of this profession, the duration of the first training program in Biomedical Science/Biomedical Laboratory Sciences, should include 180-240 ECTS credits (3-4 years, 6-8 semesters), giving a set of skills that meet the needs of the most demanding labour market on laboratory medicine, which requires staff who are rigorous in application of technique while being versatile in thought and adaptable to meet changing circumstances:

a) Reasons and requirements related to the professional intervention model in these subject areas: problem solving; full functional autonomy; scientific and technical matrix; direct intervention in the human being (user/patient); interpersonal relationship with various audiences in various exercise contexts; demanding frames with reference to ethical principles;

b) Reasons for Scientific-Pedagogic nature: integrated teaching model; referenced with European professional profiles; solid background of scientific basis; specialty disciplines and use of complex analytical equipment; compulsory clinical laboratory placements;

c) Reasons inherent in the development of requirements and maturity of recent graduates, given the nature of professional practice: scientific and technological knowledge grounded in principles of ethical and moral nature, consolidated in a longer and accompanied period of time, thus, develop critical skills, scientific and professional autonomy and leadership;

d) Socio-economic reasons in the relationship/parity with other health professions: interaction, consistency, parity between different health professionals.

The study plan to be submitted for accreditation should be designed within the autonomy of each institution of higher education, and, necessarily, it is recommended to contain a range between the 45 to 60 training ECTS credits in a clinical laboratory placement, in a professional context, in health services and/or research centres.

3.2 General Education Objectives

The overall goal of training in Biomedical Science/Biomedical Laboratory Sciences is to provide graduates with qualification for independent and autonomous practice.

The degree of Bachelor of Biomedical Science/Biomedical Laboratory Sciences should provide the student with knowledge, skills and abilities necessary for professional practice, according to the European standard, maintaining and/or enhancing their duties, attributions, and responsibilities with autonomy.

To achieve this goal the student must undertake generic science subjects and add to them the matrix of Biomedical Science Anatomical Pathology / Histopathology, Clinical and Laboratory Haematology, Clinical and Laboratory Immunology, Clinical and Laboratory Microbiology, Clinical Biochemistry, Cytopathology, Forensic Pathology, Molecular Pathology and Transfusion Science

With this course, the graduate will attain greater professional mobility in the European and global space, as the access to the profession through the course of the first cycle.

The knowledge, skills and competencies necessary for access to professions are defined in the EQF. The current framework, as expressed already in previous paragraphs, provides that certain oriented and/or specialized skills, although covered in the first cycle, can be created in the second cycle, thus setting up a training level 7 EQF.[6]

Thus it is understood that:

a) Knowledge refers to the theory and the development of a critical appraisal of the theories and principles;

b) Skills reflect the cognitive knowledge (using a logical, intuitive and creative thinking) and practical (manual dexterity and handling equipment and tools), creating professionals able to solve complex and unpredictable problems in their field of expertise;

c) Competencies refer to the responsibility and autonomy conferred by a degree in Biomedical Science/Biomedical Laboratory Science, which enables graduates to make decisions and to take responsibility for management and professional development.

3.3 Knowledge

The Biomedical Scientist/Biomedical Laboratory Scientist must be able to demonstrate knowledge and understanding and to:

a) Master the key concepts of biological, physical, social and physiological sciences supporting the practice of laboratory Biomedical Science/Biomedical Laboratory Science applied to health;
b) Understand the structure and function of the human body, relevant to their professional practice, along with knowledge of health and its determinants: disease and dysfunction, as well as in physiopathology;
c) Understand the structure, function and metabolism of organs, cells, tissues and molecules involved in the physiological mechanisms in health and disease in order to identify and recognise cell, tissue and metabolic changes , relating them to the diagnosis, prognosis and therapeutic procedure;
d) Understand the structure, function and control of normal and abnormal genetic material associated with techniques of clinical and laboratory analysis and research;
e) Understand the immune response in health and disease
f) Understand the basic structure, classification and biochemistry of pathogens and forms of control;
g) Master knowledge related to genetics and heredity;
h) Understand the role of cell morphology and histology, biochemistry and clinical microbiology in the diagnosis and treatment of disease;
i) Understand the importance of a laboratory in the diagnosis and monitoring of specific disease conditions;

j) Evaluate laboratory tests using qualitative and quantitative methods that support the diagnosis, screening, health monitoring and disorders, as well as causes of death;

k) Understand the different constituent elements of the various biological samples in normal and pathological state,

l) Evaluating experimental data using statistical analysis.

3.4 Skills

The degree in Biomedical Science / Biomedical Laboratory Science must demonstrate skills in:

a) Essential practices in the areas of measurement, production and analysis of clinical and laboratory data;

b) Use diagnostic techniques and appropriate equipment correctly and safely;

c) Awareness of the need to validate and evaluate new methods of diagnosis before the routine use;

d) Demonstrate skills in the use of information technologies and adequate communication methods;

e) Know how the professional principles are expressed and translated into practice through a number of different forms of assessment, treatment and intervention approaches and how to select or modify these approaches to meet the needs of the individual;

f) Epidemiological and scientific research capacity and evidence-based practice, research and critically interpret scientific literature.

g) Keep up the foundations of professional knowledge, skills and attitudes, by identifying the need for self-directed learning throughout life, in order to promote the development of the profession;

h) Managing control and quality assurance in laboratories;

i) Carry out an assessment of professional practice and integrate audit teams in the field of biomedical science/biomedical laboratory science applied in health;

j) Leadership ability, initiative and creativity exercising their professional skills independently and on their own initiative.

k) Have adequate knowledge and skills in order to deliver opinions within its profession and field of activity;

l) Implement legislation and international standards regarding hygiene and safety in laboratories.

3.5 Competence

The graduate from a Degree in Biomedical Science/ Biomedical Laboratory Science shall be competent in the following:

a) Be able to collect and select the appropriate biological samples and the relevant procedures for clinical and laboratory needs;
b) Select, implement and evaluate specific techniques in histopathology, cytopathology, thanatology and immunohistochemistry;
c) Screening and make diagnostic opinions of cytological nature of products;
d) Evaluate qualitatively and quantitatively analytes to help the diagnosis, detection and monitoring of health and disease including the principles and methods used in clinical biochemistry;
e) Demonstrate skills in the practical application of instrumentation and specialised clinical and laboratory techniques;
f) Understand diseases and immunological disorders including the measurement principles of the immune response and the principles of organ transplantation;
g) Know the various components of the blood in normal and pathological condition; structure and function of the bone marrow; role, structure and function of erythrocytes, leukocytes and platelets; nature and diagnosis of anaemia; hemoglobinopathies, thalassemia and hematologic malignancies;
h) Proceed to the identification of blood group antigens and antibodies so that blood transfusion is completely safe; preparation, storage and use of blood components; selection of blood components and possible adverse effects; destruction of the blood cells by the immune system and on histocompatibility transplantation;
i) Select, implement and evaluate techniques used in the study of the genetic material, including causes and consequences of change;
j) Developing macroscopic and/or microscopic examination in cells and tissues as a disease indicators and further understand the role of cellular pathology diagnosis and treatment;

k) Select, implement and evaluate techniques for clinical-laboratory analysis of environmental microorganisms, physiological and pathogenic, their classification, structure and function, epidemiology of infectious diseases; antimicrobial and antiviral therapy; vaccination and immunization and chemical and microbiological analysis to water and food;
l) Apply knowledge of agents and molecular mechanisms implicated in the dysregulation of cell proliferation and differentiation and its consequences on the histological and cell behaviour;
m) Apply basic principles of forensic genetics, including transmission, heredity, and evolution lines; collection and identification of the biological sample and characterization of forensic traces;
n) Proceed to therapeutic monitoring;
o) Be able to validate the clinical-laboratory data and observations in accordance with pre-established quality standards;
p) Use standard operating procedures including in vitro diagnostic methods and in situ
q) Be able to identify and respond appropriately to the results of quality control, recognizing the risks and consequences of errors in results of clinical-laboratory tests;
r) Be able to design research and report scientific evidence, interpreting and presenting evidence, including the application of SI units used in biomedical practice;

The degree in Biomedical Science/Biomedical Laboratory Science, will provide the framework and will provide the core competencies adopted by IFBLS in 2012, presenting itself as a regulated health professional who[10]: *"is in the crossroads between the health disciplines and a deep understanding of technology for diagnostic purposes. The Biomedical Laboratory Scientist/Biomedical Scientist education and training make the profession unique compared to other professions in the medical laboratory in terms of: knowledge within quality assurance, evaluation of pre-analytical conditions and assessment and validation of medical laboratory analysis. The Core Competences for Biomedical Laboratory Scientist/Biomedical Scientists include a thorough understanding of the fundamentals of biomedical processes and the process of medical decision-making. This includes: development of methods, implementation of new methods, quality assurance of biomedical analysis, the analytical process from when an analyte is ordered, and the sample collection through to the validation and presentation of the result. The Core Competences for*

Biomedical Laboratory Scientist/Biomedical Scientists are built on scientific methods (evidence-based) and the ethics of patient care. The Biomedical Laboratory Scientist/Biomedical Scientist is an important linkage to healthcare professionals and the public for the use of safe and appropriate diagnostic testing".[10]

4 Framework Curriculum

The curriculum of the degree proposal in Biomedical Science/Biomedical Laboratory Sciences to present themselves around a competency framework identified for training in eight[6-8] semesters, must devote the first semesters to the acquisition of general and academic skills that underpin and establish curriculum development proposed for a larger, subsequent clinical-laboratory specificity resulting in a professional output around the following major area of knowledge:

- Anatomic Pathology / Histology
- Clinical and Forensic Pathology;
- Clinical and Laboratory Haematology;
- Clinical and Laboratory Immunology;
- Clinical and Laboratory Microbiology;
- Clinical and Laboratory Transfusion Science
- Clinical Biochemistry-Laboratory
- Cytopathology;
- Immunohistochemical and Molecular Pathology Technologies.

The curriculum structure and the relevance of four years for this training, relates to the need to provide the new graduate with a proper socialisation and integration from a professional point of view. The scientific, technological and human dimensions can only be consolidate for a longer period of contact training for the autonomous practice of clinical-laboratory skills. These assumptions are to be achieved by strengthening with the inclusion of courses that promote their

learning in clinical settings such as the completion of clinical laboratory placements, professional integration seminars and components of laboratory classes, to provide appropriate clinical and laboratory preparation in the various policy areas and the guarantee of the skills for the exercise of professional life.

The curricular units configuration must provide the student with a capacity-building for analysis, reflection and synthesis, criticism, self-criticism, communication, organization, integration in multidisciplinary teams, appreciation of diversity and multiculturalism and to develop skills to apply knowledge in practice , to learn, to adapt to new situations, innovation and entrepreneurship, as well as leadership and independent and autonomous work.

This frame of reference of knowledge, skills and competencies must converge the necessarily different areas of knowledge - biomedical science/biomedical laboratory science; specialty sciences; basic science; complementary sciences with the respective curricular distribution in Table 1 and also some optional areas of study as distribution presented in Table 2.[1]

To ensure greater coherence between the overall objectives it has been proposed for the first cycle of studies, a table of the distribution of the number of ECTS credits for the different areas related to the field of Biomedical Science/Biomedical Laboratory Science.

Table 1: Curricular structure obligatory for the 1st cycle in Biomedical Science

Scientific areas / Study Areas	%
Biomedical Science/Biomedical Laboratory Science (Study of biological samples; Clinical-Laboratory Biochemistry, Cytology, Clinical and Laboratory Haematology, Histology, Clinical and Laboratory Immunology, Clinical and Laboratory Microbiology, Pathology and Forensic Science, Transfusion Science Immunohistochemical Technologies and Molecular Pathology, Research, Clinical-Laboratory Stages)	69% to 80% (Including professional laboratory training)
Specialty Sciences (e.g. Anatomy, Physiology, Pathology	7% to 17%
Base Sciences (e.g. Biophysics, Biostatistics, Biochemistry)	10% to 17%
Complementary Sciences (CC) (e.g. Psychology sociology, bioethics)	2% to 4%

Table 2: Optional fields of study for the 1st cycle (bachelor) in Biomedical Science

Optional Areas	
Science education, communication, languages, information and communication technologies, management, nanotechnology, robotics, patient safety	0% a 4%

5 Operating Conditions: Specific Resources for Study Cycles

5.1 Human Resources

For accreditation purposes of a course of study in Biomedical Science, the faculty of the higher education institution provider must meet the following minimum requirements:

a) The institution must have its own faculty (full-time teachers, preferably in exclusive dedication) based on qualification in the predominant scientific area of the course of study to accredit (Biomedical Science/Biomedical Laboratory Sciences) and adequate in number of PhD or consisting of experts;
b) the Coordinator or Director of the undergraduate course of study, which includes the very faculty of higher education institution, should be a teaching doctoral or specialist, full-time basis, preferably in an exclusive dedication, qualified in the predominant area of training cycle studies;
c) the Coordinator or Director of a cycle of master's studies should be a doctorate in teaching full-time, specialized in the training area in question;
d) The institution must have half-time teachers, linked to the labour market (e.g. hospital, laboratories industry), based on qualification in the predominant scientific area of the course of study to accredit (Biomedical Science/Biomedical Laboratory Sciences) being recognized as specialists or with the adequate knowledge, skills and competencies to educate future Biomedical Scientists/Biomedical Laboratory Scientists.

For the purposes of verifying "their own teaching staff qualified in that area and adequate in number" referred to the law, ensuring that the teaching of all curricular units of study plans for Biomedical Science/Biomedical Laboratory Science, is undertaken by qualified teachers in the respective area of knowledge and the academic load is acceptable.

5.2 Requirements and Partnerships

The study cycles proponents (first and second cycle) in Biomedical Science/Biomedical Laboratory Science must have physical facilities suitable for teaching of the course, particularly in terms of clinical and pathological laboratories and information and documentation centres.

It must have the laboratory equipment, educational, scientific and clinical as well as the indispensable materials necessary for the good teaching of the course, including those relating to information and communication technologies.

For the purpose of ensuring the viability of the clinical and laboratory teaching, practice and internships classes, the existence of partnerships with other institutions, national and/or foreign and actions to promote inter-institutional cooperation is required. These actions are promoted with the outside environment, particularly with the public and private sector.

5.3 Reference Courses with Similar Goals in Europe

For this curriculum proposal for the first cycle model, it was taken as a reference to established practice in higher education institution in Europe, whose training and duration of the course is in agreement or related to the proposed, Table 3.

A reference featured in Europe is the training in "Biomedical Science" in the UK (Benchmark Statement for Biomedical Scientists - QAA9), training of Medical Scientists in Ireland and the course of Biomedicinska Analytiker in Sweden.

Details on courses in European and Non European Countries can be found in Appendix 2

It is noted that there are European countries where the initial training cycle is mostly presented with a duration of 4 years (240 ECTS credits), such as the Ireland, Greece Portugal[1] and UK. These tend to have an integrated clinical placement period thus the graduate is eligible to practice on graduation. In the case of Sweden and Finland, the course is not part of the traineeship, and in the latter case 3½ years (210 ECTS credits).

6 Specialisation

As already mentioned, the present proposal entails a strong coherence exercise concern among teaching models for the first and second study cycle. Thus, masters or post-graduate specialisation

courses must be configured to a deepening framework of knowledge, skills and abilities in areas less depth in the first cycle or in areas of greater demand for expertise.

6.1 The Second Cycle of Studies

For level and skills benchmarks for second cycle - Master, you should invest in a professional-oriented model of proposal (60-120 credits ECTS), corresponding to a coherent set of subject areas of clinical and laboratory expertise, matching greater demands for employment in the exercise of those professions (cumulatively in areas less depth in the first cycle and specialized training requirements or postgraduate titling requirements and international certification).

The second cycle should set up a diverse range of subject areas, assuming different names according to the area of specialization of knowledge and skills to be acquired, in the referential framework Biomedical Science/Biomedical Laboratory Science.

The structure of the study plans to be submitted for accreditation of second cycle courses, training in Biomedical Science/Biomedical Laboratory Science, should take into account the autonomy of each of the higher education institutions

6.2 Biomedical Scientist: Certified Specialist

At this level is important to professionals that can choose some specialization in working areas and obtain a certain specialist certification. This kind of certification should be academic and/or continuous during professional life and complement the daily work done by the Biomedical Laboratory Scientist. Academic specialisation should contribute to upgrade professional practice, and this specialisation must add value to laboratory work of each professional.

In the context of this training proposal in Biomedical Science/Biomedical Laboratory Science and respective specializations, it is suggested to bodies with responsibilities for the protection and regulation of professional practice and agents representatives of the professions and education, the creation and implementation of models and mechanisms of certification and re-certification of skills, in regular time cycles for the performance of quality assurance professionals in view of the most high standards in the provision of clinical and laboratory services.

In addition to purely academic higher education, Biomedical Scientists/Biomedical Laboratory Scientists could use Specialist Certification to systemise and document specialist skills. This will facilitate both employers and individual Biomedical Laboratory Scientist to focus on enhancing professional skills and knowledge.

A Specialist Certification following national or international standards will provide evidence of competence in a specialty discipline at a specified level of knowledge and practical experience, promoting in this way the formation throughout life as suggested in the work done at European project level referred to as EUCOLABS[11] which was recognized as a star project by the European Union.

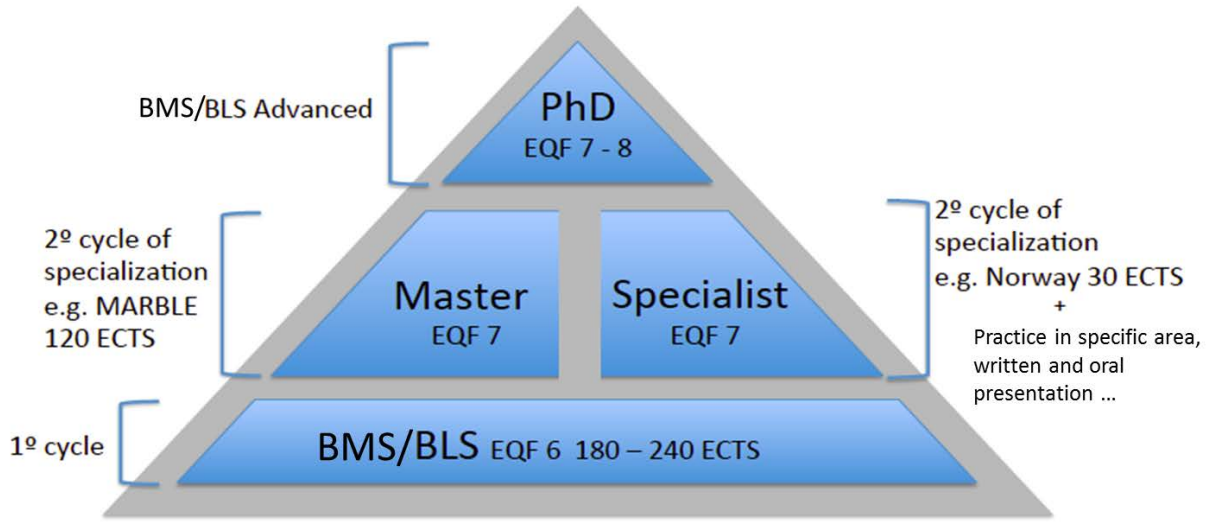

Figure 1: Education Pyramid for Biomedical Scientists/Biomedical Laboratory Scientist (BMS/BLS)

7 Conclusions

We can conclude, that countries currently teaching Biomedical Science/Biomedical Laboratory Science at the secondary level or post-secondary level, (but not at the higher education level) should rapidly change their education, to the first cycle of Bologna, with 180 to 240 ECTS (3-4 years) with clinical training supervised included.

By changing their education they are increasing student's mobility and the aims of the ERASMUS+ program. Contributing also to the free movement of professionals at the European Union, contributing in a unique way to the increase of the European identity of this profession as well as the goals of the European Union, this unique political, economic and sociological area.

The European Union Directive on the free movement of professionals defines levels of qualifications and outlines compensation measures permissible. All Biomedical Scientists/Biomedical Laboratory Scientists should be at level 6 of the European Qualification Framework.

Governments/Countries that decide to maintain Biomedical Science/Biomedical Laboratory Science students and professionals, at the level of secondary or post-secondary education, EQF levels 4 and 5, respectively, are in fact, making them “prisoners” of their own country, as it will be very difficult for them to have free mobility in Europe, with full recognition of their Professional qualifications as any other European Union citizen. They are also inhibited from access to the second and third level of education, Master degree and PhD degree, respectively.

These countries are in fact blocking Biomedical Science/Biomedical Laboratory Science to be at the cutting edge knowledge, skills and competencies. They are also depriving their citizens to the use of several European offers to develop this profession, opportunities like the European Joint Master Degree in Biomedical Laboratory Sciences that can contribute in a unique way to increase the patient care and safety in Europe.

It is a fact that we are incorrectly identified at the European Union Single Market, regulated professions database, identified as Medical/ Biomedical Laboratory Technician, the correct name should be at least Medical /Biomedical Scientist/Biomedical Laboratory Scientist.

Finally we conclude that by changing the level of education of biomedical Science/Biomedical Laboratory Scientists to higher education it is in the best interest of the patient, as they will be better cared, by better prepared Biomedical Scientists/Biomedical Laboratory Scientists, contributing to increase the efficacy and efficiency of the Health systems and the response level of the health care providers. Increasing in a unique way the European patient care and safety.

October 2015

General Governing Body of the European Association for Professions in Biomedical Science

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9 Appendices

Appendix 1: Constitution of the EPBS Working Group on Education

Fernando Mendes, General Secretary of EPBS (Portugal)

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Anneke Geurts, Director EPBS (Netherlands)

Annette Artelt (Germany)

Barbara Kappeller, Director EPBS (Austria)

Christiane Maschek (Germany)

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Hans Fleurkens (Switzerland)

Juan Carlos Rodrigues (Spain)

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Marianne Nordheim (Germany)

Marie Culliton, President EPBS, (Ireland)

Mickael Simul (Belgium)

Patricia Fernández (Spain)

Sonia Daadoucha Perroud (Switzerland)

Appendix 2: Examples of Courses in Biomedical Science/Biomedical Laboratory Sciences

Reference country	Designation Course	Nº years	Regulatory Authority	Source
Austria	Biomedizinische Analytik	3		http://www.fh-campuswien.ac.at/en/studies/health/bachelor/biomedical_science/overview/
Belgium	Medical Laboratory Technology	3	Need a "Visa" for work	http://www.khk.be/khk04/eng/opleidingen/bachelor/BioMedicalLaboratoryTechnology.asp
Belgium	Medical Laboratory Technologist	3		http://www.bvlt-abtl.be/Portal/9.php?taal=fr
Croatia	Bachelor of Medical Laboratory Diagnostics	3	University of Applied Health Sciences	http://www.zvu.hr/studij-medicinsko-laboratorijske-dijagnostike/?lang=en
Croatia	Bachelor of Medical Laboratory Diagnostics	3	University of Rijeka, Faculty of Health Studies	http://www.fzsri.uniri.hr/en/
Croatia	Bachelor of Medical Laboratory Diagnostics	3	University of Split, Department of Health Studies	http://ozs.unist.hr/studijski-programi/preddiplomski-programi/med-lab-dijagnostika
Croatia	Bachelor of Medical Laboratory Diagnostics	3	University of Osijek, Faculty of Medicine	http://www.mefos.unios.hr/index.php/en/studies/university-undergraduate-study-of-medical-laboratory-diagnostics
Denmark	Bachelor in Biomedical Laboratory Sciences	3 ½	National curriculum for the Bachelor's degree Programme in Biomedical Laboratorie Science	http://www.phmetropol.dk/English/Study+programmes/Bachelor+Programmes/Biomedical+Laboratory+Sciences
Estonia	Bioanalüütiku õppekava Biomedical Laboratory Science	3 ½		http://www.nooruse.ee/?id=989&lang=eng

Reference country	Designation Course	Nº years	Regulatory Authority	Source
USA	BS in Clinical Laboratory Science (BSCLS)	4	Board of Registry of the American Association of Bioanalysts	http://www.andrews.edu/academics/bulletin/2005-2006/cas/06-06-clinical_and_laboratory_sciences.pdf
Finland	Bioanalyytikon	3 ½		http://www.turkuamk.fi/public/default.aspx?nodeid=7563&contentlan=1&culture=fi-FI
Greece	Technological Educational Institute of Thessaloniki	4		www.teithe.gr
Ireland	Dublin Institute of Technology	4	Academy of Clinical Science and Laboratory Medicine	http://www.dit.ie/study/undergraduate/programmes/dt204/
	Cork Institute of Technology	4		http://courses.cit.ie/index.cfm/page/course/code/CR_SBISC_8
	Galway Mayo Institute of Technology	4		http://www.gmit.ie/medical-science/bachelor-science-honours-medical-science
Iceland	University of Iceland, Faculty of Medicine	4	BSc in Biomedical Science (180 ECTS) + Postgraduate diploma (60 ECTS) - total of 4 years	https://ugla.hi.is/kennsluskra/index.php?tab=skoli&chapter=content&id=24962&version=current
Italy	Universita' degli studi di Torino	3		http://www.unito.it/
	Universita' degli studi di Verona	3		http://www.univr.it/
	Universita' degli studi di Genova	3		http://www.unige.it/

Reference country	Designation Course	Nº years	Regulatory Authority	Source
Malta	Applied Biomedical Science	4		http://home.um.edu.mt/ihc/
Norway	Biomedical Laboratory Science			https://www.hials.no/eng/Home/Studies/Bachelor-programmes/Biomedical-Labratory-Science-Bachelor
	Biomedical Laboratory Science			http://www.uia.no/en/studieplaner/programme/BACBIOING
	Biomedical Laboratory Science			http://www.hib.no/studietilbud/studieprogram/bio/
	Biomedical Laboratory Science	3		http://www.hioa.no/Studier-og-kurs/HF/Bachelor/Bioingenioer
New Zealand	Medical Laboratory Science	4	New Zealand Medical Laboratory Science Board	http://www.otago.ac.nz/subjects/mels.html
	Medical Laboratory Science	4	New Zealand Medical Laboratory Science Board	http://study.massey.ac.nz/massey/students/studymassey/programme.cfm?prog_code=92410
The Netherlands	HBO	4	Domijn Applied Science (DAS)	www.appliedscience.nl
UK	Biomedical Scientists	4	Institute of Biomedical Sciences	www.brad.ac.uk
	Biomedical Scientists			www.brighton.ac.uk
	Biomedical Scientists			www.uwe.ac.uk
	Biomedical Scientists			www.bristol.ac.uk

Reference country	Designation Course	Nº years	Regulatory Authority	Source
	Biomedical Scientists			www.anglia.ac.uk
	Biomedical Scientists			www.cardiffmet.ac.uk
	Biomedical Scientists			www.chester.ac.uk
	Biomedical Scientists			www.cranfield.ac.uk/health
	Biomedical Scientists			www.ed.ac.uk
	Biomedical Scientists			www.essex.ac.uk
	Biomedical Scientists			www.caledonian.ac.uk
	Biomedical Scientists			www.gre.ac.uk
	Biomedical Scientists			www.keele.ac.uk
	Biomedical Scientists			www.kingston.ac.uk
	Biomedical Scientists			www.ljmu.ac.uk
Portugal	Ciências Biomédicas Laboratoriais	4		http://www.estsp.ipp.pt/site/index.php?m=128&s=y
	Ciências Biomédicas Laboratoriais			http://www.estescoimbra.pt/pt/cursos/detalhe/id/160
	Ciências Biomédicas Laboratoriais			http://www.estesl.ipl.pt/cursos/licenciaturas/ciencias-biomedicas-laboratoriais
Czech Republic	Medical School in Ostrava	4		www.zdrav-ova.cz/index_eng.html

Reference country	Designation Course	Nº years	Regulatory Authority	Source
Sweden	Biomedicinska analytiker			http://ki.se/utbildning/1ba13-biomedicinska-analytikerprogrammet
	Biomedicinska analytiker			http://ju.se/hhj/utbildning/program/grundutbildning/biomedicinsk-analytiker-inriktning-laboratoriemedicin.html
	Biomedicinska analytiker			http://www.hkr.se/sv/utbildningar/programsida/?pCode=nbbma
	Biomedicinska analytiker			http://lnu.se/utbildning/program/NGBAL
	Biomedicinska analytiker			http://edu.mah.se/sv/Program/VGBMV
	Biomedicinska analytiker			http://www.oru.se/Utbildning/Program/1213/?pid=79
	Biomedicinska analytiker			http://www.medfak.umu.se/utbildning/biomedicinsk-analytiker-programmet/
	Biomedicinska analytiker			http://www.uu.se/utbildning/utbildningar/selma/program/?pKod=MBM1Y&lasar=13%2F14
	Biomedicinska analytiker			http://www.miun.se/utbildning/program/biomedicinskanalytiker
	Biomedicinska analytiker			http://utbildning.gu.se/program/program_detalj/?programid=M1BMA .
(*) Course without integrated clinical training				