

Article

The training in Health Law: Academic Experiences in Brazil and Spain

La formación en Derecho Sanitario: experiencias académicas en Brasil y España

A formação em Direito Sanitário: experiências acadêmicas no Brasil e Espanha

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Abstract

Objective: To understand the training experiences in Health Law adopted in Brazil and Spain and reflect on their challenges, successes, and/or limitations, especially because it is a topic that has been little explored in academic-scientific literature. **Methodology:** The experience report method was adopted, using the storytelling technique, which allowed for the narrative of the course experiences in Brazil and Spain from the perspective and experience of their respective coordinators, without the inclusion of students or faculty in the narratives. **Results:** The study presented reports of experiences of a *lato sensu* course already consolidated in Brazil in the face-to-face modality and, to fill the educational gaps in the field of Health Law, it is also offered in the distance learning modality. The Spanish experiences, on the other hand, presented a traditional model of a *stricto sensu* course, with an academic and professional focus, offered to professionals in Law and Health, along with a modular distance learning option that allowed the acquisition of corresponding titles based on obtained credits. **Conclusion:** The consolidation of health as a right must assume a commitment to expanding the capacity of professionals in Law and Health to defend health interests. There is no doubt that training

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in Health Law is imperative for any professional working, directly or indirectly, with health-related issues.

Keywords: Health Human Resource Training; Health Law; Human Rights.

Resumen

Objetivo: conocer las experiencias de formación en Derecho Sanitario adoptadas en Brasil y en España y reflexionar sobre sus desafíos, éxitos y/o limitaciones; un tema poco explorado en la literatura académico-científica. **Metodología:** se adoptó el relato de experiencia, con el empleo de la técnica del storytelling, que permitió la crónica de las vivencias ligadas a los cursos en Derecho Sanitario en Brasil y España a partir de la visión y el bagaje de sus respectivos coordinadores, sin la inclusión del cuerpo estudiantil o docente en las narrativas. **Resultados:** el estudio da cuenta de un curso lato sensu ya consolidado en Brasil en la modalidad presencial y que, para suplir los vacíos formativos en el campo del Derecho Sanitario, también se ofrece en la modalidad de enseñanza a distancia; que se confronta con el acervo español, donde convive, por una parte, un modelo tradicional de curso stricto sensu, de carácter académico y profesional, ofertado para profesionales del Derecho y de la Salud, junto a una oferta en perspectiva modular, de enseñanza a distancia, que permite obtener los títulos correspondientes a los créditos curriculares superados. **Conclusión:** la consolidación de la salud como un derecho debe suponer el compromiso de ampliar la capacidad de los profesionales del Derecho y de la Salud para actuar en la defensa de los intereses sanitarios. No cabe duda de que la formación en Derecho Sanitario es imperativa para todo profesional que trabaja, directa o indirectamente, con los temas de salud.

Palabras clave: Capacitación de Recursos Humanos en Salud; Derecho Sanitario; Derechos Humanos.

Resumo

Objetivo: conhecer as experiências de formação em Direito Sanitário adotadas no Brasil e na Espanha e refletir sobre seus desafios, sucessos e/ou limitações, especialmente porque é um tema pouco explorado na literatura acadêmico-científica. **Metodologia:** adotou-se o relato de experiência, com o emprego da técnica de storytelling, que permitiu relatar a experiência dos cursos no Brasil e na Espanha a partir da visão e experiência de seus respectivos coordenadores, sem a inclusão do corpo discente ou docente nas narrativas. **Resultados:** o estudo demonstrou relatos de experiências de um curso lato sensu já consolidado no Brasil na modalidade presencial e que, para suprir as lacunas formativas no campo do Direito Sanitário, também é ofertado na modalidade de ensino a distância. As experiências espanholas, por sua vez, apresentaram um modelo tradicional de curso stricto sensu, de caráter acadêmico e profissional, ofertado para profissionais do Direito e da Saúde, e uma oferta em perspectiva modular, de ensino a distância, que permitia obter os títulos correspondentes aos créditos curriculares obtidos. **Conclusão:** a consolidação da saúde como direito deve pressupor o compromisso de ampliar a capacidade dos profissionais do Direito e da Saúde para atuar na defesa dos interesses sanitários. Não há dúvida de que a formação em Direito Sanitário é imperativa para todo profissional que trabalha, direta ou indiretamente, com os temas de saúde.

Palavras-chave: Capacitação de Recursos Humanos em Saúde; Direito Sanitário; Direitos Humanos.

Introduction

The recognition of health as a right, the result of a historical and progressive process of claims and conquests derived from emancipatory and social struggles in 19th century Europe, its gradual inclusion in the constitutional texts of the different countries, up to the contemporary debates on its effectiveness, demonstrate the complexity surrounding this issue.

As Bobbio states⁽¹⁾, the challenge of social rights is to guarantee their enforceability and, therefore, the States must recognize, in their national legal-normative statutes, the dimension of the obligation to fulfill them, which is not just a philosophical discussion or mere statements.

Since health is a dynamic area constantly challenged by technological, epidemiological, demographic and economic transformations, it requires States to build a specific legal and regulatory system capable of regulating actions and services aimed at providing and guaranteeing health for their citizens. It is this regulatory framework that will guide the State in terms of health care and the means to achieve the desirable health indicators for all.

The discipline in charge of studying the relationship between health and its link with the actions formulated and executed by the States is called Health Law. Health Law encompasses the human right to health and the legal-normative system oriented to the protection of people's individual health, as well as the ethical-normative approaches to the subject and the construction of public policies that make health something that citizens can enjoy. The discipline is anchored in an epistemological triad formed by the individual right to health, the public right to health and the ethical-normative relationship of individual and collective actions⁽²⁾.

In view of this, Health Law interacts with other fields of knowledge, being interdisciplinarity one of its main characteristics, especially in contemporary times of rapid technological evolution, scientific innovations and global social imperatives.

Thus, training in health law, whether in the *lato* or *stricto sensu* sense, has been gaining importance, since there is a need for specialized professionals capable of interpreting and applying the complex health regulatory framework associated with the health practices included in each of the systems adopted by the countries.

In this context, learning about the training experiences in health law adopted by the countries is an opportunity to evaluate the models and practices implemented, allowing reflection on their challenges, successes and/or limitations, especially because it is a topic little explored in the academic-scientific literature.

This study presents an account of three different health law course offerings: a *lato sensu* course, developed at the Health Law Program of the Oswaldo Cruz Foundation, in Brasília, Brazil; a *stricto sensu* training offering in Spain, carried out in classroom format at the University of Granada; and a modular proposal, offered in distance learning mode, by the National University of Distance Education of Spain.

Methodology

The experience story is a qualitative methodology whose central point is to describe and analyze specific practices, interventions or activities in a particular context, contributing greatly to the production of knowledge through the association between the experience described and the critical-reflective application of the academic-scientific environment⁽³⁾.

The narrative writing style was chosen because narrative is a prose textual genre that aims to tell a story, conveying emotions and ideas to the reader. This narrative style is also used as an information tool. The technique used was storytelling⁽⁴⁾.

The storytelling approach in this sense allowed the recounting of the experience of the courses in Brazil and Spain based on the vision and experience of their respective coordinators, without the inclusion of the student body throughout the narratives or the faculty members of the courses.

The stories also describe the successes and difficulties encountered in the offering and development of the courses and, when necessary, the clarification of the dynamics and mandatory educational regulations in the offering formats in the two different countries.

Results and Discussion

The Specialization Course in Health Law in Brazil: the experience of the Health Law Program of the Oswaldo Cruz Foundation.

The first group of the Specialization Course in Health Law offered by the Health Law Program of the Oswaldo Cruz Foundation took place in Brasilia, capital of Brazil, in 2002, and had the pedagogical support of the National School of Public Health-ENSP, a unit of Fiocruz focused on teaching at the graduate level. The precursor of these actions was researcher Maria Célia Delduque, who directed the Health Law Program until 2019, when she retired. Professor Sandra Mara Campos Alves, who succeeded her, is currently responsible for the coordination of Prodisa and the teaching actions deriving from the program, which is still fully active.

Inspired by the principle that legal tools are not only used for theoretical or philosophical formulations, but as real instruments of technical applicability in the reality of SUS, the *lato sensu* course, the only one offered free of charge in Brazil, is in its 11th on-site edition and aims to provide the student body with legal-political-health knowledge and develop expertise for understanding and acting in contemporary health issues, observing the regulatory framework in health⁽⁵⁾.

Training in Health Law in Brazil arose from the constitutional framework of 1988, which recognized health as a fundamental and social right and provided for the creation of a public health system with guidelines that privilege decentralization of actions and services, comprehensiveness with primacy of preventive actions and community participation⁽⁶⁾. This constitutional paradigm generated the need to establish a regulatory framework in accordance with the new legal situation and to train Law and Health professionals, who required specific knowledge to understand the complex legal-normative constellation of the health sector in Brazil.

The Specialization Course in Health Law arose, therefore, to fill a knowledge gap, by associating legal tools with collective health practices, with a view to strengthening actions, practices and institutions aimed at the promotion, protection and recovery of health, always with the objective of sensitizing the individual to be an agent promoting social change.

The target audience of the Prodisa/Fiocruz course is composed of legal professionals and operators of the Brazilian public health system, with different backgrounds: physicians, dentists, pharmacists, nurses, among others.

The course curriculum, which is generally updated over time to incorporate the innovations inherent to a dynamic area such as Health Law, is composed of two Learning Units - AU: (i) the first AU, with 236 classroom hours, is dedicated to the theoretical, legal and doctrinal frameworks of the Legal Sciences, with contents specific to Law from the perspective of Health. It is composed of the following disciplines:

- Introduction to Health Law (20 class hours);
- Public Health Policies (20 class hours);
- Constitutional Health Law (20 class hours);
- Participation in Health (20 class hours);
- Administrative Law and Health (40 class hours);

Health Regulation and Consolidation (20 class hours);
Civil Health Law (20 class hours);
Health Criminal Law (20 class hours);
Judicialization and Health Mediation (20 class hours);
International Law and Health (20 class hours);

Recently, the discipline of Special Topics was incorporated, with the participation of invited professors, national and foreign, who discuss contemporary issues that are not addressed in a theoretical discipline.

Learning Unit 2 - UA2, with a total of 92 class hours, is dedicated to disciplines typical of Collective Health:

1. Health and Disease (20 class hours);
2. Health Surveillance (20 class hours);
3. Environment and Health (20 class hours);
4. Bioethics (12 class hours);
5. Planning and Health (20 class hours).

The submission of a Capstone Project is mandatory for students. The project must be developed under the supervision of an academic advisor and defended before an evaluation committee.

The methodology for the elaboration of the Capstone Project is a discipline that integrates an autonomous learning unit, with 40 class hours. Focused on Empirical Law⁽⁷⁾, the discipline aims to stimulate students to seek data from reality, either in their daily work activities or in health care, and analyze them from the theoretical and methodological frameworks learned in the disciplines studied.

The teaching staff of the Specialization Course in Health Law has the collaboration of professors from the training institution itself, in addition to guests from renowned public and private universities in the country and prestigious entities in the health sector, as well as institutions of the justice system.

Since its first offer, at least 300 students have participated in our courses, with an excellent approval rate of the Health Law Specialists, with more than 200 works concluded and published in the form of articles and/or book chapters, available on the Internet and in the country's libraries.

In addition to the face-to-face course, Prodisa found it necessary to increase the coverage of the course, since the continental dimensions of Brazil do not allow interested students from several regions to travel to the capital to take the Specialization in Health Law. Faced with this challenge, it was decided to build a *lato sensu* distance postgraduate course, with 415 class hours.

In this modality, offers follow different rules from those of the free classroom course, since in order to be offered, there must be a demand from governmental bodies that finance the construction and offer of the courses, with places for more than 300 students at the same time.

The distance education model allows democratizing access to education, especially considering the vast Brazilian territory, since it enables the qualification of professionals who are located in remote regions and lack schools that offer specific courses in Health Law.

The first offering of the Online Specialization Course in Health Law took place in 2016, as a result of a partnership with the National Council of Health Secretaries (Conass), an entity representing the health sector of Brazil's 27 federative units. This course certified 160 workers from the Unified Health System (SUS).

In 2019, in partnership with the National Council of Municipal Health Secretariats (Conasems) and the Heart Hospital (Hcor), supported by the Proadi/SUS Program of the Brazilian Ministry of Health, the second distance course was held, with the same number of classroom hours and 200 students enrolled.

Despite being surprised by the Covid-19 pandemic, the course followed its normal schedule, with low desertion, being concluded within the deadline, with the defense of the course conclusion papers, which were subsequently organized in a book⁽⁸⁾. In 2023, Prodisa, with funding from the Department of Interfederative and Participatory Management of the Ministry of Health, held another Specialization Course in Health Law EAD, certifying 156 students from the five Brazilian regions.

Currently, a second group of this previous offer is underway, with 333 students enrolled, with the participation of health professionals and legal operators from strategic institutions of the country's justice system.

Thus, the Specialization Course in Health Law of Fiocruz Brasilia has established itself as an important pillar of training and dissemination of knowledge in an area relevant to the guarantee of fundamental rights, being the only permanent free offer in Brazil. The works of conclusion of the course are published in book format, edited by Prodisa/Fiocruz and available free of charge, or as scientific articles for open access journals, contributing to the academic-scientific production in the field of Health Law.

Master's Degree in Health Law, Bioethics and the right to health in the European Union: the experience of the University of Granada

The Master's Degree in Health Law, Bioethics and Right to Health in the European Union⁽⁹⁾, was an official postgraduate degree, accredited by the Directorate of Evaluation and Accreditation (DEVA) of the Andalusian Regional Government, which the Universidad de Granada offered from the academic year 2012/2013 to the academic year 2015/2016.

The management team of this Master's Degree has always been linked to the Department of Administrative Law of the University of Granada, the academic structure that promoted it. The promoter and coordinator of its first edition was Rafael Barranco Vela, *alma mater* and *vital element* of the program. After his death in 2013, Asunción Torres López took over the coordination. In all editions, Francisco Miguel Bombillar Sáenz was in charge of the Academic Secretariat.

This Master's Degree, which was developed over four academic years, was an advanced and specialized academic and professional training program in the field of Health Law, Bioethics and the right to health in the European Union, which could be taken by graduates or graduates in all those university degrees linked to the field of Social and Legal Sciences as well as Medicine and Health Sciences. Its ranks swelled from recent graduates in Law, Pharmacy or Economics to many professionals working as medical inspectors, forensic doctors or health management managers, as well as lawyers or university researchers.

The problems examined in this degree were approached from diverse and complementary methodologies and perspectives of analysis, even beyond the Legal Sciences themselves. The Master's Degree was marked by a strong interdisciplinary imprint, deploying a decided transversal and meta-legal approach to the subjects under study, corroborated by the plurality of curricula that supported the teaching of the contents that made up its Syllabus, with professors from a wide number of areas of knowledge, both from the University of Granada and from other Spanish and European Universities.

Among other universities, we can mention: Universidad Nacional de Educación a Distancia (UNED), Universidad de Almería, Universidad de Barcelona, Universidad de Bolonia, Universidad Carlos III de Madrid, Universidad de Castilla-La Mancha, Universidad de Córdoba, Universidad de Insubria, Universidad de La Laguna, Universidad de Lleida, Universidad de Málaga, Universidad Pontificia Comillas (ICADE), Universidad de Provenza y Universidad de Valencia.

Beyond the academic field, the Master had the participation of representatives and specialists linked to, among others, the following institutions: the European Medicines Agency, the Ministry of Health of the Andalusian Regional Government, the Andalusian Health Service, the Andalusian School of Public Health, the Pfizer-University of Granada-Junta de Andalucía Center for Genomics and Oncology Research (GENYO), the Institute of Legal Medicine of Granada, the Granada Health Sciences Technological Park, the Hospital La Inmaculada-ASISA, the Association of Health Lawyers, the High Court of Justice, the University of Granada, the University of Granada and the Andalusian Government, the Hospital La Inmaculada-ASISA, the Asociación Juristas de la Salud, the Tribunal Superior de Justicia de Andalucía, the Consejo Consultivo de Andalucía, the law firm Asjusa-Letramed, the Asociación de Economistas de la Salud, the Asociación de Profesionales de Informática Sanitaria de Andalucía or the ONGD Farmamundi.

This rich network of biosanitary structures at its disposal justified that Granada was the city chosen for the delivery of this degree. This was not only because the Andalusian Health Service was considered the largest company in the Andalusian region, providing healthcare to a territory inhabited by more than eight million people, but also because Granada, in particular, had already become, in those years, a benchmark in healthcare, biomedical research and new technologies applied to the field of health; which it had always been, moreover, in the legal field, since it is the judicial capital of Andalusia. The then emerging Health Sciences Technological Park of the city of Alhambra was a qualified exponent of the new challenges to which the Law could not turn its back, in addition to the already classic ones linked to health care (doctor-patient relationship) or public health. An unquestionable reality that showed how vital the training of health jurists was.

This Master's Degree was linked to the rest of the official postgraduate degrees offered by the Faculty of Law of the University of Granada, offering specialized, innovative, interdisciplinary and attractive training for a heterogeneous range of future operators in the field of biosanitation; It was adjusted to the professional interests not only of those who, as jurists, its main target audience, were going to work in the forum (without going any further, one of its graduates joined the Corps of Lawyers of the Health Administration), but also of those who, from the field of Medicine or Health Sciences, required this training complement to enrich or update their professional skills (providing them with basic tools for their daily work if, for example, they joined management positions).

Its ambitious and complete syllabus, to be developed over a single academic year, covered the following modules, including core and elective courses: health system and basic regulations; benefits; civil and criminal professional health responsibility; financial responsibility of the health administration; rights, duties and guarantees of patients and users; health organization and management; deontology and bioethics; health law in the European Union; labor relations of health personnel; legal regime of medicines and food; data protection and health documentation; legal and forensic medicine; genetics and research. This face-to-face teaching took place from October to May. The Master's sessions were held in the afternoon (from 5 to 9 p.m.), from Monday to Friday, and exceptionally on Saturday mornings (from 10 a.m. to 2 p.m.).

This Master's Degree could be completed in one year, by passing 60 ECTS credits. However, it was also possible for a student to enroll in several part-time editions, in a number of credits greater than or equal to 24 credits and no more than 42, in order to reconcile their studies with their professional and family life. The rules issued by the International Graduate School of the Universidad de Granada, the structure in charge of the administrative management of this degree, had to be followed.

The promoters of this Master's Degree sought to offer a solid educational offer, but at the same time rich in nuances, which, from a national, supranational and global perspective, would combine theoretical and practical training in core and basic, purely legal subjects (such as the legal responsibilities arising from the professional activity of health agents), with the acquisition of transversal and interdisciplinary knowledge through optional subjects and complementary training; In other words, they wanted the Master's Degree to offer, as a whole, a holistic, integral and quality training, which would facilitate the incorporation of its graduates into a highly competitive and demanding labor market.

The labor orientation of the Master was very broad, enabling its students to perform multiple professional profiles, which clearly constituted one of its great attractions. The Master was focused both on public service (at regional, state or European level) and on the professional practice of legal practice and consultancy (in health centers, insurance companies, pharmaceutical laboratories, professional associations or biomedical research centers, for example) or on the direction and management of health and hospital organizations. The management team and the Master's faculty went out of their way to show the students of this degree that there were many doors that could be opened after completing these studies.

The Master's program counted on the active collaboration of outstanding professionals who helped to develop various practical training initiatives to facilitate the labor market insertion and enhance the employability of these students. Among other innovative practices, we attended trials in which the Health Administration was a party in matters of health patrimonial responsibility or public employment, organized scientific-technical conferences with the Legal Counsel of the Andalusian Health Service and the Association of Health Jurists⁽¹⁰⁾ or visited centers linked to the world of health, where interviews were arranged with their top managers. All these activities, programmed with great care and encompassed under the slogan "the street in the classroom, the classroom in the street", provided these students with a broad overview of the sector.

Visits were made to the University Hospital of Granada, the Granada-Metropolitan Primary Care District, the Pfizer-University of Granada-Andalusian Regional Government Centre for Genomics and Oncological Research (GENYO), the Public Health System Biobank of Andalusia, the Mind, Brain, and Behaviour Research Centre (CIMCYC), the Assisted Reproduction and Reproductive Genetics Centre at the Inmaculada Clinic in Granada, as well as the Granada branches of the Institute of Legal Medicine, the Advance Healthcare Directives Registry, and the Andalusian Centre for Sports Medicine

Upon completion of the classes, in the research module, students were required to carry out a supervised research project (Master's Thesis - TFM) on a topic related to one of the research lines offered by the program, which had to be previously approved by the Master's Academic Committee.

The topics covered here ranged from the right to information in legal-healthcare relations to the legal regime of military health care, reactive medicine, biobanks, genetically modified foods, pharmacovigilance, doping in sports, telemedicine, direct-to-consumer genetic testing, private

management of public health services, *post-mortem* fertilization, counterfeit drugs, objection to abortion by health professionals and the responsibility of the Internal Medical Resident. The work could have a research profile (12 credits) or a professional profile (6 credits).

If the Master's degree was taken within the research branch, that is, the TFM of research profile (12 credits) and the subject of Methodology in research and legal science of 4 credits were taken, the student in question was enabled to carry out a Doctoral Thesis and obtain the title of Doctor. Not surprisingly, one of the objectives of this Master was the training of university teachers and researchers and many of its graduates are now professors in Spain, Colombia or Brazil.

The postgraduate training of a health jurist does not necessarily end with obtaining a Master's degree, but he/she can aspire to the highest academic degree that can be achieved in a university, acquiring advanced competencies and skills in the field of scientific research.

A Doctoral Thesis that could be framed (then and today) in this particular branch/specialty of the legal system that is Health Law. In fact, one of the lines of research of the Doctoral Program in Legal Sciences of the University of Granada⁽¹¹⁾, nourished by this Master at the beginning, as well as, later, by the ongoing research projects attached to this Faculty of Law, such as the OBE-S.O.S. project⁽¹²⁾, is devoted, very appropriately, to Health and Biotechnological Law.

Modular Program in Health Law and Biomedicine: The Experience of the Universidad Nacional de Educación a Distancia - UNED

The modular program in Health Law and Biomedicine is developed by the Department of Constitutional Law of the Universidad Nacional de Educación a Distancia - UNED⁽¹³⁾, in collaboration with the Escuela Nacional de Sanidad and the Instituto de Salud Carlos III, within the framework of the Instituto Mixto-Escuela Nacional de Sanidad (IM-ENS), through the Research Group Innovation, Research and Fundamental Rights, and was founded by Professor Yolanda Gómez Sánchez years ago, having been taught with great success.

The relevance that the development of health protection, and consequently of the provision of health care, and biomedical research have had in recent decades have motivated the need for specialized training in the field of health to respond to the profound transformations in both biotechnology and biosanitary, taking into account the profound legislative changes, both at national and supranational level, particularly at European level.

The training objective of this Modular Program is to facilitate the acquisition of a set of knowledge and competencies that allow the development of professional activities related to the subject, analysis and practical application of health legislation, as well as the legal framework of biomedical research.

The modular system allows the student to select the courses that best fit the profile and competencies he/she wishes to achieve and opens the door to the possibility of taking the modules progressively, obtaining the corresponding degrees successively. And, by using the distance learning methodology, the training can be taken by nationals (Spaniards) or foreigners who are interested in the subject.

The didactic material - syllabus, legislation, jurisprudence and exercises - is available on the course platform, with no obligation to attend face-to-face meetings. Although there is no obligation to attend in person, during the course sessions will be organized which the student can attend in person or follow online, both live and recorded, as well as video-classes.

The program consists of 21 modules:

1. Assisted human reproduction techniques: medical aspects (5 credits);
2. Psychology, Infertility and assisted reproduction (10 credits);
3. Legislation on assisted human reproduction techniques (10 credits);
4. Biomedical research (5 credits);
5. Biobanks (5 credits);
6. Clinical trials legislation (5 credits);
7. Bioethics and Human Rights (5 credits);
8. Bioethics in Clinical and Research (5 credits);
9. Ethics and Bioethics Committees (5 Credits);
10. Right to health. Health care (5 credits);
11. Patient rights: self-determination, privacy, equality, right to treatment (5 credits);
12. Information and consent. Clinical history (5 credits);
13. Data protection (5 credits);
14. Regulation on the beginning and end of life: abortion and advance directives (5 credits);
15. Organ donation and transplantation (5 credits);
16. Master's Thesis (10 credits);
17. European Health Data Space (5 credits/mandatory);
18. Law of healthcare Big Data and Artificial Intelligence (10 credits);
Neurotechnologies and human rights (5 credits);
20. The fundamental rights impact assessment of high-risk AI systems (10 credits);
21. Equality and algorithmic biases (10 credits/mandatory).

From the combination of the modules, students can obtain various qualifications from expert to master's degree. The Open Learning Certificate in Fundamental Rights Impact Assessment of High-Risk AI Systems is obtained by passing module 20.

The expert degrees are a total of 4: i) University Expert in Assisted Reproduction (15 credits): module 1 combined with modules 2 or 3; ii) University Expert in Biomedical Research and Law (15 credits): modules 4-6; iii) University Expert in Human Rights and Bioethics in Clinical and Research (15 credits): modules 7-9; iv) University Expert in Health Big Data Law and Artificial Intelligence in Biomedicine (15 credits): modules 17 and 18.

The modular system of the UNED also allows the offer of the title of Specialist in Patient's Rights (30 credits), being sufficient that the student is approved in modules 10-15.

For the master's degrees it is necessary for the student to take a total of 60 credits: i) Master of Continuing Education in Big Data Health Law and Artificial Intelligence in Biomedicine, the student must pass the 50 credits corresponding to modules 16-21 and also pass a total of 10 credits to choose between modules 7, 9 and 13; ii) Master of Continuing Education in Health Law and Biomedicine, the student must pass a total of 50 credits to choose between modules 1-15 and pass the 10 credits corresponding to module 16.

Of particular note are the two new offers - expert and master's degree - addressing the topics of big data and AI, which have been added more recently and arise from the need to reflect on the challenges and opportunities that, for health protection, healthcare and biomedical research, are posed by the digital transformation and the massive use of data, including future data spaces and in particular

the European Health Data Space. This remodeling of the offer responds to the impulse and activities of the following projects: ISAAC Chair. Individual Rights, Scientific Research and Cooperation, UNED - CNR/IFAC⁽¹⁴⁾ ; Jean Monnet Chair Governance and Regulation in the Digital Age, project 101127331, *GovReDig*⁽¹⁵⁾ , and Jean Monnet Module Empowering People in the European Health Data Space, project 101176286, *Empower-EHDS*, the last two funded by the European Union .⁵

This Modular Program in Health Law and Biomedicine provides specialized training in health protection, health care and biomedical research, in particular from a theoretical and practical perspective of the legal framework and legislation in force, both at Spanish national level and at supranational level, particularly at European and international level, and the qualifications that form part of it may be of interest to Graduates and Doctors in any of the branches of Health Sciences, in Law, in Political Sciences and to civil servants and workers in the public and private sector who develop their work and professional activity in the field of health and biomedical research and biomedicine in general.

Final considerations

The acquisition of information, skills and attitudes does not end in a formal course, whether in Brazil or in Spain, but must occur within the framework of a process of knowledge construction in which the subjects interact with each other and with the social and economic environment in which they live and act. This interaction, involving ideologies, commitments and interests, explicit or implicit, in the elaboration of information, in the selective focus of dimensions of reality and in the reactions to the stimuli and challenges of the environment, requires that the training and subsequent monitoring of the graduates allow for the consideration of the real and pluralistic conditions of interaction and the action that is intended to support and strengthen, in the field of Health Law.

Furthermore, the use of the contents addressed during a course should not be enough to qualify the performance of graduates throughout their post-course lives, but they should know how to seek knowledge and act on legal-legal bases in the face of the complexity and diversity of demands imposed by the health sector.

The development of analytical capacity and intervention in reality, the deepening of the topics addressed during the course, the monitoring of constant changes in legislation and in the situation of the sector, as well as the discussion of the problems identified from the practical application of the contents learned, require the creation of forms of continuing education and information for all those who work in the health area.

An effort to transmit information and knowledge is not enough; it is necessary to maintain continuous learning, conceived as a process in permanent construction, deconstruction and reconstruction of knowledge, attitudes and values. The courses must encourage research and the construction of knowledge in a permanent way, in confrontation with the ever-changing dynamics of the legal-health system.

As a positive effect of these courses, we highlight the necessary overcoming of the difficulties derived from the still scarce bibliography on this field of knowledge, in addition to the methodological

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techniques taught that confer the ability to solve problems in the daily work environment of our students.

The consolidation of health as a right must involve the commitment to expand the capacity of the various social segments to act in the defense of health interests, for which our students are fully qualified. There is no doubt that training in Health Law is imperative for any professional who works, directly or indirectly, with health issues.

Conflict of interest

The authors declare that there is no conflict of interest.

Authors' contribution

All authors contributed equally.

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