


Training and competency assessment of Clinical Embryologists and licensing of the profession in European countries[†]

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STUDY QUESTION: How is the acquisition and testing of theoretical and practical knowledge in Clinical Embryology and the licensing of ART laboratory personnel carried out in European countries?

SUMMARY ANSWER: Twelve out of 31 European countries have established some kind of verification of laboratory competency and skills in ART: in 7 countries, this was related to licensing, but where organized education for Clinical Embryologists existed, there were vast differences in the way these processes were undertaken.

WHAT IS KNOWN ALREADY: In 2015, a report by the ESHRE Embryology Certification Committee concluded that regardless of the large number of people working in IVF laboratories, Clinical Embryology was only recognized as an official profession in 3 out of 27 European national health systems. In most countries, Clinical Embryologists needed to be officially registered under an alternative profession and there were limited opportunities for organized education in this specialist field. Five years after this report, the ESHRE Working Group on Embryologist Training Analysis conducted a survey to collect detailed information about how Clinical Embryologists from different European countries are acquiring their theoretical knowledge and practical skills in ART, and how their level of education and competence in Clinical Embryology is verified.

STUDY DESIGN, SIZE, DURATION: Two questionnaires about the possibilities for acquiring the education and training needed to work in ART and verification of this knowledge were prepared by the ESHRE Working Group on Embryologist Training Analysis. The first was sent in 2020 to a panel of invited lead European Embryologists who attended an Expert Meeting held in Rome, Italy. In order to have a more comprehensive and updated picture, in 2021 the same survey was also sent to the ESHRE Committee of National Representatives (CNRs). At the end of 2021, the second survey with specific questions, more focused on Clinical Embryologists' training and licensing, was sent to the CNRs who reported on verification of education in Clinical Embryology.

PARTICIPANTS/MATERIALS, SETTING, METHODS: The first survey consisted of 17 questions. It was initially submitted to 14 lead Embryologists and then resubmitted to the 34 ESHRE CNRs. Representatives from 31 countries responded. A second survey with 23 questions was sent to the 12 ESHRE CNRs who reported an established national system of verification of education in Clinical Embryology, with specific questions focused on the training of Clinical Embryologists. All 12 CNRs responded.

MAIN RESULTS AND THE ROLE OF CHANCE: Analysis showed that European national education programmes in Clinical Embryology could be split into 4 categories: non-existent (13 countries), recommended (5 countries), simple compulsory (9 countries), and complex compulsory (4 countries). A national document stating the minimum education requirements for staff to work in an IVF laboratory was reported by 19 respondents. The requirement to follow a prescribed theoretical and laboratory training programme in ART was compulsory in 9 and 10 countries, respectively. Some form of verification of laboratory skills, theoretical knowledge in ART, and

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continuing professional development was required in 12, 10, and 9 countries, respectively. A national trainee's logbook format was reported by seven respondents and a national tutorial system was available in six countries. Only seven countries had official licensing of ART laboratory staff. The title of Clinical Embryologist was not recognized in 13 countries and in 6 countries, it was used only by professional bodies, while in 12 countries the profession was at least cited in governmental regulations. The ESHRE Clinical Embryologist Certificate was officially recognized in eight countries.

LIMITATIONS, REASONS FOR CAUTION: The survey took place in two steps and the results were then combined to provide a representative picture for most of the European countries sampled. The vast majority, but not all, of the CNRs answered the request to participate in the survey.

WIDER IMPLICATIONS OF THE FINDINGS: The professional recognition of Clinical Embryology within Europe is steadily evolving. However, it remains a concern that many countries continue to not recognize Clinical Embryology as a profession, with a vast difference in the reported organization of educational and training programmes and verification of skills. It is recommended that a training programme for Clinical Embryology and ART in Europe should be standardized and relevant issues should be addressed by competent authorities and European Union institutions. ESHRE is best placed to take a leading role in this educational process.

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Key words: ART laboratory / clinical embryologist / clinical embryology / education / ESHRE / licensing / training

Introduction

Most health professions undergo a well-developed form of organized training and trainees are given an introduction to routine clinical practice. Medical doctors, nurses, midwives, laboratory technicians, and similar healthcare professionals start training for their profession during undergraduate studies and continue with organized, supervised practical training during their internship or medical specialization. This includes rotation between departments to ensure that the expected skills are fully acquired. This method of introducing the trainee to practice, allowing them to gradually take on extra responsibility, is accepted as a proven way to maintain patient safety, uniformity of care, and standardization in treatment.

Some areas of healthcare also require postgraduate training for new staff with no previous exposure to a healthcare setting, such as clinical orientation, following the scientist-practitioner model. This includes psychologists, who only start specializing in clinical psychology after entering the healthcare system (Huey and Britton, 2002), and chemists, who specialize in clinical biochemistry (Jassam et al., 2018). Medical doctors also undergo specialization after initial study, and further training in subspecialist areas is also needed, for example in the field of Reproductive Medicine (Calhaz-Jorge et al., 2015).

ART laboratories have a specific role in the health system. These are therapeutic laboratories where laboratory staff work with living human material *in vitro* (tissues, gametes, and preimplantation embryos). After the gametes have been processed in the laboratory and fertilization achieved, the resulting preimplantation embryo(s) are transferred into the human body, often serving as a successful treatment for infertility. To accomplish these tasks, ART laboratories use sophisticated, highly technical equipment. The maintenance of standard laboratory conditions, as well as the manual skills, precision, persistence, and competence of Clinical Embryologists has a major impact on the final clinical outcomes of infertility treatment (Maggiulli et al., 2020; Hernandez et al., 2021). High inter- and intra-embryologist variability has been documented (Storr et al., 2017; Cimadomo et al., 2022). Furthermore, if non-conformities exist in the IVF laboratory, such as procedural or equipment errors (Sakkas et al., 2018), then suboptimal

laboratory conditions could potentially have a long-term impact on the health of offspring (Castillo et al., 2020).

The sensitivity of ART methods to a number of factors, including the strong influence of the Clinical Embryologists' skills, has been recognized by the European Directorate for the Quality of Medicines & HealthCare (EDQM). ART laboratories therefore fall under the strict regulation of the European Union Tissue and Cell Directives (European Parliament and the Council, 2004; European Commission, 2006). These directives state 'Personnel who work with cells and tissues, for human use, must be provided with initial/basic training, updated training as required when procedures change or scientific knowledge develops and adequate opportunities for relevant professional development. The training programme must ensure and document that each individual has demonstrated competence in the performance of their designated tasks and has an adequate knowledge and understanding of the scientific/technical processes and principles relevant to their designated tasks' (European Commission, 2006). However, no specifications on formal educational needs or training programmes are provided by the European Union (EU) directives.

Throughout the evolution of laboratory ART activities, it has been shown that the most common personnel working in ART laboratories are scientists with a natural science educational background, assisted by laboratory technicians. Medical doctors show less interest in working in laboratories owing to other commitments (Kovačić et al., 2020). At time of writing, there are about 7000 laboratory personnel working in European IVF laboratories (Kovačić et al., 2015).

Regardless of who does work in ART laboratories, as a whole, there is a lack of adequate ART education offered in undergraduate, postgraduate training, or specialization programmes. Such training can only be acquired through supervised practical work in a human ART laboratory. According to the ESHRE guidelines for good practice in IVF laboratories, 3 years of supervised practical work experience is needed for a trainee embryologist to finally be able to work independently in an IVF laboratory, while the head of the laboratory is expected to have as much as 6 years of IVF laboratory experience (ESHRE Guideline Group on Good Practice in IVF Labs, 2016).

Since 2008, ESHRE has been offering educational standards in Clinical Embryology with regular updates of the curriculum and recommended literature, theoretical knowledge testing in a two-level examination accredited by the Union Européenne des Médecins Spécialistes (UEMS) and their Council for European Specialists Medical Assessment (CESMA), and development of a scheme to record continuing professional development (CPD) for all certified Clinical Embryologists (Kovačić *et al.*, 2020). In 2023, ESHRE is also launching a programme to accredit European ART centres for the training of Clinical Embryologists (<https://www.eshre.eu/Accreditation-and-Certification/Accreditation-of-training-centres-in-clinical-embryology>; 10 December 2022, date last accessed).

The aims of this study were to clarify how the acquisition and testing of theoretical and practical knowledge in Clinical Embryology and the licensing of ART laboratory personnel is carried out in European countries, and to highlight the need to improve Clinical Embryologist training standards.

Materials and methods

Data collection

In February 2020, an expert meeting on the professional status of Clinical Embryologists and on formal forms of education in Clinical Embryology was hosted in Rome, Italy, by the Italian Society of Embryology, Reproduction and Research (SIERR). Representation was provided by 14 invited European experts in Clinical Embryology and the co-ordinator from the ESHRE Embryology Certification Committee (EmCC). Prior to the meeting, the organizing committee had prepared a questionnaire and sent this to the meeting participants. The invited participants were selected because of their roles in the professional bodies for Clinical Embryologists in their respective countries. The questionnaire was prepared using Survey Monkey (Momentive Inc., San Mateo, CA, USA), a free online survey tool. It consisted of 17 questions, including a mixture of close-ended (yes/no), numeric or multiple choice and open-ended questions. Some questions looked at the presence of putative standards to define the role of the Clinical Embryologist and whether a regulatory body or official national document defining the professional status existed. Other questions were focused on the educational level and training programmes needed to be considered for working as a Clinical Embryologist. The answers were elaborated and summarized in tables, which were presented and discussed during the expert meeting. All participants were asked to provide presentations to further explain the professional status and educational needs of their countries.

The proceedings of the Rome meeting and the preliminary results, which provided a small picture of the European Clinical Embryologists' situation in 2020, were analysed and discussed by the organizing committee. It was concluded that a wider involvement of all European countries under the auspices of ESHRE was needed in order to obtain a more comprehensive picture of the training needs for Clinical Embryologists in Europe. Following approval of the project proposal by the ESHRE Executive Committee, in the first trimester of 2021, the same questionnaire was sent to all 34 Basic Scientists and 6 Clinician representatives (the latter was for those countries where a Basic Scientist representative was not available) from the ESHRE Committee

of National Representatives (CNRs). CNRs from 31 countries answered the questionnaire.

The CNRs of only 12 countries (out of 31) reported some sort of organized education in Clinical Embryology at the national level. These 12 countries were highlighted as a reference to further explore the details of teaching, training, knowledge and skills verification, and licensing programmes. For this purpose, a second questionnaire composed of 23 close-ended (yes/no) or multiple-choice questions that were fine-tuned to the educational and training of Clinical Embryologists was then sent to these 12 CNRs.

Statistical analysis

The data provided in replies from the CNRs were presented in tabular form, by European country (Tables I and II). The tables contain affirmative and negative answers or offer descriptive options. The frequencies of similar responses were expressed in the results section as percentages. The answers to the open-ended questions are summarized in descriptive form in Supplementary Data File S1. More detailed information on the organized education in those countries whose representatives confirmed the presence of knowledge or skills testing is provided in Table II. The different approaches to organized education, training, and skills testing of Clinical Embryologists in European countries were categorized into four groups.

Results

Survey I

The results of the first part of the survey, comprising 17 questions, are shown in Table I. Representatives from 31 countries responded. The data showed that 19 of 31 European countries had a national document providing information about the minimum education requirements for staff to work in an IVF laboratory. The respondents most frequently mentioned a minimum MSc degree from Natural Sciences as a prerequisite to become a Clinical Embryologist (13/31), while in only 4 of 31 countries, a BSc degree was accepted. Exceptions were France, where only medical doctors were formally allowed to be lead Clinical Embryologists, and Turkey, where a PhD was required. For 17 countries, there was an official government document providing rules, while in 2 countries, it was only a recommendation from a professional body. In 12 countries, no description of the educational requirements for IVF laboratory staff existed.

There was a nationally prescribed educational programme for personnel working in the IVF laboratory in 13 countries, while 1 country (Portugal, without a national programme) recommended the ESHRE curriculum. In Greece, a MSc degree in Human Reproduction was compulsory. In Hungary, there were plans to make participation in courses organized by the Medical Faculty compulsory. In Portugal, the College of Biologists has taken the lead in awarding the title of Clinical Embryologist. In the UK, a Scientist Training Programme (STP) is supplied by the National School of Healthcare Science (NSHCS). Although participation in an STP is not compulsory, Clinical Embryologists have to register with the UK Health and Care Professions Council (HCPC) to use the title 'Clinical Embryologist', as this title is protected by UK law.

Table 1 Formal bases for education in Clinical Embryology and recognition of Clinical Embryologists in European countries.

	National document about education requirements for the staff that can apply for the work in an IVF laboratory	Minimum qualification to become a Clinical Embryologist, specified in national document	Body that issued national document about educational requirements for positions in the IVF laboratory (document type)	Any kind of prescribed educational programme for Clinical Embryology on national basis	Any kind of competence verification of laboratory staff	Recognition of Clinical Embryologist as a profession	Officially recognition of ESHRE certificate for Clinical/Senior Embryo logists
Austria	No	N.A.	N.A.	No	No	No	No
Belgium	Yes	MSc	Government (rules)	No	No	No	No
Bosnia and Herzegovina	Yes	MSc	Professional society (recommendations)	No	No	No	No
Bulgaria	Yes	MSc	Government (rules)	Yes	Yes	Yes (by the Government/ Competent authorities)	Yes
Croatia	Yes	MSc	Government (rules)	Yes	Yes	Yes (by the Government/ Competent authorities)	No
Czech Republic	Yes	MSc	Government (rules)	Yes	Yes (only for lab heads/deputies)	Yes (by the Government/ Competent authorities)	No
Denmark	No	N.A.	N.A.	No	No	No	Yes
Finland	Yes	N.A.	Government (rules)	No	No	No	No
France	Yes	MD and Lab technician	Government (rules)	Yes	Yes	Yes (by the Government/ Competent authorities)	No
Germany	Yes	MSc (defined by the Scientific Society, but not by the government)	Government (rules)	Yes	Yes	Yes (only by the Scientific Society)	Yes
Greece	Yes	BSc	Government (rules)	No	Partly	No	No
Hungary	No	N.A.	N.A.	No	No	No	No
Ireland	No	N.A.	N.A.	No	No	No	No

(continued)

Table I Continued

	National document about education requirements for the staff that can apply for the work in an IVF laboratory	Minimum qualification to become a Clinical Embryologist, specified in national document	Body that issued national document about educational requirements for positions in the IVF laboratory (document type)	Any kind of prescribed educational programme for Clinical Embryology on national basis	Any kind of competence verification of laboratory staff	Recognition of Clinical Embryologist as a profession	Officially recognition of ESHRE certificate for Clinical/Senior Embryologists
Italy	Yes	MSc	Government (rules)	Yes	No	Yes (only by the Scientific Society)	No
Montenegro	Yes	MSc	Government (rules)	No	No	Yes (by the Government/Competent authorities)	No
North Macedonia	No	N.A.	N.A.	No	No	No	Yes
Norway	No	N.A.	N.A.	No	No	Yes (only by the Scientific Society)	No
Poland	Yes	MSc	Government (rules)	Yes	Yes	Yes (by the Government/Competent authorities)	No
Portugal	No	N.A.	N.A.	No (ESHRE curriculum recommended)	Yes	Yes (only by the Scientific Society)	Yes
România	Yes	MSc, MD	Government (rules)	Yes	Yes	Yes (by the Government/Competent authorities)	Yes
Russia	Yes	MSc	Government (rules)	No	No	Yes (by the Government/Competent authorities)	No
Serbia	Yes	MSc	Government (rules)	Yes	No	No	No
Slovakia	No	N.A.	N.A.	No	No	No	No
Slovenia	No	N.A.	N.A.	No	No	Yes (by the Government/Competent authorities)	No

(continued)

Table I Continued

	National document about education requirements for the staff that can apply for the work in an IVF laboratory	Minimum qualification to become a Clinical Embryologist, specified in national document	Body that issued national document about educational requirements for positions in the IVF laboratory (document type)	Any kind of prescribed educational programme for Clinical Embryology on national basis	Any kind of competence verification of laboratory staff	Recognition of Clinical Embryologist as a profession	Officially recognition of ESHRE certificate for Clinical/Senior Embryologists
Spain	Yes	BSc	Professional society (recommendations)	No	No	No	No
Sweden	No	N.A.	N.A.	No	No	No	No
Switzerland	Yes	BSc	Government (rules)	Yes	No (qualification only)	Yes (only by the Scientific Society)	Yes
The Netherlands	Yes	MSc	Government (rules)	Yes	Yes	Yes (by the Government/Competent authorities)	Yes
Turkey	Yes	PhD	Government (rules), professional board/society (recommendations)	Yes	Yes	Yes (only by the Scientific Society)	No
UK	Yes	BSc	Government (rules)	Yes	Yes	Yes (by the Government/Competent authorities)	No
Ukraine	No	N.A.	N.A.	No	No	Yes (by the Government/Competent authorities)	No

N.A., not available; MSc, Master of Natural Science; BSc, Bachelor of Natural Science; MD, Medical Doctor.

[Supplementary Data File S1](#) provides details regarding the formal bases for education in Clinical Embryology and recognition of Clinical Embryologists in European countries.

Table II Differences in the type of organized education, training, and knowledge and skills verification in Clinical Embryology, and the licensing of laboratory staff in European countries.

	National body that is an initiator of organized verification of education in Clinical Embryology	National document with prescribed curriculum (theoretical knowledge) for trainees	National document with prescribed syllabus (practical training) for trainees	National document about minimum number of procedures to be supervised	National form of logbook for trainees	National document about tutorial system (defined criteria and roles of tutors)	National training of tutors	Organized examination of theoretical knowledge (name of organizer)	Organized verification of practical skills (name of organizer)	Organized verification of CPD (name of organizer)	Certification of IVF-laboratory staff in place (name of certification body)	Licensing of IVF-laboratory staff in place (name of licensing body)	Official qualification demonstrating acquired knowledge in Clinical Embryology means formal career advancement
* Bulgaria	Ministry of Health/University	Yes (mandatory)	Yes (mandatory)	Yes (2 years experience)	No	No	No	No	Yes (Employer/Competent authority/ISO)	Yes (Competent authority/ISO)	Yes (Employer)	No	Yes
Croatia	Embryologist Society, ISO	Yes (mandatory)	Yes (mandatory)	Yes	Yes	Yes	No	No	Yes (Embryologist Society)	Yes (mandatory) (Embryologist Society)	Yes (Embryologist Society)	Yes (Embryologist Society)	Yes
Czech Republic	Embryologist Society/ Professional Body	Yes (mandatory only for lab heads/deputies)	Yes (mandatory only for lab heads/deputies)	Yes	Yes	No	No	Yes, for lab heads/deputies (Expert body/ Ministry of Health)	Yes, for lab heads/deputies (Expert body/ Ministry of Health)	Yes, for lab heads/deputies (Expert body/ Ministry of Health)	Yes (only for lab heads/deputies) (Ministry of Health)	Yes (only for lab heads/deputies) (Ministry of Health)	Yes (only for lab heads/deputies)
France	University	Yes (mandatory)	Yes (mandatory)	No	No	No	No	Yes (Expert Body)	Yes (Institutional)	Yes (mandatory)	Yes (through diplomas)	Yes (Through the national council of the order of physicians or pharmacists)	No
Germany	Embryologist Society/ Professional Body	Yes (recommended by Embryologist Society)	Yes (recommended by Embryologist Society)	Yes	Yes self-produced	Yes (Embryologist Society)	Yes (official certificate of Embryologist Society)	Yes (Embryologist Society)	Yes (Expert Body/Embryologist Society)	Yes (not mandatory)	Yes (Embryologist Society)	No	Yes
Greece	Embryologist Society/ Professional Body	No (in progress)	Yes (mandatory)	Yes	Yes	No	No	Yes (Embryologist Society/ Professional Body)	Yes (institutional)	No (in progress)	Yes (Embryologist Society/ Professional Body)	No	No
Poland	Ministry of Health	Yes (mandatory)	Yes (mandatory)	No (only the time spent in training)	No	No	No	Yes, but not compulsory (Embryologist Society)	Yes (Ministry of Health)	Yes (not mandatory) (Professional Society)	Yes (not mandatory) (Professional Society)	No	No
Portugal	Professional Body (College of Biologists)	No (ESHRE curriculum recommended)	No	No	No	No	No	Yes, but not compulsory (Expert body)	Yes (Institutional)	No	No	Yes (College of Biologists)	Not necessary
România	Embryologist Society/approved by Ministry of Health	Yes (mandatory)	Yes (mandatory)	Yes	Yes	Yes	Yes	Yes (Expert body)	Yes (Institutional)	Yes (ESHRE)	Yes (Ministry of Health)	Yes (Ministry of Health)	Yes
The Netherlands	Embryologist Society/ Professional Body	Yes (mandatory)	Yes (mandatory)	Yes	Yes	Yes	No	Yes (Embryologist Society/ Professional Body)	Yes (Embryologist Society/ Professional Body)	Yes (Embryologist Society/ Professional Body)	Yes (Embryologist Society/ Professional Body)	Yes (Embryologist Society/ Professional Body)	Yes
Turkey	Ministry of Health	Yes (only for lab Directors)	Yes (only for lab Directors)	Yes (only for lab Directors)	Yes (only for lab Directors)	Yes	No	Yes (Ministry of Health)	Yes (Ministry of Health)	No	Yes (only for lab Directors)	Yes (only for lab directors) (Ministry of Health)	Yes
UK	Ministry of Health	Yes (mandatory, but depends on routes used)	Yes (mandatory, but depends on routes used)	Yes	Yes	Yes	Yes	Yes (Independent institution or University)	Yes (Ministry of Health)	Yes (Ministry of Health)	Yes (Ministry of Health)	Yes (Ministry of Health)	No

*Only the 12 countries that indicated that they had any kind of competence verification of Clinical Embryology from Survey 1 are included in this table. National Clinical Embryologist representatives from these countries were then invited to participate in Survey 2, and their responses are presented here.

CPD, continuous professional development; ISO, the International Organization for Standardization. Verification is performed by the national body that is a member of the international organization for accreditation bodies (ILAC) and accredits laboratories against ISO standards.

Mandatory courses in Clinical Embryology have also been reported from Russia. In Spain, some postgraduate degree studies, termed Master degrees, are organized by several IVF centres in collaboration with universities; however, these are not equivalent to a MSc title. A Turkish medical doctor with a specialization in Histology and Embryology within a Medical Faculty can be directly certified as a Clinical Embryologist; a Turkish biologist must have a PhD in embryology and 3 months of mostly self-funded training in ART in one of public medical institutions to become certified and have the possibility to then manage an IVF laboratory. Ukrainian embryologists are required to obtain 4 weeks of education annually in the National Medical Academy of Postgraduate Education to update their status to enable them to work as Clinical Embryologists.

Verification of competence and the knowledge of laboratory staff was reported for 12 countries, but the form of verification and the obligation to participate were heterogeneous. In 18 countries (see Table I), no such verification of competence of laboratory staff existed.

At present, the European health systems are still not united in recognizing the Clinical Embryology as a profession. In 13 countries, the title of Clinical Embryologist was not recognized at all, in 6 countries it was used only by professional bodies, while in 12 countries, the profession was at least cited in governmental regulations. Eight representatives mentioned that the ESHRE Clinical Embryologist Certificate is officially recognized in their country.

When answering the questionnaire, additional clarifications for specific questions were often provided by the respondents. These explanations are provided in [Supplementary Data File S1](#) and discussed below.

Survey 2

For the 12 out of 31 European countries where the profession included verification of knowledge or competence, the national Clinical Embryologist representatives were invited to participate in a second round of the survey. Their answers regarding the type of organized education, training, knowledge and skills verification in Clinical Embryology, and the licensing of laboratory staff are shown in Table II.

Where a national body was an initiator of organized verification of education in Clinical Embryology, this was a professional body of Clinical Embryologists for 19.4% (6/31) countries, an academic institution in 6.5% (2/31) countries, and the Ministry of Health for 12.9% (4/31) countries. In 22.6% (7/31) countries, some form of logbook was required for recording training. A national programme, defining the criteria (e.g. experience and qualifications) and roles of tutors, was present in only 19.4% (6/31) countries, while prescribed training for tutors was reported in only 9.7% (3/31) countries.

It was compulsory for trainees to follow a prescribed curriculum (theoretical knowledge) in 29.0% (9/31) countries, but only recommended in 16.1% (5/31) and absent in the remaining 54.9% (17/31) countries. Regarding practical training, a prescribed programme was compulsory in 32.3% (10/31) countries and recommended only in 3.2% (1/31) countries. Theoretical knowledge was reported to be assessed in 32.3% (10/31) countries, while verification of practical skills was reported for 38.7% (12/31) countries (see Table II).

The formats and the obligation for Clinical Embryologists to participate in an assessment of knowledge were diverse, as detailed in [Supplementary Data File S1](#). If carried out by a professional body, the

verification was only a recommendation, unless the professional body was authorized by the Ministry of Health to carry out the licensing itself (e.g. as in Croatia and the Netherlands). The verification of knowledge may be via an examination (e.g. as in Poland with a national exam or in the Netherlands, where the ESHRE certification exams are used for national licensing); via an interview (e.g. as in Portugal); or simply via a review of courses and congresses attended (based on certificates of attendance), logbooks, or key performance indicators by an expert body (e.g. as in Bulgaria and Ireland). In the case of France and Romania, the examination referred to an assessment of the knowledge acquired during study at the Faculty of Medicine and subsequent specialization. In Romania, biologists could also become Clinical Embryologists but only after passing an examination organized by the Order of Biologists under the auspices of the Ministry of Health. Turkey and the Czech Republic only had a compulsory examination for laboratory Directors and their deputies, respectively.

A scheme to verify CPD was reported in 29.0% (9/31) countries, but details of the CPD verification methods were lacking.

An award of a certificate of competence in Clinical Embryology was reported by 35.5% (11/31) countries: issued either by the clinic (one country), the Faculty (one country), the national Clinical Embryology professional body (five countries), or the Ministry of Health (four countries). The requirement for an official licence to work was reported by only seven countries: issued either by the Ministry (three countries), the Faculty (two countries), or the national Clinical Embryology professional body (two countries) (Table II).

An official qualification demonstrating acquired knowledge in Clinical Embryology automatically meant formal career advancement in only seven countries.

We grouped the types of educational programmes in Clinical Embryology described into four categories:

- non-existent (13 countries);
- recommended voluntary programmes in which some national elements existed (e.g. theoretical curriculum, minimum number of procedures or years of experience, certification: five countries);
- simple compulsory programmes with some compulsory elements (e.g. attending academic courses, short training, following the curriculum, minimum number of procedures, simple verification of competences, certification: nine countries);
- and complex compulsory education in line with medical education standards (four countries).

In Table III, we describe the main characteristics of each of the four categories and attribute the countries where this type of education verification was practised. The variability in education in Clinical Embryology is presented in the map of Europe (Fig. 1).

Discussion

Education requirements for Clinical Embryology

In this survey, we were interested to know whether any national official documents existed to describe the conditions required for training and competence assessment for the position of a Clinical Embryologist in Europe. Representatives from 19 out of 31 European countries

Table III Current forms of education and training in Clinical Embryology in European countries.

Type of education and training	Countries using this type of education and training
Non-organized	Austria, Belgium, Bosnia and Herzegovina, Denmark, Finland, Hungary, Ireland, Montenegro, North Macedonia, Norway, Slovakia, Slovenia, Sweden
Recommended	Germany, Italy, Serbia, Spain, Switzerland
Simple compulsory	Bulgaria, Croatia, Czech Republic, Greece, Poland, Portugal, Russia, Turkey, Ukraine
Complex compulsory and in line with medical education standards	France, Romania, Netherlands, UK
<ul style="list-style-type: none"> ● Registration as a trainee in a recognized training centre, curriculum, courses, exams, syllabus, logbook for each year, registered tutor-guided training, continuing verification of skills, maintaining continuing professional development, related to the diploma, work licence and licence renewal <ul style="list-style-type: none"> ○ Medical specialization, e.g. Clinical Biology ○ Organized complex education and verification of competences by specialized authorities (government or authorised expert body) ○ Scientist to practitioner model of specialization 	

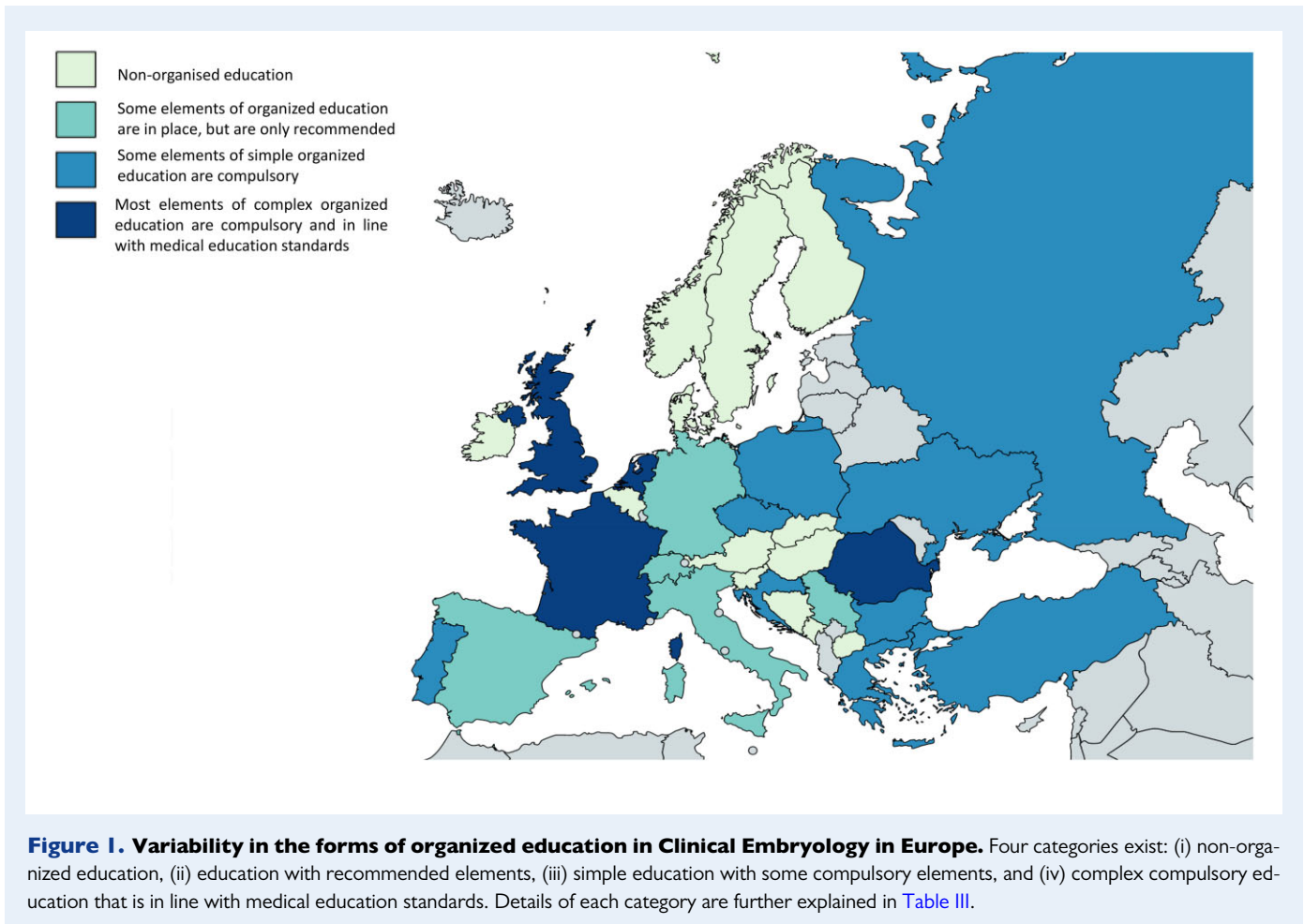
reported at least some form of national document on minimum education requirements, accepting that this could be a modest description of only the necessary basic level of education. In reply to the open-ended question on this topic, respondents most frequently mentioned a minimum MSc degree from Natural Sciences as a prerequisite.

From an analysis of the applications for the ESHRE certification examinations in Clinical Embryology (Kovačić *et al.*, 2020), it was also evident that the majority of Clinical Embryologists are from different MSc backgrounds in Natural Sciences: 43% biologists, 15% biotechnologists, 10% biomedical scientists, 60% other related profiles (biochemists, laboratory technologists, microbiologists, medical technologists, veterinarians, pharmacists, etc.), and 7.8% are medical doctors. The staffing structures of the ART laboratories were established and have evolved over the past 40 years of operation, and have proven to be appropriate and successful. Clinical Embryologists, with their scientific skills, represent a rich scientific development-oriented core of medically assisted reproduction (MAR), and are the most numerous group of all ESHRE Special Interest Groups, also submitting the highest number of scientific papers to the Annual Meetings of ESHRE, as reported at ESHRE General Assembly meetings. Only one country insists on

different staffing requirements; in France, it was stated that only health professionals are allowed to work in ART laboratories and thus only medical doctors (and laboratory technicians) can work in ART, and the position of the lead Clinical Embryologist must be filled by a medical doctor.

In an initial survey, the EmCC investigated the status of Clinical Embryology across European countries. From surveys conducted in 2013–2014, it was found that ART laboratory staff are trained in a largely unorganized way, almost exclusively by acquiring technical knowledge from their more experienced colleagues (Kovačić *et al.*, 2015).

This current survey, conducted almost 10 years later, focused on the forms of education in Clinical Embryology. The survey began by asking if any kind of prescribed educational programme for Clinical Embryology existed on a national basis. An affirmative answer came from 13 countries. Mandatory following of a prescribed programme was reported by nine countries (Bulgaria, Croatia, Czech Republic, France, Poland, Romania, the Netherlands, Turkey, and UK). This indicates some improvement in the educational status of laboratory staff: in 2013/2014 (Kovačić *et al.*, 2015), only four countries reported



having mandatory organized postgraduate education or training for independent work in IVF laboratories (France, the Netherlands, Turkey, and UK).

Recognition of the profession

Another important issue in this analysis was the format of the skills assessment of laboratory staff. Some form of competency checking was reported from 12 countries; therefore, we decided to carry out a second round of more detailed analysis of this area in these specific countries. It is likely that the absence of any form of competency checking is the reason why the title of Clinical Embryologist is recognized, or at least mentioned, in one of the official documents of the Ministries of Health in only 35.5% (11/31) of European countries. This proportion is much higher than the data from 2013/2014, when only 11.1% (3/27) European countries recognized the profession of Clinical Embryology (Kovačić et al., 2015).

It is difficult to verify how the ESHRE certification for Clinical Embryologists is officially recognized, as reported from seven countries. It is used by individuals or clinics as proof of competence, as authorities increasingly ask for this evidence during inspections. However, as the respondents indicated, the ESHRE certificate is still most often used by individuals to obtain a job or to fill a more valued position within a team. As a self-teaching programme, the ESHRE certificate is

still considered the most globally accepted form of education in Clinical Embryology.

Forms of organized education, competency testing, and licencing in Europe

According to the UEMS standards, an organized education, along the lines of other healthcare profiles, should include prescribed theoretical knowledge (curriculum), a training programme (syllabus), a tutorial system with prescribed criteria for tutors, a logbook, an independent system for checking theoretical knowledge and practical skills, competence assessment once trained, and CPD. All of these should be linked to licencing and regular renewal of the licence (<https://www.uems.eu/areas-of-expertise/postgraduate-training/european-standards-in-medical-training>; 10 December 2022, date last accessed).

The Clinical Embryology tasks undertaken in the therapeutic ART laboratory have become increasingly complex. Laboratory performance affects the sensitivity of gametes and embryos, and there are strict regulatory standards for the quality and safety of tissues and cells used for human application. Since the role of the Clinical Embryologist directly influences the outcome of any MAR treatment, it is reasonable to consider that these UEMS recommendations are applicable to ART laboratory personnel. However, this kind of training organization is complex. Not all ART centres are able to implement it, and often the

countries themselves would have difficulties in setting up such a system. This is the reason why the medical specialties in some national systems adopt European examinations and other forms of competency assessment. Such a strategy allows training and competence assessment to be administered by accredited technical organizations or institutions specialized in this activity (<https://www.uems.eu/european-examinations/cesma-appraisals>; 10 December 2022, date last accessed).

The monitoring of governance and licensing for the staff working in ART laboratories should be carried out by relevant authorities. Different methods of competency assessment can be used for licensing personnel working in ART, such as certification, examination, continuing education, periodic reporting and on-site inspection, or a combination of these methods.

A survey like ours has recently been carried out at a global level (*International Federation of Fertility Societies' Surveillance (IFFS, 2022)*). From the perspective of our study, it is interesting to compare these global data on verification of the competence and licencing of professionals potentially working in ART laboratories. The main IFFS questions on this topic related to the type of licensing criteria for physicians with advanced training in reproductive endocrinology and infertility (REI), ART laboratory Directors and ART laboratory technical staff, and how the monitoring of governance and licensing was carried out. Of the 90 countries that provided information, 57% of the respondents reported that REI physicians with specialized ART training must be licensed and only 28% reported that certification, examination, or continuing education was needed. For ART laboratory Directors and ART laboratory technical staff, these proportions were much lower since 38% and 30% of respondents, respectively, reported about specific licensing requirements in their countries, of which 31% and 24% noted the requirement of certification or examination or continuing education. Data for Europe were very similar, with 39% (13/33) of countries having established criteria for the ART laboratory Director and only 24% (8/33) for ART laboratory technical staff licensing (*International Federation of Fertility Societies' Surveillance (IFFS, 2022)*), which is in concordance with our results.

Our survey showed that, in particular, certain national professional bodies for Clinical Embryology have tried to improve the educational status of Clinical Embryologists. Nine countries have a mandatory nationally prescribed curriculum to follow. However, it is not known how complex this is and whether it is also linked to a test of theoretical knowledge, following the example of the ESHRE Clinical Embryologist Certification Programme.

Some kind of theoretical knowledge testing was carried out in only 10 countries, where this was either performed by the Ministry of Health or a professional body.

The obligation and the formats of the examination were not known. Preparing examinations in fields of medicine requires experienced professionals with education skills. It is also essential to follow accepted standards in the preparation of such medical examinations, which include regular control through the tracking of quality indicators (*Kovačić et al., 2020*). The ESHRE EmCC has more than 10 years of experience in this field and the quality of the examinations has been verified through the UEMS-CESMA accreditation process. This offers an ideal opportunity for countries to use the ESHRE Clinical Embryologist Certification Programme for national purposes, as is the practice in many European medical specialties, with respective

programmes provided by their European specialist professional bodies. In some European countries, such as the Netherlands, ESHRE Clinical Embryologist Certification has been incorporated into national licensing of Clinical Embryologists.

Today, it is incomprehensible that, for such a sensitive area as the laboratory procedures used in ART, European medical education providers do not require uniform testing of the basic knowledge, competences, and skills of professionals working with human gametes and embryos. It is commendable that Clinical Embryologists in such large numbers are opting to apply to sit the ESHRE certification examinations in Clinical Embryology on their own initiative. In some countries, the involvement of academic institutions in providing minimum education in Clinical Embryology has also been reported. For example, in the Czech Republic and Serbia, a 5-year MSc programme in Clinical Embryology has been opened; however, attendance at these programmes is not compulsory to work as a Clinical Embryologist. The authors are unaware if there are other similar courses in Clinical Embryology in Europe, as the interviewees did not report such compulsory forms of education.

We believe that involvement of academic medical institutions in the provision of theoretical knowledge in the form of lectures is certainly a welcome approach to education. However, these institutions often have no link to the clinical work of ART and would therefore find it difficult to take on complete practical training and verification of competences of Clinical Embryologists. As Hamilton and Carachi noted, Reproductive Clinical Embryology and ART laboratory techniques remain poorly represented in university curricula and even in classical medical specializations (e.g. histology and embryology) (*Hamilton and Carachi, 2014*).

The syllabus for the practical part of the training has been defined in 10 countries, but the extent of the syllabus varied. For example, it is possible that interviewees may have answered »yes« to this question in cases where only time spent in an IVF laboratory or a minimum number of procedures performed may have been defined, similar to the requirement for ESHRE certification. In fact, a tutorial system was defined in only six countries, while a logbook was required in seven countries. We did not link the question about compulsory or voluntary or recommended training to a distinct question about duration, which of course is a crucial point. An example is the simple compulsory training in Turkey, which requires only 6 months, while the recommended training in Germany takes 3–4 years.

Verification of practical competence at a national level is a challenging process. Most often, it involves the submission of a logbook, signed by the tutor, to an authority. No country reported an actual examination of the hands-on skill other than a logbook sign-off to confirm the practical task had been completed. Evidence of competence was reviewed by the Ministries of Health in four cases and by experts from professional bodies in three cases. Mandatory supervised practice in a clinical ART laboratory accredited for training is a necessary element of practical training and it was this aspect that was most often missing. ESHRE EmCC members have identified this education gap over the years of Clinical Embryologists certification and have therefore developed a syllabus of modules for two-level training in ART laboratory activities (<https://www.eshre.eu/Accreditation-and-Certification/Accreditation-of-training-centres-in-clinical-embryology>; 10 December 2022, date last accessed). It is hoped that, in the future, this ESHRE syllabus will be adopted as the standard for practical training for ART

laboratory staff. This would seem to be a natural progression beyond the established ESHRE curriculum and certification of the theoretical knowledge of Clinical Embryologists.

Owing to the rapid advances in medical science, the Continuing Medical Education (CME) system, or more commonly called CPD, based on credit points is now used as the standard for the manifestation of competence maintenance. Such a CPD system is also in place for ESHRE Certified Clinical Embryologists (<https://enmcp.eshre.eu/page/eshre-cpd-credit-system>; 10 December 2022, date last accessed). CPD as a mandatory system for demonstrating competence was used by six of the seven countries that had introduced mandatory licensing or certification of embryologists.

Range of existing national education systems and need for improvement

The results of the survey therefore provide an overview of the current systems of Clinical Embryology education in Europe, ranging from almost non-existent systems in 42% of countries, recommended education by following a prescribed curriculum in 16% of countries, a simple but compulsory system in 29% of cases and only 13% of examples (four countries) of a mandatory complex system of education with all the necessary elements typical of medical specialties. A highly formalized education standard for licensing only exists in France, Romania, the Netherlands, and UK. Some compulsory courses are provided in Bulgaria, Croatia, Czech Republic, Greece, Poland, Portugal, Russia, Turkey, and Ukraine. However, education in Clinical Embryology is only 'recommended' in the following European countries (sometimes via the national professional body for Clinical Embryologists): Germany, Italy, Serbia, Spain, and Switzerland. Many more countries provide no educational opportunities at all, among them central European countries, (including Austria and Belgium), several northern European countries (Norway, Sweden, Finland, Denmark, and Ireland), and also eastern European countries (for example, Bosnia and Herzegovina, Hungary, Montenegro, North Macedonia, Slovakia, and Slovenia).

The lack of regulation and unrecognized importance of education still places Clinical Embryologists in an unequal position compared to other members of the medical team or related profiles in healthcare: this is the reason for the constant calls by different embryological societies for standardization of education curricula and syllabi ([Alpha Scientists in Reproductive Medicine, 2015](#); [Kovačić et al., 2015](#); [Practice Committees of the American Society for Reproductive Medicine \(ASRM\) and the Society for Reproductive Biologists and Technologists \(SRBT\), 2022](#)).

Standardized and regulated education, following the example of other health professionals trained in the health system, is the basis for ensuring patient safety. Inadequate treatment of patients or their biological material may result from inadequate training of professionals for this type of work. However, as the literature cited states, 'the problem is not bad people in healthcare—it is that good people are working in bad systems that need to be made safer' ([Institute of Medicine \(US\) Committee on Quality of Health Care in America, 2000](#)). A need to standardize training and competence of Clinical Embryologists is therefore evident, not only in Europe but also across the globe.

Conclusion

Despite remarkable progress in Clinical Embryology education in Europe in the last 10 years, mainly thanks to the initiatives offered by professional bodies representing Clinical Embryologists, such as ESHRE, most countries still do not have any organized form of education and embryologists are left to self-educate. Among the countries where attempts have been made to regulate the field of Clinical Embryology, the forms of education are very heterogeneous and lack standardization to prepare the worker for work in the health system. Although academic institutions are involved in the education of Clinical Embryologists by offering lectures on embryology, these formats are not comparable to the educational standards required in the health sector.

A review of the state of the art in the field of education and Clinical Embryology in Europe was necessary and serves as an overview of the needs before the introduction of the new ESHRE programme of organized training in Clinical Embryology in certified training centres. ESHRE thus follows the highest regulatory standards of medical education by providing a formal route for this missing part of training for Clinical Embryologists. As such, the new embryology programme complements the existing training in Reproductive Medicine for clinicians (<https://www.eshre.eu/Accreditation-and-Certification/Accreditation-of-training-centres-in-clinical-embryology>; 10 December 2022, date last accessed). This new ESHRE system, together with the assessment of theoretical knowledge and CPD, fills the current gaps in complete training and education in Clinical Embryology.

Supplementary data

Supplementary data are available at *Human Reproduction Open* online.

Data availability

All data are incorporated into the article. All answers of respondents are available from the corresponding author.

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Authors' roles

B.K. coordinated the preparation of the questionnaires and writing the manuscript. C.S. and L.D.S. organized a round table with experts in Clinical Embryology on the issue of education of Clinical Embryologists in the framework of the Italian Society of Embryology, Reproduction and Research (SIERR) national meeting in 2020. B.K. and B.J.W., as members of the ESHRE Certification Committees, were responsible for the analysis of educational needs before the introduction of the new ESHRE Certification of Embryologist Training Centres. All authors were equally involved in data collection, interpretation, and manuscript writing.

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Conflict of interest

The authors reported no conflicts of interest.

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