EUROPEAN SOCIETY OF HUMAN REPRODUCTION AND EMBRYOLOGY (ESHRE)

TRAINING PROGRAMME IN CLINICAL EMBRYOLOGY

POSTGRADUATE TRAINING AND ASSESSMENT WORKING PARTY

Draft prepared: *December, 2020*
Revised and presented to the ExCo: *February, 2021*
Approved by ExCo: *March, 2021*
Available on ESHRE webpage: *January, 2022*

Steering Committee: B. Kovačič (Slovenia), A. Feki (Switzerland), B. Woodward (UK), C. Plancha (Portugal), T. Simić Motrenko (Montenegro), A. Nowak (Poland), K. Lundin (Sweden)

BACKGROUND

For around 40 years laboratories for human *in vitro* fertilisation (IVF) and clinical embryology have successfully proven and asserted themselves in the field of medicine. Very early in the development of reproductive medicine it became clear that the success of infertility treatments with assisted reproductive techniques (ART) required more than just competent physicians and IVF laboratory equipment. The results of ART procedures are especially influenced by laboratory staff skills.

ESHRE recognized the need for an international educational standard for embryologists. An ESHRE Steering Committee for Embryologist Certification (EmCC) was established and, in 2008, a two-level certification process for Clinical Embryologists began. ESHRE organised a self-reporting programme, whereby participants have to provide evidence of their academic degree(s) and professional experience, be knowledgeable about all areas of the curriculum, and become acquainted with various expert disciplines. This remains the only internationally standardised validation system for theory assessment in clinical embryology. The acquired knowledge is then verified by an examination, organised every year in connection with the ESHRE Annual meeting.

The continuing professional development (CPD) of those Clinical Embryologists who obtain the ESHRE Certificate is further followed via voluntary participation in a CPD system, also organised and overseen by the EmCC.

To pass an ESHRE exam in Clinical Embryology is considered a highly valued degree among Clinical Embryologists and employers in the majority of European countries, and it is now also attracting non-European professionals. The ESHRE certificate increasingly represents a valuable document in job applications (intra- and inter-country) and promotions. As Clinical Embryologists often look for employment in other EU States, the ESHRE Certificate acts as a kind of 'passport' and affirmation that the Clinical Embryologist can be recognised as experienced to a specific level for work in any European IVF laboratory.

The ESHRE Certification of Clinical Embryologists and Senior Clinical Embryologists is a well-established and continuously upgraded direct examination of theoretical knowledge from Clinical Embryology, celebrating the first decade in 2018. Throughout this period, a need to expand education in clinical embryology to the field of organized training and proficiency testing of the necessary practical skills was recognised.

In November 2017, the EmCC presented and the ESHRE Executive Committee (ExCo) approved an initiative for the ESHRE pages paper, which would present a syllabus for organized practical training in clinical embryology. In comparing clinical embryology with reproductive medicine educational processes, that ESHRE accreditation of clinical embryology training, as well as evaluation of practical competencies in clinical embryology are still missing. By contrast, ESHRE accreditation of reproductive medicine clinical training, as well as evaluation of practical competencies, namely through exams for ESHRE/EBCOG EFRM (European Fellowship in Reproductive Medicine) is already established.
The proposal prepared by the group formed in ESHRE Embryology Training Certification Committee was approved by ExCo in September 2020. A Steering Committee was appointed to prepare a certification programme for training centres for clinical embryologists, including the preparation of a syllabus, a logbook, and a system for verifying acquired skills. Together with the existing certification of theoretical knowledge, the new certification of practical training would complete the needs for organized education in Clinical Embryology. Specifically, the proposed project aims to:

1. Establish a training system for practical and theoretical education in field of Clinical Embryology and in ART laboratory management. The Embryologist certification is currently based on trust regarding candidates and their supervisors, stating that candidates have a threshold experience period (at least 3 or 6 years) and a minimum number of completed procedures (50 from each of the nine core laboratory methods of ART).
2. Assess the:
    a. candidate's practical training in ART.
    b. suitability of the training centres' facilities and technical possibilities to provide training in ART (procedures, equipment, scientific literature).
    c. suitability of the tutors (experience and competence).
3. Bring European and international recognition of the ESHRE programme for practical training of ART laboratory staff and for ART laboratory management.

Educational objectives
The results of ART procedures are especially influenced by laboratory staff skills to handle high-tech equipment and their accuracy, persistence, and patience in performing micromanipulations on gametes and embryos. To work competently in the field of clinical embryology, many laboratory workers had to become highly specialised in this field.
The requirements for training in these specialist areas have been defined with acknowledged experts from ESHRE and are recognized in the syllabus (Annex II). The role of professionals specialized in Clinical Embryology is complementary and not competitive to the specialist in Obstetrics and Gynaecology or to the subspecialists in Reproductive Medicine.

CLINICAL EMBRYOLOGIST TRAINING

1. Training Programme Standards

1.1. Definition of the Clinical Embryologist with completed training

The Clinical Embryologist is a laboratory professional, directly involved in the treatment of infertility with Medically Assisted Reproduction (MAR), who has had theoretical and practical training in the laboratory part of infertility treatment by reproductive cells, tissues, and embryos. Training will have involved:

a) a range of assessments and manipulations of biological samples (semen, spermatozoa, seminal plasma, testicular tissue, follicular fluid, cumulus-oocyte-complexes, oocytes, ovarian tissue, zygotes, early cleavage embryos, blastocysts and genetic material of reproductive cells and embryos)
b) processing of reproductive cells, tissues and embryos (cell separation methods, cell and embryo culture, insemination, micromanipulation techniques on reproductive cells, cryopreservation and cryobanking); preparation of reproductive cells, tissues and embryos for transfer or transplantation into the recipients, or for distribution to other tissue establishments.
c) knowledge of quality management procedure and audit according to the EU legislation on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

1.2. Advanced Senior Clinical Embryologist training

Advanced Senior Clinical Embryologist training, demanding several specific areas of knowledge, is an addition to the core training for Clinical Embryologist. These professionals should be able to set up and lead ART laboratories, andrology laboratories and cryobanks of reproductive cells. They can also coordinate work among laboratory co-workers, ensure the highest laboratory standards, troubleshoot, follow and critically interpret published innovations in the field of ART and participate in an interdisciplinary consultation with gynaecologists, reproductive medicine subspecialists, geneticists, andrologists, oncologists and other professionals, and be capable to be tutors for training in Clinical Embryology

1.3. The connection between existing certification of theoretical knowledge and practical training in Clinical Embryology

ESHRE offers theoretical knowledge certification for Clinical Embryologists from European and Non-European countries. Accreditation of training centres for the implementation of standardized training in Clinical Embryology is currently open only to European ART centres.

Although the theoretical and practical part of the education from Clinical Embryology can be performed separately, ESHRE recommends that theoretical knowledge (described in ESHRE curriculum) and practical training (described in ESHRE syllabus) are achieved simultaneously:

a. Core training (3 years) should be completed after verification of logbook and after passing the ESHRE exam for Clinical Embryologists.

b. Advanced training (3 additional years) should be completed after verification of logbook and after passing the ESHRE exam for Senior Clinical Embryologists.

The ESHRE basic level or advanced level diplomas would only be issued after the candidate has obtained the ESHRE certificate from theoretical knowledge examination for Clinical Embryologist or Senior Clinical Embryologists and also obtained the completed ESHRE accredited basic or advanced training.
Together, the certificate and diploma are documents that confirm the acquisition of knowledge and skills in a given time. Thereafter, in order to maintain competencies in Clinical Embryology, evidence that the embryologist has regularly kept up-to-date with knowledge, a continuous professional development (CPD) is needed. Therefore, after attainment, the ESHRE certificates and diplomas validity would need to be supported by the ESHRE CPD certificate, which is issued annually and certifies professional activity and development in the last three years. The first validation would begin three years after the initial awards.
It is important to know that once someone obtains the certificate and diploma, these qualifications cannot be taken away. However, it is the revalidation (reliant on compulsory CPD) that makes them "live". From 1st January 2022 onwards, the CPD is thus compulsory to maintain the validity of all certificates or diplomas obtained in the past or in the future.

1.4. Aim of defining training programme

a. To harmonize practical training according to the prescribed standards (via a syllabus), based on the example of the existing ESHRE / EBCOG subspecialisation programme in Reproductive Medicine.
b. To improve the care of patients treated by MAR techniques in collaboration with other care providers.

1.5. Objectives of training:

To train laboratory professionals to be specialized in performing MAR techniques, applying adequate laboratory procedures according to patient's needs and managing ART laboratories and cryobanks.

1.6. Organisation

1.6.1. The Steering Committee for certification of training in Clinical Embryology

This board with 6 experts + 1 trainee representative works closely with existing ESHRE Embryologist Certification Committee and Committee for the accreditation of training centres for Fellows from Reproductive Medicine. It has three main activities:

i. development and update of a roadmap for core and advanced training programmes in Clinical Embryology, promoting integration with existing ESHRE certification programmes;
ii. establishment of standards for:
    1. training facilities (adequate laboratory equipment, workflow and skilled personnel in a training centre)
    2. training tutors (experience, competence)
    3. training programme (syllabus)
    4. trainee inclusion criteria and training follow-up (logbook)
iii. establishment of an accreditation system for training centres to ensure validation of training standards in Clinical Embryology.

1.6.2. Training

a. The training programme should be in an ESHRE accredited MAR centre for training in Clinical Embryology and should preferably be organized by:

a. an ESHRE certified Senior or Clinical Embryologist, active in CPD – for the core training (name stated as tutor in the application form).
b. an ESHRE certified Senior Clinical Embryologist, active in CPD – for the advanced training (name stated as tutor in the application form).

b. The training programme can be combined between two or more MAR centres, if one centre cannot provide a complete training programme. During the application, the main training centre should provide a letter of intent to show that there is a collaboration with other MAR centres in providing a complete training programme.
c. The number of training posts in one training centre should be regulated by ESHRE in order to provide sufficient expertise.
d. The training centre should use guidelines and protocols finalized by national / international professional bodies reviewed at regular intervals.

2. Guidelines

2.1. Entry requirements to become a Trainee in Clinical Embryology:

a. At least a BSc degree from Natural /Live sciences for the first 3 years of practical training (core level) and at least a MSc degree from Natural /Live sciences for the next 3 years (advanced level). Both degrees should be validated by Nuffic (The Netherlands). If degrees have already been validated by Nuffic as part of an application for theoretical examination, this validation can be used for application for the training (and vice versa).
b. The availability of recognized training post and tutors in an ESHRE accredited MAR centre.

2.2. Training and involvement

Training should be directed towards achieving competence. Trainees should participate in all clinical laboratory activities and in educational activities, including the teaching of other health professionals. Participation in audit and clinical or basic research is essential for the completion of training programme.

2.3. Duration and content of training

The training has to be accompanied by acquiring of theoretical knowledge (see **Annex I**: Curriculum for theoretical knowledge in Clinical Embryology) from:

1. Basic Cell Biology
2. Genetics
3. Developmental Biology
4. Female Reproduction
5. Male Reproduction
6. ART Laboratory Procedures
7. Cryobiology
8. Laboratory and Quality Management

Duration of basic practical training should include **a minimum of three years** in an approved programme (see **Annex II**: Practical training programme in Clinical Embryology: **Core programme**) and should cover the clinical laboratory aspects of the following areas:

1. Basic principles of working aseptically in a medical laboratory for ART
2. Laboratory equipment and operation
3. Semen analysis
4. Sperm processing for ART
5. Oocyte processing for ART
6. Oocyte insemination via conventional IVF
7. ICSI
8. Embryo culture, evaluation of fertilisation and embryo development

9. Embryo transfer
10. Cryopreservation

Duration of advanced training should include **additional three years** in an approved programme (see **Annex II**: Practical training programme in Clinical Embryology: **Advanced programme**) and beside increasing skills in basic methods, it should cover additional clinical laboratory and research aspects of the following areas:

1. Cell, tissue and embryo cryobanking
2. Maturation *in vitro* of reproductive cells (optional)
3. Micromanipulation on embryo (biopsy) and genetic analysis (optional)
4. Laboratory set-up
5. Preparation of laboratory results and counselling
6. Managing ART laboratory and cryobank
7. Research, statistics and audit
8. Teaching
9. Ethical and legal aspects
10. Continuing Professional Development

2.4. Training plan and logbook

Training should be structured throughout with clearly defined targets to be met after specified intervals. An educational plan should be drawn up in consultation with the Trainee at the beginning of each attachment and progress should be monitored regularly by mean of the logbook. The logbook is signed by the Tutor.

2.5. Training in another laboratories

Trainee's Tutor can organize a part of the training in another (1 or 2) MAR centre. Different supervisors can be authorised from the Tutor to perform specific parts of the training. This has to be evident in the trainee's logbook. Trainees are also encouraged to visit other types of medical laboratories (genetic, endocrine, biomedical, microbiological, cyto-histological).

ACCREDITATION OF TRAINING CENTRES

3. Application to become a training centre

3.1. European MAR centre can apply to become a training centre for embryologists if all criteria are fulfilled. The centre can apply via application platform, by completing checklists and uploading all requested documents.

3.2. General Requirements for Embryology Training Centres

To be eligible for training, a centre should:

a. be open to seeing all types of patients seeking MAR; embryologists should be exposed to the wide variation of patients presenting with infertility;
b. provide a continuous service for the treatment of patients by MAR and show proven continuity of the service in the last 5 years period;
c. have an adequate workload (see bullet point ‘o’) providing a full range of required experience in reproductive medicine and in the ART laboratory, listed in ESHRE syllabus;
d. have continuing professional education and training in the field of Clinical Embryology described in the organizational scheme of the centre, and have demonstrated past experience with basic and continuous education of laboratory staff, such as certification of knowledge, expertise and co-authorship in research abstracts and papers;

e. have an adequately equipped Andrology, Cryo and ART laboratories operating in accordance with the ESHRE Good Laboratory Practice guidelines and regularly inspected by national auditors; the laboratories must have sufficient equipment that can be used for training without interfering with the regular clinical programme;
f. have one Reproductive Medicine subspecialist or specialist in Gynecology and Obstetrics, who is responsible for the clinical treatment programme in which the Trainee is actively involved;
g. have an experienced ESHRE-certified Clinical (for the core training only) or Senior Clinical Embryologist (for the core and advanced training) with proven CPD, appointed as a Tutor (training programme manager); the Tutor will become authorized by ESHRE to coordinate the training programme, accept the main responsibility for Trainee supervision and be actively involved;
h. the complete training programme with all topics (described in ESHRE syllabus) covered should be provided by the main training centre;
i. in case the training centre cannot provide all modules from the syllabus, for missing parts of the training, they can sign a letter of intention with another centre providing this service. This should be announced in the application form for training accreditation and the responsible person in the satellite centre (supervisor) should be named. This has to be evident also in the trainee's logbook;
j. Tutors and supervisors will have required experience in the relevant programme field; if the Tutor changes the training programme, the ESHRE Steering Committee has to be informed and, if needed, the training centre will be revisited;
k. trainees should have opportunity to visit and spend time in a laboratory for genetic disorder diagnosis;
l. have adequate laboratory staffing that enables the Trainee to partake in Clinical Embryology on a full-time basis (or in the case of a part-time Trainee, during all of their normal working hours); participation in work outside normal working hours and during weekends or national days is not excluded;
m. have established close collaboration with Reproductive Medicine subspecialists, ART laboratory professionals and other relevant specialists (andrologists, geneticists, endocrinologists, laboratory medicine specialists) within and outside MAR centre, providing counselling, networking and research advice;
n. have adequate library and other resources for support work and research programme related to the field of Reproductive medicine;
o. fulfill criteria for minimum clinical / laboratory activity in the centre:
    i. 150 semen analysis a year / trainee
    ii. 150 sperm preparations a year / trainee
    iii. 150 OPU cycles (must include IVF and ICSI) a year / trainee
    iv. 5 TESA/TESE a year / trainee
    v. 10 Sperm cryopreservation a year / trainee
    vi. 50 Oocyte / embryo cryopreservation cycles a year / trainee
    vii. 40 Oocyte / embryo thawing a year / trainee
    viii. IVM (optional)
    ix. Embryo biopsy (optional)

3.3. Assessment of application

The Steering Committee reviews the application to assess if criteria are met. Approval of institutions as training centres should be based on the following general and special requirements provided, and not conflict with national laws:

a. Provision of acceptable annual statistics (results of the clinic)
b. Existing internal quality control and audit

c. Organised teaching sessions
d. ESHRE prescribed training of trainees in Clinical Embryology already in place
e. Availability of:
    i. Multidisciplinary team regularly involved in the management of reproductive medicine.
    ii. Andrology laboratory.
    iii. Laboratory for IVF/ICSI and embryo morphology assessment.
    iv. Cryo-laboratory
    v. Optional: Genetic laboratory
    vi. Research activity
    vii. Fulfilment of defined criteria for minimum clinical / laboratory activity

3.4. Assessment of training, facilities and tutors

The ESHRE Steering Committee organises a site visit (virtual or physical) by 2 assessors after the application is accepted. In case of missing points, the assessors will do a reassessment after 2 years. In case all recommendations are fulfilled, accreditation will be approved for another 3 years (in total 5 years). Reaccreditation will be performed every 5 years if the centre fulfils all requirements. If necessary, withdrawal of recognition can be enacted.

ESHRE is willing to organize an extra evaluation visit to a training unit if requested.

3.5. Evaluation of the training by the Trainee

Trainees have a questionnaire available to assess the quality of training. An interview with the trainees is scheduled during the visit of ESHRE assessors. In this way, direct feedback from training participants is provided. When assessing the quality of training by trainees, the following is checked:

a. Advance of the log book and progress of clinical experience in Clinical Embryology.
b. Protected time for trainee's participation in scientific activities/research.
c. Trainee's participation in reproductive medicine and clinical embryology courses in particular those advised by ESHRE.

3.4 Assessment of national assessment committee

A representative from the ESHRE post-graduate training and assessment working party may be an observer on the national assessment committee (when and if it is established).

4. Training programme (guides to learning and training are described in ANNEX I and ANNEX II)