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REVIEW


The Alpha Consensus Meeting on the professional status of the clinical embryologist: proceedings of an expert meeting



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Abstract This proceedings report presents the outcomes from an international Workshop designed to establish consensus on the professional status of the Clinical Embryologist, and then to work towards creating international standards that can be referenced by regulators and professional societies around the world. The participants represented a total of 20 countries (Australia, Austria, Belgium, Brazil, Canada, China, Croatia, Finland, France, Germany, Ireland, Italy, the Netherlands, Russia, South Africa, Spain, Sweden, Turkey, UK and USA) and 18 national and regional societies (as presented in the list of participants). This report includes general presentations about current practice, and factors for consideration in the development of a competency-based framework for certification of Clinical Embryologists. 

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Introduction

Over the past 3 decades, governmental regulation in the area of assisted reproductive technology (ART) has increased; specifically in relation to requirement for licensing of assisted reproduction clinics, staff working in them, and in accreditation of ART centres. These increases have revealed that regulatory authorities and professional associations do not always properly recognize the key role of the Clinical Embryologist as an organization's scientific professional, or their roles in effective ART laboratory direction and management.

Clinical Embryologists do not fit neatly into any of the traditional categories of laboratory workers, such as technician or technologist. Rather, they are more like 'practitioners' in the general sense of the word, rather than the specific sense used in the UK in the definition of roles in clinical embryology. This is because the work of the Clinical Embryologist is typified by a high degree of technical skill and experience, extensive knowledge of many other, non-laboratory aspects of ART treatment, and day-to-day responsibility for making many of the routine, but crucial, decisions that directly affect patients' treatment, (albeit within the context of documented policies approved by the Medical Director). This represents a very different situation to most other 'medical laboratories' that are directed by a physician with specialist training in specific areas of laboratory medicine.

To determine how Clinical Embryologists are viewed internationally, a survey was sent globally to national and international societies for Clinical Embryologists. Some countries have more than one such society (e.g. Belgium, Turkey, USA and Japan), whereas some societies represent more than one country (e.g. SIRT [Australia and New Zealand], NILS [Denmark, Finland, Iceland, Norway, and Sweden], RED LARA [Latin America], and MEFS [Middle East]). Of the 40 survey invitations, a total of 26 responses were received (65% participation rate), representing information from 58 countries located in Africa, the Americas, Asia (including India), Europe, the Middle East, and Oceania. As would be expected, the submitted regulatory documents were often not available in English, so a translation programme was used.

From the range of information in the responses received, it was clear that international consensus on the role of the Clinical Embryologist was currently lacking. In the interest of developing international standards as a reference for the development or revision of regulations, it was decided that Alpha should develop such a consensus, as Alpha's over-arching purpose is to establish and expand the minimum requirements for safe and effective ART laboratory operation while providing a framework for achieving quality and excellence. It was agreed that, for optimum efficiency and practicality, such an exercise should be undertaken within the format of a consensus workshop by an expert panel, as with previous consensus workshops on embryo morphology and cryopreservation key performance indicators ([Alpha Scientists in Reproductive Medicine and ESHRE Special Interest Group Embryology, 2011a, 2011b](#); [Alpha Scientists in Reproductive Medicine, 2012](#)).

The aim of this workshop was to achieve an international consensus on: the role of the Clinical Embryologist; who can or should work as a Clinical Embryologist; the educational re-

quirements for becoming a Clinical Embryologist; the training required for someone to work as a Clinical Embryologist; the necessary competencies to work as a Clinical Embryologist; how those already working in the field will be protected and maintain a career path as new professional frameworks are developed and implemented; and how the profession can establish its own guidelines, rules, best practice recommendations, certification, and continuing professional development (CPD) systems for the benefit of its own members and the patients they serve. This report presents the results of this Expert Panel Consensus Meeting, held in Antalya, Turkey 7–8 May, 2014.

Workshop presentations

The format of this consensus workshop was firstly overview presentations that summarized the responses to the questionnaires, integrating the submitted information, synthesizing points of commonality or agreement, and identifying areas of disagreement. These were then followed by a series of topic presentations on key areas raised, which led into the general discussions and the consensus discussions.

Overview presentations (environmental scanning)

National regulations (presented by David Mortimer)

On the basis of the responses to the survey, great variations were identified between countries in the regulatory frameworks controlling the practice of ART, the operation of ART laboratories and the professional status of clinical embryology.

Although most European Union member states have implemented the European Union Tissues and Cells Directives ([European Union, 2004, 2006](#)), which include specific requirements for clinics and personnel, few countries designate professional status for embryologists. In some countries, however, the regulatory framework states that the embryologist works entirely under the control of the clinician (e.g. France, Italy, and the Netherlands), and in France, only specially qualified clinicians can run ART laboratories, everyone else is a technician.

In some countries, regulations and guidelines are developed by government-invited ad-hoc committees, but not all countries, even those with regulations in place, have peer group-developed Professional Standards, although ESHRE does have these. In a number of countries, the clinical embryology profession is represented through a Special Interest Group within a national fertility society or equivalent. The presence of multiple professional societies in some countries, however, seems to create a lack of professional cohesion, whereas, in other countries, there is no society representing Clinical Embryologists, so they have no voice, and cannot develop national professional standards or guidelines. Further, respondents noted that the voice of embryologists within a clinical society (even as a Special Interest Group) is often perceived to carry little weight. The result of all of this is that Clinical Embryologists in many countries report that they feel professionally 'isolated', with little or no influence over their work or careers. An

international voice for Clinical Embryologists would be greatly appreciated by many, and it was felt that this would be best achieved through a global clinical embryology society, such as Alpha.

In conclusion, there is a clear, maybe even an urgent, need for this Consensus Meeting. There are obvious roles that Alpha could and should play internationally on behalf of Clinical Embryologists. These include being the voice for their interests; promoting their recognition as an organization's scientific professional(s); establishing their professional status based on specialized knowledge and skills; and developing certification criteria based on competencies, rather than simply on knowledge alone.

Required academic qualifications (presented by Joe Conaghan)

The role of the embryologist typically encompasses clinical treatment, clinical laboratory testing and laboratory management. Within these broad categories, the Clinical Embryologist makes treatment decisions, reviews records and consults with other members of the ART team as well as with patients (in most countries).

Of the 26 responses to the survey, eight had no specific requirements for academic qualifications for embryologists, whereas a further six had minimal requirements or recommendations based on National Society guidelines. The remainder had legislated requirements or strict guidelines for the academic qualifications of embryologists. For Laboratory Director, nine specified a requirement for a doctoral qualification.

Some national or regional Professional Societies have developed certification programmes for Clinical Embryologists. In the USA, for example, the American Board of Bioanalysis has defined educational and training requirements for five different levels of certification (http://www.aab.org/aab/Certifications_Qualifications.asp), including Technical, Supervisor, Embryology Laboratory Director, and High-complexity Clinical Laboratory Director.

For certification as a Clinical Embryologist, ESHRE requires that candidates have a BSc in the Natural Sciences, 3 years' experience and a logbook documenting their experience. Certification as a Senior Embryologist requires a PhD or MSc in the Natural Sciences, 6 years' experience, and a logbook. The minimum academic qualification requirement for entry into the ACE Certificate in Clinical Embryology is a degree in Life Sciences.

Of the countries with published requirements or guidelines, BSc/MLT (medical laboratory technologist) was the minimum academic qualification for embryologists, whereas a doctorate was universally specified for a Laboratory Director. In some countries, an academic qualification of MSc was also acceptable for Laboratory Directors.

Training and education programmes (presented by Jens Hirchenhain)

From the responses to the questionnaire, it was apparent that a clear recognition of the role and professional status of the Clinical Embryologist is generally lacking, and that it is a virtually unknown qualification in the 'outside world'.

It is likely that the lack of consistent requirements for education and training have contributed to this situation. For

example, of the responses received, 12 noted no national requirement for evaluation of Clinical Embryologists' education and training, whereas a further nine had certification programmes administered through national professional societies. At present, only five countries had officially recognized certification. Although it is logical for large regional and international societies (such as ESHRE and Alpha) to develop and administer such programmes, it must be recognized that imposing further certification requirements in countries in which official certification already exists could create a sense of 'over-regulation'. In addition, it is critical that any evaluation or certification programme supports the professional development of the candidates, rather than acts as an exclusion mechanism.

All of the training programmes that currently exist involve the review and/or evaluation of both theoretical knowledge and practical know-how and skills. The emphasis on practical training, however, is not consistent between programmes, with differing numbers of cases required to be recorded in the logbook.

In conclusion, there was a common view that the development of the profession of Clinical Embryology must be as a result of self-regulation, with the existing members of the profession determining how to evaluate new members' knowledge and skills.

Continuing professional development (presented by Stephen Harbottle)

Continuing professional development (CPD) is a professional responsibility. It is an effective mechanism for keeping skills and knowledge up to date, and participation strengthens professional credibility and maintains the participant's professional reputation. Becoming involved in CPD activities, such as attendance at conferences, reduces the risk of clinical isolation, and has the added benefits of improving job satisfaction and opportunities for career development, as well as improving the standards of patient care.

The availability or requirement for CPD was not directly addressed by a specific question in the survey, but a number of respondents addressed the issue, and so highlighted a global dearth of expectations for CPD. Of the countries that commented, only three had a mandatory, regulated CPD scheme, whereas two others had voluntary, regulated CPD schemes, and one had a requirement for CPD but did not have a regulatory mechanism. A further four countries indicated that they were aspiring to a national CPD scheme.

A requirement for CPD is addressed in the relevant standards. ISO 15189 (Medical Laboratories): 5.1.8 Continuing education and professional development (ISO, 2012) states that 'a continuing education programme shall be available to personnel who participate in managerial and technical processes. Personnel shall take part in continuing education. The effectiveness of the continuing education programme shall be periodically reviewed.' and 'personnel shall take part in regular professional development or other professional liaison activities.'

Similarly, the European Union Tissues and Cells Directive 2004/23/EC - Article 18; Personnel (European Union, 2004) states that 'Personnel directly involved in activities relating to the procurement, processing, preservation, storage and distribution of tissues and cells. . . shall be qualified to perform such tasks and. . . provided training.'

On the basis of the limited responses around this issue, the UK seemed to have the most established infrastructure for CPD. Global support is mounting, however, for an international CPD scheme, or at least a model, and a consensus from respondents that Alpha is best-placed to develop this.

Roles and responsibilities of the clinical embryologist (presented by Josep Santaló)

On the basis of the survey responses, the roles and responsibilities of the members of the clinical embryology laboratory are dependent upon professional status. Three main levels were identified: assistant, embryologist and senior embryologist.

The assistants, or technicians, are not considered to be embryologists proper, but their tasks can, under some circumstances, be carried out by embryologists, so there can be some confusion between the roles. In general terms, people employed at this level carry out routine day-to-day maintenance tasks within the embryology laboratory. These tasks can include preparing cell culture dishes, as well as responsibility for monitoring incubators' temperature and gas supply, and monitoring and replenishing liquid nitrogen levels in the cryostorage tanks. They can also be responsible for stock control and ensuring correct storage conditions for consumables.

Embryologists conduct the day-to-day activities in the clinical embryology laboratory. In addition to using safe work practices (which are the responsibility of all staff), their responsibilities include selecting and using appropriate standard operating procedures (SOPs), coordinating laboratory activities with clinical activities and adapting clinical decisions in accordance with clinic policies. In many countries, the embryologist is responsible for communicating with patients about laboratory procedures and the progress of their embryo development in the laboratory. They are also responsible for effective record-keeping related to laboratory procedures, and for effective quality and risk management within the laboratory. Embryologists are expected to use critical thinking skills for problem-solving and troubleshooting, and to be aware of, and conform to, the ethical and legal issues related to ART.

Senior embryologists are ultimately responsible for the laboratory aspects of assisted reproduction techniques, and can partially delegate some of their functions and responsibilities to other professional levels. They must ensure that the laboratory environment is appropriate and safe, and that appropriate numbers of suitably qualified staff are available to meet the workload. They are also responsible for the implementation of an effective quality management system (including ensuring that all staff adhere to the approved SOPs), as well as for the hiring and training of laboratory staff, and for their continuing professional development. Senior embryologists must demonstrate effective communication with patients, colleagues and other health professionals, and create and maintain an effective team. Their administrative responsibilities include creating and managing the laboratory budget and effective resource management, as well as the implementation and maintenance of an effective laboratory records management system.

Overall, although there was not necessarily consistency between the job titles in different countries, there was a great similarity in the scope of the roles at the various professional levels.

Topic presentations (consensus-building)

Role of the clinical embryologist (presented by Ciara Hughes)

Many titles are currently used for clinical embryology positions. This leads to confusion about the roles and responsibilities for each. Professor Santaló's presentation identified three levels for Clinical Embryologists: Assistant, Embryologist and Senior Embryologist. A fourth level could be added, that of the person with the overall responsibility for the laboratory (designated as Laboratory Director, or Manager, depending on the country). It is this person's role to ensure that the embryology laboratory is compliant with all local legislation and that it operates to the highest standards in terms of the facility, staff training, number of staff, equipment, safety, quality, confidentiality, the latest technology and patient interaction.

To create an overview of each level's duties and responsibilities in the range of areas covered under clinical embryology, the PACER system was developed for this consensus meeting (**Table 1**). PACER is an acronym for Personal, Administrative, Clinical, Education, and Research. The scope of duties and responsibilities under each of these headings are as follows: Personal: patient interaction, ethics, and critical thinking; Administrative: compliance and documentation; Clinical: routine embryology, as well as clinical decision-making; Education: induction and training, certification, ongoing acquisition and maintenance of competency, and CPD; Research: expected involvement, based on level (e.g. initiation, direction, participation, or review).

In defining roles and responsibilities for each level of clinical embryology, it is important to consider whether everyone within a level has to perform exactly the same duties. This should be addressed within the consensus discussions.

Educational and academic requirements (presented by Ronny Janssens)

On the basis of the survey results, there is no standard educational pathway to becoming a Clinical Embryologist. There is a wide range of national regulations and professional standards, and a patchwork of educational trajectories, with practising embryologists having qualifications as BSc, MSc, PhD, MD, and DVM. Geographical and cultural differences also exist in the educational requirements to become a Clinical Embryologist. Similarly, in developing educational requirements, it is necessary to consider who should set the standards: national licencing boards, or (inter)national professional associations.

Having a degree or other academic qualification, however, does not automatically confer the ability to practice as a Clinical Embryologist; there is still the requirement for the acquisition of specialized knowledge and skills, and the demonstration of competency. Also, in some ART centres, Clinical Embryologists sub-specialize into certain areas, and in those cases, they will not necessarily be competent in all of the required skills. Any standard that is developed for certification or accreditation of Clinical Embryologists should take all of these aspects into account.

Care should be taken to avoid the risk of over-regulation when specifying required academic qualifications, as it has already been demonstrated that different profile-oriented qualifications, related to skillsets, can co-exist quite

Table 1 A summary of the roles and responsibilities of the various levels of staff within the clinical embryology laboratory, arranged using the PACER (Personal, Administration, Clinical, Education, Research) system developed by Ciara Hughes.

<i>Personal</i>	
Assistance level	<ul style="list-style-type: none"> •Applying ethics and integrity, critical thinking, good communication within the team, time management and team work skills. •Active participation in quality management system (QMS) •Taking reasonable care for personal health and safety and that of other personnel and visitors who may be affected by their conduct
Embryologist level	As for 'Assistance level' as well as: <ul style="list-style-type: none"> •Ability to communicate effectively
Supervisory level	As for 'Embryologist level' as well as: <ul style="list-style-type: none"> •Ability to teach and train effectively
Direction level	As for 'Supervisory level' as well as: <ul style="list-style-type: none"> •Ability to manage, lead and motivate staff. •Developing and maintaining relationships with other professionals within the field •Ensuring an effective health and safety programme is in place
<i>Administration</i>	
Assistance level	<ul style="list-style-type: none"> •Record-keeping •Adhering to standard operating procedures •Exercising budget control and cost containment measures
Embryologist level	As for 'Assistance level' as well as: <ul style="list-style-type: none"> •Cryobank operation
Supervisory level	As for 'Embryologist level' as well as: <ul style="list-style-type: none"> •Coordinating the transport of gametes and embryos between centres •Managing change control
Direction level	<ul style="list-style-type: none"> •Overall responsibility for all aspects of laboratory management •Compliance with local legislation •Maintaining authorization to practice / license •Developing a budget •Operating the service within budget •Resource management •Ensuring all job descriptions are up-to-date and accurate •Ensuring service level agreements are in place with all critical suppliers •Authorizing and implementing changes to standing operating procedures •Delegation of tasks
<i>Clinical</i>	
Assistance level	<ul style="list-style-type: none"> •Support of laboratory operations and environmental quality control •Adherence to clinic policies and standard operating procedures
Embryologist level	<ul style="list-style-type: none"> •Semen analysis, semen preparation, sperm diagnostic tests (performed to appropriate standards) •Adherence to clinic policies and standing operating procedures •Ensuring all equipment is functioning properly •All gamete and embryo handling and assessment •Generating clinical key performance indicators for review •Adopting clinical decisions •Adherence to patient consents

(continued on next page)

Table 1 (continued)

<i>Clinical</i>	
Supervisory level	<p>As for 'Embryologist level' as well as:</p> <ul style="list-style-type: none"> •Acting as the 'deputy laboratory manager' •Participating in clinical reviews and making decisions •Reviewing and acting on key performance indicators •Process validation •Supervising and training junior staff •Ensuring competency of staff working in the lab •Introducing new technologies and methods •Ensuring adherence to standing operating procedures •Participating in scheduling of cycles and cycle management •Ensuring all equipment is properly maintained
Direction level	<p>As for 'Supervisory level' as well as being ultimately responsible for:</p> <ul style="list-style-type: none"> •Ensuring that the laboratory is 'fit for purpose' in terms of security, space and cleanliness and with adequate equipment •Ensuring that standard operating procedures are up to date and accurate, according to international best practice •Developing and reviewing key performance indicators and benchmarks, as well as dealing with any deviances •Ensuring an adequate number of competent staff to cover case load •Ensuring that staff have meetings within their own department and are encouraged to attend case and clinical review meetings •Authorizing the introduction of any new technique •Ensuring an effective quality management system within the laboratory
<i>Education</i>	
Assistance level	<ul style="list-style-type: none"> •Keeping up to date with education, training, and competency
Embryologist level	<p>As for 'Assistance level' as well as:</p> <ul style="list-style-type: none"> •Keeping up to date with new guidelines, and diagnostic or therapeutic technologies •Participating in continuing professional development •Participating in training of trainees
Supervisory level	<p>As for 'Embryologist level' as well as:</p> <ul style="list-style-type: none"> •Supervising and training junior staff
Direction level	<p>As for 'Supervisory level' as well as:</p> <ul style="list-style-type: none"> •Ensuring that new staff have a comprehensive training plan or are enrolled in a certification scheme with ongoing competency assessments •Ensuring that all staff have the opportunity to participate in CPD •Encouraging, and aiming to fund, attendance at training courses, conferences, post graduate courses •Ensuring that their own CPD, training and competency is up to date •Staff appraisals
<i>Research</i>	
Assistance level	<ul style="list-style-type: none"> •Supporting or participating in any research activities, or both
Embryologist level	<ul style="list-style-type: none"> •Proposing or participating in clinical research studies, or both
Supervisory level	<ul style="list-style-type: none"> •Proposing, participating in or implementing clinical research studies, or all three
Direction level	<ul style="list-style-type: none"> •Initiating, designing and implementing research studies (including obtaining ethical approval) and following through with analysis and publication •Capable of applying for funding, grants, et cetera, and collaborating with external institutions

CPD = continuing professional development.

Table 2 Education framework as developed and presented by Nadine Richings. It is envisaged that the sections and topics of the Clinical Embryology curriculum may be taught as individual modules with increasing detail at each role level (i.e. Embryologist, Supervisory and Director). Individual modules can simply be labelled to indicate the role and topic, so for example, the topic of 'legislation and regulation' would have three modules (1.7, 2.7, and 3.7).

Sections and topics	Topic level (relative to basic structure)		
	Embryologist	Supervisory	Direction
Biology and assisted reproduction techniques			
Biology	1.1	2.1	3.1
Technology: theoretical	1.2	2.2	3.2
Technology: practical	1.3	2.3	3.3
A broader perspective: outcome, quality, safety and risk			
Monitoring outcome and quality	1.4	2.4	3.4
Safety and risk	1.5	2.5	3.5
Other professions roles in assisted reproduction techniques	1.6	2.6	3.6
More than science: administration, documentation and liaison			
Legislation and regulation	1.7	2.7	3.7
Communication, information and accuracy	1.8	2.8	3.8
Personal skills and attributes	1.9	2.9	3.9
Advancing your career			
Continuing professional development	1.10	2.10	3.10
Research and scientific principles		2.11	3.11
Management training			3.12

successfully. Metrics, however, are required to support the development of standards, and so a consensus on minimum academic requirements is needed. Similarly, a consensus is required on the development of guidelines for practical training and acquisition of competency to support a transparent and credible certification system. This might also include the development of standardized logbook templates and the requirement for laboratory accreditation (perhaps using the ISO 15189 model as a guide).

In conclusion, there is room in clinical embryology for all levels of academic qualification, but a clear definition of the range of career levels of Clinical Embryologists and development of profile-specific qualification trajectories and training modules are needed. Also, the acquisition of competence would be enhanced by the development of guidelines for practical training.

Training expectations and requirement (presented by Nadine Richings)

Training expectations and requirements should deal with what Clinical Embryologists are expected to learn and required to know. As clinical embryology has developed as a profession, the educational requirements of trainees have been met in a variety of ways, following curricula created within their laboratory or clinic, or by educational institutions and professional societies. Usually, the curriculum is tailored to meet a trainee's needs with regard to the acquisition of relevant knowledge and skills.

A complication in the development of a standardized curriculum is that many students and trainees, and even 'trained' or 'qualified' embryologists, struggle to differentiate the biology of reproduction from the technology of ART, because it is often not explained clearly in education and training programmes, or in scientific presentations. 'Biology' is what we understand occurs *in vivo*, whereas 'technology' is our inventions and applications to mimic or manipulate the biology, or both. In-vitro observations and effects are often caused by the 'system', and can differ from in-vivo responses. A true understanding of technology requires an understanding of the underlying biological system, and knowledge of both is critical for effective troubleshooting.

A better curriculum (Table 2) would circumvent this confusion by using 'processes' and 'systems' as the primary categories, with 'compare and contrast', and 'similarities and differences' topics, in contrast to the traditional method of reproductive biology instruction, where 'male' and 'female' are the primary categories.

As the educational requirements differ relative to the career stage and professional level of the Clinical Embryologist, the curriculum must be presented as a stratified model. In this model, the information presented would be tailored to the professional level; so for example, the entry-level education would cover all of the general assisted reproduction technique procedures that are required for someone to progress to becoming a fully-trained and independent Clinical Embryologist. The next level would also cover specialized and advanced techniques, as well as research and management

tasks, whereas the highest level would also include management training.

This stratified curriculum model would include clear aims and objectives with competence tested against each section's objectives. Sections would be divided into modules, and further refined through units then topics. Since the information will be presented as processes and systems to encourage greater understanding, some content will be included under more than one topic heading.

The aim of the meeting was to reach a consensus on a general curriculum for Clinical Embryologists at different career levels, using the proposed curriculum as a model for discussion.

Defining and assessing competence (presented by Sharon Mortimer)

The Oxford Dictionary defines 'competence' as 'the ability to do something successfully or efficiently', whereas the Royal College of General Practitioners defines it as 'having the abilities, knowledge and skills necessary for professional practise'. These definitions certainly apply to the practise of clinical embryology. The challenge, however, is to find a metric to evaluate the competency of a Clinical Embryologist. The qualitative evaluation could be summarized as 'would I trust this person with my gametes or embryos?'; 'would I trust this person with my professional reputation?', or both. But how can this be defined and measured?

On the basis of the overview presentations, when there is assessment of competency, it is performed via a logbook. For example, ESHRE requires the completion of 50 cases for a range of techniques; the German society for human reproductive biology (AGRBM) has a range of the number of cases required, depending upon the technique, whereas the Canadian Fertility and Andrology Society requires a declaration of competency from the person's Laboratory Director, with a completed (re)training logbook as evidence. The Royal College of Pathologists qualification includes a requirement for a Casebook, which is a 10,000–20,000 word review of seven to eight cases completed by the candidate. The advantage of using a logbook to define technical competency is that it assists reviewers by giving an objective measure for assessment, and gives the candidates a target. Logbooks, however, generally do not record the outcome of each of the replicates, so there is no indication of how well or consistently the task was performed. There is also the implication that the candidate performed the task independently, but this is not generally verified.

Therefore, in the development of a consensus on the definition and assessment of competency, it is important to consider that the number of times that a task is performed is not necessarily the same as the number of times that the task was performed correctly. Similarly, as someone could not be considered to have the rudimentary skills to perform a task until they have completed the relevant training, then the number of times a task was performed in the acquisition of competence (i.e. training) should not be included in the demonstration of competence. In other words, if it takes someone 30 attempts before they are judged competent to perform a task unsupervised, then these 30 cases should not be included in the competency logbook. In addition, a competent person will learn through their experience, so it is important that the tool used in the demonstration of

competence includes provision for reflection on what was learned.

If we don't use a simple logbook, then how can we assess competency? We must develop a competency framework. A competency framework is a model of the desired outcome that defines each competency and how to assess it. It defines how someone would be judged to be 'competent' under each competency element. This means that some competency definitions are outcome-based (e.g. accuracy of sperm concentration and motility values) whereas others are process-based (e.g. time taken for gamete or embryo handling).

The steps in developing a competency framework are as follows: define each competency element; define relevant key performance indicators for each competency element; set benchmarks for each key performance indicator, based on what a competent person would achieve; review the training manual and laboratory SOPs to ensure that they address each competency element, including key performance indicators; and design a logbook that fits within this competency framework, for example by defining how many times someone should reach this benchmark.

In summary, recognition as a 'professional' requires some form of external evaluation for certification of competency. Since evaluation of practical skills must be done within the environment in which the work is normally performed, a logbook is the most accepted tool for demonstrating practical experience. A competency-based logbook, developed within a competency framework, records outcomes as well as experience, and so would be a better tool for assessment.

Continuous professional development (presented by Sirpa Mäkinen)

Although regulations related to ART exist, such as those based on the European Union Tissues and Cells Directive, most countries do not regulate laboratory practitioners in ART, as noted by Dr Hirchenhein and Dr D Mortimer (above). Furthermore, as per Dr Harbottle's presentation, only six of the countries that responded to the survey currently have a CPD scheme in place.

The range of roles and responsibilities for each level of embryology outlined in the PACER system (Table 1), demonstrates the range of skills required in the day-to-day practice of ART in the laboratory. In addition, the 2006 EU Commission Directive (2006/86/EU, Article 3, Annex I B:Personnel) (European Union, 2006) requires that embryologists also have the responsibility to follow, understand and be aware of quality management, the scientific basis of the processes involved, advances in technology, and the consequences and ethical and legal aspects of assisted reproduction techniques. Given this, CPD is a critical tool for embryologists in the acquisition and maintenance of their skillset.

Meeting this requirement involves practical challenges, such as in defining 'relevant training', as well as the type of courses needed, and in identifying who could and should provide the training. It is the responsibility of clinics to ensure that people working in the ART laboratory are qualified, to ensure that they have access to ongoing professional education and training, and to maintain a current record of professional development, all of which can be relevant to promotion and remuneration. In some countries, this responsibility of the employer is legislated, but philosophically, it is also a personal professional responsibility to participate in professional

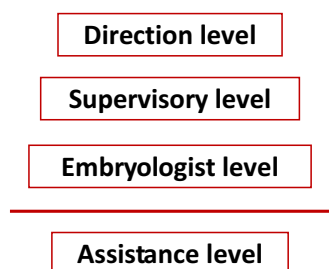


Figure 1 Basic staffing structure levels for clinical embryology laboratories. The horizontal line denotes that the assistance level is separate from the continuum of Clinical Embryologist levels above the line.

development activities. To that end, courses should also be provided in native languages, and the cost of training should be reasonable (i.e. not a barrier to participation). Professional development activities should be part of a formal CPD scheme, with a credit point system, in which certification relies on achievement of a certain number of credits over a given time period. Some CPD schemes are voluntary, such as the ESHRE CEEC (Continuous Embryology Education Credit), and do not affect certification, whereas others are mandatory (such as in the UK and New Zealand).

Developing a consensus on certification and CPD would help to standardize laboratory work while demonstrating staff (and clinic) competence, leading to improvements in patient care.

Consensus points

Except where noted, the Expert Panel reached unanimous consensus on each of the following consensus points. It should be noted that these recommendations are largely 'minimum standards', and so can be exceeded. Furthermore, if disagreement exists between these recommendations and existing local or national legislation or regulations, then the local or national legislation or regulations should take precedence. Finally, it is the intent that these recommendations should support the development of clinical embryology as a profession, and so should not be used to disenfranchise anyone currently practising.

Consensus on need

It was agreed that an international set of standards for Clinical Embryologists is needed, and that the aim of this consensus workshop was to recommend international standards that can be referenced by regulators and professional societies globally.

Consensus on basic staffing structure

The consensus on the basic staffing structure in the Clinical Embryology laboratory is presented in [Figure 1](#).

The assistance level includes all laboratory staff who support the embryologists, without performing embryology

themselves. Having Assistance-level staff can be a functionally and economically advantageous solution to many laboratory managerial issues. The Embryologist level encompasses the continuum of all embryologists, from trainee through to senior (non-supervisory) embryologist. The Supervisory level includes positions responsible for the day-to-day supervision of the laboratory, whereas the Direction level is the position with overall responsibility for the laboratory or laboratories. It should be noted that the titles used are deliberately generic, as some titles have specific meanings in some countries, which may differ from the meaning used in other countries.

To support the variety of possible positions covered by these titles, job descriptions should be tailored to reflect the roles and responsibilities within each position of each ART laboratory. In some cases, one person may be required to assume the roles and responsibilities associated with more than one level of the basic structure presented here.

Consensus on roles and responsibilities

The PACER system developed by Ciara Hughes for this meeting was used to define the roles within each staffing level of the basic staffing structure. These are presented in [Table 1](#).

Not all staff members within a particular staffing level will have the same responsibilities; these will depend upon training and competency, and should be reflected in their particular job descriptions.

If any role listed in the PACER system disagrees with, or is not appropriate, under local or national legislation or regulations, then the local or national legislation or regulations should take precedence.

Consensus on entry level qualifications

The consensus on recommended educational qualifications for entry into each level of the basic structure is presented in [Table 3](#). As noted, the panel was not unanimous in its consensus on this point as some countries already have legislated educational requirements.

These represent the minimum standard for entry, so having a higher educational qualification than the recommended minimum standard should not be a reason for disqualifying a Clinical Embryologist candidate. Furthermore, if someone is currently working in a position that has a higher recommended entry-level qualification than they possess, a 'grandfathering' clause should be applied to confirm them in that position, based on experience and competency. After the completion of the 'grandfathering' phase, the minimum standards would then be applied to anyone entering the field, or being promoted.

In cases where these minimum standards are superseded by national legislation or regulations, the national legislation or regulations should take precedence.

Consensus on staffing levels

The recommended staffing levels for a clinical embryology laboratory are one full-time equivalent 'bench' or

Table 3 Recommended educational qualifications for entry into each level of the basic staffing structure.

<i>Basic staffing level</i>	<i>Academic qualification</i>	<i>Relevant experience</i>
Assistance level	BSc or equivalent technical qualification	
Embryology level	BSc or equivalent academic or technical qualification	
Supervisory level	Ideally, MSc, but BSc ^a at a minimum	5 years' clinical embryology laboratory experience
Direction level	Ideally, earned doctorate in biomedical science, but MSc at a minimum	Doctorate: 5 years' experience MSc: 10 years' experience

^aThe inclusion of BSc in the 'Supervisory level' was not a unanimous decision, as some countries have legislated higher qualifications for laboratory supervisors.

'hands-on' embryologist per 120 stimulation cycles per year. In the context of this consensus, a 'clinical embryology laboratory' was considered to be one in which the activities encompassed obtaining and handling gametes for fertilization, embryo culture, and embryo transfer, cryopreservation, or both.

Consensus on education and training

Alpha recognizes the need for a curriculum outline to facilitate the education of Clinical Embryologists throughout their career development. The framework presented in **Table 2** is seen as a 'gold standard' that should be adopted in the education and training of Clinical Embryologists. It is the consensus that theoretical knowledge should be examined, and that progression to the next level of Clinical Embryologist (i.e. from Embryologist to Supervisory to Direction) (**Figure 1**) should be subject to the successful completion of the educational requirements for that level.

Consensus on defining and assessing competency

Each ART laboratory should use a competency framework to define each aspect of the task and how the individual is assessed (an example of this framework is that developed by the ART Laboratory Special Interest Group of the Canadian Fertility and Andrology Society; (www.cfas.ca)). In addition, logbooks should be competency-based, rather than activity-based.

Each ART Laboratory Director should set key performance indicators and benchmarks for their laboratory (e.g. *Alpha Scientists in Reproductive Medicine, 2012*). Examples of the types of key performance indicators that could be set are: proportion of cycles where no oocytes were missed in the oocyte search dish (confirmed by second observer); concentration and motility of final sperm preparation (compare with expert assessor); IVF fertilization rate (of oocytes inseminated); intracytoplasmic sperm injection (ICSI) fertilization rate (of oocytes injected); ICSI oocyte damage rate, assessed at denudation, injection, and on Day 1; cleavage rate (proportion of fertilized oocytes that cleave), this is a clinic key performance indicator, not necessarily related to a single embryologist; proportion of cell lysis after biopsy; time taken for each step; inter-operator agreement in oocyte/embryo grading (see *Alpha Scientists in Reproductive Medicine and ESHRE Special Interest Group Embryology, 2011a, 2011b*).

Competency in a task is defined by the achievement of the key performance indicator control ranges for the outcome, and is maintained over the average of at least 10 typical cases. 'Control ranges' refers to the value being between the upper and lower warning limits (i.e. the control mean \pm 2SD) for the key performance indicator in question (*Mortimer and Mortimer, 2015*).

Maintenance of competence is assessed at least annually, using the same method as for assessing achievement of competence. It is acknowledged that maintenance of competency will be harder in ART clinics with low numbers of cycles per year.

Consensus on continuing professional development

It was the consensus that it is a professional obligation of all Clinical Embryologists to participate in CPD activities, and that for Laboratory Directors, active participation in CPD activities is mandatory. There was significant discussion around whether CPD should be mandatory for all Clinical Embryologists, but it was conceded that this might not be achievable at present. Mandatory CPD for all members of the profession, however, is the ideal.

In recognition of its critical importance in the development and maintenance of professional knowledge and expertise, it was the consensus that all Clinical Embryologists must be given the opportunity to participate in CPD activities.

Furthermore, any licensing or certification scheme for Clinical Embryologists must include a requirement for ongoing CPD.

Conclusions

It was the aim of this workshop to develop a consensus framework that could assist regulators and professional societies in the development of certification or licensing requirements for Clinical Embryologists. The relevance of this aim was highlighted during the preparation of this manuscript by the launch of the American Society for Reproductive Medicine's Embryology Certification Module, created by the Society for Reproductive Biologists and Technologists.

On the basis of the Workshop discussions and the consensus points reached, Alpha is planning to develop an educational programme for Clinical Embryologists. This programme will provide the material to meet the consensus requirements for knowledge development, as well as competency-based training and continuing professional development, to

meet the current and future needs of Clinical Embryologists worldwide.

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