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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.

KEYWORDS: consensus meeting, regulatory framework

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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 Zea land], 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 requirements 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