

7. – 8. May 2014 — Antalya, Turkey

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**BASIC QUESTIONNAIRE (Dutch Society for Clinical Embryology (KLEM))**

1. *In your country are there:*
- a) *Governmental regulations and*
  - b) *National professional regulation (or guidelines) that can operate in an IVF setting? – and what form do these regulations take (e.g. qualifications as to studies/degrees and experience)?*
  - c) *What are the pros and cons of your governing rules?*
- Note:** *Please provide an electronic version of these rules.*

1a: Yes, there is legislation that requires an IVF center to obtain a permit from the government to be able to conduct IVF. Currently there are 13 legislated IVF centers. The amount of money that can be charged for IVF (and other forms of ART treatment) is fixed by law. By law, all manipulations with embryos and gametes are to be conducted by doctors although in practise doctors never do this (see below). There is of course also Dutch legislation that applies to the EU legislation on the safety and quality of tissue banking). As part of this legislation, the clinical embryologist, i.s.o. the doctor, is the responsible person. All laboratories are enrolled and periodically controlled by the Quality Control Agency (RvA/CCKL) for accreditation as IVF lab (most of them as ISO15189).

1b: There is a joint document with the gynaecology society (NVOG) that regulates the responsibilities of embryologists and gynaecologists. In this document it is stated that the embryologist and gynaecologist operate next to each other in the line of organization and that each has its own professional responsibility (i.e. the gynaecologist the patient and the embryologist the gametes and embryos). In practise there is local variation between centres how this operates (in some centres the gynaecologists are more in charge than in others; this regularly leads to discussions). Our embryology society has clear regulations who can become a certified Dutch (senior) clinical embryologist (certified by the Dutch society of Embryologists, KLEM). Only KLEM certified embryologists can work in a legislated Dutch IVF laboratory (noted in professional regulations only). In order to obtain de degree of Dutch clinical embryologist, the candidate should follow a 3 year training program in one of the 13 IVF-centres. In principle only individuals with a PhD in natural sciences/ biology/ medicine or related studies are allow to enter as a trainee; if the candidate only has a Master title, additional scientific training (1 year) is mandatory. During his/her training, the candidate has yearly evaluations with two mentors form the KLEM training committee. The study programme and requisites are described in the Dutch embryologist training document, which is largely based on the skills and competitions for professionals described in the CanMed model (Canadian model for medical specialists).

1:c: Pros: Because of the necessity of a permit there is no competition amongst laboratories and all laboratories are willing to help each other and to find together the best protocol for the best results. Multicenter randomized trials are therefore feasible. Because of the fixed costs of treatment, there is no or very limited commercial interests involved. The responsibilities of embryologists and gynaecologist are clear.

Cons: The fact that by law only doctors can manipulate embryos and gametes is confusing and not correct as in practice this is never the case. This is organized in a document from the gynaecologists an embryologist societies but this has of course a lower status that governmental regulations. In addition the embryologist has clear responsibility in case of the EU tissue directives.

Note: these regulations are only available in Dutch.

2. *In your country, are there any recognized differences among IVF laboratory professionals based on educational background and/or work experience? – do they reflect a hierarchy (job title, position or responsibility) in an IVF setting?*

There are clinical embryologists and laboratory technicians. Clinical embryologists have at least a master degree, most of them have a PhD (the rule that a PhD is necessary only stems from the most recent societal regulations). They have had a special three year educational programme to become clinical embryologist. This is set up by the Dutch Society on Embryology (KLEM) (see description in 1.b). Laboratory technicians have at least a bachelor's degree or work at that level (some do also have a master). Clinical embryologists are higher in hierarchy than lab technicians however they work closely together. Lab protocols are always directed and made by clinical embryologists.

3. *In your country is there an independent organization (whether specifically for Embryologists or not) that develops a Code of Practice or Professional Guidelines for IVF laboratory professionals?*

We have the Dutch society of Clinical Embryology (KLEM). It develops codes of practice/educational programmes for clinical embryologists and for IVF laboratories. Lab technicians are not certified but are members of the society and can actively participate in committees and other activities. The KLEM is also a well-accepted and involved organization for the government and the gynaecologist.

4. *Is there an existing international or global organization that you perceive as representing IVF laboratory professionals that could oversee a global professional framework and create guidelines for Embryologists working in IVF settings (to include educational requirements, standard theoretical knowledge and practical experience with or without independent examination)?*

This could come from Alpha but should definitely be done in joint effort with ESHRE. ESHRE of course has already certification for (senior) clinical embryologists but has not developed guidelines or international requisites for responsibilities of embryologists.

5. *In countries without formal recognition, education, training programmes or career path for the Embryology profession, could an independent global organization create the necessary universal framework and guidelines to meet this need? What would such a framework look like?*

A necessary universal framework created by an independent global organization (Alpha, ESHRE, ASRM) should be available but we estimate it will be extremely difficult. This is so because it will largely (or even solely) depend on national regulations that will differ greatly among different countries. Nevertheless, having an international recognition as a professional might aid in obtaining a better position at official/governmental national regulations. Perhaps this could involve standardisation of educational programmes and examinations (theoretical) and standardisation of requirements for clinical embryologists and lab technicians.

6. *What are your recommendations for the future for the professional status of Clinical Embryologists?*

In the Netherlands a recognition by law that states that manipulations of embryos and gametes can only be done by (or under supervision of) a registered Dutch clinical embryologist would surely be important. There is continuous discussion with the government to try to achieve this.

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P.S. Also see website for presentations from the Alpha 2012 conference held in London:  
<http://www.alphaconference.org/pages/biennial-conference--2012/registered-participants/speakers---faculty.php>

**Please return by March 31, 2013 to:**

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