Proposal for Certification

A Proposal for the Licensing of ART Laboratory Professionals in Canada Based on Competency by the Canadian Fertility and Andrology Society ART Laboratory Special Interest Group

Background

The ART Laboratory Special Interest Group ("ART Lab SIG") of the Canadian Fertility and Andrology Society (CFAS) is the professional body representing all laboratory professionals working in the field of human assisted reproductive technology in Canada. The ART Lab SIG's Professional Standards Sub-committee has developed this set of competency guidelines, which include a proposed model for the evaluation process, to be used in licensing ART Laboratory Professionals in Canada.

The sub-committee also has an ongoing project to develop the indicators for the assessment of competency – in other words, the requirements that must be met before a person can be considered to have mastered a procedure. In addition, the process and mechanisms for implementing the Professional Standards as laid out in this document are under development, and are expected to be completed before the end of 2007.

"Grandfathering" and a statement of assumed competency

For the introduction of licensing to work, there must be an assumption made that everyone who is working in an ART laboratory on the day that the licensing regulations come into effect is competent in the position that they hold. This will then allow a grace period in which applications for licensing can be made and considered, so that nobody would be disenfranchised and lose their livelihood while awaiting the deliberations of the licensing agency, and so that the provision of ART services would not be disrupted.

Organizational charts

The first step in developing the competency guidelines was a review of the organizational charts for ART laboratories across Canada, and in November 2006 all directors of Canadian ART laboratories were invited to submit generic job descriptions for the positions in their laboratories. From those who responded, two main models for ART laboratory organization in Canada were apparent: one which has a "hands-on" Laboratory Director (Figure 1), the other which has an executive ScientificDirector (Figure 2).

Figure 1: Generic Organizational Chart for an ART Laboratory with a "hands-on" Laboratory Director responsible for its day-to-day management and operation

Figure 2: Generic Organizational Chart for an ART Laboratory with an executive Scientific Director responsible for research and development. Day-to-day management of the ART Laboratory is performed by Laboratory Supervisor(s).

The sub-committee found that each of these models met the particular requirements of ART laboratory practice in Canada, and therefore the considerations were based on both models. However, it is emphasized that these are not the only viable models for ART laboratory practice.

Recommendations for Qualifications Related to each ART Laboratory Position

(a) Formal qualifications

At present, there is no congruence of formal qualifications for those performing particular roles (or, indeed, of the titles of the various roles) in Canadian ART laboratories. Therefore, it must be accepted that the competency of each individual in their current position cannot be questioned in relation to their formal qualifications and, furthermore, that it is understood that vocational training and experience are deemed to provide an equivalent level of "qualification" for a role.

However, for individuals entering the profession in the future (i.e. after licensing has come into force), the sub-committee recommends the following formal qualifications for each position:

• Laboratory Andrologist: Registered Medical Laboratory Technologist and/or earned BSc in biological sciences.
• Embryologist: earned BSc in biological sciences and/or Registered Medical Laboratory Technologist with experience in andrology.
• Laboratory Supervisor: earned MSc, preferably with a clinical ART component; or earned BSc in biological sciences with extensive vocational experience.
• "Hands-on" Laboratory Director: earned MSc, preferably with a clinical ART component.
• Scientific Director – earned PhD in biological sciences, preferably with a clinical ART component.

(b) Knowledge and experience

In addition to formal qualifications, further knowledge and experience is required for many of these positions:

"Hands-on" Laboratory Director:

5 years of clinical ART experience
Supervisory experience
Knowledge and expertise in:

- Quality and risk management
- Accreditation processes
- Laboratory operation
- General management skills

Laboratory Supervisor (reporting to a Scientific Director):

2 years of clinical ART experience
Supervisory experience
General laboratory management skills

Scientific Director:

5 years of clinical ART experience
Knowledge and expertise in:

- Quality and risk management
- Accreditation processes
- General and executive management skills
- Operation of a clinic

As is the case at present, promotion within a laboratory to a more senior position will be at the discretion of the Director, and will be related to experience, and demonstration of supervisory and/or other relevant management skills.

Proposed Licensing Model

The licensing body for ART professionals in Canada is expected to be the Assisted Human Reproduction Agency of Canada (AHRAC). According to the current model proposed by the Assisted Human Reproduction Implementation Office (AHRIO), individuals will submit a checklist, with substantiating documentation, of the number of times they have performed particular tasks within a range of ART laboratory procedures. A criticism of this proposed model is that because people attain mastery of skills at different rates, licensing of individuals based solely on the number of times they have performed a procedure is not necessarily a guarantee that they are competent to perform it without supervision (which is the implication of a license). Furthermore, given the range of sizes of Canadian ART programmes, it may not be possible for an individual to have performed a particular number of repetitions of a procedure within a given time frame, and so, even though the person may be competent, they would not be eligible for a license for the procedure.

The ART Lab SIG sub-committee has developed a model that differs from the current AHRIO model by taking into account these considerations. The model draws on that used in the UK, which gives the responsibility for the judgment of functional competency to the Director of the ART laboratory, but uses peer review to judge the individual's working knowledge of each procedure.

In this model, a person wanting to apply for an ART scientist license would prepare a portfolio for submission to a licensing sub-committee of the CFAS ART Lab SIG, composed of senior ART laboratory professionals. The sub-committee would review the portfolio, and the applicant would then have a formal interview to allow the sub-committee to verify both the contents of the portfolio and the applicant's understanding of the professional code of conduct for ART laboratory professionals. When the sub-committee is satisfied that the applicant has the necessary knowledge and experience, the submission of the person's licensing application to AHRIO will be approved.

It is proposed that the contents of the portfolio be substantially the same as that required for licensing in the UK. It would contain a summary of the applicant's educational and work experience in the field of ART, and would be used to support the applicant's assertion that each of the competency guidelines presented below have been met. Evidence of the mastery of each individual procedure included in the licensing application would be provided by a summary of the person's experience in each procedure, supported by a statement from the Laboratory Director or Scientific Director that the applicant has met the laboratory's requirements to perform the task unsupervised. This would resolve the problem of the time taken by an individual to become competent in performing a procedure, as well as recognizing that procedures may differ between laboratories, thereby requiring more or less time for mastery to be achieved.

COMPETENCY GUIDELINES

Preamble

The clinical treatment of infertility in Canada has evolved rapidly since the early 1980s when new technologies such as In Vitro Fertilization were being developed and improved worldwide. IVF clinics started to appear across Canada, somewhat independently, and each with their own approach to clinical ART treatments.

ART laboratory professionals work in the fields of embryology, andrology and endocrinology. In Canada, there is currently no comprehensive educational programme which can provide specialized training in these areas, and a diploma in medical laboratory technologies or a university degree in the sciences has often been stipulated as a minimum requirement for an entry-level position. This was generally followed by on-site training during a probationary period. This competency profile for Canadian ART laboratory professionals has been developed in response to the new initiatives by the federal government to regulate the laboratory-based aspects in the field of Assisted Human Reproduction.

ART laboratory science continues to undergo profound changes with health reform and technological change evolving at a rapid pace. The competencies proposed here create a vision of an ART laboratory professional who can not only apply basic principles but also communicate, evaluate and extend learned principles through research, critical thinking, and continuous learning in their interaction with patients, clients, and other health care professionals to meet the needs of this changing profession.

Code of Conduct for ART Laboratory Professionals

1. ART laboratory professionals are dedicated to servicing the reproductive health needs of the public and promoting the welfare of the patient and resulting offspring.

2. ART laboratory professionals shall respect and protect the integrity of the reproductive material.

3. ART laboratory professionals work with other health care professionals, to provide effective patient care.

4. ART laboratory professionals shall promote the image and status of their profession by demonstrating honesty, integrity and high standards in their professional practice through active support of their professional bodies.

5. ART laboratory professionals shall protect the confidentiality of all patient information.

6. ART laboratory professionals shall practise within the scope of their professional competence and take responsibility for their actions.

7. ART laboratory professionals shall endeavour to maintain and improve their skills and knowledge and keep current with scientific advances.

8. ART laboratory professionals shall share their knowledge with colleagues and promote learning.

9. ART laboratory professionals shall be aware of the laws and regulations governing ART laboratory technology and shall apply them in practice.

10. ART laboratory professionals shall practise safe work procedures at all times to ensure the safety of reproductive materials and the protection of the environment and colleagues.

Competency Guidelines for ART Laboratory Professionals

It is expected that a competent ART Laboratory professional shall have all of the following competencies.

1. Safe Work Practices

The ART laboratory professional conducts professional practice according to established protocols, safety guidelines and existing legislation.

1.01 Applies the principles of standard precautions

1.02 Uses appropriate personal protective equipment e.g. gloves, gowns, masks

1.03 Applies appropriate laboratory hygiene and infection control practices

1.04 Minimizes possible dangers from biological specimens, laboratory supplies, and equipment

1.05 Operates laboratory equipment in a correct and safe manner

1.06 Complies with WHMIS legislation.

1.07 Handles and disposes of biological material and “sharps” according to existing legislation

1.08 Utilizes the appropriate method for items to be disinfected/sterilized

1.09 Applies appropriate spill containment and clean up procedures for biological and other hazardous materials

1.10 Responds appropriately to fire emergencies

1.11 Responds to and reports incidents related to safety and personal injury (e.g. needle stick injuries), in a timely manner

2. Obtaining and processing of gametes and embryos

The ART laboratory professional applies appropriate standard operating procedures (SOPs) to obtain and process gametes and embryos in a timely, accurate manner that contributes to successful outcomes.

2.01 Performs scheduled ART procedures only at the written or electronic request of an authorized person

2.02 Organizes workflow to accommodate changes in priorities.

2.03 Provides information to the client on specimen collection, transportation and storage.

2.04 Verifies that patient identifier on requisition corresponds with the specimen.

2.05 Identifies discrepancies in specimen procurement and/or documentation and initiates corrective action as required.

2.06 Assesses the suitability of the sample for requested ART procedure, and initiates corrective action if required.

2.07 Selects the most appropriate SOP to perform the requested procedure according to the Centre’s established policies.

2.08 Processes gametes and embryos according to selected SOP, thereby ensuring the integrity and identity of the specimens.

2.09 Verifies that specimen identification is traceable throughout analysis/procedure.

2.10 Evaluates the quality of gametes and embryos against set criteria using a standardized grading, rating, or scoring system.

2.11 Ensures procedures are performed to achieve expected outcomes.

2.12 Identifies implausible results and takes appropriate action.

2.13 Recognizes possible specimen deficiencies and takes appropriate action.

2.14 Accounts for all obtained sperm samples, oocytes and embryos.

2.15 Maintains a complete laboratory record for each ART procedure.

2.16 Verifies that all requested procedures have been completed.

2.17 Protects the patient's confidentiality throughout the ART process.

3. Communication

The ART laboratory professional, using scientific knowledge as the basis, interprets, communicates and documents confidential data.

3.01 Ensures that laboratory results are accurately documented and retained in accordance with existing legislation.

3.02 Demonstrates the ability to communicate clearly, effectively and promptly within the laboratory team.

3.03 Enters data into laboratory information system.

3.04 Liaises effectively with other members of the clinical team.

3.05 Releases results of laboratory analyses/procedures that meet internal quality control criteria in a timely and efficient manner.

3.06 Communicates with patients with sensitivity and empathy.

3.07 Recognizes the implications of laboratory findings on outcomes.

4. Quality and risk management

The ART laboratory professional practises and promotes the principles of quality management.

4.01 Understands the principles of quality management and quality improvement.

4.02 Follows established protocols as defined in policy and procedure manuals.

4.03 Maintains established standards for quality control in specimen collection, transportation,storage, preparation, analysis and reporting.

4.04 Maintains comprehensive quality assurance documentation.

4.05 Identifies and reports deficiencies in the workplace that may affect safety and outcomes.

4.06 Maintains logs for laboratory equipment/instruments.

4.07 Performs and/or documents quality control on reagents and media.

4.08 Initiates reordering of reagents and supplies as required.

4.09 Assesses the quality of new reagents and supplies.

4.10 Understands the importance of identifying and reporting errors or oversights in processes that may affect safety and outcomes.

4.11 Applies continuous quality improvement techniques and risk management processes to ensure quality clinical laboratory services.

5. Critical thinking

The ART laboratory professional applies critical thinking skills to constructively solve problems and troubleshoot.

5.01 Understands the science that underpins assisted reproductive technology.

5.02 Understand the principles of the techniques and methods employed in the discipline.

5.03 Demonstrates an open inquiring mind and self-directed learning processes in resolving analytical, workplace and career challenges.

5.04 Demonstrates the ability to critique and assess limitations of published methodology and outcomes.

5.05 Demonstrates the ability to adapt to rapidly changing situations e.g.: responds appropriately to critical situations; retains composure in stressful situations; applies existing skills to new situations.

5.06 Demonstrates knowledge of the ART standards and professional ART organizations and responsibilities.

5.07 Demonstrates knowledge of the determinants of reproductive health and their implications for ART outcomes.

5.08 Understands the basics of external factors that have the potential to affect laboratory performance.

5.09 Recognizes that change initiated in one area will impact on other areas of the ART team.

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