

Competency-Based Licensing of Assisted Reproductive Technology (ART) Laboratory Professionals

To the Editor:

On behalf of the Canadian Fertility and Andrology Society (CFAS), we would like to draw readers' attention to the publication of a proposal for the competency-based licensing of assisted reproductive technology (ART) laboratory professionals in Canada. This document was prepared by the ART Laboratory Special Interest Group ("ART Lab SIG") of the CFAS and has been sent to Health Canada's Assisted Human Reproduction Implementation Office as the profession's proposal for the future licensing of ART laboratory professionals working in assisted human reproduction centres (i.e., In-Vitro Fertilization, or IVF, clinics) in Canada. This licensing will be administered via the Assisted Human Reproduction Agency of Canada that is currently being established pursuant to the Assisted Human Reproduction Act of 2004.

The ART Lab SIG's proposal was finalized in consultation with all ART laboratories across Canada, and is comparable to similar documents developed by other professional groups working in this area of infertility therapy around the world but tailored specifically to the situations that exist in Canadian IVF centres. The document, which is available in PDF on the CFAS website at www.cfas.ca, contains proposals for "grandfathering" and a statement of assumed competency, generic organizational charts for IVF laboratories, recommendations for qualifications related to each ART laboratory position, a proposal for a licensing model that includes mentoring via the CFAS ART Lab SIG, a professional code of conduct, and draft competency guidelines for ART laboratory professionals. The ART Lab SIG is now working on the development of guidelines for education and evaluation of licensing applicants, as well as on the development of competency guidelines for laboratory supervisors.

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The Summer Institutes in Maternal-Fetal Pharmacology: Building Critical Mass in a Neglected Area

To the Editor:

The reluctance of physicians, scientists, drug companies, and regulatory agencies to study medications in pregnancy has led to "orphaning" of women and their unborn babies from the benefits of new medications.^{1,2}

Presently, only a handful of obstetricians and perinatologists have obtained formal education in this subspecialty, which further limits the appropriate study of drugs in pregnancy.

Acknowledging this serious void, the Institute of Human Development, Child and Youth Health (IHDCYH) of the Canadian Institutes of Health Research (CIHR), the National Institute of Child Health and Human Development (NICHD), and the Office of Research on Women's Health (ORWH) at the National Institutes of Health (NIH), initiated an annual Summer Institute in Maternal-Fetal Pharmacology.³ The first Summer Institute took place in July 2005 in Mt. Tremblant, Quebec, and the Summer Institutes are now held alternately in the US and Canada.

The overall objective of the Summer Institute is to foster the development of a critical mass of researchers in basic, clinical, and population health and health services research in this neglected area.

The course is designed for clinical and non-clinical scientists who are planning academic careers in studying therapeutics during pregnancy, childbirth, and lactation.

In each of the Summer Institutes held so far, 20 applicants have been selected and mentored by faculty from American and Canadian universities who are national and international leaders in various aspects of obstetric and perinatal pharmacology. The seven-day course is based on a mixture of lectures by experts, small-group studies, and discussions, with a high ratio of faculty to learners. Special focus is given to interaction among faculty members and participants.

The major topics covered in the course include physiological changes in pregnancy, pharmacokinetics/pharmacodynamics, study design, biostatistics, and bioethics. In addition to lectures and small-group discussions, the curriculum includes a hands-on pharmacokinetic exercise and a study design and bioethics discussion based on the movie *Awakening*.⁴

A typical protocol assignment

Pre-Emptive Management of Women with Previous Severe Nausea and Vomiting of Pregnancy (NVP)

NVP affects up to 80% of pregnant women. Its severe form, hyperemesis gravidarum, is associated with dehydration, fluid and electrolyte imbalance, and hospitalization. A woman with a previous experience of severe NVP has a 70% likelihood of repeat of a similar untoward experience. Recently, a prospective controlled, unrandomized study suggested that pre-emptive treatment with antiemetics (i.e., before the nausea and vomiting have started) can prevent a repeat of severe NVP in many cases.

After reading the relevant literature, please design a protocol that will answer the following research question:

"Is pre-emptive use of antiemetics effective in preventing severe forms of NVP?"

Each participant is expected to develop a preclinical or clinical drug therapy protocol before the course. These protocols are discussed by groups of six or seven applicants and two or three faculty members and subsequently by the whole group of 20 learners and six to eight faculty members. The Figure shows a typical protocol assignment.

Learner evaluations of the first two Summer Institutes were overwhelmingly positive. The elements learners identified as most positive were the informed interactions with world-renowned faculty on site, the small-group

interactions, and the multidisciplinary nature of the learning and discussions, taking all participants outside their own "comfort zone."

We encourage readers to refer to the website of the Summer Institutes for more information.³

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