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SYMPOSIUM: QUALITY MANAGEMENT IN ASSISTED REPRODUCTIVE TECHNOLOGY
REVIEW

'By the work, one knows the workman': the practice and profession of the embryologist and its translation to quality in the embryology laboratory

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Abstract The embryologist presides over the fulfillment of a patient's treatment in the laboratory for IVF through use of assisted reproduction techniques, and is in a unique position to impart quality to the process. Although the technical skill of the embryologist is critical, the embryologist's contribution to quality is equally conveyed through a knowledge of reproductive biology, keen observation and judgment, astute decision-making, the 'grit' to work under pressure and time constraints, and a sense of mission in the provision and continual development of a safe and effective laboratory. The embryologist also ensures that the laboratory complies with the regulations of federal, state, local and institutional authorities and the recommendations and guidelines of professional associations. In these roles, the embryologist assumes unique responsibilities counterbalanced by the unique rewards of assisting patients in having a family. This article aspires to illuminate this singular profession for those who may be contemplating a career in embryology and act as a resource for those who seek insight into this amalgam of basic science, technical proficiency, and managerial skill and acumen that characterize the practice of clinical embryology and the myriad of ways that practitioners contribute to the quality of assisted reproduction techniques and patient care.

KEYWORDS: embryologist, management of quality, proficiency, qualifications, training

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Introduction

An axiom in virtually any human industry is that the personnel who carry out the mission of the company are its greatest resource, bringing the expertise and creativity that are vital to the product or service. So, while it is both wonderful and fortunate to have a spacious, well-designed, and secure physical plant with an abundance of latest-model-year equipment and ample highest-quality supplies, the most valuable and critical asset of an assisted reproduction technique laboratory is the team of embryologists.

Through their hands, safe conduct of patients' gametes and embryos is achieved. In this article, the issues underpinning how the embryologist imparts quality to the performance of the assisted reproduction technique laboratory and to patient care are addressed. It also aims to act as an informative resource for individuals contemplating careers in this uniquely rewarding profession, as well as enlightening those seeking more knowledge about what constitutes the discipline and practice of clinical embryology.

The practice and profession of clinical embryology

With the birth of Louise Brown in 1978 (Steptoe and Edwards, 1978), a new laboratory specialty wedded and integral to the treatment of infertility using IVF emerged. Although other medical specialties are dependent on interpretations and diagnoses made in laboratories from patient samples, IVF was unique in requiring a laboratory that would not only evaluate, characterize, prepare and process samples, but act as an effective substitute for a human organ – the Fallopian tube. The scientific and technical specialists possessing this expertise provide a biological culture environment and carry out an array of technical procedures allowing gametes to unite and realize their developmental potential to become embryos, and for some of these embryos to ultimately complete the processes of implantation and growth providing the offspring so keenly desired by the patients.

Although the technical aspects of the embryologists' role in carrying out the prescribed array of assisted reproduction techniques in a patient's treatment may eclipse all their other activities, there is, indeed, a formidable array of tasks and responsibilities that accompany the laboratory's operation and are integrally involved in its ability to possess quality.

To appraise how the embryologist and the laboratory under his or her stewardship impart quality, the following are considered: the array of technical skills comprising assisted reproduction techniques: what an embryologist does; the educational, technical and experiential backgrounds and intangible qualities of personality and character that can make an embryologist exceptional; who an embryologist is; what is quality in an assisted reproduction technique laboratory and clinic? How the embryologist carries out the mission of ensuring quality in an assisted reproduction technique laboratory and clinic; and how the embryology team can be optimally supported in its mission of providing quality to the function of the laboratory and the care of patients.

The craft of embryology

The embryologist provides the knowledge and technical skill to carry out the process of IVF and its continually evolving collection of techniques comprising assisted reproduction techniques. The portfolio of the embryologist includes the following: oversight and maintenance of a laboratory and its instruments, equipment and supplies; preparation and quality control of culture media and all labware used for assisted reproduction techniques; processing of sperm for insemination or intracytoplasmic sperm injection (ICSI) and sperm cryopreservation (freezing); egg retrieval; conventional insemination; ICSI; assessment of eggs for fertilization; culture of embryos to cleavage stage or blastocyst; embryo selection and transfer; embryo cryopreservation and thawing; assisted hatching; biopsy of cleavage stage embryos (blastomere biopsy) or of blastocysts (trophectoderm biopsy); preparation of biopsies for shipping to and analysis by the genetics laboratory for preimplantation genetic screening and preimplantation genetic diagnosis (PGD); oocyte cryopreservation; maintenance of the cryopreserved inventory of sperm, eggs and embryos; ensurance that the laboratory is in compliance with regulations from local, national and federal authorities for licensure and accreditation; training in new techniques and training of new embryologists; recording and documentation of all events relevant to patient care and the laboratory's operation; participation in continuing education to always be knowledgeable about emerging technologies and concepts in the treatment of infertility; and active and effective membership on the clinical team for delivery of optimal patient care through excellent communication and collaboration.

A categorization of these activities is presented in **Table 1**. Each can be considered in its context as a technical, administrative or regulatory compliance activity.

Although detailed descriptions of the techniques can be found in the handbooks and technical reviews devoted to assisted reproduction techniques (Gardner, 2006; Gardner et al., 2012; Nagy et al., 2012), each assisted reproduction technique laboratory will have its own manual. This will provide complete step-by-step protocols for each procedure written specifically to address the laboratory's instruments, materials and organization. All protocols in all laboratories should observe the same universal principles of good general and IVF-specific laboratory practice and patient safety. These include appropriately educated and trained practitioners; secure physical space and controlled environment; appropriate instruments, equipment and supplies; freedom from distraction; an organized plan for carrying out the procedures; strong record-keeping for full accountability; a database for evaluating outcomes and identifying trends; responsive resources to tap for assistance and support; and consistent and effective channels of communication.

Because of the unique nature of the embryology laboratory and the fruits of its work – human embryos for transfer – the embryologist bears a unique responsibility in achieving maximal risk- and error-avoidance. The embryologist must carry out all technical tasks with meticulous attention and

Table 1 A list and categorization of procedures and activities of a clinical embryologist.

	Technical	*Administrative and laboratory support and development*	*Compliance with regulatory authorities*
Fundamental IVF procedures	Preparation and quality control testing of culture media and labware. Prepare sperm for insemination. Egg retrieval. Egg insemination. Assessment of eggs for fertilization. Embryo culture and assessment for transfer or cryopreservation. Embryo thawing and cryopreservation. Embryo transfer. Training of new embryologists.	Maintenance of the laboratory and its instruments, equipment and supplies. Daily calibration and quality control of instruments. Daily assessment of laboratory climate (temperature, relative humidity and air quality). Record-keeping and documentation of treatment cycle results and outcomes. Preparation of glassware. Maintenance of cryopreserved gamete and embryo inventories. Communication with patients about cryopreserved samples. Professional development through continuing medical education. Appraisal and development of new laboratory techniques, procedures and protocols. Review and revision of laboratory protocols and manuals. Regularly scheduled meetings with laboratory, clinical and administrative teams to assess outcomes, evaluate trends, describe new initiatives to develop the laboratory and the clinic, and describe and implement best practices. Error or 'near miss' analysis for risk avoidance and abatement. Scheduling of laboratory procedures. Education of clinical staff and patients about laboratory procedures and protocols . Ensuring security and surveillance of laboratory's physical plant and instrument integrity at all times.	Participation in proficiency testing. Compliance with accreditation authorities (CAP, JCAHO, FDA, state and local departments of health for licensure). Compliance with medical practice, company or hospital administration policies. Preparation and readiness for laboratory inspections or surveys. Laboratory records and archive maintenance. Acquisition and reporting of clinical data to SART/CDC.
Advanced IVF – Micromanipulation and ICSI	Assisted hatching by mechanical or chemical methods or by LASER. Preparation of eggs for ICSI. Harvesting of sperm from severely oligo-astheno-spermic samples or testicular tissue. ICSI.		
Advanced IVF – embryo and blastocyst biopsy	Blastomere biopsy. Trophectoderm biopsy. Preparation of biopsies for genetic analysis.		
Advanced IVF – egg cryopreservation	Egg vitrification and warming.		
Research	Clinical trials. Retrospective data analysis.		

CAP = College of American Pathologists; CDC = Centers for Disease Control and Prevention; FDA = US Food and Drug Administration; ICSI = intracytoplasmic sperm injection; JCAHO = Joint Commission on accreditation of Healthcare Organizations; SART = Society for Assisted Reproductive Technologies.

be mindful of the hopes and expectations of the patients in their care. We need only to put ourselves in the patients' place to know that this translates to confidence that the embryologist is skilled and careful, will do everything to optimize the technical outcome and is personally invested in driving towards the patient's achievement of clinical pregnancy. In addition, to the embryologist falls the vigilance that will be no loss or damage to any cells or tissues in the laboratory, nor mis-matching of gametes for IVF or embryos for cryopreservation or transfer, or, with cases requiring PGD, no mis-assignment of genetic testing result to biopsied embryo.

An unwavering attention to labelling and focus on each procedure and an internal compass set for excellence and pride in one's work are the embryologist's allies in this endeavour.

Who can be an embryologist?

With the array of responsibilities of the embryologist described, we turn to identifying the individual who is both qualified and motivated to assume and, ideally, embrace, them.

Unlike other professions, such as medicine, there is no standardized or formal course of study and training that one pursues to become an embryologist. A student of medicine, for example, attends and completes medical school, fulfills a residency in a medical specialty and attains board-certification, and potentially sub-specializes via a fellowship to earn this additional certification. In contrast, there is no analogous prescribed and structured career path to clinical embryology. In the earliest years of IVF and continuing to the present, embryologists have been drawn from the ranks of individuals in basic life science research laboratories, particularly those specializing in reproductive biology, cell biology and microbiology, or from animal science and agricultural settings, where experience in handling gametes and embryos was obtained. Another excellent resource is the clinical laboratory, the domain of medical technicians and technologists, where adherence to technical protocol and an appreciation for producing diagnostic and therapeutic information are intrinsic to the profession. These individuals and college or university graduates with degrees in the life sciences may find embryology particularly attractive in its combining laboratory science and technology with patient care. Assisted reproduction techniques has also benefited from the inclusion of individuals with non-science degrees but sufficient educational background, intrinsic aptitude and motivation.

Embryologists, it is fair to observe, have driven the development and recognition of their own profession through early efforts to meet, organize and define standards of education, experience, technical and administrative competence. The documentation and validation of these parameters were integral to establishing appropriate professional credentials for the clinical embryologist. The American Society of Reproductive Medicine (ASRM), historically a medical society, was among the first professional organizations to provide a forum and educational and professional support for the multidisciplinary and collaborative role that the embryologist fulfills in the treatment of infertility through assisted reproduction techniques. The first meeting to consider a society of embryologists and reproductive biologists was held at the 45th meeting of the ASRM in 1989 and was the progenitor of the Society of Reproductive Biologists and Technologists. In conjunction with the practice committees of the ASRM and the Society for Assisted Reproductive Technology (SART), the Society of Reproductive Biologists and Technologists recently provided recommendations for the management of the embryology laboratory, reflecting its development, engagement and partnership with its clinical colleagues in the ASRM over the intervening 25 years in this continuing endeavour to define optimal practice of IVF (Practice Committee of the American Society for Reproductive Medicine et al, 2014).

The early efforts of embryologists to inform the definition of their profession was timely, given the passage of the Fertility Clinic Success Rate and Certification Act (102nd Congress, Second Session, 1992). This federal legislation directed all clinics carrying out assisted reproduction techniques to submit their clinic-specific pregnancy rates to the Centers for Disease Control for publication and the Secretary of Departments of Health and Human Services to work with the Centers for Disease Control to develop a model programme for the certification of embryology laboratories. Included in this model were standards for procedures, quality management, instruments and equipment and, importantly, the personnel – the embryologists.

Although virtually all clinical laboratories in the USA must comply with the standards set forth by the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) (https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html), embryology laboratories are unique in carrying out assisted reproductive technology as an integral part of a medical practice for infertility. This distinguishes it from other laboratories, such as those for endocrine or pathology that carry out testing on samples and report results, e.g., testing on blood to report levels of oestradiol or progesterone, or histologic analysis of tissue to identify normal or abnormal cells. An embryology laboratory, in contrast, manages human gametes to generate embryos for transfer and implantation. Diagnostic information is obtained about egg maturity, sperm quality and embryo morphology, but the embryos represent a therapy or treatment in the alleviation of infertility. Embryology laboratories provide both diagnostic and therapeutic services. The key precepts of CLIA 88, however, must be observed in assisted reproduction technique laboratories: requirements for proficiency testing, test sample management, quality control and assurance, inspections and sanctions for violations, and criteria for education and experience for the laboratory's personnel (Keel and Schalue, 2001).

In response to the Fertility Clinic Success Rate and Certification Act requirement for a model laboratory programme for embryology laboratories, a multi-disciplinary team from both ASRM and the College of American Pathology (CAP), including embryologists, physicians, and administrators, convened to write checklists to provide a meaningful inspection and survey process for the model (Visscher, 1991; Federal Register, 1999). These checklists underpin CAP's Reproductive Laboratory Accreditation Programme (http://www.cap.org/apps/docs/laboratory_accreditation/build/pdf/standards_repro.pdf) and provide both an extensive and specific survey of general and embryology-specific attributes. The Joint Commission on the Accreditation of Healthcare Organizations has also developed a survey and accreditation process specific for reproductive laboratories (http://www.jointcommission.org/facts_about_laboratory_accreditation/). An understanding of the regulations governing assisted reproduction technique laboratories is central to an embryologist's management and operation of the unit, and the clinic is frequently dependent on that knowledge (Baker, 2012).

Recognition of the leadership, management and expertise required for embryology laboratories was significantly augmented by the provision of specific professional certification of embryology laboratory directors, technical supervisors and technical consultants conferred by the American Board of Bioanalysts (www.aab.org/). The first examinations for certification were dispensed in 1994, yielding the first generation of certified High Complexity Laboratory Directors and Technical Supervisors for embryology.

In 2008, the ASRM published a compendium of guidelines and recommendations for the leadership and specialists of embryology laboratories (Practice Committees of the American Society for Reproductive Medicine, 2008). These are presented in **Table 2**, describing the educational credentials and experience for each position. The profession of clinical embryology has been continuously fortified and burnished by important activities and contributions of the European Society of Human Reproduction and Embryology (ESHRE) and its recommendations (Magli et al., 2008), Alpha Scientists, the College of Reproductive Biology of the American Association of Bioanalysts and the American College of Embryology (ACE).

Certification is awarded by ESHRE and ACE to qualified embryologists through a multi-level and multi-track system described at http://www.eshre.eu/accreditation_and_certification/page.aspx/17 and www.embcol.org/, respectively, that accommodates embryologists at various levels of education and experience.

Alpha Scientists, a society for scientists in reproductive medicine (alphascientists.org/), has championed the goal of developing the professional status of clinical embryology, organizing a meeting in 2013 to seek consensus on defining the embryologist as a technician, technologist or scientist, and outlining the educational requirements for this profession, the scope of responsibilities, the structure and content of training and education programmes and how proficiency and competence should be defined and assessed (Alpha Scientists in Reproductive Medicine, 2015).

A quality management system, UNE 179007, has been developed to specifically to address assisted reproduction technique laboratories for Standard International Organization for Standardization 9001 (Ortiz et al., 2014). In this document

Table 2 Guidelines for the laboratory personnel of human embryology laboratories provided by the American Society of Reproductive Medicine in the 2008 Compendium of Practice Committee Reports.

	Laboratory Director	*Laboratory Supervisor*	*Embryologist*
Educational credentials and certification	Have an earned doctoral degree (PhD) in a chemical, physical or biological science from an accredited institution, or, MD or DO from an accredited institution. Have certification as a High Complexity Laboratory Director or Embryology Laboratory Director (through the ABB) or equivalent.	Meet requirements for laboratory director, or, have an earned bachelor's or master's degree in chemical, physical, biological, medical technology, clinical or reproductive laboratory science from an accredited institution.	Meet requirements for laboratory supervisor.
Training	A minimum of 6 months training and completion of 60 assisted reproduction technique procedures under supervision. 2 years documented experience performing IVF-related procedures.	Documented training and performance of at least 60 assisted reproduction technique procedures under supervision.	Documented training and performance of at least 30 assisted reproduction technique procedures under supervision.
Maintenance of proficiency	Demonstration of technical competency by documentation of performance of specific procedures and results within acceptable standards for the laboratory.	Performance of at least 20 assisted reproduction technique procedures per year.	Performance of at least 20 assisted reproduction technique procedures per year.
Continuing education	12 hours accredited continuing education.	12 hours accredited continuing education.	12 hours accredited continuing education.
Responsibilities	Availability for consultations with laboratory and clinical teams as needed. Ensurance that the physical plant and environment of the laboratory are safe. Ensurance that patient confidentiality is maintained. Provision of approved laboratory manual and quality management programme. Ensurance that laboratory staffing is appropriate, their training is complete and proficiency is maintained.	Daily supervision and oversight of the laboratory.	Independent performance of all routine technical procedures of the laboratory and reporting of results.

are included educational and experience requirements for embryologists as well as definitions of their responsibilities in laboratory operations.

At present, the still-frequently taken route to embarking on a career in embryology is to join the staff of an infertility clinic as an embryologist and become initiated into the array of technical and administrative tasks that comprise this specialty. The acquisition and expansion of experience and expertise are continuous in embryology, providing one with a profession that evolves and challenges and can inspire the seeking of further education, certification, or both, and the opportunities for career development. To the benefit of all clinical embryologists, and in the service of ensuring that clinical embryology is supported and nurtured as a laboratory and scientific specialty, these organizations and others similar in mission around the world are contributing to the articulation of the highest standards that will impart quality to the provision of assisted reproduction techniques.

The 'intangibles'

In addition to appropriate credentials of education and experience, there is a host of intangible qualities that characterize the individual well-suited to be an embryologist.

Because the technical aspects of an embryologist's work often eclipse the array of other activities he or she completes, e.g. collecting eggs from follicular aspirates, injecting eggs during ICSI or collecting biopsies from embryos, excellent hand-eye coordination may be the first attribute that comes to mind: the ability to work, at the microscopic level, in three dimensions with deftness and facility. The interview of candidates for an embryologist position could reasonably include tests for fine motor skills and dexterity.

Another inestimable attribute is that of being observant and discerning. Embryology involves the examination of individual cells and embryos, and their characterization and scoring or grading based on those observations. The capture of fine detail and knowing what is significant are integral to providing information for the patients' treatment, e.g. sperm morphology, egg maturity, embryo and blastocyst development, multinucleation of a blastomere, post-thaw survival of a gamete or embryo or the appearance of seminiferous tubules in a testicular biopsy or granulosa cells in a follicular aspirate. The information reported and recorded by the embryologist is central to the diagnostic and therapeutic goals of treatment with assisted reproduction technqiues.

Unlike other laboratory tasks or tasks in other professional positions, time required to completed assignments in an embryology laboratory may be open-ended. In the practice of embryology, a fixed 8-h day or shift may not characterize his or her work schedule in carrying out assisted reproduction techniques and fulfilling patient care. Although there are some 'routine' procedures in embryology, some cases demand sheer perseverance and motivation. Examples are searching for and harvesting sperm for ICSI in severely oligo-spermic patients or from the testicular biopsies from patients with non-obstructive azoospermia, or waiting for the ideal time at which to carry out biopsy on blastocysts in which the trophectoderm has not adequately emerged. The expertise and commitment of the embryologist are central to all outcomes in the assisted reproduction technology laboratory but especially in cases like these, where doggedness and dedication come to bear and enhance the laboratory's quality and productivity.

The embryologist must have an appreciation that each task in assisted reproduction techniques translates to patient care (Sunde and Balaban, 2013). Sound judgment and the ability to make decisions should develop with experience and the guidance from training with a supportive and knowledgeable team. In addition, in some clinics, the embryologist may have patient contact to provide first hand information on the outcomes from the laboratory. In this role, the embryologist must possess the communication skills and empathy that make this interaction productive and beneficial in the mission of the clinic's quality of care and the patient's treatment experience (Flin, 2014).

Finally, the embryologist must exert control over the environment of the laboratory. Attention to detail and global overview must co-exist so that oversight is exercised, deviations are prevented, treatment plans are carried out, and operations are optimized and un-impeded. Anticipation of problems and design of solutions, effective troubleshooting and the ability to manage emergencies are all attributes that characterize the successful embryologist.

Training

With IVF and assisted reproduction techniques in their fourth decade as treatment modalities for infertility, the training of embryologists is still largely achieved as it has been from the beginning: by apprenticeship in individual laboratories and learning a specific laboratory's protocols and practices. A structured programme of training and an articulate, patient and skilled trainer are indispensable to the development of an embryologist and the learning of good technique and practice. By an organized progression through a catalogue of techniques, procedures and protocols, the embryologist acquires technical skill and the scientific knowledge base that will provide insight into how and why each task is done, and how to participate in the laboratory's operation and maintenance.

Although IVF is perceived primarily as a technical procedure, of retrieval and transfer, ICSI and biopsy, the embryologist will be most successful when he or she possesses a solid grounding in the science of culture medium design and biochemistry of metabolism, reproductive cell physiology and events of early reproduction. Satisfaction awaits the student who mastered the chemistry lessons of osmolality, surface tension, equilibration, thermodynamics, pH and the Henderson–Hasselbalch equation.

The embryologist-in-training will build proficiency in methods that ascend in order of difficulty. Experience allows skill to expand both in depth and in breadth, with repetition and honing of established skills and constant acquisition of new ones. In this, embryology selects for individuals who are curious and confident, and who constantly push the confines of a comfort or complacency zone.

Keeping a training log is an important complement to the learning process, allowing tracking of progress and identifying exceptional aptitude as well as weak areas that demand more attention. This will also assist the trainer in determining when a technique has been mastered and it is appropriate to advance to something new.

When proficiency and confidence are attained through repetition under supervision, the embryologist is authorized to carry out the procedure independently. The authorization for each technique should be documented with date and name of trainer as the complete training record for each embryologist.

Records related to training, authorization and maintenance of proficiency are essential for accreditation of the assisted reproduction technique laboratory by the regulatory agencies who have established the standards and requirements. These can include some or all of the authorities who have jurisdiction over specific aspects of the embryology laboratory, including CAP, The Joint Commission on Accreditation of Healthcare Organizations, the American Association for Accreditation of HealthCare, the American Association of Tissue Banks, the Federal Drug Administration, and the International Standards Organization, as well as state departments of health who issue licenses for laboratories and tissue banks.

Continuing education and networking with professional colleagues

Because an embryologist's training is obtained at the laboratory where he or she is employed, i.e., is site-specific, local, national or international professional meetings related to assisted reproduction techniques can be a valuable source of new knowledge and techniques, reinforcement of current concepts and emerging methodologies and enhancements. In addition to building knowledge and perspective in assisted reproduction techniques, continuing education feeds creativity and continued interest.

Highly motivated and committed embryologists may wish to earn advanced degrees in clinical embryology, earn certification from a board that recognizes the specialty of clinical embryology such as the American Board of Bioanalysts or ACE, or both. These credentials may afford them opportunities for advancement and employment, and help them achieve supervisory or directorial positions to fulfill their personal professional ambitions.

Master of Clinical Embryology degree programmes are available at the Jones Institute at Eastern Virginia Medical School, Colorado State University, and at several universities in the UK, as well as Monash University in Australia. Some programmes are non-residential or partially residential, and allow the master's candidate to attend lectures and participate in classes electronically. The candidate can thus maintain their full-time employment while pursuing their degree-related research in their own laboratories.

Optimal staffing requirements for an assisted reproduction technique laboratory

Assisted reproduction techniques have evolved rapidly over the last three decades since the birth of Louise Brown in 1978, the first baby conceived through in IVF and Elizabeth Jordan Carr, the first IVF baby in the USA in 1981. After its establishment as a procedure using conventional insemination, IVF involved short-term embryo culture (to cleavage stage, day 2 of embryo development) and cryopreservation by slow-cooling. Assisted reproduction techniques rapidly accrued increasingly more complex and technically demanding methodologies. The addition of micromanipulation techniques of assisted hatching, assisted fertilization through ICSI, and embryo biopsy and biopsy management of PGD dramatically increased the requirement for intensive training, practice, and validation of technique to rapidly integrate these into the laboratory's repertoire and enhance the level of patient care. These procedures also involved the need for new channels of communication to be created with medical and scientific partners outside the clinic. To coordinate ICSI cases requiring surgically retrieved sperm or PGD cases, for instance, the embryologist must communicate with urologists and genetics laboratories, respectively, to address the logistics for patient care. Both technically and administratively, the allocation of time and resources in the embryology laboratory for patient care has evolved dramatically.

The 2008 guidelines provided by the ASRM for the staffing of assisted reproduction technique laboratories indicated that a minimum of two qualified people should be available to provide all technical services. Recently, in light of how assisted reproduction techniques and the operations of the embryology laboratory have gained in complexity, an analysis of how appropriate staffing of embryology laboratories has correspondingly evolved provides a model relating task volume and task intensity (Alikani et al., 2014). The greater complexity and time requirements of contemporary assisted reproduction techniques, e.g., ICSI, PGD and egg vitrification, have resulted in a significant increase in how much time each patient's treatment cycle can require, from 9 embryologist hours to as many as 20 h to fulfill the techniques prescribed for each treatment. With the demands of laboratory maintenance, record keeping, training and regulatory compliance, this increased intensity of embryologist time and effort per treatment indicates that the number of personnel required for efficient and safe operation of the embryology laboratory must be adjusted upwards to meet these demands. An interactive Personnel Calculator was offered to assist clinics in identifying the appropriate number of embryologists and support staff for their assisted reproduction technique volume. This model may be useful in assisting laboratories to understand the evolving technical and administrative/regulatory compliance work load in their laboratories and respond with appropriate staffing.

What is quality in assisted reproduction techniques?

The embryologist is a member of a multi-disciplinary team whose mission is to provide patient treatment. The team must have a plan and means to imbue the patient's experience with quality (Gameiro et al., 2013), a global term we attribute to an experience as a patient, client, customer or consumer. A process that assures and controls quality encompasses the provision of a service (infertility treatment with assisted reproduction techniques) or product in a validated and effective form subject to standards set by an appropriate regulatory body; continuous monitoring of the service or product to ensure it is provided in a consistent and reproducible way to meet consumer expectations; ensuring that the professional individuals and site involved in the service or product are qualified and appropriate, respectively; surveillance of all processes, procedures and materials involved in the service or product for effectiveness, consistency and safety; an active and continuous process for improvement of the service or product; an effective process to identify, analyse and correct mistakes or adverse events and prevent recurrence; and a means of communication between the organization and consumer allowing questions or concerns to be addressed.

The embryologist's contribution to quality in assisted reproduction techniques

Over-arching the array of instruments – the incubators, microscopes, laminar flow hoods, lasers and recording devices for morphokinetic analysis that characterize a 21st century assisted reproduction technique laboratory – are the embryologists who use them to fulfill a patient's treatment plan.

As in any discipline in which technical proficiency can directly influence a measurable outcome, monitoring performance is essential to confirming that a procedure is carried out correctly and optimally and to discovering departure from protocol and opportunity for correction and improvement.

A database that captures parameters of performance is invaluable in this effort, allowing immediate access to and analysis of an indicator or a selected panel of indicators and peer-to-peer comparison. Examples of performance metrics for assisted reproduction techniques are presented in Table 3.

Table 3 Parameters that can reveal proficiency or deficiency in a given assisted reproduction technqiue procedure.

Proficiency parameter for embryologist performing:	*Data*
ICSI	Number of two procnuclei per total number of mature eggs injected.
Cryopreservation or vitrification	Number of embryos recovered intact and viable per number cryopreserved.
Thawing	Number of embryos recovered intact and viable per number thawed.
Embryo transfer	Number of clinical pregnancies per number of embryo transfers.
	Number of gestational sacs per total number of embryos transferred.
Embryo biopsy	Number of embryos continuing development per number of embryos biopsied.
	Number of embryos with molecular signal per number of embryos biopsied.
Egg vitrification	Number of eggs survived and intact per number of eggs vitrified.
Assisted hatching	Number of gestational sacs per total number of hatched embryos.

ICSI = intracytoplasmic sperm injection.

An informative database will allow recording and analysis of as many variables as desired. An important proviso, though, is that in the treatment of infertility, outcomes are the products of multiple factors, some of which are outside the control of the laboratory and the embryologist. These can include patient age and indication, ovarian reserve, number of previous unsuccessful treatments, medical history and factors, severity of male factor, age of male patient, course of the ovulation induction and endometrial receptivity. Some or all of these will influence the result of treatment. Still, the ability to survey and evaluate quality of the embryologist-driven procedures provides reassuring information and is an indispensable activity for the laboratory.

Review of these parameters in a given interval, e.g., monthly, quarterly, allows the team to take stock of general performance and address any outliers. This is also a collegial exercise that, while inspiring a constructive competitiveness, can as well, foster mentorship, coaching and exchange of valuable information within the laboratory and clinical teams. One hopes that elevating everyone's performance is the team's goal rather than the isolation and stratification of skilled versus less-skilled embryologists.

Peer evaluation is a strong means to monitor adherence to protocol and to identify deviations or nuances in technical performance. Having an embryologist observe another's execution of a laboratory protocol and using a checklist to survey critical points of the protocol can uncover drift from prescribed method and allow opportunity for its correction. As importantly, this exercise can also provide evidence that the protocol is faithfully followed with expected outcome, a key precept of quality assurance and control. Documentation of these peer-to-peer comparisons and critiques are recommended as part of the laboratory's records for self-monitoring as well as compliance for accreditation.

Quality and safety

Although we would aspire for all medical treatments and indeed all human commerce to be error-free, assisted reproduction techniques are singularly unforgiving in the face of mistakes or accidents given the unique nature of the cells and the embryos. The repercussions of errors in assisted reproduction techniques are far-reaching (Bender, 2006; Liebler, 2002; Spriggs, 2003), as the emergence of a sub-discipline in healthcare law to address the novel issues presented by assisted reproduction techniques attests (Crockin and Debele, 2015). To the best of their ability, embryologists must ensure that chain of custody of all samples is always intact, instruments and equipment do not fail or malfunction, inappropriate gametes are not united, incorrect embryos are not transferred to a patient, and there is no loss or damage to any gametes or embryos. Adverse circumstances must be anticipated, encouraging emergency and contingency plans and their ready deployment. Provisions for power failures, un-inhabitable buildings secondary to natural disasters, or other system-wide challenges falls within the scope of responsibility of the embryologist and must be addressed in the strategy of both quality provision for and 'prophylactic management' (Mortimer and Mortimer, 2015) of the laboratory.

Quality is also delivered in terms of safety. Two components are relevant to the embryologist's role in achieving and contributing to quality through safety in the assisted reproduction technique laboratory. The first is that the workplace practices a philosophy of transparency and integrity so that any errors and mistakes are objects of analysis and not ammunition for assigning blame. The provision of strong protocols designed with error-prevention as an objective and their enforcement through a united team culture should mitigate against any mistakes. Yet, if errors should occur, an atmosphere that encourages disclosure and investigation should prevail, allowing address of the error and remedial action. As painful as errors are, they are educational in revealing flaws in a protocol, an instrument or a supply, a distractive environment, or deficiencies in training, and provide the chance for correction, fortifying the laboratory's operation.

Insight into the types of errors that can be encountered by an embryologist was provided in an analysis of tens of thousands of IVF treatment cycles at a single centre (Sakkas et al., 2014) during an interval of over 10 years. The authors found that the most serious errors arose from human factors and equipment malfunction, underscoring the central position of the embryologist in the performance of assisted reproduction techniques, but also the environment. Root causes analysis (http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/downloads/GuidanceforRCA.pdf), failure mode and effects analysis (Rienzi et al., 2015) and error tracking are valuable tools to the embryologist in understanding and managing vulnerabilities in the laboratory and staving off mistakes and accidents.

Adherence to protocol also achieves the requisite value of safety and error-aversion. Protocols are developed with not only a therapeutic goal in mind (fertilization, blastocyst development, post-thaw survival) but for reliability and security. Effective protocols will assist the embryologist in keeping an intact chain of custody and performing the technique in the way prescribed to avoid loss or damage.

Quality through team culture

A hallmark of assisted reproduction techniques is that success of treatment is the product of the performance of the embryology laboratory, the acumen of the physicians, and the specific clinical factors presented by the patient. This demands a tightly woven collaboration between embryologist and clinician in developing a patient's treatment plan, e.g. ICSI versus conventional insemination, number of embryos to transfer, review of genetic results after PGD for embryo selection for transfer, design of contingency plans for cases in which sperm may not be available from testicular biopsy.

A team approach will also be especially advantageous when sub-optimal outcomes are encountered. The best response to these stressful times is a conjoint investigation into the outcome data and what it may reflect. Consideration of both laboratory factors, e.g. supplies, equipment or personnel, and patient-related factors, e.g. female age, ovarian reserve, severity of male factor, trajectory of ovarian stimulation, progesterone level at retrieval – all factors that could have influenced a poor or unexpected outcome – is vital in productive analysis and resisting assigning blame or deficiency (Go et al., 2012).

The most effective assisted reproduction technique teams will meet regularly to review clinical outcomes and discuss individual cases that may have presented specific challenges.

Conclusion

In his groundbreaking achievement of the first birth from IVF in collaboration with Patrick Steptoe, Professor Robert Edwards established a new profession: clinical embryology. The birth of Louise Brown in 1978 was a triumph of science, medicine, perseverance and courage on their part as well as that of Mr and Mrs Brown. In the intervening years, clinical embryology has advanced and evolved technically, with the integration of embryo and egg cryopreservation, ICSI, assisted hatching and the more frequent inclusion of preimplantation genetic testing of embryos. Embryologists enjoy the benefits of IVF-specific products, such as culture media and labware, instrumentation including LASERs, low oxygen incubators, and tools such as morphokinetic video analyses for embryo assessment. Concurrent with these advances, assisted reproduction techniques have offered the possibility of parenthood to a greater number of patients, such as those with the most severe male factor infertility, or with significant risk of having offspring with genetically transmitted disease, and to individuals requiring third party reproductive strategies.

Embryology has also advanced and matured professionally, with its own organizations and societies, a voice in the regulation of assisted reproduction techniques, specific educational programmes and accreditation and certification of its practitioners.

During treatment with assisted reproduction techniques, patients consign their gametes or embryos to the custody and care of the embryologist who carries out the assisted reproduction technique treatment plan. If we were to ask an embryologist how he or she can be best prepared to contribute quality to this work and to the operation of the laboratory, the following are likely to be mentioned: structured and complete training with the opportunity to develop professionally and earn certification from an accrediting agency; well-written effective protocols and data-driven methods to continuously survey outcomes; clear communication of treatment plans for patient care; responsibility with autonomy, authority and readily available support; distraction-free workplace; a well-equipped, well-maintained laboratory; adequate staffing; a culture of recognition and engagement; provision of continued education and access to networks of professional colleagues; a clinical team and workplace with integrity, transparency and accountability. These are all integral to the engagement, support and development of the embryologist, an individual in a unique profession whose work contributes to an incomparable outcome: a live-born child.

"By the work, one knows the workman". – Jean de la Fontaine.

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