

Revised minimum standards for practices offering assisted reproductive technologies: a committee opinion

Practice Committee of the American Society for Reproductive Medicine, Practice Committee of the Society for Assisted Reproductive Technology, and Practice Committee of the Society of Reproductive Biology and Technology

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This document is designed to assist assisted reproductive technology (ART) programs in establishing and maintaining a successful clinical practice and set criteria that meet or exceed the requirements suggested by the Centers for Disease Control and Prevention (CDC) for certification of ART laboratories. This document replaces the document of the same name last published in 2008 (Fertil Steril 2008;90:S165–8). (Fertil Steril® 2014;102:682–6. ©2014 by American Society for Reproductive Medicine.)

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Treatments for the infertile couple are evolving rapidly, and advances in assisted reproductive technology (ART) are the best example. Periodically, the American Society for Reproductive Medicine (ASRM) reviews and publishes updated guidelines to define the minimum standards for ART programs and for human embryology and andrology laboratories. This document is designed to assist ART programs in establishing and maintaining a successful clinical practice and sets criteria that meet or exceed the requirements suggested by the Centers for Disease Control and Prevention (CDC) for certification of ART laboratories (1). This document replaces that entitled "Revised minimum standards for practices offering assisted reproductive technologies" that was previously published in September 2008.

This document is not designed to cover all clinical situations or practices, but rather should be reviewed carefully by ART program and laboratory directors to ensure that their programs' practice reflects current recommendations. More specific guidance on laboratory procedures is presented in the Practice Committee report titled, "Revised guidelines for human embryology and andrology laboratories."

DEFINITIONS

ART encompasses a variety of clinical treatments and laboratory procedures that include the handling of human oocytes, sperm, or embryos, with the intent of establishing a pregnancy. This includes, but is not limited to, in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote

intrafallopian transfer (ZIFT), embryo biopsy, preimplantation genetic testing (PGT), embryo and gamete cryopreservation, oocyte or embryo donation, and gestational surrogacy.

PERSONNEL

There should be a backup system in place for all personnel essential to a program. A single individual may fulfill the requirement for expertise in one or more areas. An ART program must include the following personnel:

- A designated overall practice director, medical director, and laboratory director. One individual may fulfill more than one of these positions, but the medical director must be a licensed physician.
- An individual with training and experience in reproductive endocrinology, particularly in the use of ovulation-inducing agents and hormonal control of the menstrual cycle. An individual who has completed an American Board of Obstetrics and Gynecology

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(ABOG)-approved fellowship in reproductive endocrinology and infertility and is board certified in reproductive endocrinology and infertility by the ABOG or is an active candidate for the same fulfills this requirement.

- A physician with experience in oocyte retrieval techniques. The physician should have special expertise in reproductive endocrinology and infertility and be able to manage IVF-related complications such as bleeding, infection, ovarian hyperstimulation syndrome (OHSS), and ovarian torsion.
- An individual with specialized training and experience in gynecologic ultrasonography who provides the monitoring of follicular development.
- An individual experienced in sperm physiology with special competence in laboratory andrology laboratory procedures.
- An individual experienced in male reproduction. If this individual is not a urologist, a consultant urologist with expertise in reproductive surgery should be available.
- An embryology laboratory director with personal experience in the organization and maintenance of a clinical embryology laboratory and in tissue culture techniques.
- A consultant/mental health professional with expertise in reproductive issues.
- An individual with specialized training and experience in gamete and embryo cryopreservation techniques, when gamete and/or embryo cryopreservation is offered.
- An individual with specialized training in gamete biology and micromanipulation techniques, if oocyte and/or embryo micromanipulation techniques are offered.
- Appropriate personnel to perform hormonal assays. An outside laboratory that has demonstrated adequate competence, quality control, and service may be used for rapid assays of all the necessary reproductive hormones (including estradiol and progesterone). Such hormone assays should be performed by a laboratory that meets Clinical Laboratory Improvement Amendments of 1988 (CLIA) standards.
- Appropriate nursing support.
- An individual or consultant with specialized expertise in genetics or genetic counseling.

SPECIALIZED TRAINING AND EXPERIENCE

Medical Director

As of January 1, 2000, a program's medical director must be board certified in reproductive endocrinology and infertility by the ABOG, be an active candidate for the same, or be grandfathered as a medical director, provided the individual has training and experience equivalent to a board-certified reproductive endocrinologist.

Practice Director

The practice director is responsible and accountable for the activity of the practice relating to ART, and is responsible for officially communicating with the Society for Assisted Reproductive Technology (SART) and ensuring that the practice follows SART requirements for membership.

Physician Performing Oocyte Retrievals and Embryo Transfers

Each physician performing oocyte retrievals and embryo transfers should have performed an adequate number of aspirations and transfer procedures under direct supervision that demonstrates proficiency within a practice that meets these standards. Satisfactory completion of this training should be documented by the practice director. Each physician should continue performing a minimum number of aspirations per year to maintain their proficiency.

It is recommended that the physicians involved in the supervision of follicular recruitment and oocyte retrieval procedures be responsible for ultrasound monitoring of follicular development. Physicians responsible for ultrasound follicular monitoring should have familiarity with basic ultrasound physical principles and equipment. These physicians should have evidence of training and the requisite competence to adequately perform diagnostic ultrasound examinations.

Embryology Laboratory Director

The embryology laboratory director should be an individual with demonstrated knowledge of all laboratory aspects of ART. To be acceptable as an embryology laboratory director, an applicant should fulfill the following requirements:

- An earned doctorate degree (PhD) from an accredited institution in a chemical, physical, or biological science as the major subject, or a medical degree (MD or DO) from an accredited institution, or have qualified as a laboratory director prior to July 20, 1999. Effective January 1, 2006, all new laboratory directors should hold a High-complexity Clinical Laboratory Director (HCLD) or Embryology Laboratory Director (ELD) certification or its equivalent from the American Board of Bioanalysis (ABB). Laboratories that participate in high-complexity procedures (i.e., quantitative sperm preparations and some hormone analyses) must be supervised by a laboratory director that is certified as a High-complexity Clinical Laboratory Director. The laboratory director should have expertise and/or specialized training in biochemistry, cell biology, and physiology of reproduction with experience in experimental design, statistics, and problem solving. The laboratory director should be responsible for formulating laboratory policies and protocols and for communicating with the medical director regarding patient progress and protocols as they affect the laboratory aspects of treatment.
- Two years of documented pertinent experience in a program performing IVF-related procedures. This experience should include:
 - Familiarity with laboratory quality control, inspection, and accreditation procedures.
 - Detailed knowledge of cell culture, ART, and andrology procedures performed in mammalian systems.
 - A period of training of at least 6 months (may be concurrent with documented experience) and have completed at least 60 ART procedures under supervision. A procedure is defined as a combination of the examination of follicular aspirates, insemination,

documentation of fertilization, and preparation for embryo transfer. Satisfactory completion of this period of training should be documented by the laboratory director of the training practice.

- Obtain at least 12 hours of accredited continuing education annually in assisted reproductive technology or clinical laboratory practice.
- Demonstrate technical competence in the embryology laboratory by documenting performance of specific procedures and results that are within acceptable standards for that program.

The responsibilities of the embryology laboratory director include:

- Providing accessibility for on-site, telephone, or electronic consultations as needed.
- Ensuring that the physical plant (space, facilities, and equipment) and environmental conditions of the laboratory are appropriate and safe.
- Maintaining aseptic conditions in the laboratory.
- Ensuring that patient confidentiality is maintained throughout the laboratory ART process.
- Providing an approved procedural manual to all laboratory personnel and establishing and maintaining a laboratory quality assurance program.
- Providing consultation to physicians and others, as appropriate, regarding laboratory aspects of treatment.
- Employing a sufficient number of qualified laboratory personnel to perform the quality laboratory procedures. There should be a backup plan in case of emergency.
- Ensuring that all personnel receive appropriate training for the ART laboratory procedures to be performed, obtain the required number of annual continuing education hours, and demonstrate continued competence for the ART laboratory procedures performed.

Off-site Embryology Laboratory Director

An “off-site” laboratory director is one whose primary directorship is at another physical facility, which has a separate identification number (SART number) and a separate medical director. An off-site director has the same responsibilities as an on-site director. While the laboratory is actively treating patients, the off-site director is required to physically visit the laboratory with a frequency that will ensure the proper functioning of the laboratory and assure appropriate patient care. Minimum standards would require a frequency of no less than 4 visits per year. The lab director should also be available at all times by fax, phone, or email for any issues that may arise. The off-site director must be present on-site for any accreditation or certification procedures. A laboratory director shall direct no more than 5 separate laboratories of any type.

Embryology Laboratory Supervisor

The embryology laboratory may have one or more qualified laboratory supervisors who, under the direction of the laboratory director, provide day-to-day supervision of laboratory

personnel performing ART procedures. In small ART programs, an embryology lab director can function as the embryology laboratory supervisor. However, if the medical director is also the laboratory director, there should be a designated laboratory supervisor. If the embryo laboratory director is primarily located off-site, there should be a designated laboratory supervisor. The embryology laboratory supervisor should either meet the qualification requirements designated for laboratory director, or fulfill both of the following requirements:

- Have an earned bachelor’s or master’s degree in chemical, physical, biological, medical technology, clinical, or reproductive laboratory science from an accredited institution.
- Have documented training, which includes performing, at a minimum, at least 60 ART procedures under supervision.

In addition to meeting these requirements, the embryology laboratory supervisor should:

- Obtain at least 12 hours of accredited continuing education annually in assisted reproductive technology or clinical laboratory practice.
- Perform an adequate number of ART procedures per year to maintain proficiency.

Responsibilities of the embryology laboratory supervisor include the day-to-day supervision and oversight of the embryo laboratory and laboratory director responsibilities as authorized in writing by the embryology laboratory director.

Embryology Laboratory Technologist

Embryology laboratory technologists who perform ART laboratory procedures should either meet the qualification requirements for laboratory supervisor, or fulfill both of the following requirements:

- Have an earned bachelor’s or master’s degree in chemical, physical, biological, medical technology, clinical, or reproductive laboratory science from an accredited institution.
- Have documented training, which includes performing, at a minimum, at least 30 ART procedures under continuous supervision of the laboratory director or supervisor.

In addition to meeting these requirements, the embryology laboratory technologist should:

- Obtain at least 12 hours of accredited continuing education annually in ART or clinical laboratory practice.
- Perform a satisfactory number of ART procedures per year to maintain proficiency.

Experience and documented training in cell culture, sperm-egg interaction, or related areas of animal reproduction are desirable. The embryology laboratory technologist works under the supervision of a laboratory director or supervisor. Programs for the appropriate training of embryology laboratory technologists should be in place with documentation of completion for each employee.

Nursing

The registered nurse in the ART setting provides education, counseling, support, and nursing care to patients seeking assistance with conception. This role requires structured orientation to the clinical setting and demonstrated competence in the specialty.

Other roles in the ART setting may include assistive personnel such as medical assistants with specialized training in patient-care management and technical procedures for the infertile patient.

GIFT AND RELATED PROCEDURES

ASRM has issued a list of minimum standards for GIFT (2). Because technical considerations at the time of oocyte retrieval may prevent tubal transfer or because supernumerary oocytes may be obtained, GIFT should only be performed in a facility that has an embryology laboratory and personnel who are capable of performing IVF. Ideally, the program should be able to cryopreserve the remaining good-quality gametes or embryos. GIFT may not be an appropriate choice for certain patients, but the embryology laboratory equipment, procedures, quality control, and personnel must be similar to those indicated for IVF.

ETHICAL AND EXPERIMENTAL PROCEDURES

ART treatments are evolving rapidly. Because of the ethical concerns of treatments that involve the laboratory handling and manipulation of human gametes and embryos, ASRM's Ethics Committee has issued a report on the ethical considerations of ART procedures (3). All ART procedures should be performed in accordance with the recommendations contained in that report, as well as all other reports from the ASRM Ethics Committee.

Procedures considered experimental must be conducted under the supervision of a properly constituted Institutional Review Board or equivalent committee.

From time to time, the ASRM Board of Directors will issue statements indicating that certain procedures previously considered experimental will henceforth be considered clinically proven treatments.

RECORDKEEPING

It is required that all ART practices participate in the CDC registry data collection. Furthermore, it is required that each practice release (or permit the release from the registry) identifiable, clinic-specific success rates. ASRM and SART member practices must adhere to all relevant ASRM, SART, and Federal Trade Commission policies and procedures relating to advertising and the use of SART statistics.

The embryology laboratory must retain records of all of its policies and procedures as well as personnel employment, training, evaluations, and continuing education activities. In addition, documentation of the proper identification, outcome, and disposition of all oocytes and embryos is important. This documentation should identify all clinical and laboratory personnel who have handled gametes and embryos during each procedure.

The laboratory must maintain these records for a period of time specified by federal, state, and local laws or for 10 years beyond the final disposition of all specimens obtained during each patient's ART cycle, whichever is later. All "paper" records must be maintained on-site for 2 years; electronic records must have appropriate safeguards against data loss. In the event that the laboratory ceases operation, provisions must be made for these records to be maintained according to the time frame required.

INFORMED CONSENT

The concept of informed consent is rooted in medical ethics and has been codified as legal principle. As with all medical procedures and treatments, ART patients have the right to self-determination and must make the final decision as to what is appropriate and acceptable treatment in his or her particular situation. To comply with this requirement, each prospective patient/couple must be provided with all relevant information necessary to make an informed decision regarding the proposed treatment and must be given the opportunity to ask questions in order to gain a better understanding. It is also important that couples are provided with full information concerning risks, benefits, and alternative procedures available to circumvent their specific infertility problem, including procedures that are not performed by the treating center, as well as nonmedical options such as adoption and no treatment.

The communications process should be documented in the medical record and the patient must provide full written informed consent. Specific consent should be obtained for gamete micromanipulation techniques or cryopreservation procedures. Consent forms should indicate that data concerning the patient's IVF cycle are required by law to be released for external validation. ART practices should conform to the ASRM/SART recommendations concerning informed consent (4–11). The laboratory must have evidence of informed consent for all procedures prior to their performance. It is expected that practices will comply with all applicable local, state, and federal guidelines.

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This document was reviewed by ASRM members and their input was considered in the preparation of the final document. The following members of the ASRM Practice Committee

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