Oversight of Assisted Reproductive Technology

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Executive Summary: Oversight of Assisted Reproductive Technology

The American Society for Reproductive Medicine (ASRM) convened a meeting of professionals, patient advocates, government representatives and legal experts in December 2009 to examine the oversight of assisted reproductive technology (ART). ART is one of several therapies used by specialists to treat the disease of infertility. The most widely used ART procedure is in vitro fertilization.

As with all medical practice, safety in reproductive medicine is assured by a combination of state and federal government regulation. On the state level, physicians are licensed by medical boards which also monitor physician practice and discipline or revoke the license of individuals who fail to uphold the law.

On the federal level, three agencies regulate ART. The Centers for Disease Control and Prevention (CDC) collects and publishes data on ART procedures. The Food and Drug Administration (FDA) controls approval and use of drugs, biological products, and medical devices and has jurisdiction over screening and testing of reproductive tissues, such as donor eggs and sperm. The Centers for Medicare and Medicaid Services (CMS) is responsible for implementation of the Clinical Laboratory Improvement Act to ensure the quality of laboratory testing.

Additionally, the medical profession exercises significant self-regulation to assure the continuing competence of practicing physicians. Specialists in reproductive medicine are certified by the American Board of Obstetrics and Gynecology or the American Board of Urology after completing residency training and passing examinations. They may achieve subspecialty certification with additional training in infertility and endocrinology. Continuing medical education and periodic re-examination are required to maintain certification.

ASRM and the College of American Pathologists administer a reproductive laboratory accreditation program for embryology labs to assure that they conform to high national standards of quality. ASRM also produces ethics and practice guidelines. Its affiliate, the Society for Assisted Reproductive Technology (SART), strictly monitors member clinics for adherence to ASRM guidelines, accreditation of their embryology labs, qualification of their staff, and submission of data to the CDC.

The ASRM meeting produced evidence that the current oversight of ART could be improved by the addition of insurance coverage for infertility treatments. Such coverage could promote the most medically appropriate procedures and reduce the incidence of multiple births with their accompanying risks and costs. Insurance coverage for infertility could also strengthen existing oversight and quality controls by requiring adherence to ASRM guidelines or performance of ART procedures only at clinics subject to SART standards. While properly crafted language in a widely adopted medical practice act requiring specialists in ART to follow ASRM guidelines unless otherwise indicated might improve the uniformity of practice nationwide, it is important to recognize that **ART is already one of most highly regulated of all medical practices in the United States**.

Precis

After examination of the complex network of state and federal regulation as well as professional self-regulation governing ART practice, we conclude that Assisted Reproductive Technologies are among the most regulated medical procedures in the United States.

Introduction

Infertility is a disease of the reproductive system that impairs one of the body's most basic functions: the conception of children. In the United States, infertility affects about 7.3 million women and their partners, or about 12% of the reproductive-aged population. For many of these couples, the answer lies in conventional medical therapy, such as drug treatment or surgery to repair reproductive organs. Since 1978, ART has provided another solution for many would-be parents. ART is defined as all treatments or procedures that involve manipulating eggs and sperm in vitro to help a woman become pregnant. This involves several different methodologies, the most widely used being in vitro fertilization (IVF).

Today, approximately one in every hundred babies born in the US is conceived using ART. Growth in the use and scientific refinement of ART is carefully monitored by the American Society for Reproductive Medicine (ASRM) and its affiliate, the Society for Assisted Reproductive Technology (SART), whose memberships consist of specialists in this field of medicine. In December 2009, ASRM convened a meeting of professionals, patient advocates, congressional and federal agency representatives, legal experts, and consumers to examine the oversight of ART. This document reflects the information provided at the conference.

As with all medical practice in the United States, safety in reproductive medicine is assured by a combination of state and federal government regulation and professional self-regulation that includes facility accreditation and practitioner certification. On the state level, there is a strict physician licensure system. On the federal level, several agencies enforce standards and practices designed to protect public health and safety. Several national groups accredit laboratories as well. In the realm of professional self-regulation, an on-going system of quality assurance includes specialty training and certification of physicians, accreditation of clinics and ethical and practice guidelines developed by professional organizations through consensus and evidence.

State Regulation

The American medical regulatory system was established to limit the practice of medicine to qualified practitioners and thereby protect the public from unprofessional, improper, and incompetent individuals. The states exercise their police powers to license only those practitioners who meet minimum standards of education and skill. This regulatory authority is administered by a medical licensing board or other state agency. It is based on a medical practice act passed by the legislature and regulations written by the board that define a scope of practice for licensees, require ongoing educational training through approved continuing medical education, and authorize discipline for those who break the law or fail to uphold certain professional standards.

State law defines the grounds for misconduct, such as negligence, deceit, fraud, or exploitation of the physician-patient relationship. A physician will face restrictions, suspension, or revocation of his or her license to practice following investigation and conviction of charges filed against him or her.

Physicians are required to complete medical school and several years of postgraduate training. They must also pass a rigorous medical licensing examination to be eligible for licensure. The license to practice is broad and not restricted to particular fields of medicine. An additional layer of professional self-regulation - board certification - is where specialization is addressed.

In addition, some states have imposed specific regulatory requirements for some aspects of reproductive medicine. These have most often come in the form of regulating tissue facilities that handle reproductive tissues.

Federal Regulation

The federal government plays a strong role in the oversight of ART. The Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and Centers for Medicare and Medicaid Services (CMS) have regulatory responsibilities in this area.

Centers for Disease Control and Prevention

Federal legislation on assisted reproductive technology was passed by Congress in 1992. Public Law 102-493, the Fertility Clinic Success Rate and Certification Act (FCSRCA), endorsed standard definitions and required complete reporting of ART cycle data to support the quality and reliability of fertility programs. As implemented by the Centers for Disease Control and Prevention (CDC), the law results in an annual report containing data from

individual clinics and aggregate national data on infertility procedures and their success rates. A statistical survey research organization maintains a data collection system that all ART clinics use. The data collected include the patients' infertility diagnoses, clinical information pertaining to the ART procedure, and statistics on resulting pregnancies and births. Consumer access to the report enables would-be parents to review details about ART clinics nationwide. It also serves the professional community by providing a way to monitor the operation of individual clinics and the number of multiple births, which are more dangerous for the infants and mothers and more costly for parents and society (www.cdc.gov/ART).

Another result of FCSRCA has been the development of a model program for certification of embryology laboratories. The CDC published these requirements in 1999. They include requirements for administration of a continuing certification program by the states, quality assurance and control standards, an inspection system, and conditions under which certification can be suspended or revoked. Adoption of such a laboratory certification program is left up to the states.

Food and Drug Administration

The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of drugs, biological products, and medical devices. Physicians working in reproductive medicine, as in other fields of medicine, can prescribe only FDA-approved medications.

The FDA also has jurisdiction over screening and testing of reproductive tissues, such as the eggs and sperm that will be implanted in human recipients. Regulations issued by the agency contain strict requirements for egg and sperm donors, including thorough medical histories, identification controls, freedom from infectious diseases, and rigorous inspection of the facilities in which these tissues are handled. Inspectors can order the recall or destruction of tissue that is infected with a communicable disease. The agency has established good tissue practices that are codified in 21 CFR 1271 (www.accessdata.fda.gov/scripts/cdrh/ cfdocs/cfcfr/CFRSearch.cfm? CFRPart=1271).

CMS and the Clinical Laboratory Improvement Act

Diagnostic testing, an important component of ART, is handled by clinical laboratories and the highly skilled individuals who run them. All laboratory testing performed on humans in the United States, including the tests used in reproductive medicine, is regulated by the Centers for Medicare and

Medicaid Services (CMS) under the Clinical Laboratory Improvement Act (CLIA). The objective of the CLIA program is to ensure quality laboratory testing by establishing standards for accuracy, reliability, and timeliness of patient test results. A laboratory is defined as any facility that tests specimens derived from humans for the assessment of health or the diagnosis, prevention, and treatment of disease.

CLIA regulations, published in 1992, are based on the complexity of the test method; thus, the more complicated the test, the more stringent the requirements. Lab tests used in the diagnosis of infertility, such as semen and blood analysis, are covered by CLIA. The procedures performed in embryology labs, which are not considered diagnostic, do not fall under CLIA's mandate.

To comply with CLIA, laboratories must register and be surveyed to become certified. The survey process is outcome oriented and utilizes a quality assurance focus to assess compliance. Data indicate that CLIA has helped to improve the quality of testing in the United States. The total number of quality deficiencies has decreased approximately 40% from the first laboratory survey to the second (www.cms.hhs.gov/CLIA/07_Program_Descriptions_Projects.asp#TopOfPage).

Professional Self-Regulation

A profession is characterized by skill based on a unique body of knowledge, a code of ethics, and a social contract with society or government that grants it a certain degree of autonomy in exchange for self-regulation. The responsibilities of self-regulation in the medical profession are complex and involve many levels of oversight aimed at guaranteeing the continuing competence of practicing physicians. Today, professional associations in the United States play a significant role in upholding the ethical, educational, scientific, and practice standards of the medical profession. In reproductive medicine, as in other fields of medicine, highly respected physicians participate in accreditation, certification, and membership organizations that promote quality and protect patient safety.

Laboratory accreditation

The College of American Pathologists (CAP) and ASRM developed the Reproductive Laboratory Accreditation Program for embryology laboratories. This program was established because the functions of ART labs are highly specialized. Recognized as an authorized accrediting agency, CAP uses multi-disciplinary teams of practicing laboratory professionals as

inspectors. The goal of the inspection teams is to ensure that reproductive laboratories conform to national standards. The standards are specific as to the education, certification, and expertise of laboratory personnel, as well as their authority and responsibilities. The laboratory must have a performance improvement plan and a quality control program to anticipate and prevent errors. Its instruments must be properly maintained and calibrated. A proficiency testing system that assures test reliability through an inter-laboratory comparison program must be in place. To maintain accreditation, laboratories are inspected regularly. They must perform periodic self-evaluations and document any necessary corrective actions between site visits. Hospital-based ART programs are often accredited through a similar program administered by the Joint Commission which is responsible for accreditation of hospital organizations (www.cap.org/apps/docs/laboratory_accreditation/ standards/standards_repro.pdf).

Physician board certification

Because the scope of modern medical knowledge is vast, medical school graduates undergo additional training before entering clinical practice. Those choosing to become specialists take at least three years of residency training. The American Board of Medical Specialties establishes criteria for its member organizations, such as the American Board of Obstetrics and Gynecology (ABOG). In turn, ABOG sets high standards for training and performance for those physicians who wish to work in this specialty (www.abog.org/index.asp).

An obstetrician/gynecologist possesses specialized knowledge, skills, and professional capability in the medical and surgical care of the female reproductive system and associated disorders. To become certified by ABOG requires four years of training, plus two years in clinical practice and passage of both written and oral examinations before certification is complete. Specialists in reproductive medicine usually undergo training in obstetrics and gynecology, followed by training in reproductive endocrinology and infertility, or in urology followed by training in andrology. Subspecialty certification is available after passing the appropriate rigorous examinations.

Board-certified physicians participate in life-long learning to keep their skills and knowledge current. They maintain their certification through participating in a maintenance of certification (MOC) program. MOCs use evidence-based guidelines and national standards as well as best practices in combination with customized continuing education and periodic re-

examination. Professional ethics, hospital privileges, membership in the medical community, and the need for successful clinical outcomes in a patient-centered environment are the internal and external forces that promote lifelong learning and continued certification.

Professional guidance

The American Society for Reproductive Medicine (ASRM) is the specialty society for physicians that focus on infertility. The organization has a Practice Committee that issues regular reports, including guidelines on minimal standards for providing ART, informed consent, and on the number of embryos to be transferred in IVF procedures. The guidelines are distributed to all members of ASRM, are published in the Society's journal, *Fertility and Sterility*, and are available to the public on ASRM's website (www.asrm.org). The ASRM Guidelines on Number of Embryos Transferred, updated in November 2009, recommend that when treating women under age 35 consideration should be given to transferring only one embryo at a time and no more than two embryos should be transferred for women of this age range in order to reduce the number of higher-order multiple pregnancies.

ASRM also has an Ethics Committee that produces a broad range of statements and guiding principles for physicians and others in the field of reproductive medicine. Members of the Ethics Committee include doctors, lawyers, and theologians. Their ethical guidelines are published in ASRM's journal, *Fertility and Sterility*, and on the Society's website, and are circulated worldwide.

The Society for Assisted Reproductive Technology (SART) is an affiliate of ASRM. Its membership includes more than 90% of American fertility clinics. SART has strict membership requirements. As a condition of membership, clinics must report their outcomes to the CDC as well as to SART, have accredited embryology laboratories, adhere to the Ethics and Practice Committee guidelines of ASRM, and have appropriately trained staff. Failure to adhere to these criteria can result in revocation of membership. Although this does not prevent the continued operation of the clinic, the membership status of a clinic is included in the CDC's federally mandated annual report on ART success rates. Through its Validation, Registry and Quality Assurance Committees, SART also regularly reviews member clinics' data, assists with the CDC-regulated inspection of ART clinics to verify the accuracy of reported data, and, when success rates fall below a certain threshold, SART mandates underperforming clinics obtain outside consultants to improve performance and provides financial assistance for this process.

ASRM and SART membership is voluntary and signifies a practitioner's commitment to adhering to the best practices in reproductive medicine. The Societies' by-laws provide means for their boards of directors to issue a warning, censure, or suspend or revoke membership for failure to maintain the requirements for membership, for ethical violations, or for any other cause they deem sufficient.

Changes to Consider

Insurance coverage

Unlike most medical procedures to treat most diseases, insurance coverage for ART treatments remains rare in the United States. In a study published in the New England Journal of Medicine, researchers reviewed national data to examine how a requirement that insurers provide coverage for IVF affected the outcome of IVF treatments. The data showed that states without insurance coverage have the highest number of embryos transferred per IVF cycle and the highest number of high-order multiple births (triplets or more). The underlying assumption is that the patients' financial burden may lead to a transfer of more embryos in order to increase the chances of success in just one cycle. If patients have no insurance coverage to help with the costs, they may be able to afford only one or two treatment cycles. If, on the other hand, IVF is covered by an insurance mandate like those existing in a handful of states, physicians and patients can make decisions that are most medically appropriate. They can follow, without emotional or financial pressure, the growing evidence that the transfer of a single embryo, in the right circumstances, results in the birth of a single, healthy child. (Jain T, Harlow BL, Hornstein MD. Uniform Insurance Coverage and Outcomes of In Vitro Fertilization. NEJM 2002;347-661-6.)

In addition to reducing the risks and costs associated with multiple births, insurance coverage for infertility would provide oversight and quality controls. Payers, both public and private, generally set eligibility criteria for who may receive or perform certain procedures. Such criteria could recommend a limit on the number of embryos transferred in ART. The most efficient method to accomplish this would be to require adherence to ASRM guidelines, which are updated periodically. Another requirement could be to require that ART procedures be performed only at clinics that are subject to SART standards. SART has voluntarily assumed an advocacy role in terms of reducing high risk pregnancies achieved through ART. It has notified its member clinics that data showing greater than two standard deviations below national means would trigger an onsite inspection of the clinic in question. This self-policing role has been influential. As a result of

implementing embryo transfer guidelines, SART clinics showed an 80% decrease in the percentage of triplet births between 1999 and 2007 and an increase in live births per transfer from 38% to 46% (SART National Summary, www.sart.org; Society for Assisted Reproductive Technology and the American Society for Reproductive Medicine. Assisted reproductive technology in the United States: 1999 results generated from the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology Registry, Fertil Steril 2002;78:918-31.)

Guidelines as regulation

Standards set by members of the profession for the practice of reproductive medicine are widely followed and successful. However in some instances in which the professional guidelines are breached, such as the recent octuplet pregnancy and birth in California, the public, spurred by sensationalized media coverage and largely unaware of the way medical practice is regulated in the United States, calls out for additional legal enforcements and punishments.

In fact, existing regulation, both private and governmental, is working to punish the individual responsible in that case. However, a simple legal restriction on the number of embryos transferred would not be desirable. It is preferable that the clinical judgment of highly trained specialty physicians, brought to bear on the particular circumstances of each case and made with evidence-based national guidelines in mind, determine the course of treatment. While properly crafted language in a widely adopted medical practice act requiring specialists in ART to follow ASRM guidelines unless otherwise indicated might improve the uniformity of practice nationwide, it is important to recognize that **ART is already one of most highly regulated of all medical practices in the United States.**

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