

4.2.1 Assisted Reproductive Technology

Assisted reproduction offers hope to patients who want children but are unable to have a child without medical assistance. In many cases, patients who seek assistance have been repeatedly frustrated in their attempts to have a child and are psychologically very vulnerable. Patients whose health insurance does not cover assisted reproductive services may also be financially vulnerable. Candor and respect are thus essential for ethical practice.

“Assisted reproductive technology” is understood as all treatments or procedures that include the handling of human oocytes or embryos. It encompasses an increasingly complex range of interventions—such as therapeutic donor insemination, ovarian stimulation, ova and sperm retrieval, in vitro fertilization, gamete intrafallopian transfer—and may involve multiple participants.

Physicians should increase their awareness of infertility treatments and options for their patients. Physicians who offer assisted reproductive services should:

- (a) Value the well-being of the patient and potential offspring as paramount.
- (b) Ensure that all advertising for services and promotional materials are accurate and not misleading.
- (c) Provide patients with all of the information they need to make an informed decision, including investigational techniques to be used (if any); risks, benefits, and limitations of treatment options and alternatives, for the patient and potential offspring; accurate, clinic-specific success rates; and costs.
- (d) Provide patients with psychological assessment, support and counseling or a referral to such services.
- (e) Base fees on the value of the service provided. Physicians may enter into agreements with patients to refund all or a portion of fees if the patient does not conceive where such agreements are legally permitted.
- (f) Not discriminate against patients who have difficult-to-treat conditions, whose infertility has multiple causes, or on the basis of race, socioeconomic status, or sexual orientation or gender identity.
- (g) Participate in the development of peer-established guidelines and self-regulation.

AMA Principles of Medical Ethics: I,V,VI

Background report(s):

CEJA Report 3-A-16 Modernized *Code of Medical Ethics*

CEJA-CSA Report A-96 Issues of ethical conduct in assisted reproductive technology

Report of the Judicial Council A-A-83 In vitro fertilization

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- (a) *Value the well-being of the patient and potential offspring as paramount. [new content sets out key ethical values and concerns explicitly]*
- (b) Ensure that all advertising for services and promotional materials are accurate and not misleading.
- (c) Provide patients with all of the information they need to make an informed decision, including investigational techniques to be used (if any); risks, benefits, and limitations of treatment options and alternatives, for the patient and potential offspring; accurate, clinic-specific success rates; and costs.
- (d) *Provide patients with psychological assessment, support and counseling or a referral to such services. [new content updates guidance to reflect contemporary best ethics practice]*
- (e) Base fees on the value of the service provided. Physicians may enter into agreements with patients to refund all or a portion of fees if the patient does not conceive where such agreements are legally permitted.
- (f) *Not discriminate against patients who have difficult-to-treat conditions, whose infertility has multiple causes, or on the basis of race, socioeconomic status, or sexual orientation or gender identity. [new content addresses gap in current guidance]*
- (g) Participate in the development of peer-established guidelines and self-regulation.

Joint Report of the Council on Ethical and Judicial Affairs
and the Council on Scientific Affairs, A-96
Issues of Ethical Conduct in Assisted Reproductive Technology

INTRODUCTION

Certain examples of actual and alleged unethical conduct in the practice of assisted reproductive technologies (ART) have generated public debate about these rapidly progressing technologies. In one case, it was charged that eggs stored for future use by patients were used to impregnate others without explanation, permission, or the informed consent of the parties. Although this was not the first case to reveal the potential for deception in provision of ART, it was all the more significant for having occurred at an esteemed and successful center for fertility treatment. Another case involved a physician (not an obstetrician or reproductive endocrinologist) who operated a private fertility clinic where inappropriate and nonindividualized drug therapy was prescribed for ovulation induction; the physician also used his own sperm for artificial insemination of patients, again without their knowledge or consent. This physician was later convicted in a court of law.

The practice of ART has become increasingly complex with advances in methods of ovarian stimulation, ova and sperm retrieval, fertilization, storage of embryos, and use of donor gametes. In addition to the rapid pace of innovation in these services, fertility treatment is more frequently sought by patients. Delay of childbearing to later years when reproductive function is declining in both sexes and damage to the female reproductive tract by sexually transmitted diseases may be contributing causes to infertility, and therefore, the increased requests for infertility treatment. This patient population is often desperate for help after being frustrated consistently in attempts to have a child. In addition, the costly ART procedures often are not covered by insurance and must be paid out-of-pocket by patients. Patients who undergo many cycles of treatment hoping to achieve pregnancy face daunting expense. All of these factors make patients seeking ART particularly vulnerable. In addition, reported outcome measures of ART success are not always standardized, and the possible use of a combination of techniques in a single treatment cycle further confuses measures of outcome.

AMA RESPONSE

Reacting to the cases described above and reflecting concern about the practice of ART in general, the American Medical Association convened a meeting of representatives from relevant specialty societies and federal agencies in December 1995 (see Appendix for list of organizations). This meeting was held to identify the special ethical challenges involved with the provision of ART, primarily focusing on assessment of already existing practice guidelines, including ethical standards, and the status of professional selfregulation in this field. The exchange of information at the meeting made it clear that medical specialty societies, primarily the American Society for Reproductive Medicine (ASRM), have made impressive efforts to develop and codify guidelines on acceptable practice. The meeting also highlighted the efforts of the profession, particularly the Society for Assisted Reproductive Technology (SART), an affiliate of ASRM, to create a registry for clinics and to report clinical data on fertility treatment. Also, the establishment of the National Advisory Board on Ethics in Reproduction (NABER) is evidence of the recognition by the American College of Obstetricians and Gynecologists (ACOG) and ASRM of the need for an independent body to deliberate and make recommendations concerning the issues confronted by practitioners in the field of ART.

Reports from government entities outlined problems in implementing the provisions of the Fertility Clinic Success Rate and Certification Act (1992). This legislation called for accreditation and inspection of fertility clinics and uniform reporting of success rates. However, this would be a voluntary process with no penalties for clinics that fail to report or report falsely. The Centers for Disease Control and Prevention has been engaged in implementing the requirements of the Act, but scarcity of both financial and staff resources has prevented full implementation. Given the unlikelihood of the federal government allocating sufficient funds to support this undertaking and the increasing burden to SART in performing this service, there was considerable discussion of how this data collection and oversight can be continued.

ETHICAL INFRACTIONS AND THEIR PREVENTION

Meeting participants identified two types of ethical infractions in the practice of ART: blatant exploitation and more subtle deception. The alleged cases of unauthorized egg transfer and the physician who used his own sperm for insemination are examples of blatant exploitation. Such egregious conduct must be condemned. The second form of infraction, which may be unintentional, is less serious but presumably more prevalent and harder to identify. Deceptive advertising and insufficient informed consent are probably the most common manifestations of this type of ethical violation. All of these practices constitute unethical conduct and threaten both professional integrity and the patients involved.

Better professional guidelines might not have prevented the flagrant violations of ethical conduct described above. Indeed, there will always exist some unscrupulous individuals who, although aware of ethical guidelines, continue to willfully violate those guidelines. However, when a physician is identified as acting unethically, professional censure should be swift and stern. Additionally, professional organizations should provide information and testimony about professional standards in actions taken against physicians who commit such fraud.

Professional standards are more likely to have an impact on the second form of ethics violation. When patients seek consultation on pursuing ART, physicians must honestly characterize success rates for individuals according to age, general health and specific diagnosis; inform them about investigational techniques that may be used; and be forthright about the considerable limitations of ART in achieving live births in general. Projected costs of the procedure also should be fully disclosed. Physicians must provide fair assessment of the chance of success of remaining options when a patient has undergone repeated cycles of treatment and faces decisions about continuing. This is especially important given the financial incentive for physicians and clinics to have patients continue treatment; those with severe fertility problems may be exploited by an unscrupulous practitioner. In this sensitive area, physicians must be careful not to raise false hopes.

There also is potential for discrimination in provision of ART. Patients with difficult-to-treat conditions or multiple causes of infertility may not be able to secure access to these technologies as some centers may not want their outcomes data negatively affected by treatment failures. Such policies are unacceptable and should be actively condemned by specialty societies and other medical organizations. Reporting success rates associated with specific diagnoses and treatments would avoid skewing success data of patients with more favorable prognoses. Informed consent for ART must be comprehensive, covering every aspect of the procedure from the laboratory handling of embryos to intentions for preservation of frozen embryos. The AMA supports the need to standardize a recommended informed consent form for ART. Ideally, such a document would be developed and endorsed by all the relevant specialty societies, who would then assume responsibility for subsequent dissemination. Model state legislation detailing minimal standards for informed consent is another possibility.

PROFESSIONAL SELF-REGULATION

The AMA Code of Medical Ethics: Current Opinions with Annotations clearly states physicians' responsibility to report unethical behavior of colleagues to the proper authority. To the extent that such reporting may cause legal repercussions, physicians need adequate protection under the law to prevent intimidation.

Several challenges confront the medical profession in regulating ART. Currently, SART incorporates data collected annually from member laboratories into a national registry. SART members are required to submit laboratory data, but there currently is no means to validate submitted information. Furthermore, membership in SART is voluntary. Therefore, while lack of membership clearly reflects badly on a fertility program, membership in SART does not ensure high quality.

There has been discussion of establishing a reporting mechanism for fertility clinics like that of the Human Fertilization and Embryology Authority in Great Britain, which coordinates data submitted under a mandatory program. A good model would be the program of the College of American Pathology (CAP), which accredits laboratories performing moderate- and high-complexity testing by regular mandatory inspection. CAP accreditation provides deemed status with the standards set by the Clinical Laboratory Improvement Act of 1967 and the Clinical Laboratory Improvement Amendments of 1988. A voluntary program for accreditation of fertility laboratories that requires regular inspection has been developed jointly by CAP and ASRM. In general, support for a strengthened voluntary reporting system far outweighs that for a compulsory plan.

The medical specialty societies, including ASRM, ACOG, and the American Urological Association, are undecided about assuming the primary responsibility for oversight of ART, where they would rely on local entities to review compliance and enforcement pursuant to a national independent authority to oversee and validate practices and accredit clinics. First, they are concerned about funding, although such an effort could be funded primarily by the fertility professionals who themselves have an interest in validation of their programs. Second, they are concerned about liability for assuming a disciplinary role.

The Councils encourage specialty societies to maintain their ongoing development and review of professional guidelines in this area. Improved dissemination of guidelines, particularly ethical considerations and reporting standards, also must be pursued. Specialty societies are encouraged to establish mechanisms for disciplining their members. In particular, a review panel should evaluate reports of unethical behavior of physicians and report to the state medical board and National Practitioner Data Bank when appropriate.

Given the rapid technological progress and unique profit motive in ART, reinforcing ethical guidelines is especially vital. Currently, compliance with ethical guidelines is not mandated for membership in relevant specialty societies. Requiring members' written commitment to the ethical principles articulated in ASRM policy at the time of membership renewal would increase awareness, underscore the importance of, and reinforce adherence to these valuable guidelines. Given the relatively small number of ART clinics, it may be worthwhile for specialty societies to develop a physician education campaign to highlight these challenging issues and impart ethical guidance. In terms of public perception and professional integrity, such efforts would serve the interests of specialists, all physicians, and the public.

PATIENT INFORMATION

While it is important to promote awareness of practice standards within the specialty, it is also important to educate physicians outside the specialty, as well as patients seeking reproductive services. Information materials, including a checklist for patients' use when considering fertility services and clinic selection, should be available in a variety of practice settings. Educational outreach should be conducted to keep referring physicians (e.g., obstetrician/ gynecologists, family physicians, urologists) updated and aware of available technologies and reputable clinics for referral. In addition, information currently available to potential consumers of reproductive services should be more widely publicized. Many patients seek treatment on the basis of recommendations from friends, colleagues, or physicians not trained in reproductive medicine. Patients seeking information about clinics must be informed of the availability of reliable information on clinic outcomes for types of procedures applied to specific diagnoses, as well as potential risks associated with treatment (e.g., ovarian hyperstimulation from fertility drugs). Patient advocacy groups, such as RESOLVE have been very active in providing this information, but their reach may be limited. Referring physicians must be aware of the potential for patient access to clinic information and should advise their patients to consult this and other resources. If patients perceive they have received substandard counsel or service, or have been subjected to unethical practices in the provision of reproductive services, specialty societies should provide information on ethical standards upon request and referral to the appropriate disciplinary body (e.g., county and state medical societies, licensing boards).

COMMERCIAL REGULATION

Another troubling aspect of ART concerns promotion of these services. Fertility clinics sometimes claim inflated success rates in advertising. Providers have included data on outcomes in media promotion, in some cases giving exaggerated estimates of success or defining success differently from the accepted standard. Even if the figures are genuine, predictors are so mercurial in ART that a cited figure may not represent the chances of successful outcomes for the majority of patients. Furthermore, average success rates do not necessarily reflect the results of a specific clinic since outcomes are affected by the nature of the pathology (some types of infertility are more successfully treated than others) as well as the skill of the professional and technical staff.

At least one fertility clinic has offered an indemnity for treatment, promising to refund the cost of the services if a pregnancy does not result within three treatment cycles. However, under the agreement, anyone with an identifiable fertility problem would not be eligible. Such publicized "guarantees" manipulate and unfairly attract patients. In addition, basing payment for medical treatments on outcomes is unethical according to Opinion 6.01, AMA Code Of Medical Ethics.

The Federal Trade Commission (FTC) has initiated disciplinary actions against six clinics since 1991 for misrepresentation of reproductive service successes. With the assistance of ASRM, the FTC has established guidelines for advertising of reproductive services. NABER also is seeking to identify false advertising claims. It may be helpful for the profession to undertake systematic review of the promotional practices of individual clinics and recommend acceptable and professional representations of services offered.

CONCLUSION

This report is intended to emphasize the value of existing guidelines to ensure ethical practices in ART. Areas of potential deception and exploitation of patients, particularly informed consent, advertising, and payment arrangements, have been identified.

The relevant specialty societies must find a means to validate clinic data so that reliable information can be more widely disseminated to potential patients. It is important to note that all of these efforts to emphasize ethics in provision of ART will require significant resources. Legislation to promote certification must allocate the funds to have mandates carried out. Likewise, practitioners of ART may need to assume further financial responsibility to ensure verification of data and the promotion of standards. The profession cannot abrogate responsibility for the practice of its members. Improved self-regulation is essential to effective patient care and to maintaining public trust in ART.

RECOMMENDATIONS

Based on deliberations of the AMA's Task Force on Ethical Issues in Assisted Reproductive Technology (ART), the Council on Ethical and Judicial Affairs and the Council on Scientific Affairs recommend the following statements be adopted as policy positions of the AMA and the remainder of this report be filed:

- (1) Medical specialty societies involved in the provision of Assisted Reproductive Technology (ART) services should continue to set technical and ethical guidelines for ART and educate the profession and patients through wide dissemination of this information through physician and patient advocacy groups. Such material should include standardized information on clinic-specific success rates.
- (2) Fertility laboratories not currently participating in the College of American Pathologists/American Society of Reproductive Medicine accreditation program are encouraged to do so.
- (3) Professional self-regulation is encouraged through signed pledges to meet established ethical standards and to comply with laboratory accreditation efforts. Physicians who become aware of

unethical practices must report such conduct to the appropriate body. Physicians also should be willing to provide expert testimony when needed. Specialty societies should discuss the development of mechanisms for disciplinary action, such as revocation of membership, for members who fail to comply with ethical standards.

(4) Patients should be fully informed about all aspects of ART applicable to their particular clinical profile. A standardized informed consent instrument should be developed for the benefit of patients and professionals. Payment based on clinical outcome is unacceptable.

(5) Physicians and clinics practicing ART should use accurate descriptors of available services, success rates, and fee structure and payment obligations in promotional materials.

(6) If legislation on regulation of ART laboratories, advertising practices, or related issues is adopted, it should include adequate financial resources to ensure the intended action can be implemented. Improved legislative protection may be needed to protect physicians and their professional organizations when they provide testimony on unethical conduct of colleagues.

APPENDIX**AMA Task Force on Ethical Issues in Assisted Reproductive Technology**

Invited organizations and representatives who attended the meeting of the Task Force on Ethical Issues in Assisted Reproductive Technology:

American College of Obstetricians and Gynecologists

(Daniel H. Riddick, MD, PhD; Stanley Zinberg, MD)

American Society of Reproductive Medicine (Robert D. Visscher, MD)

Association of Professors of Gynecology and Obstetrics (Robert W. Rebar, MD)

American Urological Association (Laurence A. Levine, MD)

College of American Pathologists (William Byrd, PhD)

Society for Assisted Reproductive Technology (Paul W. Zarutskie, MD)

Federation of State Medical Boards of the United States, Inc. (James R. Winn, MD)

National Advisory Board of Ethics and Reproduction (Mary Martin, MD)

Centers for Disease Control and Prevention (Lynne Wilcox, MD, MPH)

Federal Trade Commission (Matthew Daynard)

Food and Drug Administration (Thomas Arrowsmith-Lowe, MD)

(Judicial Council - A)

ARTIFICIAL INSEMINATION BY DONOR

Physicians have an ethical responsibility to use the utmost caution and scientifically available screening techniques in the selection of donors for use in artificial insemination. Relying only upon the verbal representations of donors as to their health, without any medical screening, is precarious. The donor should be screened for genetic defects, inheritable and infectious disease, Rh factor incompatibility and other disorders that may affect the fetus. When the physician is not equipped to fulfill these responsibilities, the services of a skilled medical geneticist or other appropriate specialist should be sought.

Since the identity of donors usually should not be available to recipients or the offspring that may result, the risk of inadvertent inbred and serious undesirable genetic and biological consequences should not be ignored. Physicians have an ethical and social responsibility to avoid the frequent use of semen from the same sources.

IN VITRO FERTILIZATION

The technique of in vitro fertilization and embryo transplantation enables certain couples previously incapable of conception to bear a child. It is also useful in the field of research directed toward an understanding of how genetic defects arise and are transmitted and how they might be prevented or treated. Because of serious ethical and moral concerns, however, any fertilized egg that has the potential for human life and that will be implanted in the uterus of a woman should not be subjected to laboratory research.

All fertilized ova not utilized for implantation and that are maintained for research purposes shall be handled with the strictest adherence to the Principles of Medical Ethics, to the guidelines for research and medical practice expressed in the Judicial Council's opinion on fetal research (2.07), and to the highest standards of medical practice.

B. INTERPROFESSIONAL RELATIONS WITH NURSES (Reference Committee on Amendments to Constitution and Bylaws, page 313)

HOUSE ACTION: ADOPTED

Physicians and nurses must work cooperatively together to provide optimum patient care. The Judicial Council has adopted the following opinion on Interprofessional Relations Between Physicians and Nurses, and submits this opinion to the House of Delegates.

INTERPROFESSIONAL RELATIONS WITH NURSES

The primary bond between medical practice and nursing is mutual ethical concern for patients. One of the duties in providing reasonable care is fulfilled by a nurse who carries out the orders of the attending physician. Where orders appear to the nurse to be in error or contrary to customary medical and nursing practice, the physician has an ethical obligation to explain those orders to the nurse involved. Whenever a nurse recognizes or suspects error or discrepancy in a physician's orders, the nurse has an obligation to call this to the attention of the physician. The ethical physician should neither expect nor insist that nurses follow orders contrary to standards of good medical and nursing practice. In emergencies when prompt action is necessary and the physician is not immediately available, in the performance of reasonable care a nurse may be justified in acting contrary to the physician's standing orders for the safety of the patient. Such occurrences should not be considered to be a breakdown in professional relations.