CHAPTER 4: OPINIONS ON GENETICS & REPRODUCTIVE MEDICINE

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

4.1 Genetics

4.2 Reproductive Medicine

4.1.1 Genetic Testing & Counseling

Genetic testing can provide valuable information to support informed decision making about personal health risks and care options as well as reproductive choices. The fact that genetic information carries implications for others to whom the individual is biologically related raises ethical challenges of balancing confidentiality against the well-being of others.

Because genetic contribution to disease can be complex and highly variable, interpreting findings and helping patients understand the implications for their health and health care requires special skill and attention.

Genetic testing is most appropriate when the results of testing will have meaningful impact on the patient's care. Physicians should not encourage testing unless there is effective therapy available to prevent or ameliorate the condition tested for. Whether a genetic test is performed to help diagnose an existing health condition, or to predict future health risks, or to provide information for managing a disease, it is important that the patient receives appropriate counseling.

Physicians who order genetic tests (individually or as part of a multi-test panel or large-scale sequencing) or who offer clinical genetic services should:

(a) Have appropriate knowledge and expertise to counsel patients about heritable conditions, risks for disease, and implications for health management, and to interpret findings of individual genetic tests or collaborate with other health care professionals who can provide these services, such as licensed genetic counselors.

(b) Adhere to standards of nondirective counseling and avoid imposing their personal moral values or judgment on the patient.

(c) Discuss with the patient:

(i) what can and cannot be learned from the proposed genetic test(s) and reasons for and against testing, including the possibility of incidental findings. Physicians should ascertain whether the patient wishes to be informed about findings unrelated to the goal of testing;

(ii) medical and psychological implications for the individual's biological relatives;

(iii) circumstances under which the physician will expect the patient to notify biological relatives of test findings; and

(iv) that the physician will be available to assist in communicating with relatives.

(d) Obtain the individual's informed consent for the specific test or tests to be performed.

(e) Ensure that appropriate measures are taken to protect the confidentiality of the patient's and their biological relatives' genetic information.

AMA Principles of Medical Ethics: II,IV,V,VI

4.1.2 Genetic Testing for Reproductive Decision Making

Genetic testing can provide information to help prospective parents make informed decisions about childbearing.

Genetic testing to inform reproductive decisions was once recommended only for women/couples whose family history or medical record indicated elevated risk for a limited set of genetically mediated conditions. As procreation among individuals of diverse ancestries becomes more common and tests for more conditions become more accurate and less costly, the relevance of broad preconception, pre-implantation, or prenatal genetic screening grows stronger. Physicians may ethically provide genetic testing to inform reproductive decision making when the patient requests, but may also wish to offer broad screening to all persons who are considering having a child.

Physicians who provide reproductive health care that includes genetic testing should:

(a) Adhere to standards of nondirective counseling and avoid imposing their personal moral values or judgment on the patient.

(b) Discuss reasons for and against genetic testing and ethically inappropriate uses of genetic testing, such as to identify non-disease-related characteristics or traits.

(c) Obtain the individual's informed consent to the specific test or tests to be performed. Physicians should ascertain whether the person wishes to be informed about incidental findings.

(d) Inform the individual about any abnormal findings for the tests ordered and discuss the severity of the associated health condition, likelihood of clinical manifestation (penetrance), age at onset, and other factors relevant to a decision about childbearing.

(e) Respect an individual's decision to terminate or continue a pregnancy when testing reveals a genetic abnormality in the fetus, in accordance with applicable law.

(f) Refer the individual to another qualified physician when personal moral values prohibit the physician from providing lawful abortion services when this is a service that the person desires, in keeping with ethics guidance.

AMA Principles of Medical Ethics: II,IV,V,VI

4.1.3 Third-Party Access to Genetic Information

The rapid pace of development and dissemination of genetic testing has made it possible to generate information about individuals across a wide and growing spectrum of genetic variations associated with disease risk. The prospect of access to and use of such information by third parties who have a stake in an individual's health raises ethical concerns about confidentiality and potentially inappropriate use of genetic information.

Patients who undergo genetic testing have a right to have their information kept in confidence, and a variety of state and federal laws prohibit discrimination by employers, insurers, and other third parties based on genetic information they obtain about an individual.

Physicians who provide and interpret genetic tests, or who maintain patient records that include the findings of genetic tests, have professional ethical obligations to:

(a) Maintain the confidentiality of the patient's health information, including genetic information.

(b) Release a patient's genetic information to third parties only with the patient's informed consent.

(c) Decline to participate in genetic testing at the request of third parties (for example, for purposes of establishing health care or other benefits or coverage for the individual) except when at the patient's request and with their informed consent.

AMA Principles of Medical Ethics: IV

4.1.4 Forensic Genetics

With the exception of genetic information (or material) collected under the jurisdiction of a coroner, medical examiner, or other medical legal officer, the release of genetic information from a physician's records without the patient's informed consent constitutes a breach of confidentiality. However, under limited circumstances with overriding legal and social considerations, all physicians may disclose such information to the criminal justice system.

Physicians from whom genetic information is sought for purposes of criminal justice:

(a) May ethically carry out DNA analysis on stored tissue samples or release genetic information without the consent of a living or deceased patient (or the patient's authorized surrogate) in response to a warrant or court order.

(b) Should release only the minimum information necessary for the specific purpose.

(c) Should not be required to provide genetic information when:

(i) a suspect whose location is known refuses to provide a tissue sample for genetic analysis; or

(ii) a tissue sample for the suspect can be obtained from other sources (such as the body of a deceased suspect).

(d) Should decline to participate in the use of information from a genetic database created exclusively for criminal justice for any purpose other than identification.

AMA Principles of Medical Ethics: III,IV

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,VII

4.2.2 Gamete Donation

Donating eggs or sperm for others to use in reproduction can enable individuals who would not otherwise be able to do so to have children. However, gamete donation also raises ethical concerns about the privacy of donors and the nature of relationships among donors and children born through use of their gametes by means of assisted reproductive technologies.

Physicians who participate in gamete retrieval and storage should:

(a) Inform prospective donors of sperm or ova:

(i) about the clinical risks of gamete donation, including the near and long-term risks and the discomforts of ovarian hyperstimulation and egg retrieval as appropriate;

(ii) about the need for full medical disclosure and that prospective donors will be tested for infectious disease agents and genetic disorders;

(iii) whether and how the donor will be informed if testing indicates the presence of infectious disease or genetic disorder;

(iv) that all information collected, including test results, will be stored indefinitely;

(v) what additional personal information will be collected about the donor;

(vi) under what circumstances and with whom personal information, including identifying information, will be shared for clinical purposes;

(vii) how donated gametes will be stored and policies and procedures governing the use of stored gametes;

(viii) whether and how the donor will be compensated;

(ix) the fact that state law will govern the relationship between the donor and any resulting child (or children).

(b) Exclude prospective donors for whom testing reveals the presence of infectious disease agents.

(c) Obtain the prospective donor's consent for gamete retrieval.

(d) Discuss, document and respect the prospective donor's preferences for how gametes may be used, including whether they may be donated for research purposes.

(e) Discuss, document, and respect the prospective donor's preferences regarding release of identifying information to any child (or children) resulting from use of the donated gametes.

(f) Adhere to good clinical practices, including ensuring that identifying information is maintained indefinitely so that:

(i) donors can be notified in the event a child born through use of his/her gametes subsequently tests positive for infectious disease or genetic disorder that may have been transmitted by the donor;

(ii) the number of pregnancies resulting from a single gamete donor is limited.

AMA Principles of Medical Ethics: I,V

4.2.3 Therapeutic Donor Insemination

Therapeutic donor insemination using sperm from a woman's partner or a third-party donor can enable a woman or couple who might not otherwise be able to do so to fulfill the important life choice of becoming a parent (or parents).

However, the procedure also raises ethical considerations about safety for the woman and potential offspring, donor privacy, and the disposition of frozen semen, as well as the use of screening to select the sex of a resulting embryo.

Physicians who choose to provide artificial insemination should:

(a) Provide therapeutic donor insemination in a nondiscriminatory manner. Physicians should not withhold or refuse services on the basis of nonclinical considerations, such as a patient's marital status.

(b) Obtain informed consent for therapeutic donor insemination, after informing the patient (and partner, if appropriate):

  (i) about the risks, benefits, likelihood of success, and costs of the intervention;

  (ii) about the need to screen donated semen for infectious disease agents and genetic disorders when an individual proposes to donate sperm specifically for the patient's use in therapeutic donor insemination;

  (iii) about the need to address in advance what will be done with frozen sperm (if any) from a known donor in the event the donor dies;

  (iv) that state law will govern the status, obligations, and rights of the sperm donor, known or anonymous, in relation to a resulting child.

(c) When sperm is collected specifically for use by an identified patient, obtain informed consent from the prospective donor, after informing the individual:

  (i) about the need to test donated semen for infectious disease agents and genetic disorders;

  (ii) whether and how the donor will be informed in the event the semen tests positive for infectious disease or genetic disorder;

  (iii) that state law will govern the status, obligations, and rights of the donor in relation to a resulting child.

(d) Counsel patients who choose to be inseminated with sperm from an anonymous donor to involve their partner (if any) in the decision.

(e) Provide sex selection of sperm only for purposes of avoiding a sex-linked inheritable disorder. Physicians should not participate in sex selection of sperm for reasons of gender preference.

AMA Principles of Medical Ethics: I,V

4.2.4 Third-Party Reproduction

Third-party reproduction is a form of assisted reproduction in which a woman agrees to bear a child on behalf of and relinquish the child to an individual or couple who intend to rear the child. Such arrangements can promote fundamental human values by enabling individuals or couples who are otherwise unable to do so to fulfill deeply held desires to raise a child. Gestational carriers in their turn can take satisfaction in expressing altruism by helping others fulfill such desires.

Third-party reproduction may involve therapeutic donor insemination or use of assisted reproductive technologies, such as in vitro fertilization and embryo transfer. The biological and social relationships among participants in these arrangements can form a complex matrix of roles among gestational carrier, gamete donor(s), and rearing parent(s).

Third-party reproduction can alter social understandings of parenthood and family structure. They can also raise concerns about the voluntariness of the gestational carrier's participation and about possible psychosocial harms to those involved, such as distress on the part of the gestational carrier at relinquishing the child or on the part of the child at learning of the circumstances of his or her birth. Third-party reproduction can also carry potential to depersonalize carriers, exploit economically disadvantaged women, and commodify human gametes and children. These concerns may be especially challenging when carriers or gamete donors are compensated financially for their services. Finally, third-party reproduction can raise concerns about dual loyalties or conflict of interest if a physician establishes patient-physician relationships with multiple parties to the arrangement.

Individual physicians who care for patients in the context of third-party reproduction should:

(a) Establish a patient-physician relationship with only one party (gestational carriers, gamete donor[s] or intended rearing parent[s]) to avoid situations of dual loyalty or conflict of interest.

(b) Ensure that the patient undergoes appropriate medical screening and psychological assessment.

(c) Encourage the parties to agree in advance on the terms of the agreement, including identifying possible contingencies and deciding how they will be handled.

(d) Inform the patient about the risks of third-party reproduction for that individual (those including individuals), possible psychological harms to the individual(s), the resulting child, and other relationships.

(e) Satisfy themselves that the patient's decision to participate in third-party reproduction is free of coercion before agreeing to provide assisted reproductive services.

Collectively, the profession should advocate for public policy that will help ensure that the practice of third-party reproduction does not exploit disadvantaged women or commodify human gametes or children.

AMA Principles of Medical Ethics: I,II,IV

4.2.5 Storage & Use of Human Embryos

Embryos created during cycles of in vitro fertilization (IVF) that are not intended for immediate transfer are often frozen for future use. The primary goal is to minimize risk and burden by minimizing the number of cycles of ovarian stimulation and egg retrieval that an IVF patient undergoes.

While embryos are usually frozen with the expectation that they will be used for reproductive purposes by the prospective parent(s) for whom they were created, frozen embryos may also offer hope to other prospective parent(s) who would otherwise not be able to have a child. Frozen embryos also offer the prospect of advancing scientific knowledge when made available for research purposes. In all of these possible scenarios, ethical concerns arise regarding who has authority to make decisions about stored embryos and what kinds of choices they may ethically make. Decision-making authority with respect to stored embryos varies depending on the relationships between the prospective rearing parent(s) and any individual(s) who may provide gametes. At stake are individuals' interests in procreating.

When gametes are provided by the prospective rearing parent(s) or a known donor, physicians who provide clinical services that include creation and storage of embryos have an ethical responsibility to proactively discuss with the parties whether, when, and under what circumstances stored embryos may be:

(a) Used by a surviving party for purposes of reproduction in the event of the death of a partner or gamete donor.

(b) Made available to other patients for purposes of reproduction.

(c) Made available to investigators for research purposes, in keeping with ethics guidance and on the understanding that embryo(s) used for research will not subsequently be used for reproduction.

(d) Allowed to thaw and deteriorate.

(e) Otherwise disposed of.

Under no circumstances should physicians participate in the sale of stored embryos.

AMA Principles of Medical Ethics: I,III,IV,V

4.2.6 Cloning for Reproduction

Somatic cell nuclear transfer (SCNT) is the process in which the nucleus of a somatic cell of an organism is transferred into an enucleated oocyte. Cloning for reproduction, that is, the application of SCNT to create a human embryo that shares all of its nuclear genes with the donor of the human somatic cell, has been debated as having possible clinical benefit. It has been suggested that reproductive cloning might be ethically acceptable to assist individuals or couples to reproduce and to create a compatible tissue donor.

Misconceptions often surround proposals for reproductive cloning, including the mistaken notion that one's genotype determines one's individuality and using SCNT to create a human embryo would replicate a person (the donor of the somatic cell).

The possible use of SCNT in reproductive medicine also poses risks of unknown physical harms from the technology itself, including concerns about long-term safety, and the possibility that SCNT will be associated with genetic anomalies or have other unforeseen medical consequences. Reproductive cloning also carries the risk of psychosocial harm, including violations of privacy and autonomy and the possibility of compromising the cloned child's right to an open future by creating enormous pressures to live up to expectations based on the life of the somatic cell donor.

Reproductive cloning may have adverse effects on familial and societal relations and on the gene pool in altering reproductive patterns and the resulting genetic characteristics of a population, including posing harms to future generations if deleterious genetic mutations are introduced. Moreover, reproductive cloning has the potential to be used in a eugenic or discriminatory fashion—practices that are incompatible with the ethical norms of medicine.

In light of the physical risks of SCNT, ongoing moral debate about the status of the human embryo, and concerns about the impact of reproductive cloning on cloned children, families and communities, reproductive cloning is not endorsed by the medical profession or by society.

Should reproductive cloning at some point be introduced into medical practice, physicians must be aware that cloning techniques must not be used without the informed consent of the somatic cell donor, the oocyte donor, and the prospective rearing parent(s), in keeping with ethics guidance for assisted reproduction.

Further, any child produced by reproductive cloning would be entitled to the same rights, freedoms, and protections as every other individual in society, irrespective of the fact that the child's nuclear genes derive from a single individual.

As professionals dedicated to protecting the well-being of patients, physicians should not participate in using SCNT to produce children. Because SCNT technology is not limited to any single country, physicians should help establish international guidelines governing its uses before experimentally proven techniques are introduced into clinical practice.

AMA Principles of Medical Ethics: V

4.2.7 Abortion

The Principles of Medical Ethics of the AMA do not prohibit a physician from performing an abortion in accordance with good medical practice and under circumstances that do not violate the law.

AMA Principles of Medical Ethics: III,IV