

Transferring embryos with genetic anomalies detected in preimplantation testing: an Ethics Committee Opinion

Ethics Committee of the American Society for Reproductive Medicine

American Society for Reproductive Medicine, Birmingham, Alabama

Patient requests for transfer of embryos with genetic anomalies linked to serious health-affecting disorders detected in preimplantation testing are rare but do exist. This Opinion sets out the possible rationales for a provider's decision to assist or decline to assist in such transfers. The Committee concludes in most clinical cases it is ethically permissible to assist or decline to assist in transferring such embryos. In circumstances in which a child is highly likely to be born with a life-threatening condition that causes severe and early debility with no possibility of reasonable function, provider transfer of such embryos is ethically problematic and highly discouraged. (*Fertil Steril*® 2017;107:1130–5. ©2017 by American Society for Reproductive Medicine.)

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KEY POINTS

- Preimplantation genetic testing (PGT) can be used to investigate the genetic composition of preimplantation embryos. Patients whose embryos undergo such testing, which includes both preimplantation genetic screening (PGS) and preimplantation genetic diagnosis (PGD), should be informed about the risks, benefits, and uncertainties of any given technique, including the fact that normal results do not guarantee that the resulting offspring will be genetically normal (a false negative) and that anomalous results do not guarantee that offspring will be genetically abnormal (a false positive).
- Patient requests for the transfer of embryos with a known genetic anomaly linked to a serious health-affecting disorder are rare but do occur in the clinical setting.
 - Valid and reasoned arguments exist to support provider decisions to either assist in transferring genetically anomalous embryos or to decline to assist in such transfers. Principles of reproductive liberty, physician autonomy, professional conscience, nonmaleficence, procreative beneficence, and child welfare are potentially invoked in decision making in this area.
 - Many genetic disorders produce highly variable phenotypes in affected individuals, creating uncertainty about the health status of any live-born child as a result of embryo transfer and live birth. This uncertainty is an important factor that counsels in favor of individualized decision making rather than categorical directives once a genetic anomaly is detected.
 - In circumstances in which a child is highly likely to be born with a life-threatening condition that causes severe and early debility with no possibility of reasonable function, it is ethically acceptable for a provider to decline a patient's request to transfer such embryos. Physician assistance in the transfer of embryos in this category is ethically problematic and therefore highly discouraged.
 - In circumstances in which a child is highly likely to be born with a condition that is treatable or effectively manageable through medical interventions, it is ethically acceptable for providers to transfer such embryos upon patient request. Provider refusals to transfer embryos in this category also fall within appropriate ethical boundaries so long as they are made and applied in a nonarbitrary manner that does not discriminate against the patient on any basis.
 - Fertility clinics are strongly encouraged to make available consultation by mental health professionals, genetic counselors, or other relevant experts upon patient request or as needed.
 - Fertility clinics are strongly encouraged to draft and make available to

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Reprint requests: Ethics Committee, American Society for Reproductive Medicine, 1209 Montgomery Hwy, Birmingham, Alabama 35216 (E-mail: ASRM@asrm.org).

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all patients written policies on whether or not the program agrees to the transfer of embryos with known health-affecting genetic anomalies. To the extent possible, these policies should be the product of an informed, deliberative, and collaborative process that includes all relevant clinic personnel.

INTRODUCTION

The burgeoning field of embryonic genetics enables prospective parents to learn about the genetic makeup of their preimplantation embryos, information that can both aid and complicate their reproductive decision making. Sophisticated diagnostic techniques involving embryo biopsy can currently detect several hundred genetic anomalies associated with a range of diseases whose health impacts span from benign to lethal (1). Moreover, advances in whole-genome sequencing of embryos suggest that in the near future prospective parents will have access to even more information about the genetic makeup of their preimplantation embryos, including the detection of aneuploidies, gene mutations, and mitochondrial abnormalities (2, 3). Generally, patients and their partners who utilize these genetic technologies do so for the purpose of maximizing their chances of birthing a healthy child. Preimplantation embryos that express genetic anomalies associated with significant health-affecting disorders are typically not selected for transfer into the uterus but instead are donated for research, cryopreserved, or discarded. In some cases, however, patients may request that embryos with known genetic anomalies be transferred. Such requests may be the result of prospective parents actively seeking to birth a child with a condition that one or both of the intended parents express, or it may be that all the viable embryos produced are genetically anomalous and thus represent the patient's only opportunity for biologic parenthood. Whether intentional or incidental, the discovery and request for transfer of embryos likely to result in the birth of offspring with health-affecting conditions pose ethical dilemmas for physicians and their staff, patients, and society.

This opinion proceeds in three parts. First, it discusses the clinical circumstances in which providers detect health-affecting conditions in embryos, revealing that in most cases such detection is incidental to a general request for preimplantation genetic testing but in rare cases patients actively seek to birth a child with a known genetic anomaly. Second, newly emerging data surrounding the accuracy of embryonic genetic testing are set out, not to direct clinical practices but rather to highlight the difficulties and complexities surrounding decision making once an embryo is deemed genetically abnormal. Finally, this opinion discusses at least four separate interests that are potentially invoked when a patient requests transfer of genetically anomalous embryos. These interests are: 1) the patient's reproductive autonomy; 2) the welfare of any resulting offspring; 3) the provider's professional conscience; and 4) the impact on third parties, including the patient's family as well as the larger society. Each of these interests is considered in the context of an ethical analysis that sets out arguments for honoring patient requests and arguments for declining such requests.

DETECTION OF GENETICALLY ANOMALOUS EMBRYOS

The utilization of PGT through the techniques of preimplantation genetic PGS and PGD is an important component in many patients' assisted reproductive efforts. According to the Centers for Disease Control, 6% of all in vitro fertilization (IVF) cycles performed in 2013 included the use of PGD, translating into approximately 10,000 procedures during that calendar year (4). Patient motivation for utilizing embryonic genetic testing varies. In one study looking at indications for PGD and PGS usage, researchers found that the primary reason patients opted for genetic testing was to detect aneuploidy, followed by elective sex selection, then diagnosis for a specific genetic abnormality, and finally to perform translocation analysis (5). Whatever the motivating indication, preimplantation genetic testing results can provide patients the specific information they seek, or it can yield unanticipated genetic information correlated with a health-affecting condition.

The detection of a genetically anomalous embryo in an IVF cycle can be an unwelcome occurrence for prospective parents. Anecdotal evidence suggests that most patients whose embryos contain a serious health-affecting genetic anomaly choose not to transfer those embryos, electing either discard or cryopreservation (6). Under certain circumstances, however, patients will request that such embryos be transferred, even when counseled about the near certainty their children will manifest symptoms of a serious genetic disorder. Three main reasons for such requests are: 1) the affected embryos are the only embryos the patient and/or her partner produced, thus providing the only opportunity for biologic parenthood; 2) the patient and/or her partner have religious or psychosocial beliefs that inform their decision to treat all their embryos with equal respect, thus permitting the transfer of genetically anomalous embryos in the face of some or no other healthy embryos; and 3) the intended parents themselves express the genetic anomaly and wish to rear children with the same characteristics. This latter scenario is sometimes referred to as "intentional diminishment" and primarily involves selection for sensory or mobility disorders such as deafness or achondroplasia (dwarfism) (7).

While each of the above-mentioned rationales could motivate patient requests for transfer of genetically abnormal embryos, logic suggests the first scenario in which all embryos are affected is the most likely to present in clinical practice. Patients whose religious beliefs or other values would guide them to seek transfer of genetically anomalous embryos may be less likely to seek embryonic testing than patients for whom this information would impact decision making. While such patients may "want to know" in order to prepare for the birth of an affected child, other approaches to prenatal diagnostic testing are likely to be preferable. In cases in which a certain genetic anomaly is intentionally sought, patients are likely to have discussed this reproductive plan with their provider, giving the clinician an a priori opportunity to consider whether to assist or decline to assist in their reproductive efforts.

No specific formal law in the United States governs the transfer of genetically anomalous embryos. Survey research

and anecdotal reports suggest that such requests are made by a very small number of patients and clinics vary in their willingness to accommodate such requests. A 2008 survey of genetic testing practices in US fertility clinics reports that 3% of clinics that provide PGT permit the technology to be used to select an embryo for the presence of a disability (8). Other clinics, in published policies, make clear they will not participate in the transfer of certain genetically anomalous embryos, citing Down syndrome and Turner syndrome as specific examples (9). Law and policymakers outside the United States have issued formal regulations on the acceptability of transferring embryos with known health-affecting conditions. In the United Kingdom, the Human Fertilisation & Embryology Authority prohibits the selection of an embryo known to “have a gene, chromosome or mitochondrial abnormality involving a significant risk that [the child] will develop a serious physical or mental disability, a serious illness, or a serious medical condition” (10). An exception, however, is made where there is no other embryo suitable for transfer; in such cases an anomalous embryo may be transferred.

Assisted reproductive technology (ART) clinics that offer genetic detection services should be aware of the range of choices their patients may seek to make, both in requesting genetic analysis and in seeking subsequent transfer of their embryos. Providers are encouraged to develop and make available to patients written policies regarding the testing and transferring of embryos, especially when those policies preclude patients from exercising one or more potential choices. Developing policies that best reflect a clinic’s preferred approach can be a complex and difficult task. In developing transfer policies, clinics should research and consider the most up-to-date data surrounding the availability and accuracy of genetic testing technologies. Below we discuss some of the clinical uncertainties surrounding embryo testing as they impact decision making about embryo transfer. Thereafter, we set out some of the arguments that could inform a clinic’s decision to assist or decline to assist in the transfer of embryos with serious health-affecting genetic anomalies. The Committee is cognizant that the term “serious health-affecting genetic anomaly” is subject to individual patient and provider interpretation and assessment, and that genetic disorders can vary in their penetrance, time of onset, and symptomology, but believes that certain normative thresholds do exist to shape and support guidance in most instances.

THE IMPACT OF CLINICAL UNCERTAINTY IN GENETIC TESTING OF EMBRYOS

The uncertainties of life find no refuge at its beginnings. Genetic testing of embryos can produce results that are indeterminate, inaccurate, or both. While the results obtained in genetic screening and testing of embryos are highly reliable as a percentage of biopsies performed, a certain number of misdiagnoses and adverse outcomes have been reported (11). The causes of misdiagnosis include confusion of embryo and cell number, transfer of the wrong embryo, maternal or paternal contamination, allele dropout, use of incorrect and inappropriate probes or primers, probe or primer failure, and chromosomal mosaicism. Each of these events could produce

a false-negative result in which the patient is told an embryo is normal when it is not, or a false-positive result in which the patient is told an embryo is abnormal when it is not. Providers who offer genetic testing of embryos have a duty to inform patients about the limitations of testing and the possibility of misdiagnosis, as such information is clearly material to a patient’s decision making and thus captured within the doctrine of informed consent.

In the specific scenario of a false-positive result stemming from chromosomal mosaicism—the situation in which an embryo contains two distinct cell lines (including the potential for both a euploid and an aneuploid cell line)—clinicians are beginning to discuss and publish reports of healthy offspring being born after PGS results indicating mosaicism. In one study, 18 women who produced only mosaic embryos were offered transfer of those embryos; of those transfers, six resulted in the birth of singleton, chromosomally healthy infants. The study authors hypothesized that the mosaic embryos either self-corrected or the aneuploid cell line had migrated to the trophectoderm and thus did not inhabit the developing infant (12). Whatever the mechanism, the ability of embryos initially classified as genetically abnormal after genetic testing to then produce genetically normal offspring is both fascinating and confounding. Additional research may illuminate the extent to which mosaic embryos should no longer be considered highly likely to result in the birth of a chromosomally abnormal infant.

Further institutional review board-guided research is clearly warranted. Pending evidence-based clinical recommendations, providers may struggle with how best to inform and treat their patients. Arguments for and against transferring genetically anomalous-presenting embryos cluster around a host of factors, including whether there are other embryos that are deemed normal in the cohort under consideration, whether the anomaly is lethal—meaning it is highly likely to either not implant or result in an early miscarriage—and what preferences the patient has expressed. At the time genetic testing results are obtained, it generally is not possible to know whether those results include false positives or false negatives; therefore, providers are best served by developing transfer policies that, unless they have reason to believe otherwise, assume the clinical accuracy of a given result. What follows is a framework for developing clinic policies to either assist or refuse to assist in the transfer of embryos presumed to be genetically anomalous.

ARGUMENTS FOR HONORING PATIENT REQUESTS FOR TRANSFER

Arguments for honoring patient requests to transfer embryos with serious health-affecting genetic anomalies dwell primarily, though not exclusively, in the realm of reproductive liberty and patient autonomy. Additional arguments focus on the overall benefit to the affected child from being born as opposed to never being born. Described more fully below, these positions might be labeled by their governing value: 1) reproductive liberty, 2) equal protection, 3) preemptive dispositional authority, and 4) the benefits of existence.

The importance and accompanying legal protections surrounding patient autonomy and reproductive liberty in the practice of reproductive medicine have long guided patient/physician relationships in the field. This Committee has acknowledged that some requests for assistance in reproduction may include features that are material to a patient's decision making for reasons that are deeply private and deserving of respect (13). Parents who request transfer of genetically anomalous embryos may so choose because it is their only opportunity for biologic parenthood, or they are willing to rear a child with an impaired health status, or they desire a child who mirrors their own health experience, or they are unwilling to discard, donate for research, or cryopreserve. Each of these rationales is compatible with the exercise of reproductive liberty, and infringements by physicians should be avoided. According robust protection of reproductive liberty may be particularly vital in the disability community where discrimination and barriers to ART access have been previously documented (14).

Applying an equality model lens, an argument arises that physicians, governments, and society should make no distinction in the treatment of fertile and infertile prospective parents. Just as fertile individuals are free to conceive and birth a child with serious, even lethal, health conditions without third-party interference, individuals who seek or require assistance in reproduction should likewise enjoy this same freedom. The notion that certain individuals should be prohibited from reproducing or forced to terminate ongoing pregnancies because their offspring are deemed "unworthy" of participation in the human race is deeply repugnant to our contemporary values, harkening to long-rejected eugenics-era tenets (15). Treating all prospective parents and their potential offspring as equally worthy is consistent with honoring patient requests to transfer genetically anomalous embryos.

A third argument rests on the issue of who possesses dispositional authority over preimplantation embryos. Embryos awaiting possible transfer are, by definition, extracorporeal and thus theoretically subject to claims of control by the intended parents, progenitors (in the case of gamete donation), or clinic personnel. While disputes between intended parents and physicians as to the disposition of embryos are rare, in at least one case a court awarded full control to the intended parents, deeming the fertility clinic to occupy the role of bailee whose sole responsibility was to exercise reasonable care over the bailment subject (16). Applying this holding to instances in which the wisdom of transfer is disputed, patients could assert their superior dispositional authority over the embryos in question, and correspondingly obtain transfer as an exercise of their established legal rights, dominion, and control.

A final argument in favor of honoring patient requests for embryo transfer derives from philosophical precepts that illuminate the comparative value of human existence versus nonexistence. If one views human life, no matter its quality or quantity, as an absolute good, then its deprivation could be said to work an overall harm—to those denied the opportunity to parent that child and possibly to society. A slight variation of this view would be to deem certain lives not worth living, due to extreme pain and suffering or lack of any interactive cognitive abilities, and thus not bringing such a person

into existence would not be deemed an overall harm. In the context of embryo transfer, there may be a clash of values between the provider and the intended parents as to whether that prospective child would have a life not worth living. Complicating this analysis are the unknowns about the life the child will actually lead and the weight, if any, to be accorded the parents' preference for existence over nonexistence. This argument attaches to each embryo regardless of the availability of one or more embryos for transfer. It is the value of the embryo and its potential to evolve into a resulting child that is at stake, not the relative health or well-being of that offspring compared to other possible lives. The presentation of these philosophical quandaries in clinical practice by no means guarantees their resolution; rather, highlighting the declared interests and potential benefits and harms to the patient and the child to be born may facilitate a provider's understanding of the complexities inherent in the transfer of genetically anomalous embryos.

Arguments in favor of honoring patient requests for transfer of genetically anomalous embryos can gain and lose in strength depending upon a host of clinical factors, including whether other unaffected embryos are available for transfer, whether the child is highly likely to be born with a life-threatening condition that causes severe and early debility with no possibility of reasonable function, whether the intended parents are desirous of raising a child with conditions similar to their own, and whether the intended parents are in accord with each other about the appropriateness of transfer. Providers who agree to honor patient requests for transfer of genetically anomalous embryos should discuss the limits, if any, of their willingness to provide treatment as well as the expected health complications a resulting child is likely to experience. This latter duty can be fulfilled by referral to a specialist trained in the particular disease process at issue.

ARGUMENTS FOR DECLINING PATIENT REQUESTS FOR TRANSFER

Arguments for declining patient requests for genetically anomalous embryo transfer collect around the principles of physician autonomy and professional duties, and the welfare of ART offspring. A minor but extant additional factor is the possibility of incurring legal or professional liability in the future for assisting a patient in a way that works harm to another. The governing values that comprise these arguments might be summarized as: 1) physician autonomy and professional conscience, 2) reproductive nonmaleficence, 3) procreative beneficence, 4) offspring and societal well-being, and 5) liability avoidance.

The concept that a physician is free to determine whether or not to enter into a doctor-patient relationship with a prospective patient is embedded in medical ethics and health law. The American Medical Association recognizes physician autonomy in the selection of patients as a basic principle of medical ethics (17). Once a relationship is formed, physicians are not obligated to meet every patient demand, with particular examples arising in the context of nonbeneficial treatment or treatment that poses harm to another (18, 19). Further,

physicians' values, personal backgrounds, and professional experiences—informing their professional conscience—might counsel against transferring a particular embryo even in the face of a sincerely held patient belief that the child should be given an opportunity to be born. Exercises of physician autonomy and professional conscience that are nonarbitrary and do not discriminate against the patient on any basis, and that can be accomplished without inflicting harm or abandonment upon the patient, should be accommodated. Solutions might include transferring the patient to another willing provider or transferring the affected embryo(s) to a clinic willing to make the requested transfer.

The precept of reproductive nonmaleficence describes a physician's obligation not to inflict harm in the course of delivering reproductive health care (19, 20). Transferring an embryo that is highly likely to result in the birth of a child with a serious disease or disability can be interpreted as the physician causing harm by facilitating the birth of an unhealthy person. At the same time, it should be acknowledged that the physician is not responsible for causing the genetic anomaly and it is the anomaly that directly causes harm to the resulting child. A further interpretation of the principle of nonmaleficence might include a duty to prevent or avoid harm (19, 20). Under this configuration, a stronger argument can be made that assisting in the transfer of genetically anomalous embryos violates the principle of nonmaleficence because the physician can avoid the harm to an affected child by refusing to transfer the particular embryo.

Philosophical discourse offers a counterpoint to the “do no harm” principle in the form of a theory dubbed procreative beneficence. This theory posits that prospective parents (in conjunction with their reproductive medicine collaborators) have a moral duty to select the child, of the possible children they could have, who is expected to have the best life, based on available information (21). This edict to “do good, whenever possible” argues against transferring genetically anomalous embryos when at least one unaffected embryo remains for possible transfer. Such is the policy adopted in the United Kingdom that prohibits the selection of a health-affected genetically anomalous embryo, except when there is no other embryo “suitable for transfer” (1). The acknowledged weakness of procreative beneficence is in determining what constitutes the “best child” and the “best life.” If the intended parents alone are vested with this decisional authority, their good faith judgment about what would constitute their best child may be preemptive of a provider's conflicting view. A decision to transfer an abnormal rather than a normal embryo would, however, still be considered in violation of procreative beneficence, which measures the “best life” in terms of health and well-being.

Child welfare concerns occupy an important role in reproductive medicine. This Committee has previously addressed offspring health and well-being as a factor in provider decision making about whether to agree or decline to provide treatment under certain circumstances (22). When a provider has a substantial basis for thinking that treating an intended parent will result in significant harm to a future child, this Committee has supported such treatment denials. Similarly, when an embryo is highly likely to give rise to a child who

will suffer significantly from a disease or disorder, a strong argument exists that providers can ethically decline to participate in the embryo's transfer. Additional concerns about harms to society from the birth of children with diseases or disabilities can be made, but are highly problematic as arguable affronts to principles of justice and nondiscrimination. The value of child welfare concerns as a basis for declining embryo transfer are further complicated by the possibility of a provider's mistaken judgment about the likely capabilities or quality of life of the prospective child.

Finally, it is reasonable for providers to have concerns about potential legal or professional liability for assisting in the transfer of embryos that result in the birth of a seriously health-affected child. While the intended parents may agree to waive any future claims against an assisting physician, no such waiver can be made on behalf of a future child or a professional licensing authority or society charged with maintaining high standards within the practice of reproductive medicine. Legal scholars have postulated that civil and even criminal claims may be available against providers who knowingly assist in the birth of a genetically unhealthy child whose status was known prior to embryo transfer (23, 24). The prospect of future liability should not deter a provider from acting in the best interest of his or her patient. At the same time, providers who are in a legitimate position to exercise discretion over treatment decisions may reasonably consider their potential liability for providing or refusing to provide care. Such liability could attach when care is provided or when it is withheld.

RECOMMENDATIONS

Patient requests to transfer embryos known to express serious health-affecting genetic anomalies raise clinical, ethical, and legal dilemmas that impact a variety of ART stakeholders, including patients and their partners, providers, offspring, and society. The rare but small chance that an embryo deemed abnormal through genetic testing will result in the birth of a genetically normal child, coupled with the phenotypic variability associated with some genetic disorders, creates challenges for providers striving to counsel patients about the risks and benefits of their reproductive options. Additionally, patient preferences, values surrounding health and disease, expectations, and options for parenthood impact their decision whether or not to seek transfer, or some other disposition, when an embryo is deemed genetically anomalous.

Valid and reasoned arguments exist to support provider decisions to assist in transferring genetically anomalous embryos, and in declining to assist in such transfers. Principles of reproductive liberty, physician autonomy, and child welfare are invoked in this clinical setting, creating challenges in the prioritization and application of these and other principles as clinics work to establish guiding policies. Fertility clinics are strongly encouraged to draft and make available to all patients their written policies on the transfer of embryos with known health-affecting genetic anomalies. To the extent possible, these policies should be the product of an informed, deliberative, and collaborative process that includes all relevant clinic personnel. Furthermore, patients should be made aware of these policies prior to starting a treatment cycle that may result

in the creation of genetically anomalous embryos, so that they are fully informed of their options as early as possible.

The Ethics Committee concludes that in circumstances in which a child is highly likely to be born with a life-threatening condition that causes severe and early debility with no possibility of reasonable function, it is ethically acceptable to refuse to transfer such embryos upon patient request. Physician assistance in the transfer of embryos in this category is ethically problematic and therefore highly discouraged. This conclusion is consonant with prior Committee analysis that physicians may be morally obligated to withhold services when significant harm to future children is likely (22). In other circumstances in which a child is highly likely to be born with a condition that is treatable or effectively manageable through medical interventions, it is ethically acceptable for providers to adopt a policy that they will transfer such embryos upon patient request. Providers who agree to honor patient requests for transfer of embryos in this category should discuss the limits, if any, of their willingness to provide treatment as well as the expected health complications a resulting child is likely to experience. Provider refusals to transfer embryos in this category also fall within appropriate ethical boundaries so long as they are made and applied in a nonarbitrary manner that does not discriminate against the patient on any basis. The presence or absence of one or more unaffected or healthy embryos can be taken into account in generating clinic policies. Finally, clinics are strongly encouraged to make available consultation by mental health professionals, genetic counselors, or other relevant specialists and experts upon patient request or as needed.

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Judith Daar, J.D.; Jean Benward, M.S.W.; Lee Collins, J.D.; Joseph Davis, D.O.; Leslie Francis, Ph.D., J.D.; Elena Gates, M.D.; Elizabeth Ginsburg, M.D.; Sigal Klipstein, M.D.; Barbara Koenig, Ph.D.; Andrew La Barbera, Ph.D., H.C.L.D.; Laurence McCullough, Ph.D.; Richard Reindollar, M.D.; Mark Sauer, M.D.; Rebecca Sokol, M.D., M.P.H.; Sean Tipton, M.A.; Lynn Westphal, M.D.

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