

Fertility treatment when the prognosis is very poor or futile: an Ethics Committee opinion

Ethics Committee of the American Society for Reproductive Medicine

American Society for Reproductive Medicine, Birmingham, Alabama

The Ethics Committee recommends that in vitro fertilization (IVF) centers develop patient-centered policies regarding requests for futile treatment. In most cases, clear communication can avoid a direct conflict, but clinicians ethically may refuse to provide treatment believed to be futile or to carry a very poor prognosis. In certain instances, clinicians may provide limited treatment which they judge likely to be futile, but must be vigilant in their presentation of risks, benefits, and alternatives. This version replaces the previous published draft of this name (Fertil Steril 2012;98:e6-9). (Fertil Steril® 2019;111:659-63. ©2019 by American Society for Reproductive Medicine.)

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KEY POINTS

- For the purposes of this statement, “futility” refers to treatment that has a <1% chance of achieving a live birth; “very poor prognosis” refers to treatment for which the odds of achieving a live birth are very low but not nonexistent (1% to <5% per cycle).
- Clinicians may refuse to initiate a treatment option they regard as futile or having a very poor prognosis. Referral information should be offered, if appropriate.
- Decisions about treating or refusing to treat couples or individuals always should be patient-centered. Protection of a fertility center’s success rates is not an ethical basis for refusing to treat those with futile or very poor prognoses. Conversely, care should not be provided to benefit the provider or center financially.
- Upon request, clinicians may treat patients in cases of futility or very poor prognosis on a limited basis to fulfill patients’ psychological needs, but only if the clinician has assessed the risks and benefits and has implemented a process, detailed in this opinion, for fully informing the patients of the low chance of success, eliciting their values, and ensuring their comprehension.
- Thorough discussions are advisable at the beginning of the patient-physician interaction when patients have indicators of futile or very poor prognosis.
- Fertility centers should develop policies to guide evidence-based decisions about treating those with futile or very poor prognoses. They should provide their patients with clinic-specific success rates and should inform them if they are aware of other centers with better outcomes, where their prognoses may be improved.
- Clinicians should make decisions to refuse to initiate or continue infertility treatment in cooperation with the patients. Toward this end, it is advisable for clinicians periodically to revisit the treatment plan in a process of shared decision-making with patients.

INTRODUCTION

Many patients who seek fertility services have a reasonable chance of succeeding in their goal of having a child. Others, however, have a very low or, in some cases, nearly nonexistent chance of achieving that goal. While most patients set their own limits to treatment, others, when told of remote prospects of success, have difficulty changing treatment protocols or ending their efforts to reproduce. Such situations may produce conflicts between clinicians and their patients. On the one hand, patients have interests in trying to do all they can to have a child and in making autonomous decisions about medical treatment. On the other hand, the clinician’s duty as a medical professional is to provide care that offers benefits to patients, which is not served by offering treatments that are virtually

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Correspondence: Ethics Committee, American Society for Reproductive Medicine, 1209 Montgomery Highway, Birmingham, Alabama 35216 (E-mail: asrm@asrm.org).

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certain to fail. Misunderstandings, disagreements, or conflicts may arise when patients seek to initiate or continue treatment regarded by practitioners as having either a very low or virtually nonexistent chance of success.

How should disagreements between patients and practitioners over the utility of treatment be managed? This document first reviews the applicable ethical precepts. Next, it addresses the conditions under which clinicians may refuse treatment based on predictions of remote success. Third, it discusses ways of minimizing confusion, of imparting bad news, and of preventing conflicts between clinicians and patients over the usefulness of requested treatments.

ETHICAL PRECEPTS

For Patients

Reproductive autonomy. Reproductive autonomy is a core value in reproductive medical ethics. It represents a right to be protected from interference with one's access to treatment by the state or others. It also can be understood as an ethical claim to have reproductive services provided. This aspect of reproductive autonomy is limited, however, as will be discussed herein. When a patient seeks treatment that is judged by the physician, based on evidence, to be futile or to carry a very poor prognosis, the patient does not have an absolute right to insist upon that treatment (1-3).

The American Medical Association (AMA) has described the balance of these values in this way: "Requests for interventions that are not medically appropriate challenge the physician to balance obligations to respect patient autonomy and not to abandon the patient with obligations to be compassionate, yet candid, and to preserve the integrity of medical judgment" (4).

For the Physician

Beneficence and professional integrity. The question of handling conflicts between physicians and patients over whether to initiate or continue with a treatment option raises basic ethical issues about rights and duties in the physician-patient relationship. This relationship is typically consensual, with couples or individuals and physicians free to enter or not enter into a relationship as they choose. The ability to decline to provide medical treatment relates directly to fertility treatments that have a very low or nonexistent chance of success, particularly when the physician believes the requested treatment may harm the patient (5-7).

The ethical principle of beneficence creates the professional responsibility to act for the patient's welfare. Thus, after accepting a patient, clinicians must use their best efforts on the patient's behalf, provide the applicable standard of medical services, engage in a process of informed consent, and respect the patient's autonomy. These duties do not, however, obligate physicians to provide services when, in their good faith medical judgment, the treatment is unlikely to achieve the patient's treatment goals. If a clinical intervention is reliably predicted to produce no such benefit, there is no ethical obligation to provide it (Brett 1986; Brett 2007). Professional integrity creates an ethical obligation to pursue

excellence in patient care and also serves the values of the medical profession as a whole (1, 2).

SITUATIONS OF FUTILE OR VERY POOR PROGNOSIS

The chances that fertility treatment will successfully lead to a live birth vary with the patient, treatment, and other conditions. Some treatments have such a low chance of success that they may be considered futile, while others, though not futile, may have a very poor prognosis. Because classifying a treatment as "futile" or "very poor prognosis" has different implications, we discuss each separately.

Futility

The term "futility" usually is used in situations in which a given treatment has virtually no chance of achieving the desired medical end. The concept is most commonly used in relation to end-of-life decisions. In that context, the AMA and others have elaborated on the complex meanings of futility and on the challenges of defining it (1, 4, 8). Many recognize both quantitative and qualitative aspects of the concept: on the quantitative side, there is likelihood that a treatment will achieve physiologic goals; on the qualitative side, the value of the treatment may contribute to the patient's quality of life (9). The AMA has identified as futile "interventions that, in [the physician's] best medical judgment, cannot reasonably be expected to yield the intended clinical benefit or achieve agreed-on goals for care" (4).

We believe this definition for futile care can be applied to the treatment of infertility. Treatment is futile in the quantitative sense when the desired physiologic goal is a live birth but there is no or virtually no reasonable likelihood that this goal will be achieved through the proposed treatment. Treatment can also be judged as futile in the qualitative sense when it will not serve to fulfill a goal important to the patient's quality of life.

Assessing Clinical Futility

The Ethics Committee views treatment (for example, an in vitro fertilization [IVF] or insemination cycle) as "futile" if it has a <1% chance of achieving a live birth. This calculation relies on various criteria that clinicians take into account when considering a likely outcome, such as the non-availability of adequate spermatozoa, the age of the female partner, or the patient's previous poor response. Clinicians should be circumspect about using ovarian reserve testing to assess futility in light of its limited predictive capacity, as detailed in this Society's recent review of the research literature (10). Futility also may be judged from a fertility center's own data, such as if the center has never achieved a pregnancy during application of the treatment to a patient with a particular profile, or, with caution, from national or international data. With this and all assessments of patients' chances, clinicians should be wary of erroneously estimating that a given individual's chances are the same as the average of the group to which he or she belongs (11).

Examples of treatment plans likely to be futile are those in which couples try IVF treatments with their own gametes when the female partner has ovarian failure, the male partner lacks viable spermatozoa, or the couple has undergone several IVF cycles without adequate egg production, fertilization, or embryo development. The determination of futility may change if patients modify their treatment plan, for example, by trying gamete or embryo donation after unsuccessful attempts with their own gametes.

Recognizing Psychological Goals

Situations may arise where the clinician fairly determines that treatment has little or no chance of resulting in pregnancy and live birth, but the patient nonetheless requests it in order only to receive a psychological benefit or to fulfill a religious belief. Benefits such as resolving questions about their fertility, being able to have hope, obtaining closure, acting in accord with their faith, and knowing they tried assiduously can be valid goals for limited treatment. Thus, an unsuccessful outcome, while disappointing, may still bring benefit from the patient's perspective, although the amount of benefit should be weighed carefully against the physical risks and costs of treatment (12).

Several things complicate defining and assessing futility. Patients and clinicians may interpret prognoses differently. Patients who hear that the odds of a live birth for their particular profile are 1% may perceive this as hopeful, and therefore not futile, when members of the medical team conclude that these odds are too low to proceed. At the same time, assessing the odds of success often is not a straightforward matter. Any clinician who has been surprised by an unexpected pregnancy knows to be humble about the limits of our capacity to predict outcomes perfectly. In addition to nature's capriciousness, a growing literature indicates that clinicians are not immune to cognitive biases and shortcuts that may cause them to overestimate or underestimate a treatment's utility (13).

The values clinicians hold as medical professionals may also affect their assessments in such situations. They may consider it wasteful or even fraudulent to participate in a treatment they believe in advance will not work. With large professional teams necessary to carry out some treatments, the entire staff may experience frustration and a sense of failure when they provide services that have a very remote chance of success. On the other hand, clinicians may empathize with their patients' overriding desire to attempt pregnancy and may wish to avoid delivering (and enforcing) bad news.

The Ethics Committee finds that it is an appropriate exercise of professional integrity for clinicians to refuse to offer, initiate, or continue treatment when, in their informed professional judgment, they regard such treatments as having a <1% chance of success and, thus, as being futile. In refusing to offer such treatment, physicians may consider not only the extremely remote chance of success but also the physical and psychological risk posed by the treatment. Physical risks may arise in fertility treatments for both men and women, but the risks generally are of greater concern for the woman undergoing IVF. If the risks are heightened, such as when a woman

would need complex reconstructive surgery prior to assisted reproduction or when a man with nonobstructive azoospermia has already experienced several failed sperm retrieval procedures, there is further basis for refusing to provide futile treatment.

Psychological risks arise when, among other things, repeated efforts are unproductive and prevent patients from reassessing their reproductive options. Physicians may believe these risks are justified when the prognosis is very poor but not when the odds of success are virtually zero. In reaching a decision not to proceed, clinicians should follow guidelines and policies of the fertility practice that avoid arbitrary decisions. They should clearly explain their reasoning to the patients, including why they regard the proposed treatment to be futile, and should discuss gamete donation, adoption, and other alternatives. The discussion may include referral to another practice, either for a second opinion or because the patient's prognosis at another practice might be improved.

However, the Ethics Committee also finds that clinicians may ethically offer treatments they deem to be physiologically futile in circumstances where the risks are minimal, and the understood goal of the patient is to receive a psychological benefit from proceeding (14). In such a case, the patient's general welfare may be enhanced by a limited attempt at treatment, a goal still compatible with the duty of beneficence understood in its psychosocial dimension.

Before undertaking such treatment, however, the Committee recommends that a stepwise process be implemented. First, the clinician should explain the evidence base for his or her clinical judgment that the requested assisted reproduction is futile. In doing so, the physician should be attentive to indications that the patient possesses false or incomplete information, in which case s/he should respond by respectfully providing the information the patient needs to make an informed and reflective assessment of the clinician's recommendation. The clinician also should be attentive to external influences, such as pressure from a partner, spouse, or other family member. If such influences unjustifiably interfere with the patient's reproductive autonomy, the clinician should seek to minimize their role. The clinician should ask the patient what is important to him or her regarding reproductive treatment, to elicit the patient's values, and should repeat the recommendation against assisted reproduction with their own gametes and/or uterus. If the patient reaches an informed judgment that, despite the high predicted failure rate and risk of physical and psychological harms, the fertility treatment supports his/her values and/or psychological needs, it is compatible with professional integrity and reproductive liberty either to provide assisted reproduction on a limited basis or to refuse to provide assisted reproduction.

Psychological consultation is highly recommended for couples and individuals prior to undertaking treatment in such situations. For patients whose motivations are religious, suggesting that they seek religious advice about forgoing assisted reproductive technology may be valued. Informed consent conversations should be appropriately documented, including success rates, risks, outcomes, and alternative treatments. Financial benefit to the physician or center is not an

acceptable ground for providing a treatment the physician believes is futile.

Very Poor Prognosis

In cases of very poor prognosis, the odds that a treatment (for example, an IVF or insemination cycle) will achieve a live birth are very low but not nonexistent (1% to <5% per cycle) and are thus not described here as futile. For example, a 44-year-old woman with a normal follicle-stimulating hormone level may have a very low but not nonexistent prospect for success with IVF at some fertility centers.

Decision-making in cases of very poor prognosis may be more complex than in cases of futility. Patients have a greater justification for insisting on their desired treatment option when the odds of success are somewhat higher. Also, when the outcome is more difficult to predict, some patients may view their chance of success as greater than that estimated by the physician. Indeed, as research proceeds and experience evolves, situations that once appeared to yield very poor prognoses may now produce improved outcomes in some centers, as has occurred with treatments for nonobstructive azoospermia (15).

As with futile prognoses, the values and goals of patients and clinicians in cases of very poor prognosis may differ. The patients may have an emotional need to feel that all reasonable medical avenues for having a child have been tried. Clinicians may be concerned about providing care with very low likelihood of success and must factor in the physical risks that are posed. In addition, current requirements to report outcome data may reward centers that accept only couples or individuals with good prognoses and thus create a motivation for refusing to treat those with very poor prognoses. Protecting success rates, however, is not an ethical basis for refusing to treat those with poor prognoses; neither is providing treatment for the financial benefit of the provider(s). In cases of very poor prognosis, the Ethics Committee finds that clinicians who determine that the chances of physiologic or psychological benefit are sufficient to make risks acceptable may justifiably proceed with the patient's preferred treatment on a limited basis; the patient must be fully informed of the prognosis, risks, and costs of treatment. It is recommended that clinicians initiate a stepwise communication process with patients, as was described in the case of futility, to elicit the bases for their treatment wishes and their values.

However, clinicians may ethically refuse to accept or to provide further treatment to couples and individuals with very poor prognoses provided that they make an evidence-based determination and follow guidelines and policies of the fertility practice that avoid arbitrary decisions. In either case, sufficient information must be conveyed to the couple or individual for them to understand what is being recommended and why. This information should be tailored and individualized as much as possible to the circumstances of the individual or couple. The interchange should include referral to psychological counseling. In deciding whether to proceed, the treatment team should, together with the couples or individuals, carefully consider the value systems and other factors that affect the couple's or individual's insistence on further treatment.

PREVENTING CONFLICTS

Fertility practices can take several steps to prevent disagreements or conflicts over initiating or continuing fertility treatments. One important step is to develop explicit policies to guide decisions about initiating or stopping treatment due to futile or very poor prognosis. An example would be the "conscientious practice policy," developed in response to a recommendation of the AMA (16). Although not all situations can be anticipated, policies can encourage clinicians and patients to think prospectively about poor outcomes. Policies should inform couples and individuals of the medical criteria used to accept patients, the program's limits concerning treatment, and the circumstances in which the program may refuse to provide additional services. For example, a policy may state that IVF treatment will be refused or stopped when it has never succeeded at the clinic for a particular patient profile. Or, a policy may state that physicians will confer as a team to make futility determinations; for some patients, bad news will be easier to accept if it is the consensus of several physicians. It is advisable to retain some flexibility in developing the policies, however, and policies should not be so strict as to fail to take into account the circumstances or emotional needs of patients or the differences of opinion among clinicians within a practice. The policies should stress communication and agreement (4, 17).

A second important step is for clinicians to discuss these policies with potential patients when initial treatment decisions are made and as treatment proceeds (18). These discussions should include information about the chances of success and the circumstances in which treatment may not be offered or continued. Such discussion is especially important if patients present with a profile associated with a low likelihood of success, but it is not limited to these groups since the balance of benefits and probabilities facing any patient may shift over time. Patients should be apprised of endpoints and results in the treatment plan that signal when the team will reconsider continuing the treatment (19). During the consent process, physicians should be forthright and thorough in explaining the proposed treatment plan. Information about success rates should be conveyed to all couples and individuals, and it should include rates at the program as well as national averages. It is also appropriate to disclose if, to the clinician's knowledge, other programs have reported greater success in treating the patient's conditions and, if so, to offer referral if the patients desire. Referral to psychological counselors and other professionals should be discussed. Clinicians should recognize that their refusal to continue when faced with very poor or futile prognoses may help patients by encouraging them to consider alternative ways of achieving parenthood or to accept not having children.

After patients begin treatment, it is also important for them periodically to reevaluate their situation and goals. Members of the medical team should be involved in discussions about currently available treatments, steps that will be taken if certain events occur or fail to occur, and decisions regarding when it will be time to stop and examine other options. The discussion may need to be very specific. At the same time, the treatment team must consider the needs of the

patients, realizing that the drive to continue may be enhanced by specific circumstances or psychological needs.

A third approach that may help minimize conflicts is for clinicians to learn to become more comfortable imparting the bad news of futile or very poor prognosis. Since Dr. John Gregory (1724-1773) wrote the first professional medical ethics, it has been recognized that to a physician “of compassionate and feeling heart, this is one of the most disagreeable duties in the profession: but it is indispensable.” We encourage clinicians to pursue education and training in the art of imparting bad news. The medical literature provides a range of recommended approaches, all of them generally incorporating advice to establish a setting free from interruption; to elicit the patient’s understanding of his or her medical situation; to gently share information about the prognosis, ensure it is understood, and compassionately deal with reactions, including validating the patient’s emotions (20).

SUMMARY

Most patients recognize when they have reached a point where further treatment is not going to result in a successful pregnancy, and they will either stop their efforts or look for other means of achieving parenthood. Some, however, find it difficult to stop pursuing their hoped-for goal and they insist on further treatment. The Ethics Committee recommends development of patient-centered policies for each IVF center to enable clinicians to make evidence-based assessments. In most cases, the provision of futile therapies is not ethically justifiable, but when a patient seeks to receive only a psychological benefit, limited treatment may be provided after a process of explicit education and examination of values. For those treatments with very poor success rates, clinicians must be vigilant in their presentation of risks, benefits, and alternatives.

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Judith Daar, J.D.; Jean Benward, M.S.W.; Lee Collins, J.D.; Joseph Davis, D.O.; Owen Davis, M.D.; Leslie Francis, Ph.D., J.D.; Elena Gates, M.D.; Elizabeth Ginsburg, M.D.; Susan Gitlin, Ph.D.; William Hurd, M.D., M.P.H.; Sigal Klipstein, M.D.; Laurence McCullough, Ph.D.; Richard Reindollar, M.D.; Ginny Ryan, M.D.; Mark Sauer, M.D., M.S.; Sean Tipton, M.A.; Lynn Westphal, M.D.; Julianne Zweifel, Ph.D.

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