

Fertility treatment when the prognosis is very poor or futile

The Ethics Committee of the American Society for Reproductive Medicine

American Society for Reproductive Medicine, Birmingham, Alabama

The Ethics Committee recommends development of evidence-based policies that are patient centered for each IVF center. In most cases, the provision of futile therapies is not ethically justifiable. For those treatments with very poor success rates, clinicians must be vigilant in their presentation of risks, benefits, and alternatives. This document was reviewed in June 2009. This version replaces the previous version of this document, published in October 2004. (Fertil Steril® 2009;92:1194–7. ©2009 by American Society for Reproductive Medicine.)

1. For the purposes of this statement, “futility” refers to treatment that has a $\leq 1\%$ 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 $\leq 5\%$ per cycle).
2. 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.
3. Decisions about treating or refusing to treat couples and/or individuals always should be patient-centered. Protecting fertility center success rates is not an ethical basis for refusing to treat couples and/or individuals with futile or very poor prognoses. Conversely, care should not be provided solely for the financial benefit of the provider or center.
4. Upon request, clinicians may treat couples and/or individuals in cases of futility or very poor prognosis provided the clinician has assessed the risks and benefits and fully informed the couples and/or individuals of the low chance of success.
5. Thorough discussions are advisable at the beginning of the patient-physician interaction when couples and/or individuals have indicators of futility or very poor prognosis.
6. Fertility centers should develop evidence-based policies to guide decisions about treating couples and/or individuals with futile or very poor prognoses. In such cases the couples and/or individuals should be fully informed and offered information about referrals, especially if other clinics have had greater success with similar medical indications.
7. Decisions to refuse to initiate or continue infertility treatment should be made in cooperation with couples and/or individuals. Toward this end, it is advisable for clinicians periodically to revisit the treatment plan with couples and/or individuals.

Many couples and/or individuals that 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.

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While most couples and/or individuals 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 reveal conflicting interests among clinicians and their patients. On the one hand, couples and/or individuals have interests in trying to do all they can to bear a child and in making autonomous decisions about medical treatment. On the other hand, clinicians have interests in minimizing harm to prospective donors and in avoiding the frustration of providing treatments that are virtually certain to fail. Misunderstandings may arise when couples and/or individuals seek to initiate or continue treatment regarded by practitioners as having either a very low or virtually nonexistent chance of success.

How should conflicting interests between couples and/or individuals and practitioners over the utility of treatment be managed? This document first reviews the interests of clinicians in entering into and continuing physician-patient relationships. Next, it addresses the conditions under which clinicians may refuse treatment based on predictions of remote success. Third, it discusses ways of minimizing confusion and preventing conflicts between clinicians and couples and/or individuals over the usefulness of treatment plans requested by couples and/or individuals.

CLINICIAN AUTONOMY

The question of handling conflicts among physicians and couples and/or individuals 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 and/or individuals and physicians free to enter or not enter into a relationship as they choose. Just as patients may refuse medical services, so may physicians decline to accept couples and/or individuals as patients as long as they do not violate laws against impermissible discrimination. In addition, they are free to terminate a physician-patient relationship as long as they provide timely notice to patients (1).

This ability to decline 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. In such circumstances, clinicians may refuse to begin treatment or decline to continue with the current protocol (2). Indeed, some ethicists argue that clinicians have a duty to withhold treatments that threaten harm and probably will not achieve their intended goal (3, 4).

After accepting a couple and/or individual, clinicians must use their best efforts on the patient's behalf, provide the applicable standard of medical services, secure 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 will not achieve the patient's treatment goals.

SITUATIONS OF FUTILITY OR VERY POOR PROGNOSIS

The chances that fertility treatment will successfully lead to a live birth vary with the couple, individual, 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. It also arises in the context of fertility services, where the desired physiologic goal is a live birth and there is no or virtually no reasonable likelihood that this goal will be achieved through the proposed treatment.

Although there are no clear quantitative indices of futility in the fertility context, the Ethics Committee views as "futile" treatment (e.g., an IVF or insemination cycle) that has a $\leq 1\%$ chance of achieving a live birth. This calculation relies on various criteria clinicians take into account when considering a likely outcome, such as a markedly elevated FSH level, the non-availability of adequate spermatozoa, and the age of the female partner. It also may be deduced from national or international data and from the fertility center's own data, such as if the center has never achieved a pregnancy during application of the treatment to women with a particular profile.

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 numerous IVF cycles without adequate egg production, fertilization, and/or embryo development. The determination of futility may change if couples modify their treatment plan, for example, by trying gamete or embryo donation after unsuccessful attempts with their own gametes.

The concept of futility has both quantitative and qualitative dimensions (5). The Council on Ethical and Judicial Affairs of the American Medical Association and others have elaborated on the complex meanings of futility and on the challenges of defining it in the context of end-of-life treatment (6–8). A not uncommon definition in that context casts a futile intervention as one that "does not have its intended physiologic effect" (9). Futility in the context of fertility treatment is less studied. The Ethics Committee of the American College of Obstetricians and Gynecologists (ACOG) has referred to care as futile if it is "incapable of producing a desired result" or is unable "to achieve a physiologic goal" (10). We believe that the ACOG's definition for futile care can be applied to the treatment of infertility.

Several things complicate defining and assessing futility. For example, couples and/or individuals and clinicians may interpret prognoses differently. Couples or individuals who hear that the odds of a live birth for their particular profile are 1% may perceive this as hopeful, and therefore not futile, whereas members of the medical team may conclude that these odds are too low to proceed. In addition, couples and/or individuals and clinicians may perceive benefit differently. Couples and/or individuals may regard a medical intervention as beneficial if it answers questions about their fertility, lets them know whether they can produce eggs or achieve fertilization, or helps them feel they have tried all efforts to reproduce, even if the intervention does not result in a live birth. From this perspective, an unsuccessful outcome, while disappointing, may still bring benefit.

The professional interests of clinicians may also affect their judgment about futility. For some clinicians, avoiding futile efforts is a matter of professional integrity. They may consider it wasteful or even fraudulent to participate in a treatment they know 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. For these and other reasons, physicians may prefer not to proceed with treatment they deem futile.

The Ethics Committee finds that clinicians may ethically refuse to initiate or continue treatment when, in their professional judgment, they regard such treatments as having a $\leq 1\%$ chance of success and thus as being futile for the couple and/or individual. In refusing to offer such treatment, physicians may consider not only the extremely remote chance of success but also the physiologic and psychological risk posed by the treatment. Physiologic risks may arise in fertility treatments for both partners, but the risks are of particular concern for the female partner undergoing IVF. Psychological risks arise when, among other things, repeated efforts are unproductive and, furthermore, prevent couples and/or individuals from reassessing their reproductive options. Physicians may feel they can justify these risks 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 clearly explain their reasoning to the couples and/or individuals, including why they

regard the proposed treatment to be futile and they should discuss gamete donation, adoption and other alternatives.

However, the Ethics Committee also finds that clinicians may ethically offer treatments they deem to be futile if, in their professional judgment and in consultation with a mental health professional, they believe the couple and/or individual will receive some psychological benefit from proceeding (11). Psychological consultation is highly recommended for couples and/or individuals prior to undertaking this treatment. Physicians who offer treatment in this situation should thoroughly counsel the couple and/or individual that the odds of success are virtually nonexistent and appear to be futile. The informed consent should be appropriately documented, include success rates and detail 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 (e.g., an IVF or insemination cycle) will achieve a live birth are very low but not nonexistent ($>1\%$ and $\leq 5\%$ per cycle), and are thus not described here as futile. For example, a 40-year-old woman with a slightly elevated FSH level or a 44-year-old woman with a normal FSH level may have a very low but not nonexistent prospect for success with IVF within this range at some fertility centers.

Decision making in cases of very poor prognosis may be more complex than in cases of futility. For one thing, couples and/or individuals have a greater justification for insisting on their desired treatment option when the odds of success are low while not nonexistent. For another, when the outcome is more difficult to predict, some couples and/or individuals may view their chance of success as greater than that estimated by the physician. Indeed, as research proceeds and experience grows, situations that once appeared to yield very poor prognoses may now produce improved outcomes in some centers, as has occurred with treatments for non-obstructive azoospermia (12).

As with futility, the interests of couples and/or individuals and clinicians in cases of very poor prognosis may differ. The couples and/or individuals may have an emotional need to feel that all reasonable medical avenues for bearing a child have been tried. Clinicians may be concerned about providing care with very low likelihood of success. In addition, current requirements to report outcome data may reward centers that accept only couples and/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 couples and/or individuals with very poor prognoses. Neither is providing treatment solely for the financial benefit of the provider(s).

In cases of very poor prognosis, the Ethics Committee finds that physicians 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 plan; the couples and/or individuals must be fully informed of the prognosis, risks and costs of treatment. However, physicians may ethically refuse to accept couples and/or individuals with very poor prognoses or to provide further treatment (i.e. exercise conscientious refusal), provided they follow guidelines and evidence-based policies of the fertility center that avoid arbitrary decisions. In either case, sufficient information must be conveyed to the couple and/or individual for them to understand what is being recommended and why. This information should be tailored and particularized 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 and/or individuals, carefully consider the value systems and other factors that affect the couples and/or individuals insistence on further treatment.

PREVENTING CONFLICTS

Fertility centers can take several steps to prevent 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 futility or very poor prognosis. Although not all situations can be anticipated, policies can encourage clinicians and couples and/or individuals to think prospectively about poor outcomes. Policies should inform couples and/or individuals of the medical criteria used to accept couples and/or individuals, the program's limits concerning treatment, and the circumstances in which the program may refuse to provide additional services. For example, centers may adopt a policy stating that treatment will be refused or stopped when the treatment has never succeeded at the clinic or at other facilities for a particular couple or individual profile. 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 couples and/or individuals (10) or the differences of opinion among clinicians within a practice. The policies should stress communication and agreement rather than decision-making by physicians alone (10).

A second important step is for clinicians to discuss these policies with couples and/or individuals at the time that initial treatment decisions are made. This discussion should include information about the chances of success and the circumstances in which it may not be offered or continued. Such discussion is especially important if couples and/or individuals present with a profile associated with a low likelihood of success, but it is not limited to these groups. Couples and individuals should be apprised of end points and markers in the treatment plan that signal when the team will reconsider continuing the treatment (10, 13).

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/or 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 couples and/or individuals desire. Referral to psychological counselors and other professionals should be discussed. Clinicians should recognize that their refusal to continue when faced with very poor prognosis or futility may help couples and/or individuals by encouraging them to consider alternative ways of achieving parenthood or to accept not having children.

After couples and/or individuals 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 about 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 take into account the needs of the couple and/or individual, realizing that the drive to continue may be enhanced by specific circumstances or emotional needs.

SUMMARY

Most couples 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 evidence-based policies that are patient centered for each IVF center. In most cases, the provision of futile therapies is not ethically justifiable. For those treatments with very poor success rates, clinicians must be vigilant in their presentation of risks, benefits, and alternatives.

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