

Ethics of guaranteeing patient outcomes: a complex issue whose time has not come

Richard T. Scott, Jr., M.D., and Kaylen Silverberg, M.D.

The Institute for Reproductive Medicine and Science of Saint Barnabas Medical Center, Livingston,
New Jersey

In this issue of *Fertility and Sterility*, Andereck et al. (1) discuss the ethics of guaranteeing outcomes for patients attempting to conceive through IVF or related assisted reproductive technologies. Andereck leads a team of ethicists who evaluate this clinically important question and ultimately conclude that the practice is ethical and that when properly executed, may be in keeping with the best interests of both patients and physicians. The authors are paid consultants to a specific “fertility center in the San Francisco area.” The center offers a “money-back guarantee program” within their ART program in which 90% of the cost paid by the couples for the actual ART cycle is refunded to the patients if a pregnancy is not achieved and carried through the first 12 weeks of gestation. Although we appreciate the thoughtfulness of the investigators’ arguments, the complexity of the issues and the potential for conflicts of interest which compromise patient care go beyond those addressed in this published opinion.

Andereck et al. focus principally on refuting the policy statement from the American Medical Association (AMA) which states that contingent physician fees are unethical and should be prohibited (2). They provide a logical argument that a guarantee in this setting is not the same as guaranteeing clinical outcome, but rather represents a “sharing of risk” with the patient so that the patients’ personal loss is minimized if the treatment cycle is unsuccessful. While this reasoning is largely successful in separating this type of indemnification from the examples given in the AMA policy statement, several disturbing issues remain which call the ethics of these arrangements into serious question.

The authors suggest that these programs represent “shared risk” between the patients who pay more for successful cycles and the program, which receives little or no financial remuneration if the treatment fails. In fact, this is not the case. The authors state clearly that these programs have a sufficiently large volume of experience to predict their success rates, and have adjusted the fee structure to ensure that they will remain profitable if their success rates remain constant. Thus the risk is not being shared by the program and the patients, but rather is being distributed amongst the patient population as whole. To represent these programs as “shared risk” is deceptive and should be considered unethical.

Andereck et al. claim that a money-back guarantee addresses only the connotation of the word guarantee that promises financial or some other remuneration if the promised outcome is not achieved. They further state that “since no medical intervention can ensure a result, it is obviously immoral to raise expectations based on an impossibility.” This amounts to little more than semantic games and is problematic. If the most ethical course is the one that provides the greatest honesty and clarity, then why not provide a more precise description of the program. Perhaps the program could be described as *a means of sharing risk with other patients to limit your individual liability in the event of a failed treatment cycle and paying*

Received and accepted
June 2, 1998.

Reprint requests: Richard
T. Scott, Jr, M.D., The
Institute for Reproductive
Medicine and Science of
Saint Barnabas Medical
Center, 94 Old Short Hills
Road, Livingston, New
Jersey 07039.

The opinions and
commentary expressed in
Editor’s Corner articles are
solely those of the author.
Its publication does not
imply endorsement by the
Editor or American Society
for Reproductive Medicine.

0015-0282/98/\$19.00
PII S0015-0282(98)00215-5

150%–220% of the usual cost for a successful cycle while extending minimal risk to the ART program.

Andereck et al. point to the widely accepted reimbursement model of capitation as an equivalent situation where physicians share risk with the insurers. In fact, these two settings are not at all equivalent. Physicians who accept capitation are generally required to accept all patients within their specialty who are within their catchment area. They do not have the privilege of withholding care based on the patient's diagnosis, complexity of care, or quantity of resources consumed. Additionally, there is generally external peer review to assure that the quality of care is maintained. These controls may not be in place in programs offering "guaranteed outcomes."

The authors discuss the variation in the fee structure relative to age but fail to point out that many programs use other criteria to include or exclude patients or to increase the cost of participation. This creates a number of serious potential ethical problems. Patients may be attracted to the program because of the potential to participate in the "shared risk program" only to find out that they have some factor which disqualifies them. There is substantial potential for abuse in this setting. An example might be telling a patient that their "factor X" level is too low and that they are no longer candidates for the "shared risk program" but that they remain reasonable candidates and may want to try an IVF cycle anyway.

Even if unintentional, this may be construed as a "bait-and-switch" ploy and raises disturbing ethical issues. Programs may choose to adjust the fee structure based on a variety of screening results. Many types of screening tests (semen analysis, basal FSH levels, etc) are quite logical and easily defensible. In contrast, the use of inadequately evaluated or frankly unproven screening tests to increase the cost is also possible and has major abuse potential, for example, increasing the cost of participation based on the results of anti-phospholipid antibody testing.

Another potential ethical conflict arises from requiring patients to have additional testing, repeat testing, or adjunctive treatments prior to being approved for the "shared risk" program. One example might be the requirement that patients have procedures such as hysteroscopy done at the specific center even though they have had their endometrial cavity evaluated in the recent past. Another might be the requirement of very expensive IVIg therapy as an adjunct to the actual treatment cycle (it might be different if the IVIg were presented as experimental and an option). These types of precycle screening and adjunctive treatments result in significant additional costs to the patients and revenue to the program and may not be included in the global program charge. Various types of pretreatment screening are done at virtually all centers and may clearly be valuable.

The ethical conflict arises when programs can compel

patients to have additional or repetitive things done at additional cost because it is a requirement to be allowed to participate in the "shared risk" program. Clearly the potential exists for programs to minimize their portion of the "shared" financial risk by charging "a la carte" for these services.

The presence of a guarantee gives the IVF team a substantial incentive to make certain that the patient conceives and progresses through the first trimester. This should, in general, be a positive factor that encourages the program to provide the highest quality care. Unfortunately, this could also motivate the team to transfer larger numbers of embryos to increase overall pregnancy rates with less regard to the risk of multifetal gestation and the elevated risk of preterm labor and poor neonatal outcome. This area represents a clear separation of the interest of the center and that of the patient based on the "shared risk program" and is a major ethical issue. The authors acknowledge this conflict but do not provide guidance on how it might be resolved.

The costs of obstetrical and pediatric care for high multifetal gestations, not to mention the personal and financial burdens of caring for multiple children of the same age, are substantial and their potential impact on patients cannot be neglected. Perhaps the programs should agree to rigidly abide by the recent Society for Assisted Reproductive Technology/American Society for Reproductive Medicine guidelines regarding the number of embryos transferred for *all* patients participating in the "shared risk" program.

The separation of the centers' interests from those of the patients may have a significant adverse effect on the physician/patient relationship. Patients implicitly trust that their physician will act in their best interest and the presence of even a perception of a conflict of interest is not in the patients' best interest.

Potential ethical conflicts also arise for patients who have insurance for a portion of their care. If the cycles fail, does the program reimburse the insurance companies for covered services? The potential to structure the program in a way which exposes the patients to risk (paying more if they are successful, but having the center still receive substantial compensation if unsuccessful) is clearly present. Are these plans only available to those patients with no coverage of any kind? Will the temptation of a guarantee cause patients to abandon their insurance coverage to get this deal? Depending on the local reimbursement rates and the inflation factor for the cost of a successful cycle, there is a very large incentive for the program to avoid less favorable insurance coverage which at times may be at the patients' expense.

Andereck et al. imply that only the best IVF centers in the country can afford to offer a money-back guarantee and that the presence of such a program would ultimately enhance the quality of patient care. In fact, charges are not a medical issue. Rather, they are an actuarial issue, such that any

program can calculate a fee based on their success rates that would allow them to offer this type of guarantee. The same lack of logic follows their comment that, "physicians who are recognized as successful in treating their patients command higher fees than those who are not." The heavy penetration of managed care and standardization of reimbursement schedules among insurers in most parts of the country have seen the evolution of fixed payments independent of treatment quality or outcome.

The authors specifically avoid the issue of conflict resolution. For example, who decides if the center is paid in the following circumstances: selective reduction of high order multifetal gestations with subsequent loss of the entire pregnancy in the second trimester, or termination for chromosomal abnormality discovered after the 12-week cutoff; the pregnancy was obviously abnormal throughout gestation and was diagnosed after 12 weeks.

The authors' contention that the AMA's perspective reflects an overall distrust of outcome analysis as a valid tool for assessing the benefit of any intervention is unnecessarily inflammatory. The AMA supports outcome analysis as a tool for assessing the benefit of any intervention. There is NO intervention here, this is purely a marketing issue. The money-back guarantee does not improve outcomes or lower costs. It is solely about developing a marketing program to

attract new patients without adversely impacting the financial condition of the practice.

The authors of the manuscript are paid consultants to a program with an active money-back guarantee program. While the clinic should be congratulated for seeking out ethical consultation regarding policies within their program, the potential conflict of interest created by any financial relationship between the "ethicists" and the program should also be acknowledged.

In summary, the ethics of providing money-back guarantees for patients participating in ART programs are complex at best. The arguments advanced by Andereck et al. provide insight into this area but fail to adequately address many areas where the potential for exploitation exists. Any realization of the potential abuses created in these situations may lead not only to a lower quality of patient care but also to a decrease in the credibility of our specialty among patients, the media, and lay press. Such a scenario may also risk further increases in burdensome government oversight and regulation.

References

1. Andereck WS, Thomasma DC, Goldworth A, Kushner T. The ethics of guaranteeing outcomes. *Fertil Steril* 1998;70:416-21.
2. American Medical Association. Code of medical ethics: current opinions with annotations—1996-1997 edition. Chicago: AMA Press, 1996.