Financial "risk-sharing" or refund programs in assisted reproduction: an Ethics Committee opinion

Ethics Committee of the American Society for Reproductive Medicine

American Society for Reproductive Medicine, Birmingham, Alabama

Financial "risk-sharing" fee structures in assisted reproduction programs charge patients a higher initial fee but provide reduced fees for subsequent cycles and often a partial or complete refund if treatment fails. This opinion of the ASRM Ethics Committee analyzes the ethical issues raised by these fee structures, including patient selection criteria, conflicts of interest, success rate transparency, and patient informed consent. This document replaces the document of the same name, last published in 2013 (Fertil Steril 2013;100:334–6). (Fertil Steril® 2016;106:e8–11. ©2016 by American Society for Reproductive Medicine.)

Key Words: Assisted reproductive technology, in vitro fertilization, cost, Ethics

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KEY POINTS

- Financial "risk-sharing" programs offer patients a payment structure under which they pay a higher initial fee but provide reduced fees for subsequent cycles and may receive a refund if they do not become pregnant or deliver a baby. These programs also may offer financing of in vitro fertilization (IVF) costs.
- Financial "risk-sharing" programs present a potential conflict of interest between the patient's desire to become pregnant without compromising their financial ability to pursue other methods of becoming a parent, such as adoption, and the provider's financial interests.
- Financial "risk-sharing" programs may be ethically acceptable if they are practiced under certain carefully limited guidelines:
    - Criteria for program inclusion and termination must be clearly specified.
    - Patients must be fully informed of the financial costs, advantages and disadvantages of the programs and available alternatives. Participants must be clearly informed of their chances of success if found eligible for the financial "risk-sharing" program, and must be informed that the program is not guaranteeing pregnancy and/or delivery.
    - Programs must adhere to all ASRM practice guidelines with respect to ovarian stimulation, number of embryos to transfer, and ancillary procedures and must not take medically inappropriate risks in order to increase the likelihood of achieving a pregnancy.

Some assisted reproduction programs now offer IVF on a financial "risk-sharing," "warranty," "refund," or "outcome" basis, in addition to traditional fee-for-service pricing. Initially, financial "risk-sharing" patients pay a higher fee. If a "risk-sharing" patient has an ongoing pregnancy or delivery (depending on the structure of the program), the provider keeps the entire fee. If treatment fails, however, the patient may be entitled to additional IVF cycles following which, if unsuccessful, a specified percentage of the fee is returned to the patient. Pretreatment screening and medication costs, both of which can be considerable, are ordinarily not covered in these plans. These programs often offer patients the chance to finance the cost of the program fees with variable interest rates.

Such programs have been criticized as being exploitative, misleading, and contrary to long-standing professional norms against charging contingent fees for medical services. Proponents, on the other hand, argue that this form of payment is a legitimate response to the lack of health insurance coverage for IVF and to patient concerns about the high cost and substantial risk of IVF failure. Only 15 states currently have laws that mandate insurance coverage for fertility care, and only six states mandate coverage that includes IVF (1). Patients who are not covered by insurance may bear the

Received June 30, 2016; accepted July 1, 2016; published online July 21, 2016.
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Fertility and Sterility® Vol. 106, No. 5, October 2016 0015-0282/$36.00
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http://dx.doi.org/10.1016/j.fertnstert.2016.07.003

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entire cost of IVF out of pocket, which can exceed 50% of their disposable income (2). In effect, the higher initial fee to enter a financial "risk-sharing" program cross-subsidizes the refunds for patients who are unsuccessful. Although little published literature is available, at least one company managing a financial "risk-sharing" program reported that 20% of participants received refunds due to not achieving a pregnancy (3).

Focusing on the positive impact on patients, financial "risk-sharing" plans may serve as a form of insurance against the risk of catastrophic costs associated with failure of IVF and might appeal to couples who would wish to recuperate financial resources in order to attempt other methods of becoming parents, such as adoption or third-party reproduction, should IVF prove unsuccessful (4). Clinics must make efforts to accurately describe the details of the program to patients before enrollment. Results from one study, however, suggest that fertility clinics frequently do not disclose these criteria or the benefits and detriments of participation, with one author recommending that more oversight may be needed to ensure ethical administration of these programs (5). In structuring a financial "risk-sharing" program, providers must strive to ensure that potential profit motives do not inappropriately affect the care that is provided. Transparency about success rates and adherence to standard stimulation protocols, including the number of embryos to transfer, aids in this endeavor.

ETHICAL ANALYSIS

The ethical acceptability of these plans must be judged by their impact on patients and not on the profit motive or entrepreneurial impulse that also may have motivated their emergence. Financial "risk-sharing" programs are likely to appeal to, and are most often only available to, patients who must self-pay for IVF, thus taking on the financial "risk-sharing" role of health insurance plans. In exchange for a higher initial fee compared to the cost of one IVF cycle, financial "risk-sharing" programs agree to provide up to a specified number of IVF cycles to eligible patients. If IVF is successful before the agreed-upon number of cycles is reached, the clinic keeps the entire amount of the fee. If no pregnancy or delivery occurs within a certain number of embryo transfers or in a specified amount of time, the patient receives a refund of all or a specified percentage of the fee (exclusive of screening and medication costs) (6). The higher initial fee is intended to cover the cost of refunds to unsuccessful patients; however, in some situations, even if patients become pregnant before the program is complete, the cost of their financial "risk-sharing" program is comparable to the costs they would have incurred if paying for each IVF cycle individually, depending on how the fees are structured.

One ethical concern raised about financial "risk-sharing" programs is that they are misleading or exploitative in that they have the potential to coerce patients who are desperate to have a child into purchasing a more expensive form of IVF service than is necessary. In order to meet this concern, programs must be careful to ensure that patients who are offered the financial "risk-sharing" option are suitable candidates for it. Patients must be made fully aware of the specific costs, advantages, and disadvantages of the programs, must be clearly informed of their chance of success at that clinic and its criteria for refund or exclusion of refund, and must be informed that the program is not guaranteeing pregnancy and/or delivery. Patients should be counseled about alternatives to financial "risk-sharing" programs, including undergoing IVF without enrolling in the program (fee for service) and the decision not to undergo IVF. It is especially important for patients to have as clear an understanding as possible about their own per cycle chances of success so that they are not induced to purchase services that are more expensive than necessary. Equally, patients who meet program qualifications for these plans should know whether they are otherwise good candidates for successful IVF and thus might not need to purchase this form of service. Patients also should understand that clinics may have different records of success for different types of patients. Although it should be noted that there are difficulties in comparing clinics in terms of efficacy, these difficulties exist independently of financial arrangements such as financial "shared-risk" programs. It is reasonable to provide consultation with financial counselors prior to participation in financial "risk-sharing" programs to ensure that the cost structure is understandable to the patients, and if patients are traveling to the United States for their care from another country, that it is clear in what currency the fees are to be paid.

A second ethical concern has arisen because financial "risk-sharing" programs appear to violate long-standing ethical prohibitions against paying contingency fees in medicine. This concern is based on Opinion 6.01 of the American Medical Association (AMA) Code of Medical Ethics, which states that "a physician's fee should not be made contingent on the successful outcome of medical treatment" (7). However, neither of the following two reasons given in support of Opinion 6.01 applies to IVF financial "risk-sharing" plans that are appropriately structured.

The first reason relates to doctors making their professional fees contingent on the success of a patient's pending medical malpractice or worker's compensation claim, thereby potentially skewing the medical opinion that they render in such a case (8). But this concern has no bearing on the propriety of financial "risk-sharing" plans for IVF services, for they make fees contingent on the outcome of the treatment itself, not on the outcome of a lawsuit.

The second reason cited in support of Opinion 6.01 is that hinging fees on the success of medical treatment implies that "successful outcomes from treatment are guaranteed, thus creating unrealistic expectations of medicine and false promises to consumers." While it is unethical to create unrealistic expectations or make false promises, financial "risk-sharing" plans do not appear to have that intent or effect. Providers charge a substantial premium to those who enter the plan, compared with their conventional fee-for-service charge. While the provider's willingness to assume some of the risk of failure may convey a message of confidence in its services, patients should be appropriately counseled not to regard the

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arrangement as a guarantee of success. On the contrary, the "premium" built into financial "risk-sharing" fees signals to the patient that the provider needs to be compensated for assuming some of the risk of failure precisely because there is a significant risk that treatment will fail. What is guaranteed is not success, but a potential refund if treatment fails. Moreover, when the fee structures of programs are aimed to offset the costs of failure (refunds) by the increased initial charge (retained by the clinic in case of success), patients are in effect serving as an insurance pool. The program permits patients the additional option of recovering some of what they have paid if they are unsuccessful so that they may pursue other options.

Another rationale not mentioned in Opinion 6.01 that might justify an ethical objection to contingent fees in medicine is that it is often hard to define medical success and determine whether it has occurred in a given case. Where the measure of success is not clearly specifiable, contingent fees will inevitably spawn doctor-patient disputes over whether a fee has been earned. This concern may be obviated, however, if financial "risk-sharing" plans clearly specify measures of success, either delivery of a child or a pregnancy of specified duration. These measures, however, must not be specified in a manner that encourages inappropriate medical practices, such as embryo transfers that do not meet practice guidelines (8).

A third set of concerns is that such programs have a built-in potential conflict of interest that is likely to skew clinical decision making toward achieving pregnancy regardless of the impact on the patient in order to avoid paying a refund. Two such dangers may be cited. One is that the provider will be biased in favor of stimulation protocols that tend to produce more oocytes and pose increased risks to the woman's health. The other is that the provider will be biased in favor of transferring a relatively large number of embryos, thereby increasing the likelihood not only of pregnancy but of multiple gestations, which can harm women, fetuses, and potential offspring. On the other hand, patients in financial "shared-risk" programs may choose elective single embryo transfer (eSET) more often than those patients without insurance and not participating in financial "risk-sharing" programs as they have already committed to potentially undertaking multiple transfer cycles (9). Efforts should be made by providers to promote single blastocyst embryo transfer when appropriate to reduce the risks of multiple gestations. Relatedly, programs may have incentives to add in ancillary tests such as sonohysterography, in cases in which they are not indicated.

When providing traditional fee-for-service or financial "risk-sharing" programs, beneficence should be practiced and standard of care should be followed. Non-"risk-sharing" fee-for-service programs also have incentives to overstimulate the ovaries or transfer multiple embryos in order to have high enough success rates to attract future patients or to add expensive ancillary services. The Committee did not find that the incentives are so much greater in "risk-sharing" plans that they deserve condemnation independently of comparable risks in fee-for-service plans. Because of the potential for conflicts of interest, however, programs should be cautioned to follow recommended ASRM practice guidelines when financial "risk-sharing" programs are in place, as they would be expected to do in any event. Additionally, outcomes for patients participating in financial "risk-sharing" programs should periodically be reviewed to ensure that the ethical concerns addressed in this document are not violated.

CONCLUSION

The Committee finds that the financial "risk-sharing" form of payment for IVF is an option that might be ethically offered to patients without health insurance coverage for IVF if certain conditions that protect patient interests are met. These conditions are that the criterion of success is clearly specified in advance of enrollment, that patients are fully informed of the financial costs and advantages and disadvantages of such programs, that informed consent materials clearly inform patients of their clinic-specific chances of success if found eligible for the financial "risk-sharing" program, that clinics follow standard protocols/guidelines for these patients (i.e., standard stimulation and number of embryos transferred), and that the program is not guaranteeing pregnancy and/or delivery. It also should be clear to patients that they will be paying a higher cost for IVF if they in fact succeed on the first or second cycle than if they had not chosen the financial "risk-sharing" program, and that in any event the costs of screening and drugs are not included. Finally, programs should not engage in medical practices that fall outside of ASRM practice guidelines in the effort to achieve success.

Acknowledgments: This report was developed by the Ethics Committee of the American Society for Reproductive Medicine as a service to its members and other practicing clinicians. While this document reflects the views of members of that Committee, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment in all cases. This report was approved by the Ethics Committee of the American Society for Reproductive Medicine and the Board of Directors of the American Society for Reproductive Medicine.

This document was reviewed by ASRM members and their input was considered in the preparation of the final document. The following members of the ASRM Ethics Committee participated in the development of this document. All Committee members disclosed commercial and financial relationships with manufacturers or distributors of goods or services used to treat patients. Members of the Committee who were found to have conflicts of interest based on the relationships disclosed did not participate in the discussion or development of this document.

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