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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, Washington, D.C.

Financial "risk-sharing" fee structures in assisted reproduction programs charge patients a higher initial fee that includes multiple cycles but offers a partial or complete refund if treatment fails. This opinion of the American Society for Reproductive Medicine 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 2016. (Fertil Steril® 2024;121:783–6. ©2023 by American Society for Reproductive Medicine.)
El resumen está disponible en Español al final del artículo.

Key Words: Risk, ethics, reproduction, refund, ART

KEY POINTS

- Financial "risk-sharing" programs offer patients a payment structure under which they pay a higher initial fee for a package of multiple cycles that is discounted over the per-cycle fee, and patients may receive a partial or complete refund when they do not become pregnant or deliver an infant.
- 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 when they are practiced under certain carefully limited guidelines:
  - Criteria for program inclusion and termination must be specified clearly on marketing materials or as early in the evaluation process as possible. This information must be available to all current and prospective patients in a transparent manner.
  - Patients must be fully informed: of the financial costs, advantages, and disadvantages of the programs and available alternatives; of their chances of success when found eligible for the financial "risk-sharing" program; and that acceptance into the program is not (and cannot be) a guarantee of pregnancy and/or delivery.
  - Programs must adhere to all American Society for Reproductive Medicine (ASRM) practice guidelines with respect to ovarian stimulation, the number of embryos to transfer, and ancillary procedures, and they must not take medically inappropriate risks to increase the likelihood of achieving a pregnancy.
- Ultimately, health insurance coverage that includes fertility treatment is the ideal model for financial risk mitigation for patients and would eliminate the need for risk-sharing programs. All providers should advocate for adequate coverage for their patients.

Some assisted reproduction programs offer in vitro fertilization (IVF) treatment on a financial "risk-sharing," "warranty," "refund," or "outcome" basis, in addition to traditional fee-for-service pricing. Broadly, financial "risk-sharing" patients initially pay a higher fee for treatment, which typically includes more than one IVF attempt (1). When a "risk-sharing" patient has an ongoing pregnancy or delivery (depending on the structure of the program) with the first or subsequent cycles, the provider keeps the entire fee. When treatment fails, however, the patient may be entitled to have some or all of the fees refunded. Pretreatment screening and the cost of medication, both of which can be considerable, are ordinarily not included in these plans.

Such programs have been criticized as being exploitative, misleading, and contrary to long-standing professional norms against charging contingency 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-financial cost

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and substantial risk of IVF failure. Only 20 states currently have laws that mandate insurance coverage for fertility care, and only 14 states mandate coverage that includes IVF treatment (2). Patients who are not covered by insurance may bear the entire cost of IVF out of pocket, which can exceed 50% of their disposable income (3). In effect, the higher initial fee to enter a financial ‘‘risk-sharing’’ program 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 because of not achieving a pregnancy (4), and a recent survey of members of the Society of Reproductive Endocrinology and Infertility noted that 58% of group practices offered some sort of refund program, and only 6% of respondents offered a refund to >25% of their patients (5).

ETHICAL ANALYSIS

The ethical acceptability of these plans must be judged by their impact on patients and not by the profit motive or entrepreneurial impulse that may also 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 treatment, thus mirroring the financial ‘‘risk-sharing’’ role of health insurance plans. Proponents note that financial ‘‘risk-sharing’’ plans may serve as a form of insurance against the risk of catastrophic costs associated with failure of IVF treatment and might appeal to patients who would wish to recoup financial resources to attempt other methods of becoming parents, such as adoption or third-party reproduction, should autologous IVF treatment prove unsuccessful (6).

There are several concerns that must be addressed to ensure that these plans are executed in an ethical manner. Financial ‘‘risk-sharing’’ programs can be 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 (7). Good prognosis patients who achieve pregnancy after the first cycle or before the program is complete will often end up paying more for IVF treatment than when they had not chosen the financial ‘‘risk-sharing’’ program. To address this concern, programs must strive for the utmost transparency. Clinics should accurately describe the details of the program to patients before enrollment. Patients should be counseled about alternatives to financial ‘‘risk-sharing’’ programs, including undergoing IVF treatment without enrolling in the program (fee for service) and the decision not to undergo IVF treatment. It is important for patients to have as clear an understanding as possible about their own chances of success with various treatment modalities so that they are not induced to purchase services that are more expensive than may be necessary. Equally, patients who meet program qualifications for these plans should be informed by the program whether they are otherwise good candidates for successful IVF treatment outcomes, and their individual per-cycle chances of success. This information will help them determine whether the higher costs are worth the guarantee given their level of risk tolerance. 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. Consultation with financial counselors before participation in financial ‘‘risk-sharing’’ programs is recommended to ensure that the cost structure is understandable to the patients and to discuss whether it is financially feasible for them. Costs not included in the program, such as medications and the diagnostic evaluation, should be clearly delineated. Finally, the definition of “success,” whether live birth or pregnancy of a specified duration, should be clearly specified.

Financial ‘‘risk-sharing’’ programs appear to violate long-standing ethical prohibitions against paying contingency fees in medicine. A prior version of the American Medical Association’s Code of Medical Ethics stated 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.” Although this statement has since been removed from the American Medical Association’s opinion, it still prohibits contingent fees (8). Although it is unethical to create unrealistic expectations or make false promises or guarantees, financial ‘‘risk-sharing’’ plans do not appear to have that intent or effect. Although 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 arrangement as a guarantee of success. On the contrary, the ‘‘premium’’ built into financial ‘‘risk-sharing’’ fees signals to the patient that risks need to be pooled precisely because there is a significant chance that treatment will fail. What is guaranteed is not success, but a partial or full refund when treatment fails.

Providers must strive to ensure that potential profit motives do not inappropriately affect the care that is provided when offering “risk-sharing programs.” Some have argued 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, 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 >1 embryo at a time, thereby increasing the likelihood not only of pregnancy but of multiple gestations, which can harm women, fetuses, and potential offspring. Adherence to standard stimulation protocols and ASRM’s embryo transfer guidelines (9) is critical to ensuring that potential profit motives do not inappropriately affect the care that is provided. Conversely, it could be argued that patients in financial ‘‘shared-risk’’ programs may choose elective single embryo transfer more often than those patients without insurance and not participating in financial ‘‘risk-sharing’’ programs because they have already committed to potentially undergoing multiple transfer cycles (10).

When providing traditional fee-for-service or financial ‘‘risk-sharing’’ programs, benefits should be practiced and standards of care should be followed. Non ‘‘risk-sharing’’ fee-for-service programs also have incentives to overstimulate the ovaries or transfer multiple embryos to increase

success rates with the goal of attracting future patients. The Committee did not find that the incentives are so much greater in ''risk-sharing'' plans that they deserve special consideration independently of comparable risks in fee-for-service plans. Because of the potential for conflicts of interest, programs should adhere to recommended ASRM practice guidelines regardless of how the treatment cycle is financed. Additionally, outcomes for patients participating in financial ''risk-sharing'' programs should be periodically reviewed to ensure that the ethical concerns addressed in this document are not violated.

Ultimately, patients must be given the information they need to fully evaluate "risk-sharing" programs and determine if they are appropriate for them as a means of providing some degree of financial recourse to offset the substantial expenses incurred should their treatment not succeed. Mandated insurance coverage for fertility treatment is the best way to provide this support for patients, and all physicians should advocate for the expansion of this coverage to ultimately obviate the need for these alternative fee structures.

CONCLUSION

The Committee finds that the financial ''risk-sharing'' form of payment for IVF treatment is an option that can ethically be offered to patients without health insurance coverage for IVF treatment when certain conditions that protect patient interests are met. These conditions include: the criterion of success is clearly specified in advance of enrollment; patients are fully informed of the financial costs, advantages, and disadvantages of such programs; excluded costs, such as screening and medication are clearly delineated, informed consent materials accurately describe clinic-specific chances of success when found eligible for the financial ''risk-sharing'' program; clinics follow standard protocols and guidelines as well as adhere to the relevant ASRM practice guidelines for these patients (i.e., standard stimulation and number of embryos transferred); and patients understand that the program cannot guarantee pregnancy and/or delivery. It also should be made clear to patients that when they achieve success before completing all of the allotted prepaid cycles, they may end up paying a higher cost for IVF treatment than when they had not chosen the financial ''risk-sharing'' program.

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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: Sigal Klipstein, M.D.; Deborah Anderson-Bialis, B.A.; Kavita Shah Arora, M.D., M.B.E., M.S.; Ricardo Azziz, M.D., M.P.H., M.B.A.; Tolulope Bakare, M.D., M.P.H.; Katherine Cameron, M.D.; Susan Crockin, J.D.; Ruth Farrell, M.D.; Catherine Hammack-Aviran, M.A., J.D.; Elizabeth Ginsburg, M.D.; Jessica Goldstein, R.N.; Mandy Katz-Jaffe, Ph.D.; Edward Martinez, M.H.A., M.S.; Joshua Morris, M.D., M.A.; Jennifer Kawwass, M.D.; Catherine Racowsky, Ph.D.; Robert Rebar, M.D.; Jared Robins, M.D.; Mary Samplaski, M.D.; David Shalowitz, M.D.; Chevis Shannon, Dr.P.H., M.P.H., M.B.A.; Hugh Taylor, M.D.; Sean Tipton, M.A.; Lynn Westphal, M.D.; Julianne Zweifel, Ph.D. 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 on the basis of the relationships disclosed did not participate in the discussion or development of this document.

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Programas financieros de "riesgo compartido" o reembolso en reproducción asistida: una opinión del Comité de Ética

Estructuras de tarifas de riesgo financiero compartido en programas de reproducción asistida cargan a los pacientes con una tarifa inicial más alta que incluye múltiples ciclos pero ofrecen un reembolso parcial o completo si el tratamiento falla. Esta opinión de la Sociedad Americana para el Comité de Ética en Medicina Reproductiva analiza las cuestiones éticas que plantean estas estructuras de tarifas, incluyendo criterio de selección de paciente, conflictos de interés, transparencia de tasa de éxito, y consentimiento informado del paciente. Este documento reemplaza al documento del mismo nombre, publicado por última vez en 2016.