Contemporary OB/GYN®

IVF GUARANTEES

Money-back IVF guarantees: weighing the pros and cons

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IVF "refund" programs have been around for more than a decade and patients seem to like them. But critics question whether such "money-back" offers —and the physicians involved— are ethical or exploitative. This article will help you better answer patients' questions about the pros and cons.

"Money-back guarantee," "shared risk," and "refund guarantee" are terms usually not associated with the practice of medicine. Many critics of money-back plans say they violate historical ethical prohibitions against paying contingency fees in medicine. Yet money-back plans have been offered by in vitro fertilization (IVF) practices for more than 10 years and continue to be available, despite ongoing controversy about their existence.

What are money-back plans and how do they work? Are all the plans the same? Are the physicians involved doing anything unethical? Why are physicians involved with money-back plans? Do patients want them, and if so, why? Is it possible to structure these plans so as to avoid exploiting patients? This article will answer these questions and provide you with the information you need to weigh the pros and cons of money-back IVF plans.

The rationale for money-back plans

Money-back plans are offered because insurance covers only 15% to 25% of IVF costs. IVF is a high-technology medical service with costs ranging from $6,000 to $12,000. Medications and specialized laboratory services can cost $3,000 to $10,000 more. Another $5,000 to $30,000 can be spent if donor eggs or a gestational carrier are used.

Although the IVF live-birth rate per egg retrieval for younger patients has doubled in the past decade, to approximately 40%, many women do not conceive on their first attempt, and it is impossible to guarantee any medical outcome with the technology. After three IVF cycles—including use of frozen embryos from those cycles—the likelihood of having a baby increases to 60% to 90% in women younger than age 40. If IVF fails, however, a substantial refund may help a couple adopt (which can cost $20,000 to $40,000), try other forms of assisted reproduction (such as a gestational carrier, which costs up to $60,000), or recoup part of their original investment. For many couples, it

would be impossible to pursue these other options without the IVF refund. A money-back guarantee also can make the cost of attempting IVF predictable, because a patient knows she will pay a certain amount if she is successful, and much less if she is not.

Types of plans

All money-back plans are based on the premise of returning to a patient some or all of the money she spent on medical care related to IVF, if the procedure does not produce a pregnancy. There are important differences, however, among individual programs. Some plans reimburse 100% of the cost of clinical care, whereas others offer only partial refunds (such as 50% to 80%). Timing of refunds also varies, from one failed IVF cycle to a requirement that two, three, or even four cycles fail before reimbursement. Some plans will not refund a patient's money until all of her cryopreserved embryos have been replaced, whereas others specifically *exclude* use of cryopreserved embryos. While premiums for participating vary from program to program, the cost is always more if the patient has a baby than if she did not participate in a refund program, and far less if she does not become pregnant.

Other distinctions between programs have received more criticism. These include defining "success" as being pregnant or establishing a clinical pregnancy, rather than live birth, and excluding many costs associated with IVF, such as screening tests, medications, and special laboratory services like embryo cryopreservation. An even bigger criticism is that many, but not all, refund programs are so selective about who they will accept that only women with the most favorable prognosis qualify. As a result, many patients may be interested in a refund program but few may actually have a chance to enroll. Some practices also reserve the right to terminate a patient's participation in a refund program if she does not respond well to ovarian stimulation or has other untoward clinical events during an IVF cycle.

In the past, some practices have required that women undergo certain possibly unnecessary treatments (such as immunization therapy) in order to participate in a refund program, and then have not provided coverage for those services. To date, most refund programs have been backed only by the medical practice involved, creating the risk that a patient entitled to a refund might not get it if the practice goes out of business. There are no reports of that actually happening, but to prevent it, a few programs are backed by companies with the resources necessary to ensure that refunds can be paid. Communication styles among plans also vary, leaving open the possibility that a patient may not really understand what she is purchasing from certain groups.

Advantages of refund programs

The popularity of refund programs is testament to patients' positive sentiments about them. Not only do patients who receive money back like these plans, but they also are favored by women who go on to have babies, and by consumers who like to have financial choices.

Cost considerations. A refund program allows a patient to know exactly what the cost of successful IVF treatment will be, and also how much she will spend if she is unsuccessful. Thus couples can do financial planning up front, determine the maximum they are willing to spend to try to have a baby, and possibly be better able to finance care. Refund programs, then, give patients with limited resources increased access to assisted reproduction services, increase their confidence and security in meeting the financial demands of fertility treatment, and reduce couples' anxiety about the potential cost of an unsuccessful IVF cycle or other form of treatment. Patients have even more options with programs that allow use of donor eggs, and those that define success as a live birth afford protection against the unfortunate and largely unpredictable outcome of miscarriage.

Quality-of-care considerations. Refund programs also foster higher pregnancy rates through high-quality care because an IVF clinic must have a reasonably good pregnancy rate in order to participate in one. Many such programs—but not all—offer higher profit margins to clinics with higher pregnancy rates, thereby rewarding physicians for providing quality care, which is a reasonable objective. Furthermore, patients who conceive in an early IVF cycle rather than in a later one achieve their objective with less medical intervention and less risk, which is a good value proposition. This scenario is similar to managed care, in which an HMO makes more profit if patients remain healthy and use fewer services. While the pricing of refund programs has been criticized, the reality is that all IVF clinics—like any other medical or non-medical business—have to be profitable to stay afloat. Pricing services too low means no profits, whereas pricing too high results in too few patients. Refund programs allow physicians to focus on providing medical care rather than worrying

about their patients' finances.

The impact of screening. All refund programs screen patients for eligibility or to set the level of guaranteed reimbursement. Screening provides valuable information to a woman about her real chance for success and involves tests—such as FSH level or antral follicle count—that would be done even if she were not participating in a refund program. Furthermore, screening results in reduced costs for some patients, because the better the prognosis and lower the likelihood of paying a refund, the cheaper the coverage. Women with better screening results tend to be younger and also are more likely to need financial assistance and/or a guaranteed refund in order to afford treatment.

Disadvantages of refund programs

The most damaging criticism that has been leveled against refund programs—and one that can neither be proven nor disproved—is that they encourage physicians to practice bad medicine by replacing more embryos than they should in order to achieve a pregnancy and avoid paying a refund. In theory, the result would be more multiple pregnancies and increased maternal and perinatal morbidity and mortality, which is clearly a situation to be avoided.

The lure of success rates. Similar concern is that physicians may be motivated to use higher doses of fertility drugs to obtain more eggs and increase success rates. While this is a potential danger, there are no data to suggest that it is happening. IVF practices that do not offer refund programs also have incentives to overstimulate or to replace more embryos so as to increase their pregnancy rates and attract patients. The existence of a refund program should not significantly increase this risk, and good doctors should practice good medicine regardless of the payment arrangements. A legitimate concern is that a physician may have a conflict of interest if he or she knows that a patient is participating in a "money-back" program. This ethical dilemma can be addressed within the construct of a refund program, as described below.

Ethical considerations. Another major criticism of money-back programs is that they are unethical because they "guarantee" an outcome, which contravenes Section 6.01 of the American Medical Association Code of Medical Ethics: "…a physician's fee should not be made contingent on the successful outcome of medical treatment."[1] The code is designed to discourage doctors from making their professional fees contingent on the success of a patient's pending medical malpractice or worker's compensation claim, which could skew the medical opinion rendered by the physician. It also prevents physicians from charging fees to imply that "successful outcomes from treatment are guaranteed, thus creating unrealistic expectations of medicine and false promises to consumers."

There is no evidence that clinics offering refund plans are attempting to guarantee an outcome, nor that patients interpret the programs as such. It is the refund—not the outcome—that is guaranteed. Patients know they are paying extra to participate in a refund program precisely because there can be no guarantee of medical success. This fact is underscored by exclusion of some patients from the plans. What is guaranteed is simply a refund of money if treatment does not result in success.

Measuring outcomes. Another potential issue is difficulty in measuring medical outcomes. Some critics believe that patients who are attracted to refund guarantees may, as a result, decide to undergo IVF rather than other treatments (such as tubal reversal, vasovasostomy, controlled ovarian hyperstimulation, or a surgical procedure) that might be more appropriate for them. While this is a legitimate concern, any patient may choose less-than-optimal treatment, regardless of the availability of a refund program. Most refund programs do place a time limit on treatment, but they are usually very generous, do not limit care under ordinary circumstances, and allow a patient to cancel coverage if she feels she cannot complete her care within the time allotted.

Refund limitations. A major disadvantage of refund programs is that some do not return all of the money spent on an IVF cycle. For example, screening with hormone tests, uterine assessment, and sperm evaluation, and the cost of drugs almost never are covered. Facility fees, anesthesia charges, and special laboratory fees for intracytoplasmic sperm injection, assisted hatching, and cryopreservation also may not be covered. Frozen/thaw transfer cycles and fees for a donor egg agency, surrogacy, and legal work are almost never covered. It may be difficult for patients to understand exactly what all the costs are and which are reimbursable in the event that they do not have a baby, but these hurdles can be overcome by appropriate informed consent.

Other concerns. Many critics say that refund programs are misleading, manipulative, and even exploitive.

They believe that the programs unfairly attract patients and encourage them to purchase more care than they would need if they conceived during the first cycle. Because most patients do not conceive during the first cycle, however, a refund guarantee is a legitimate option. In almost all instances, patients receive sufficient information to make an informed decision about participating. Patient satisfaction with such programs appears to be high. The American Society for Reproductive Medicine (ASRM) Ethics Committee found "that the plans it examined provided sufficient information to enable patients to make an informed choice about whether to choose this option." Refund guarantees do not, by themselves, intend to or create unrealistic expectations and false promises.

Concerns also have been raised about the difficulty in comparing various refund plans, but the same can be said of comparing IVF programs that do not offer refund guarantees. Early on, a few clinics that promoted money-back programs did require patients to accept additional costly screening tests and treatments in order to participate. Now, however, that is generally not the case.

Finally, some critics have questioned why certain plans consider an 8-week pregnancy a success, whereas for others, the criterion is a 12-week pregnancy or even a pregnancy taken to the third trimester. Recently, some programs have circumvented this concern by refunding money in all situations except a live birth, which also offers patients financial protection against the risk of miscarriage.

Current status of money-back refund programs

Despite the many criticisms, some of them legitimate, money-back refund programs have persisted because patients demand them. Modifications in newer programs have overcome most of the criticisms about and deficiencies associated with earlier programs.

ASRM perspective. The ASRM Ethics Committee found that it might be ethical to offer shared-risk or refund programs in assisted reproduction to patients who did not have health insurance for IVF, if certain conditions to protect patient interests are met: "These conditions are that the criterion of success is clearly specified, 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 chances of success if they are found eligible for the shared-risk program, and that the program is not guaranteeing pregnancy and delivery. It should also 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 shared-risk program, and that, in any event, the costs of screening and drugs are not included."[2] The Committee also felt that for shared-risk programs to be ethical, patients must be aware of the potential conflict of interest for providers to overstimulate the patient to obtain more eggs or to replace more embryos to increase pregnancy rates, and that patients should be fully informed of risks of multifetal gestation.

The ARC program. The Advanced Reproductive Care (ARC) Refund Guarantee Program was designed to address the concerns and criticisms that have been leveled against the concept of money-back arrangements. The following description of the plan illustrates how it is possible to structure such a program so as to maintain high medical and ethical standards.

First, all ARC physicians agree in writing to follow ASRM practice and ethical guidelines. This includes providing informed consent to patients, using only treatments recognized as effective, providing experimental treatment under Institution Review Board (IRB) protocols, and replacing only the recommended number of embryos. No additional testing or treatment is required, beyond what is dictated by a patient's own clinical situation.

Second, physicians have no financial interest in the ARC Refund Guarantee. Patients purchase the clinical care they need in consultation with their physician and have the option of investing in the refund program or not. Physicians are paid the same amount of money for the clinical care they provide regardless of whether a patient participates in the refund program, becomes pregnant, or has a live birth. ARC and not the physician is responsible for refunding a patient's money, which completely circumvents the conflict-of-interest issues raised by the AMA and others. A patient who purchases the ARC Refund Guarantee pays a premium to ARC and ARC refunds money to her if she does not have a live birth, according to the World Health Organization (WHO) definition, which is recognized, standardized, and legally interpretable. ARC's 100% reinsurance by Lloyd's of London gives both patient and physician complete assurance that money will be refunded if there is no live birth.

With the ARC program, a patient receives objective financial counsel-

ing from both the practice and ARC. She has freedom to choose a package of treatment (case rate) or another payment option offered by a particular practice. However, to receive a refund guarantee, she must purchase three cycles of IVF, which can be done with donor eggs. In most cases, the package can be individualized to coordinate with any insurance coverage a patient may have and modified to include much of the cost associated with drugs, facilities, and even donor egg agency fees.

A patient also has the flexibility to purchase any refund amount she wishes, from $1,500 to the total cost of medical care, associated IVF costs, and pharmaceuticals. The likelihood that a woman will not have a baby is independently determined for her, relative to national results for IVF that are published by the Society for Assisted Reproductive Technology (SART) and the Centers for Disease Control and Prevention. As a result, each patient makes a choice about purchasing the warranty based on her own odds of having a live birth, not the chances of others. Furthermore, because pricing is individualized, the ARC Refund Guarantee can be sold to anyone, although the price will obviously be higher for patients who are older or who have poor prognostic factors.

A woman can cancel her package of treatment for any reason approved by her physician. When that happens, her money is returned, less the cost of administrative fees and other actual charges incurred. ARC cannot unilaterally cancel a refund once a patient has purchased the plan, unless the patient and her physician decide to cancel treatment or participation in the plan. However, if a woman elects to terminate her pregnancy for any reason, she will not receive a refund.

In addition, all cryopreserved embryos created while the program is in effect must be replaced before a refund will be paid. This encourages clinicians to be conservative about the number of embryos replaced and to use frozen embryos in subsequent cycles, thereby reducing the risk of multiple pregnancy. With the three-cycle IVF package, one frozen embryo cycle is provided free with each of three fresh cycles. This packaging encourages patients to limit the number of embryos because those frozen potentially can be used for free in the future. For about the price of two fresh cycles, a woman can have up to three fresh and three frozen embryo replacement cycles. Knowing that she will have several opportunities to become pregnant reduces the pressure on a woman to risk replacing a large number of embryos during any one cycle.

The ARC program's package pricing with a refund guarantee gives a woman: (1) her best chances for a singleton pregnancy by reducing the probability of multiple pregnancy; (2) a realistic assessment of her own odds of having a singleton pregnancy; (3) protection against the financial risks of miscarriage; and (4) a financial buffer if treatment is not successful. It also avoids physician conflict-of-interest and therefore is an ethical economic option that addresses the high costs of insurance coverage for IVF.

Conclusions

There is no question that abuses have occurred in presentation of money-back, shared-risk, and refund-guarantee programs to infertility patients. Any kind of refund program—whether for a medical service or in another type of business—can be distorted by unethical behavior. The fact that such distortions have occurred and continue to occur does not, by itself, invalidate the refund concept. Fee-for-service care can result in unnecessary "churning" of patients, unlimited insurance coverage can breed indifference to success rates, and managed care can lead to depersonalized care and poor physician-patient relationships. With refund guarantees, the financial relationship is at least focused on the outcome a patient values—a baby.

The test of an economic transaction lies in its integrity and value to those involved in the program. Money-back, shared-risk and refund-guarantee plans can be provided to patients in a harmful way, or they can be designed and delivered such that they bring ethical, valuable choices to patients, increase their quality of care and maximize their chances of having a baby, and provide financial security and relief in the event IVF is not successful. Comprehensive, accurate, objective and understandable patient information about refund programs is essential. It is reasonable for IVF physicians and professional organizations to expect that refund programs will meet the highest standards so that patients can benefit from their existence. □

REFERENCES

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