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ETHICS CASE
Are IVF Risk-Sharing Programs Ethical?
Commentary by Leslie P. Francis, PhD, JD

Dr. Rearden, the head of a fertility clinic in Philadelphia, called a meeting with his staff to discuss budgeting for the coming year. During the meeting, Dr. Rearden proposed implementing a "risk-sharing" program. Patients selected for such programs would initially pay a higher fee to the clinic. If a patient had a successful pregnancy, then the clinic would keep her entire fee. If the patient did not become pregnant, a previously specified proportion of the fee would be returned to her.

In his presentation to the staff, Dr. Rearden explained that the program would be beneficial to both the clinic and patients. The program represents a safety net for patients who pay for IVF out of pocket by leaving them money to pursue other options should their treatment fail. Moreover, the higher fee paid by patients who become pregnant ensures that the clinic will have money to reimburse the patients for whom treatment is unsuccessful.

At the conclusion of Dr. Rearden's presentation, Dr. Whipple, a long-time ob-gyn physician in the clinic, asked to speak. "I can appreciate wanting to offer a safety net for patients, especially given that IVF is not covered by insurance," Dr. Whipple began. "But I have some serious reservations about implementing such a program. First, it seems that those who would be selected as candidates for the program are also those most likely to become pregnant, so we would be taking advantage of patients in a moment of substantial emotional stress by essentially overcharging them. Second, and more importantly, if medical payment is based on outcome, our focus will inevitably shift from doing what is best for our patients to trying to get the desired outcome, in this case pregnancy, regardless of what that means for the people we're treating. I just don't think we should go down this road."

Commentary
As use of IVF continues to increase, risk sharing [1] has emerged as a potential financing method, with some commentators estimating that such programs are in fact quite common [2]. A survey of the websites of the 10 fertility clinics top ranked for achieving pregnancy by *Parents* magazine indicated that 3—University Fertility Consultants at Oregon Health & Science University, Portland (AttainIVF), Nevada Center for Reproductive Medicine, Reno (AttainIVF), and Florida Institute for Reproductive Medicine, Jacksonville (Guarantee Program)—advertise risk sharing [3-13].

IVF is an expensive procedure that, in the United States, is typically not covered by insurance and thus is paid for out of pocket by patients. It appears unlikely that coverage for the procedure will increase in the near future, given cost pressures on the US health care system. Because patients seeking IVF are highly motivated to become parents and may wish to preserve resources for surrogacy or adoption should IVF be unsuccessful, risk sharing is appealing to them, which makes these high costs especially problematic.

Risk-sharing programs also appear to be advantageous to clinics because they promise higher fees (albeit with the possibility that a percentage of at least some of these fees will need to be returned), coupled with the ability to provide at least some recompense to understandably disappointed patients. Risk-sharing programs thus appear to be a "win-win" for patients and clinics—but are they? Whether Dr. Whipple's concerns are well founded depends on how the clinic structures its program.

Insurance Coverage for IVF

Many health insurance plans offered through the individual market or provided by employers do not include IVF. In response, a few states (Connecticut, Illinois, Massachusetts, New Jersey, and Rhode Island) have put in place statutes mandating the coverage, although these mandates do not apply to the plans offered by most large employers who self-insure [14].

Under the Affordable Care Act, individuals and small businesses will be able to purchase plans offered through exchanges that opened in late 2013, and the requirement for individual coverage will go into effect in 2014. Plans offered through the exchanges must provide "minimum essential benefits," including those in the following categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and "habilitative" services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care [15]. Notably, infertility care is not included in this list (although management of a chronic disease such as diabetes may improve fertility for some patients). More specific requirements for each state are set by the selection of "benchmark" plans in that state. States may choose their benchmarks; if they don't, they are assigned as a default benchmark the largest plan by enrollment in the largest product in the state's small-group market [16].

Of the currently listed benchmark plans, only a few include IVF. Connecticut covers two cycles of IVF [17]; Nevada covers six [18]; Hawaii covers IVF after five years of unsuccessful efforts at achieving pregnancy or for specified indications such as endometriosis [19]; Illinois covers four cycles with two more for a subsequent pregnancy [20]; Massachusetts, Michigan, and Rhode Island cover IVF without specified exclusions [21-23]; and Texas includes an option to purchase IVF services [24]. Benchmark plans in all other states either offer no coverage for infertility or

cover limited services such as diagnostic interventions but specifically exclude IVF [25]. This limited coverage of IVF means that most patients are likely to continue to pay entirely for the procedure in at least the near future.

Conflict of Interest

The overarching ethical problem raised by risk-sharing programs is conflict of interest [26]. Clinicians and practices have financial interests in these programs that may not always align with the interests of their patients. If patients enter the programs and become pregnant, they pay more for the service than they would pay in a clinic that did not have risk sharing. Patients who do not become pregnant receive partial refunds, but the refunds may not adequately reflect the degree of unlikelihood that those patients could achieve pregnancy. For example, if the patient had a very low chance of achieving pregnancy (say, 10 percent), and received a refund of 65 percent of the initial fee instead of 90 percent, her refund would not reflect the slim chance she had of becoming pregnant. Patients who are unlikely to become pregnant through IVF may be encouraged to pursue it by the possibility of a refund, even when it is not a good option for them. Moreover, having to refund money to patients who do not conceive may be an incentive for clinicians to engage in risky practices such as multiple-embryo transfers even when in appropriate. In light of these conflicts, the American Society for Reproductive Medicine (ASRM) emphasizes the importance of informed consent and adherence to practice guidelines in structuring refund programs [26].

Informed Consent

Despite the importance placed on informed consent documents, however, achievement of genuinely autonomous consent can be difficult. Though patients seeking reproductive assistance are highly likely to have decision making capacity and clear wishes, they may also be emotionally vulnerable and under stress [27]. They may be so desperate to become pregnant that they do not evaluate risks rationally. Cognitive biases such as anchoring (overreliance on a particular piece of information), attentional bias influenced by emotion, confirmation bias (focus on the information that confirms rather than refutes existing beliefs), framing effects (the impact of whether the decision is structured in terms of the likelihood of success or failure), or sunk cost bias (the desire to continue down a path when costs already incurred cannot be recovered) may complicate patients' decision making.

In light of these challenges to reasoned decision making about risk sharing, several aspects of the informed consent process are especially worth noting. Patients should be given sufficient time to consider risk programs and alternatives to them. They should be given clear explanations of their chances of achieving pregnancy, of what they would pay if they did not enroll in the program, and of payments retained by the program if pregnancy is not achieved. Patients should be given clear explanations of whether "success" is defined by achieving pregnancy or by live birth and should also understand what costs are covered by the risk-sharing payment and whether any additional costs may be billed to them.

Patients may overestimate their chances of success; clinics should guard carefully against encouraging cognitive biases that influence this tendency. For example, giving patients examples of others who have been highly satisfied by risk-sharing programs—either because they achieved pregnancy or because they were able to adopt a child using funds received as a refund—could inappropriately invoke cognitive biases favoring the decision to use risk sharing. Clinicians must convey only accurate information to patients in a manner intended to counteract likely cognitive biases.

Because of the difficulties with fully informed and carefully reasoned consent to risk sharing, and because of the significant financial and health risks involved, risk-sharing programs must also be structured in ways that protect patients who enter into them.

Adherence to Practice Guidelines

Programs that offer risk sharing must take care to adhere to practice guidelines in the care they provide in order to protect their patients. The ASRM Ethics Committee opinion cites several ways in which conflicts of interest that result from risk-sharing may encourage inappropriate care [26]. Clinicians should guard against recommending ancillary procedures such as sonohysterograms unless they are clearly indicated, especially if the costs of these procedures are extra and significant. In order to bring about pregnancy and avoid refunds, physicians may try procedures with higher risks than guidelines recommend, such as stimulation protocols that produce more oocytes or embryo transfers in numbers that could result in multiple gestations. The ASRM Practice Committee presently recommends offering single-embryo transfer to women under 35 who are likely to become pregnant and transferring at maximum two embryos [28]. The committee also advises practices to monitor their outcomes continuously to adjust transfer numbers to avoid undesirable pregnancy outcomes [28]. To keep the patient's best interest at the forefront, it is especially important to assess patients according to appropriate diagnostic criteria [29].

Pricing

A common objection to risk-sharing programs is that they constitute illicit contingent fees—that is, pay based on results. The ASRM opinion determining that risk sharing is permissible suggests that these programs pool patients' risks and allow the practice to earn a modest return for assuming the risk [26]. The refund program should be structured so that it does not undermine this analysis. Of particular importance are the fee increase for the program, the percentage of the fee refunded, the exclusion of ancillary costs from the risk-sharing fee so that patients must incur these costs in addition, and the number of IVF cycles included in the program. If fees or ancillary costs are excessive, if refunds are low, or if only limited services are included in the program, patients may reasonably complain that the program's intent appears primarily to benefit the practice rather than to share risks fairly.

Conclusion

Dr. Whipple is right to raise concerns about risk-sharing programs. However, these concerns can be alleviated by careful attention to informed consent, adherence to practice guidelines, and fair pricing structures. Clinics considering these programs must be especially vigilant in assessing whether their actions avoid conflicts of interest. Under such circumstances, risk-sharing programs may indeed be beneficial to both providers and patients—but only under such circumstances.

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Leslie P. Francis, PhD, JD, is Distinguished Alfred C. Emery Professor of Law and Distinguished Professor of Philosophy at the University of Utah in Salt Lake City. She is a member of the ethics committee of the American Society of Reproductive Medicine and is editing the *Handbook on Reproductive Ethics* for Oxford University Press.

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