Even though Scott and Silverberg (3) illustrate all the complexity of refund programs with great insight, I cannot accept their conclusion that these programs represent an idea “whose time has not come.” From the vantage point of being right across the bay from San Francisco, the consumer appeal of refund programs is obvious. This appeal goes beyond that of a mere marketing ploy. Refund programs are popular because they address a deep-seated anxiety shared by many infertile patients who feel abandoned by the health insurance industry. The challenge now is to define the conditions necessary for an ethically acceptable refund program. Clearly, live births need to replace ongoing pregnancies as the end point. Special attention must be given to ensuring that patients who sign up for a typical three-cycle plan can readily terminate their participation in midstream. Now that the Ethics Committee has issued its report, perhaps the American Society for Reproductive Medicine Practice Committee, in cooperation with Resolve, can work out the guidelines for real-world ethical refund programs.

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References

PII S0015-0282(99)00170-3

Reply of the Authors:

We very much appreciate the comments that Dr. Chetkowski has added to the important discussions about the use of “refund” or “guaranteed outcome” programs by assisted reproduction clinics. In particular, we concur with his comments about the importance of evaluating these types of programs in the context of the real world. Economic realities may lead clinicians to practice patterns that are in conflict with their patients’ best interests.

We also share a similar general philosophy that efforts to help patients navigate the personal economic issues that influence treatment availability are worthwhile. Our original opinion complimented programs that provide these types of guarantees for at least attempting to find innovative ways to provide deserving patients with much-needed access to effective health care (1, 2).

We remain concerned about several issues surrounding money-back guarantees of clinical outcomes, but are not opposed to having them receive thoughtful consideration in an open forum. It would be most important to identify a mechanism that provides honest, direct, and complete information to patients about all the risks they are assuming. Issues to be addressed directly include what rights and freedoms they may be surrendering and the overall cost per live birth for equivalent patients who do or do not participate in these programs. Efforts to ensure availability of these programs to the broadest possible population of patients also would be important—patients of all ages and prognoses struggle with the financial burden of treatment.

These programs may improve access to care initially, but several new and significant stressors may be added. Patients initially presenting to take advantage of the program may not qualify and then are told that they still should consider proceeding with treatment. (This might be construed as a bait-and-switch strategy.) Patients may be required to consider gamete donation or to undergo expensive adjunctive treatments. One need look no further than the issues surrounding assisted reproduction’s principal complication (i.e., multiple pregnancy) to see the ethical dichotomy that would be faced when determining the number of embryos to be transferred. Would these programs allow a healthy young patient with morphologically normal embryos to undergo a one- or two-embryo transfer solely at her discretion?

Perhaps it is time to revisit these issues and fully explore the implications that various iterations of refund-based programs might have on patients and assisted reproduction programs in an open and broad-based forum. We still believe that the current structures of the programs with which we are familiar represent ideas “whose times have not come.” Who knows what the future may bring.

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References

PII S0015-0282(99)00171-5

Sperm Viability Assays—A Matter of Life and Death!

To the Editor:

We read with great interest the articles by Lin et al. (1) and Vendrell et al. (2) that investigated the suitability of the hypoosmotic swelling test (HOST) and the heparin-glutathione test (HEGLUT) for selecting viable sperm for intracytoplasmic sperm injection (ICSI). Our main interest sprang
from the investigation we carried out on the same subject, which was cited by Lin et al. (1).

In the discussion section of their article, Lin et al. stated that “the hypoosmotic swelling test has been used clinically as a tool in identifying immotile sperm with an intact membrane in fresh and cryopreserved sperm for ICSI,” and then they cited our article. Finally, the investigators concluded that the value of the HOST for detecting intact cryopreserved sperm for micromanipulation procedures might be revisited. Our study examined the suitability of the HOST for assessing the viability of fresh and cryopreserved sperm under experimental, not clinical, conditions. We performed simultaneous assessments of tail swelling and sperm viability after exposure to the hypoosmotic solution and to the DNA vital stain Hoechst-33258, respectively. Our measurements demonstrated that the results of the HOST and Hoechst-33258 were highly correlated in fresh specimens (r = 0.95), but not in cryopreserved ones (r = 0.22). Therefore, we concluded in our study that the HOST cannot be used to select viable cells in cryopreserved samples for assisted reproductive procedures.

Vendrell et al. (2) presented interesting data focusing on a new test to assess the viability of immotile sperm for ICSI as an alternative to the HOST. Although the investigators demonstrated that the HEGLUT could select viable sperm for ICSI, their work was undertaken on fresh specimens only. Because total asthenozoospermia in fresh specimens is a rare condition, it is necessary to validate our results on cryopreserved specimens to improve the clinical application of the HEGLUT. At this time, it appears that the HEGLUT is more labor-intensive and expensive than the simple and inexpensive HOST for assessing viability in fresh specimens.

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References

PII S0015-0282(99)00173-9

Reply of the Authors:

We thank Dr. Agarwal and his colleagues for their interest in our article in the December 1998 issue of Fertility and Sterility and for their comments. We recognized that the investigations of Esteves et al. (1) were of an experimental and not a clinical nature. However, we also recognized that the hypoosmotic swelling test (HOST) has been used clinically in many centers to select both fresh and cryopreserved immotile sperm for intracytoplasmic sperm injection (ICSI). Our findings related to the value (or lack thereof) of the HOST for assessing the viability of immotile cryopreserved sperm are similar to the findings reported by Esteves et al. (1). This points to the fact that the cryopreserved sperm cell behaves differently than the fresh sperm. As we indicated, the tail membrane in a cryopreserved, thawed sperm may not exhibit characteristics similar to those of the head membrane. In addition, the cryopreserved sperm may exhibit a higher degree of so-called “membrane leakiness” immediately after thawing. Whether this phenomenon contributes to one of the differences observed between fresh and cryopreserved sperm remains to be investigated more fully. Likewise, in the absence of an alternative, we need to explore which is more suitable for ICSI, a cryopreserved immotile sperm with an intact head membrane or one with an intact tail membrane. To evaluate the utility and comparability of viability tests, we may need to modify the procedures used. Modification(s) of the HOST or combined assays to assess the viability of cryopreserved immotile sperm reflecting the timing of sperm exposure to the hypoosmotic swelling medium or the media used in combined assays should be investigated. We also agree with the correspondents that the heparin-glutathione test (2) is more labor-intensive than the HOST and its utility for the cryopreserved immotile sperm needs to be examined.

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PII S0015-0282(99)00172-7

The First Hope for the “Big Picture” of Infection—DNA Microarrays

To the Editor:

Chlamydia trachomatis infection of the endometrium should be considered as a possible cause of decreased implantation in recipients of donated oocytes who have a his-