

ASRM Practice Committee response to Rybak and Lieman: elective self-donation of oocytes

The Practice Committee of the American Society for Reproductive Medicine

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Oocyte cryopreservation has great promise for applications in oocyte donation and fertility preservation and for decreasing the number of unused cryopreserved embryos. The Practice Committee has and will continue to review the published medical literature relating to oocyte cryopreservation at regular intervals and is prepared to reconsider its position when evidence warrants. (Fertil Steril® 2009;92:1513–4. ©2009 by American Society for Reproductive Medicine.)

The Practice Committee of the American Society for Reproductive Medicine (ASRM) thanks Drs. Rybak and Lieman for their thoughtful essay and the editors for providing the opportunity to respond. The authors identified four specific arguments as the basis for their opinion that the ASRM should reconsider its assessment of elective oocyte cryopreservation.

First, Rybak and Lieman assert that novel technologies should not be declared “experimental” in an effort to restrict their availability or mandate oversight by an Institutional Review Board (IRB), or simply because they are less effective than other techniques or do not exceed some “arbitrarily chosen success-rate threshold.” The ASRM did not classify elective oocyte cryopreservation as experimental for those reasons. Rather, the ASRM opinion reflects the view that available outcomes data are insufficient to consider elective oocyte cryopreservation established medical practice. The great majority of published outcomes data, including those cited by the authors (1–3), derives from experience with cryopreserved oocytes obtained from healthy young oocyte donors under the age of 30 years. For several obvious reasons, those data cannot reasonably be extrapolated to women who are older. A key requirement in any valid informed consent process is a reasonably accurate estimate of the likelihood that a proposed treatment or procedure will achieve its intended purpose. In the absence of any meaningful age-stratified outcomes data, there is no logical foundation for estimates of success for the majority of women expressing interest in elective oocyte cryopreservation already in their late reproductive years. The ASRM opinion that oocyte cryopreservation merits IRB review reflects the firm belief that independent oversight helps to ensure that the informed consent process relating to innovative technologies is truly valid.

Second, the authors argue that standards for judging the safety and efficacy of novel technologies must be consistently applied, and they challenge the justification for subjecting oocyte cryopreservation to “closer scrutiny and stricter criteria” than earlier innovations in reproductive medicine,

such as intracytoplasmic sperm injection (ICSI). The task of determining the standard that must be met before a novel technology can be considered established medical practice is difficult but important, and the Practice Committee is charged with that responsibility. The Practice Committee endeavors to apply a consistent standard, insofar as that is possible, or reasonable. However, the applicable standard inevitably evolves and clearly has changed greatly since the introduction of ICSI more than 15 years ago. To apply to elective oocyte cryopreservation now the standard that existed then for ICSI would be both imprudent and medically inappropriate. Precedence should guide action only when there is no compelling reason for change. Rybak and Lieman acknowledge that “clinical prudence and ethical practice dictate withholding sanction of novel technology pending evidence of efficacy and safety.” In the view of the ASRM, the requisite evidentiary standard now existing has not been met. There is considerable risk, and potential significant harm, associated with applying novel technologies prematurely, before both their safety and their efficacy have been reasonably established. Witness the recent revelations regarding the efficacy of using fluorescence in situ hybridization (FISH) for preimplantation genetic screening among women of advanced reproductive age. The premise was logically sound. The technology was widely applied and regarded by many to be established medical practice, despite the absence of any substantive evidence for its efficacy, and ultimately was proven ineffective (4–7). The standard to be met for a novel technology to be considered established medical practice must be higher than in the past. Experience has taught us that “closer scrutiny and stricter criteria” are necessary. Whereas the authors acknowledge that “a cautious approach to elective self-donation of eggs is warranted” because “the potential for manipulative, dishonest, and unseemly marketing is great,” they consider the ASRM position regarding elective oocyte cryopreservation “excessively deliberate.” The ASRM believes that a cautious and deliberate approach to innovative technologies is essential, that the continued freedom to practice reproductive medicine without unreasonable regulation likely depends on our circumspection, and that its position on elective oocyte cryopreservation is therefore justified and responsible.

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Third, Rybak and Lieman suggest that instead of relying on IRB oversight, the interests of safety would be served better if the ASRM sponsored a registry with mandatory reporting. Although a registry is important and would be helpful, the evidence that derives from registries frequently is not sufficiently robust or timely to guide practice relating to emerging technologies. Moreover, the responsibility of the practice committee of a medical society is to critically evaluate the published medical evidence, not to produce or collect that evidence. Rybak and Lieman also suggest that the ASRM should “guide” the informed consent process relating to elective oocyte cryopreservation. Indeed, recognizing that many women understandably have interest in the technology and view oocyte cryopreservation as an elective fertility preservation strategy that may help them to realize their longer-term reproductive goals, the ASRM already has published a document focused specifically on the essential elements of informed consent for elective oocyte cryopreservation (8).

Finally, Rybak and Lieman urge the ASRM to focus on formulating and strengthening practice guidelines and to refrain from efforts at “socioethical gate keeping.” The ASRM is obligated, and dedicated, to formulating and strengthening practice guidelines and has devoted substantial time, effort, and resources to that task. The ASRM also has no motivation or interest in serving as a gate keeper in any context, and has no authority to do so. Rybak and Lieman contend that the ASRM’s “experimental” classification of elective oocyte cryopreservation prohibits the procedure and thus denies women “procreative liberty” and the opportunity to protect or preserve their reproductive function. If that were indeed so, elective oocyte cryopreservation most certainly would not be as prevalent as it already is. The ASRM supports oocyte cryopreservation as a fertility preservation strategy for women with cancer and other illnesses requiring treatments that pose a serious threat to their future fertility, because they may have no other viable option (8, 9). The position statements and opinions of the ASRM do not and cannot prevent those who believe earnestly that elective oocyte cryopreservation “has arrived” from offering the procedure to healthy women. The Practice Committee is charged with the responsibility of providing objective recommendations reflecting the highest standards of practice, based on a critical evaluation of the published medical evidence. To

that end, if the published opinions of the ASRM have discouraged a wider premature application of the technology, then they have accomplished an intended purpose.

Clearly, oocyte cryopreservation has great promise for applications in oocyte donation and fertility preservation and for decreasing the number of unused cryopreserved embryos. The Practice Committee has and will continue to review the published medical literature relating to oocyte cryopreservation at regular intervals and is prepared to reconsider its position when evidence warrants.

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