

Essential elements of informed consent for elective oocyte cryopreservation: a Practice Committee opinion

The Practice Committee of the Society for Assisted Reproductive Technology and the Practice Committee of the American Society for Reproductive Medicine

American Society for Reproductive Medicine, Birmingham, Alabama

Oocyte cryopreservation is an experimental procedure that should not be offered or marketed as a means to defer reproductive aging, primarily because data relating to clinical outcomes are limited (1). Nonetheless, many women understandably have interest in this emerging technology and view oocyte cryopreservation as an elective fertility preservation strategy that may help them to realize their longer-term reproductive goals. Oocyte cryopreservation is not an established medical treatment. Women who may be considering the procedure must be informed fully about the process involved and the clinical outcomes that reasonably can be expected so that they can make a truly informed decision and give valid consent. Counseling by a qualified mental health professional also should be provided.

To ensure that all women seeking oocyte cryopreservation as a fertility preservation strategy understand the potential benefits, limitations, and risks of the developing technology, thorough pre-treatment counseling must be provided, and documented in the medical record. Pre-treatment counseling of appropriate candidates for oocyte cryopreservation specifically should include all of the following information:

- 1) Ovarian stimulation and oocyte retrieval.
 - a) The side effects and potential risks associated with all of the medications that may be received.
 - b) The requirements for monitoring with serial blood sampling and transvaginal ultrasonography.
 - c) The potential risks associated with oocyte retrieval procedures.
 - d) A reasonable estimate of the number of oocytes that may be retrieved.
 - e) The costs relating to medications, monitoring, and oocyte retrieval.
- 2) The methods that will be used for oocyte cryopreservation.
- 3) Annual storage fees for cryopreserved oocytes.
- 4) The expected thaw-survival rate for oocytes and the possibility that none may survive.

- 5) The requirement for intracytoplasmic sperm injection, the associated costs, and the average or expected fertilization rate per surviving thawed oocyte.
- 6) Clinic-specific data and outcomes, including:
 - a) The total number of women who have cryopreserved oocytes in the facility.
 - b) The number of women who have thawed some or all of the oocytes previously cryopreserved and stored in the facility.
 - c) The survival, fertilization, and embryo development rates for all thawed oocytes in the facility.
 - d) The live-birth rate per oocyte thawed and per embryo transferred in the facility.
- 7) In the absence of clinic-specific outcomes data, the following estimates based on published peer-reviewed medical literature should be used (2):
 - a) An approximate overall 2% live-birth rate per oocyte thawed for cryopreservation using slow-freeze methods.
 - b) An approximate overall 4% live-birth rate per oocyte thawed for cryopreservation using vitrification.
 - c) The likelihood that success rates may be significantly lower than current overall estimates for women who cryopreserve oocytes after age 35, given that most published reports have described outcomes for younger women.
 - d) The comparable age-related probabilities for success per cycle with in vitro fertilization using fresh non-donor oocytes.
- 8) The relatively high likelihood that women who cryopreserve oocytes before age 35 never will need or use them, because the large majority of women marry by age 35 and have a relatively low incidence of childlessness (Table 1) (3).
- 9) The disposition of any cryopreserved oocytes not used by a pre-determined age or in the event of death.
- 10) Applicable state and federal laws relating to screening and testing requirements for potential donation(s) of cryopreserved oocytes.
- 11) The potential risks of basing important life decisions and expectations on a limited number of cryopreserved oocytes.
- 12) The possibility that the facility may cease operations, resulting in the need for cryopreserved oocytes to be transferred to a different storage facility.

Received and accepted October 4, 2007.

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TABLE 1	
Estimated proportions of women who are sterile (3).	
Age at marriage (years)	Risk of childlessness (%)
20-24	5.7
25-29	9.3
30-34	15.5
35-39	29.6
40-44	63.6

ASRM Practice Committee. Informed consent and oocyte cryopreservation. Fertil Steril 2007.

13) The possibility that cryopreserved oocytes may be lost as a result of a laboratory accident or events beyond the control of the storage facility.

Women with cancer or other illnesses requiring immediate treatments that seriously threaten their future fertility who are considering oocyte cryopreservation should receive the same thorough counseling. However, unlike healthy women, they may have no viable options and therefore may be appropriate candidates for such treatment despite its experimental status.

Acknowledgments: This report was developed under the direction of the Practice Committee of the Society for Assisted Reproductive Technology and the Practice Committee of the American Society for Reproductive Medicine as a service to their members and other practicing clinicians. While this document reflects appropriate management of a problem encountered in the practice of reproductive medicine, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Other plans of management may be appropriate, taking into account the needs of the individual patient, available resources, and institutional or clinical practice limitations. This report has been approved by the Executive Council of the Society for Assisted Reproductive Technology and by the Board of Directors of the American Society for Reproductive Medicine.

The members of the SART and ASRM Practice Committees have the following potential conflicts of interest to disclose:

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Robert Rebar, M.D.: Nothing to disclose.

Nancy Frankel, M.B.A.: Nothing to disclose.

Andrew La Barbera, Ph.D.: Nothing to disclose.

REFERENCES

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