

Guidelines for oocyte donation

The American Society for Reproductive Medicine

Birmingham, Alabama

I. Introduction

Sperm from donors has been used in the treatment of male infertility for more than 100 years. The use of eggs from donors has been made possible more recently as a result of in vitro fertilization (IVF) techniques. Procedures for oocyte donation require superovulation with monitoring and oocyte recovery, which present significant inconvenience as well as discomfort and risks to the donor.

II. Indications for Considering the Use of Donor Oocytes

- A. Women with hypergonadotropic hypogonadism.
- B. Women of advanced reproductive age.
- C. Women who have diminished ovarian reserve.
- D. Women who are known to be affected by or be the carrier of a significant genetic defect or who have a family history of a condition and whose carrier status cannot be determined.
- E. Women with poor oocyte, and/or embryo quality or multiple failures during prior attempts to conceive via one of the assisted reproductive technologies.

III. Evaluation of the Oocyte Recipient

- A. Medical and Reproductive History Routine medical and reproductive history should be obtained according to the standards that are applied to women anticipating pregnancy. Reproductive abnormalities detected from history or physical examination may require more detailed evaluation and treatment before donor oocytes are used. (See Appendix A with respect to genetic screening and testing.)
- B. Physical Examination
A complete general physical examination should be performed, including a pelvic examination.
- C. Standard Preconception Testing and Counseling
The recommended tests include blood type and Rh factor, and rubella and varicella titers. Recipients should be offered immunization if nonimmune.

D. Laboratory Tests

The following laboratory tests should be recommended as part of the evaluation of the female recipients: a serologic test for syphilis along with serum testing for hepatitis B surface antigen, hepatitis C antibody (HCV), cytomegalovirus (CMV) antibody, human immunodeficiency virus 1 (HIV-1).

E. Psychological Evaluation

The decision to proceed with donated oocytes is complex, and patients may benefit from psychological counseling to aid in this decision. The physician should offer psychological counseling to all couples and should require psychological consultation for couples in whom there appear to be factors that warrant further evaluation.

F. Assessment of Uterine Cavity

When clinical evaluation suggests a possible uterine abnormality, hysterosalpingography (HSG) or other suitable procedure should be performed.

IV. Evaluation of the Partner of the Oocyte Recipient

A. Laboratory Tests

1. Semen analysis
2. Blood type and Rh
3. Serologic test for syphilis, hepatitis B surface antigen, hepatitis C antibody (HCV), cytomegalovirus (CMV) antibody, HIV-1
4. Appropriate genetic screening and testing

B. Psychological Evaluation

The decision to proceed with donated oocytes is complex, and patients may benefit from psychological counseling to aid in this decision. The physician should offer psychological counseling to all couples and should require psychological consultation for couples in whom there appear to be factors that warrant further evaluation.

V. Solicitation of Potential Oocyte Donors

Solicitation of donors should be in accordance with the ASRM Ethics Committee Report [*Fertil Steril* 2000;74:216–20].

Guidelines

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VI. Selection of Donors

- A. Anonymous versus known donors: Pragmatic considerations such as the difficulty in recruiting suitable donors support the use of known oocyte donors. Psychological evaluation and counseling should be recommended to the donor and her partner. Psychological consultation should be required for individuals in whom there appear to be factors that warrant further evaluation. In the case of known donors, related issues such as the potential impact of the relationship between donor and recipient should be explored.
- B. Oocyte donors should have attained their state's age of legal majority and preferably be between the ages of 21 and 34.
- C. If a prospective donor is over 34 years of age, the age of the donor should be revealed to the recipient as part of the informed consent discussion concerning cytogenetic risks and the effect of donor age on pregnancy rates.
- D. Proven fertility in the donor is desirable but not required.
- E. The donor should undergo appropriate genetic evaluation as outlined in Appendix A.
- F. Sharing of oocytes from an assisted reproduction cycle: If sharing of oocytes is contemplated, informed consent must be obtained prior to the cycle of retrieval. The conditions governing the sharing of oocytes should be specified in advance, should be included in the informed consent, and should conform with the ASRM Ethics Committee Guidelines [*Fertil Steril* 1998;70(Suppl 3)].

VII. Screening and Testing of Oocyte Donors

- A. A personal and sexual history should be obtained to exclude as donors individuals who might be at high risk for HIV and other sexually transmitted infections (STIs) as well as transmissible spongiform encephalopathies (TSEs). These risk factors include:
 1. Women who have injected drugs for a nonmedical reason.
 2. Women who have had sex in exchange for money or drugs.
 3. Women who have had sex in the preceding 12 months with any person described in the items above or with any person suspected of having HIV or hepatitis infection.
 4. Women who have been exposed through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane within the last 12 months to blood that is known or suspected to be infected with HIV, hepatitis B, and/or hepatitis C virus.
 5. Prisoners.
 6. Women who have had close contact with another person having viral hepatitis within 12 months preceding the donation.
 7. Women who have had or have been treated for syphilis or gonorrhea within the preceding 12 months.
 8. Women who within 1 year of donation have undergone acupuncture, body piercing, and/or tattooing procedures in which sterile procedures were not used, or when it is unclear whether sterile procedures were used.

9. Family history of transmissible spongiform encephalopathy (TSE) such as Creutzfeldt-Jakob disease (CJD); or a history of changes in cognition, speech, or gait; or exposure to tissues suspected of harboring TSEs.

10. Recipients of human organ or tissue transplants or human extracts.

- B. Appropriate testing should be performed for STIs, including:
 1. Serologic testing for syphilis.
 2. Serum hepatitis B surface antigen and hepatitis C antibody.
 3. Cervical cultures for *Neisseria gonorrhoeae* and *Chlamydia trachomatis*.
 4. Serum testing for HIV-1 and HIV-2.
 5. Additional testing as dictated by local state requirements.
- C. If the use of donor oocytes creates the potential for Rh incompatibility, couples should be informed about the obstetrical significance of this condition.

VIII. Quarantining of Embryos

At this time, oocyte freezing cannot be performed reliably; therefore, the quarantining of oocytes is not practical. All potential recipient couples should be offered the option of cryopreserving and quarantining embryos derived from donor oocytes for 6 months, with release after the donor has been retested. However, couples should be informed that embryo cryopreservation may significantly reduce implantation rates. The recipient couple should be appropriately counseled in the event of seroconversion of the oocyte donor after cryopreservation of the embryos.

IX. Payment to the Donor

- A. Compensation to the donor should be in compliance with the ASRM Ethics Committee Report [*Fertil Steril* 2000; 74:216–20].
- B. Monetary compensation of the donor should reflect the time, inconvenience, and physical and emotional demands and risks associated with oocyte donation and should be at a level that minimizes the possibility of undue inducement of donors and the suggestion that payment is for the oocytes themselves.
- C. Financial obligations and responsibilities in the event of complications or medical expenses of a donor should be contractually agreed upon prior to initiation of a stimulation cycle.
- D. Payment may be prorated based on the number of steps completed in the procedure.
- E. Payment should not be predicated on clinical outcome.

X. Multiple Oocyte Donations

This is addressed in the ASRM Practice Committee Opinion *Repetitive Oocyte Donation*, January 2001.

XI. Unintended Donor Pregnancies

The donor should be counseled about the possibility of unintended pregnancy and offered options for prevention.

XII. Age of the Recipient

In view of the concerns about pregnancy in women of advanced reproductive age, it is recommended that potential recipients over the age of 45 undergo thorough medical evaluation (including cardiovascular testing) and a high-risk

obstetrical consultation before undertaking IVF with donor oocytes.

XIII. Record Keeping

It is necessary to maintain permanent records about each donor's initial selection process and subsequent follow-up evaluation. To the extent possible, clinical outcome should be recorded for each treatment cycle. A mechanism must exist to maintain these records as a future medical resource for any offspring produced.

XIV. Legal Issues/Consent

A. All individuals involved in ovum donation should be explicitly advised of the risks and adverse effects of ovarian stimulation and retrieval, and this process should be documented by informed consent.

- B. Donors and recipients and their partners should execute documents that define or limit their rights and duties with regard to any offspring.
- C. Couples and donors who have legal concerns not addressed in the informed consent process should be advised to seek legal consultation.
- D. Protection of confidentiality: Individuals participating in donor programs should be assured of protection of confidentiality insofar as local statutes permit. Medical records detailing the donation should be maintained as stipulated by local requirements.
- E. It is recommended that the donor acknowledge in the consent form her responsibility to report any changes in any of her risk factors.

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