

Guidelines for sperm donation

The American Society for Reproductive Medicine

Birmingham, Alabama

I. Introduction

Therapeutic donor insemination (TDI) may be employed to achieve conception where appropriate indications exist. The clinical procedures should take into account the age and health status of the recipient.

II. Indications for Considering TDI

- A. The male partner has azoospermia, severe oligospermia, or other significant sperm or seminal fluid abnormalities.
- B. The male partner has ejaculatory dysfunction.
- C. In assisted reproductive technologies (in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer), the male partner demonstrates significant male factor infertility (i.e., previous failure to fertilize, significant oligoasthenospermia, male immunologic infertility) and in vitro fertilization (IVF) with intracytoplasmic sperm injection (ICSI) is not elected or feasible.
- D. The male partner has a significant genetic defect and the recipient also is known either to be affected or to be a carrier of it, or the recipient has previously produced an offspring affected by a condition and carrier status cannot be determined.
- E. The male partner has an ineradicable sexually transmissible infection.
- F. The female partner is Rh-negative and severely Rh-immunized, and the male partner is Rh-positive.
- G. Females without male partners.

III. The Recipient

- A. The decision to proceed with donor insemination 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 factors appear to warrant further evaluation.
- B. Consent forms should be signed by the couple or by the recipient if she is single.

IV. Evaluation of the Male Partner

- A. The male partner in any couple that requests TDI should have completed an appropriate clinical evaluation. Medical records should be reviewed before performing the insemination procedure. If appropriate, alternative treatments should be discussed with the couple.

- B. Human immunodeficiency virus (HIV) testing of the male partner is strongly recommended to address potential medical/legal complications that could arise if his partner seroconverts during or after TDI. In addition, if the male partner is HIV infected, he should be referred to an appropriate infectious disease unit for counseling on safe sex practices for preventing HIV transmission, on treatment options, and on other issues concerning HIV disease. A positive HIV-1 test result for the male partner should not be used as an exclusionary criterion for treatment of a couple with TDI, provided that the semen is provided by an HIV-1 negative donor.

- C. Testing for other sexually transmissible infections (STIs) should be recommended.

V. Evaluation of the Female 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 insemination. (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 Screening, Testing, and Counseling
 1. Recommended tests include blood type, Rh factor, and rubella and varicella titers. Vaccination should be offered if the individual is not immune to

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either virus. Rh-negative women should undergo antibody screening.

2. HIV-1 testing should be mandatory to address potential medical/legal complications that could arise if the recipient seroconverts during or after treatment. In addition, if the female recipient is found to be HIV-1 infected before treatment, she should be referred to an appropriate infectious disease unit for counseling on issues concerning HIV-1 disease, including reproductive issues such as safe sex practices for preventing HIV-1 transmission to uninfected partners, and treatment options to reduce the probability of transmission to her child. A positive HIV-1 test of the female recipient should not be used as an exclusionary criterion for treatment with TDI as long as the couple makes an informed decision following counseling and is compliant with recommended clinical management for the positive HIV state. Other tests to be obtained include serologic test for syphilis, and serum testing for hepatitis B surface antigen, hepatitis C antibody (HCV), cytomegalovirus (CMV) antibody, HIV-2, human T-cell lymphotropic virus type I (HTLV-I) and HTLV-II. Individuals should be screened for possible exposure to transmissible spongiform encephalopathies (TSEs).
3. Cervical cultures may be obtained for gonorrhea and chlamydia at the discretion of the physician.
4. Guidelines for testing for the cystic fibrosis carrier should be discussed and implemented.

E. Documentation and Timing of Ovulation

Women with regular cyclic menses and minimal symptoms are considered to be ovulating. When doubt exists, an index of ovulation, such as serum progesterone level, may be used. Techniques to time ovulation may include basal body temperature, luteinizing hormone (LH) surge measurements, and ultrasound monitoring of follicular maturation.

- F. Evaluation of Possible Tubal or Peritoneal Abnormalities
Patients who fail to conceive after four to six well-timed inseminations may be candidates for hystero-salpingography (HSG), laparoscopy, and other appropriate tests to detect other possible causes of persistent infertility. Consideration may be given to performing an HSG before inseminations, and pretreatment laparoscopy may be indicated by the history and/or physical findings.

VI. Donors

A. Selection of Donor

1. The main qualities to look for in selecting the donor for TDI are assurance of good health status and absence of genetic abnormalities. Suggestions to follow are provided in Appendix A.
2. The donor should be of legal age but younger than 40 years of age so that potential hazards related to aging are diminished.
3. Selecting donors who have established fertility is desirable but not an absolute requirement.
4. Anonymous donors have traditionally been used, but directed (nonanonymous or known) donation is acceptable if all parties agree. Directed donors should undergo the same evaluations as anonymous donors.

TABLE 1

Minimal semen parameters recommended for donors.

Volume	>2 mL
Sperm motility	>50% moving actively in a purposeful direction
Sperm concentration	>50 × 10 ⁶ motile sperm/mL
Sperm morphology	Normal range
Cryosurvival	>50% of initial motility

Both anonymous and directed-donor specimens should be quarantined for 180 days with appropriate retesting and follow-up evaluation prior to use (see section VI.B.6).

5. Psychological assessment by a qualified mental health professional is recommended for all sperm donors. Psychological consultation should be required for individuals in whom there appear to be factors that warrant further evaluation. In the case of directed donation, psychological evaluation and counseling should be strongly recommended to the donor and his partner, as well as the recipient couple. Issues such as the potential impact of the relationship between the donor and recipient should be explored. The psychological assessment should also address the potential psychological risks and evaluate for evidence of coercion (financial or emotional). It is also important to ascertain whether the donor is knowledgeable about the degree of disclosure and whether any plans exist for future contact.
 6. No owner, operator, laboratory director, or employee of a facility performing TDI may serve as a donor in that practice.
 7. Neither the patient's physician nor the individual performing the actual insemination can be the provider of the sperm sample.
- #### B. Screening and Testing of Donors
1. Semen testing
 - a. It is suggested that several samples be examined (abstinence 2 to 3 days) before proceeding with more extensive evaluation.
 - b. The sample should be examined within 1 to 2 hours after ejaculation into a sterile container. The criteria used to judge the normality of the sample may vary among laboratories. There are no agreed upon standards, but in general the minimal criteria for semen quality can be used (see Table 1).
 2. Genetic Evaluation
Genetic screening of potential donors is important. Some institutions require complete chromosomal analysis before accepting a donor. This analysis is not required if adequate attention is paid to obtaining a proper family history with respect to potential hereditary disorders. (See Appendix A for further details.)
 3. Medical History
 - a. The donors should be healthy and give no history to suggest hereditary disease.

- b. A complete personal and sexual history should be obtained to exclude as donors individuals who might be at high risk for HIV and other STIs. Prospective sperm donors with any of the following factors should not be accepted:
 - Men with a history of sex with men.
 - Men who have injected drugs for a nonmedical reason.
 - Persons who have had sex in exchange for money or drugs.
 - Men 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.
 - Men 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.
 - Men who have been incarcerated in jail for more than 72 hours.
 - Men who have had close contact within 12 months preceding the donation with another person who has viral hepatitis.
 - Men who have had or have been treated for syphilis or gonorrhea within the preceding 12 months.
 - Persons 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.
 - Persons with a family history of transmissible spongiform encephalopathy (TSE) such as Creutzfeldt-Jakob disease (CJD); a history of changes in cognition, speech, or gait; or exposure to tissues (e.g., dura mater grafts, corneal transplants) suspected of harboring TSEs.
 - Recipients of human organ or tissue transplants or human extracts.
 4. Physical Examination
 - a. The donor should undergo a complete physical examination including evaluation for urethral discharge, genital warts, and genital ulcers as well as routine laboratory testing, including blood type and Rh-factor testing before enlisting him in the practice.
 - b. Donors should have follow-up examinations annually for urethral discharge, genital warts, and genital ulcers. Donors should not be used if any of these findings are present.
 5. Use of Frozen Semen

The use of fresh semen for donor insemination is not justifiable. It is possible for HIV and other infectious organisms to be transmitted by fresh donor semen before the donor has become seropositive. Consequently, the potential for transmission of HIV by fresh semen cannot be eliminated. All frozen specimens should be quarantined for 180 days and the donor should be retested as described below and found to be seronegative before the specimen is released.
 6. Laboratory Testing

There is no method of completely ensuring that infectious agents will not be transmitted by TDI, but the following guidelines, in addition to adequate history taking and exclusion of individuals at high risk for HIV and other STIs should dramatically reduce risks.

 - a. Serologic tests for syphilis should be obtained initially on blood serum and repeated at 6-month intervals.
 - b. Serum hepatitis B antigen (HBsAg) and hepatitis C antibody should be obtained initially and at 6-month intervals, and individuals who are positive should be excluded.
 - c. Semen or urethral tests should be obtained initially for *Neisseria gonorrhoeae*. Either urethral or urinary testing for *Chlamydia trachomatis* should be performed. These tests should be repeated at 6-month intervals or more frequently if clinically indicated. Donors who are found to be positive should be treated and retested before being reconsidered.
 - d. The potential donor should be tested for active infection with CMV and retested at 6-month intervals. Those testing positive for active infection should be excluded and all quarantined samples discarded.
 - e. Initial serum testing for donors should include HIV-1, HIV-2, HTLV-1, and HTLV-II. These should be repeated at 6-month intervals.
 7. Managing Laboratory Results
 - a. A positive assay should be verified before notifying the potential donor. If a test is confirmed positive, the individual should be referred for appropriate counseling and management.
 - b. If a test is negative, semen samples may be collected and prepared for cryopreservation.
 - c. The donor should be retested a minimum of 180 days later and the specimen should be released only if the results are negative.
 - d. Additional testing should be performed as dictated by local state requirements.
- C. Management of Donors
1. Monitoring health status

The single most important method of diminishing the risk of transmitting infectious agents to women during insemination is to carefully screen and test the potential donors and to develop an ongoing procedure for monitoring their health status.
 2. Payment to Donors

Payment to donors varies from area to area, but should not be such that the monetary incentive is the primary motivation in donating sperm. However, the donor may be compensated for his time and expenses.
 3. Limitations to Donor Use

Institutions, clinics, and sperm banks should maintain sufficient records so that they may set a limit to the number of pregnancies for which a given donor is responsible. It is difficult to provide a precise number

of times that a given donor can be used because one must take into consideration the population base from which the donor is selected and the catchment area that might be served by a given donor. It has been suggested that in a population of 800,000 limiting a single donor to no more than 25 births would avoid an increased risk of inadvertent consanguineous conception. This suggestion may require modification if the population using donor insemination represents an isolated sub-group or the specimens are distributed over a wide geographic area.

4. Consent

It is essential for the donor to sign a consent form, which includes a firm denial of having recognized risk factors for STIs and genetic diseases. It is recommended that the donor acknowledge in the consent form his responsibility to notify the donor program of any changes in any of these risk factors.

5. Record Keeping

It is essential 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 insemination cycle. A mechanism must exist to maintain these records as a future medical resource for any offspring produced.

6. Protection of Confidentiality

Individuals participating in donor programs should be assured of protection of confidentiality in so far as local statutes permit. Medical records detailing the donation should be maintained as stipulated by local requirements.

VII. Choosing Donor Characteristics

There are several ways to match the male partner with the donor. The couple should be encouraged to list the characteristics that they desire in a prospective donor, including race and/or ethnic group, height, body build, complexion, eye color, and hair color and texture. Consideration should be given to blood type and Rh factor, particularly with Rh-negative recipients. If the use of donor sperm creates the potential for Rh incompatibility, recipients should be informed of the obstetrical significance of this condition.

Revised by the Ad Hoc Committee of the American Society for Reproductive Medicine: Deborah J. Anderson, Ph.D., Owen K. Davis, M.D., Marc A. Fritz, M.D., David I. Hoffman, M.D., Delores J. Lamb, Ph.D., Larry I. Lipshultz, M.D., Jacob F. Mayer, Ph.D., Steven J. Ory, M.D., Deidra T. Rausch, Ph.D., Joe Leigh Simpson, M.D., Michael R. Soules, M.D., and the Practice Committee of the American Society for Reproductive Medicine. Approved by the Board of Directors of the American Society for Reproductive Medicine in 2001.