

Embryo donation: Improved IVF pregnancy rates signal opportunity

New options to meet the needs of patients and providers

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In vitro fertilization (IVF) cycles often include ovarian stimulation to produce multiple mature oocytes and, therefore, multiple embryos for transfer, although often only 1 or 2 are used. Patients may preserve the remainder for future pregnancy attempts. Cryopreservation increases patient optimism and decreases pessimism about the IVF cycle outcome.¹ However, patients who have completed their families must decide what to do with the embryos and deal with the moral, ethical, religious, and personal implications of their decision.

Options for embryo disposition

Options exist for disposition of supernumerary embryos, and careful patient counseling must address the factors that guide individual decision-making,^{2,3} including patient perception and opinion about the embryos.⁴ Even in the best of circumstances, the process can be distressing.⁵

Continued storage. Patients may continue to store embryos for future use or until they are comfortable deciding on a route of disposition. Facilities' storage requirements differ; embryos may be moved to long-term storage facilities.

Donation to research. Patients who choose this route often must identify research centers themselves and arrange for embryo transportation.

Donation for laboratory training. The IVF program may allow donation to facilitate training of laboratory technicians and embryologists. Successful patients may view this as a way to express gratitude to the program and help improve results for future patients.

Discard the embryos. Patients may opt to thaw and dispose of the embryos. The program may



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allow patient participation and disposal ceremonies to accommodate moral and ethical sensitivity.⁶

Donation to another infertile patient. Patients who have completed their own families may anonymously donate embryos to an infertile patient to help her attempt pregnancy. This altruistic donation can be a very positive option for patients who are reluctant to discard embryos or donate them for research and training purposes.

Is there a need for embryo donation?

The literature confirms a need for and an interest in embryo donation. A survey of all assisted reproduction programs in the United States reported nearly 400,000 cryopreserved embryos,⁷ of which 20% were no longer wanted by the original patient/couple. That percentage is likely to grow. Between 2001 and 2007, the number of yearly IVF cycles increased from approximately 65,000 to

DISCLOSURE: Ms Hammond reports that she served as a consultant to Schering-Plough Corp and Walgreen's Specialty Pharmacy.



more than 95,000, adding to storage needs.^{8,9} The success rates increased from less than 25% to as much as 39.6% in certain age groups, making patient use of embryos less likely.

Embryo donation represents a significantly less expensive technique compared with donor oocyte use, which has increased from 7,722 treatment cycles in 2001 to 10,515 cycles in 2007, with pregnancy rates increasing from 47% to 55%, respectively.^{8,9}

Finally, some US state laws prohibit the destruction of cryopreserved embryos. Other countries, such as England and Denmark, limit the duration of storage.

Who are embryo donors and recipients?

Donors have generally completed their family; recipients are typically patients who cannot afford donor gametes. Clinicians may be able to tailor the discussion of the options for surplus embryos by understanding the factors that motivate and concern donors.

Characteristics of embryo donors

The primary motivation for donation is altruism.^{5,10,11} Others see it as a way to use the embryos for their intended purpose. Patients may object to other disposal options, believing them to resemble elective pregnancy termination.¹² Still, the decision to donate is complicated by personal factors, including the possibility that a genetic sibling of their children may result.

Limited published data help predict which patients will choose donation. However, moral or religious views that dictate embryo use only for pregnancy make donation the only plausible option.¹² Patients who have achieved their own family-building goals and are comfortable with disclosing personal information are more likely to donate,¹³ as are patients who perceive nurture to be more influential than genetic lineage in parental bonding.¹⁰

Characteristics of donor embryo recipients

Candidates include those who require donor oocytes (typically less available than donor embryos) and/or donor sperm, but have inadequate financial resources for these procedures. Patients who are unsuccessful with conventional treatments also may be suitable. Little has been published regarding psychological outcomes of recipients or the resulting offspring; social and cultural ramifications; or disclosure.

Establishing a donor embryo program

VanVoorhis and colleagues described the medical, ethical, and policy issues involved in establishing a successful embryo donation program based on their own work¹⁴; however, they did not detail specific development components.

Anonymous donation of human embryos from one individual/couple to another requires significant preparation to streamline the processes, ensure safety, and maximize success. Careful steps to facilitate the decision-making process should be taken.^{3-5,12,15} The American Society for Reproductive Medicine (ASRM) has published evidence-based guidelines to promote the sound practice of all methods of third-party reproduction, including embryo donation.¹⁶ To increase safety, the US Food and Drug Administration (FDA) has published evidence-based federal regulations on actual and potential risks for transmission of infectious disease.¹⁷ Individual practice policies and procedures should incorporate these guidelines and regulations, and also integrate other evidence in the literature.

Detailed policies, procedures, and protocols for screening, matching, and obtaining medical histories and non-identifying information must be attentively written and reviewed by the assisted reproduction health care team. Specific talking points may also help the health care team to promote patient information depth and consistency. Comprehensive written information and consents for donors and recipients should be available. Strong consideration should be given to psychological screening and care, especially with respect to decision-making and disclosure issues.

Practices may impose fees for services associated with embryo donation; however, fees may not be charged for the embryos per se. Similarly, embryo donors should not receive financial remuneration.¹⁶

Screening and informed consent: Donors

ASRM Practice Guidelines clearly delineate the appropriate screening of the donors of cryopreserved embryos to minimize risks to the recipients and resulting offspring.¹⁶ Obtaining a careful genetic and medical history is essential. Laboratory screening and testing for transmissible infection is outlined by the ASRM and the FDA in detail. Rescreening after a 6-month quarantine should be performed. If screening was not performed prior to embryo cryopreservation, the recipients must be informed. Screening may still occur prior to donation. If the donors are unable

KEY POINT

In 6 years, IVF success rates have risen from 25% to almost 40%.

or unwilling to undergo testing prior to donation, donation may still occur, but recipients should be advised of the communicable disease risk.

Informed consent for embryo donors must include statements that relinquish rights to the embryos or resulting offspring, the risk of inadvertent loss or damage to the embryos, the right of the practice to refuse transfer of embryos to unsuitable recipients, and the process for medical/legal resolution of disputes. These components are also outlined by the ASRM Practice Guidelines.¹⁶

Screening and informed consent: Recipients

Potential recipients must sign informed consent for receiving donated embryos, undergo infectious disease screening and testing, and comply with program policies for the actual embryo transfer. Psychological counseling should be strongly considered.

Informed consent must include willingness to take full responsibility for offspring that may result, as well as release the donors and the program from liability from potential complications with the pregnancy or offspring.

Matching donor embryos with recipient(s)

There are no published guidelines for matching donor embryos with recipients. A survey of reproductive health professionals showed that matching was equally done by practices and recipients.¹⁸ Programs that routinely offer embryo donation may elect to provide a list from which patients may choose their donor embryos. This list may include non-identifying physical characteristics and whether or not screening was

performed. Recipients should be provided ample non-identifying personal, psychological, and health information about the embryo donors to maximize their informed decision to accept the embryos for transfer.

Record keeping and confidentiality

FDA regulations require that all records for embryo donors and recipients be maintained for a minimum of 10 years. The ASRM guidelines advocate for permanent records that include pregnancy outcomes as a medical resource for resulting offspring, if necessary. Confidentiality of this medical information and patient identity should be judiciously maintained and kept in compliance with HIPAA and other regulations.

Summary and resources

A successful embryo donation program will always be a work in progress. As technology and evidence evolves, so will the program. Resources for patients and providers regarding embryo donation include the American Society for Reproductive Medicine (www.asrm.org), the National Embryo Donation Center (www.embryo-donation.org), the Embryo Adoption Awareness Center (www.embryo-adoption.org), the American Fertility Association (www.theafa.org), and RESOLVE (www.resolve.org).

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The FDA and ASRM provide guidelines for third-party reproduction.

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