Reproductive Care Center

Informed Consent for Frozen Embryo Transfer

The number of embryos to be thawed and transferred should be agreed upon by the couple and their physician. Based on our experience at the Reproductive Care Center and the guidelines set forth by the American Society for Reproductive Medicine (ASRM), the number chosen should optimize the chance for achieving a pregnancy while minimizing the likelihood of higher order multiple pregnancy. Multiple gestations (particularly triplet and higher order multiple pregnancy) are an undesirable consequence of assisted reproductive technologies. Multiple gestations lead to an increased risk of significant complications in both the fetuses and the mother. Patients should also be aware that even though the likelihood is low (<2%) it is possible for an embryo to split into "identical twins". Thus even with the transfer of 1 embryo, twins could develop. Although multifetal pregnancy reduction can be performed to reduce fetal number, the procedure does not completely eliminate the risks associated with multiple pregnancies. We do not perform this procedure but can refer patients if needed. Fetal reduction may result in the loss of all fetuses (usually <5% risk) and even successful reductions may have adverse psychological consequences. If multifetal pregnancy reduction is not an acceptable option, we usually recommend that you not transfer more than two embryos.

Embryos are usually frozen 2 to 6 days after egg retrieval. When cleavage stage embryos are frozen, the number of cells that the embryo has is usually recorded. Embryos with the best chance for implantation have at least half of the cells survive the freeze/thaw process. If less than half the cells survive the freeze/thaw process, the likelihood of pregnancy from the embryo is very low (<1%) and it is usually discarded. Usually, greater than 50% of the embryos survive the freeze/thaw process intact. The following guidelines apply to intact embryos (≥50% of the cells survive). Embryos that have been frozen and thawed usually have approximately a 50% lower implantation rate than fresh embryos. Once embryos have been thawed they usually are not refrozen. Since frozen embryos are often stored in groups, it may not be possible to thaw the exact number requested for transfer. If too many embryos (frozen on day 2 or 3 after embryo transfer) survive intact after the thaw, consideration should be given to attempting to grow the embryos to the blastocyst stage (usually takes 2-3 days) in culture and then transfer the 2 best embryos available. If a couple has a number of fair or poor quality cleavage stage embryos frozen, they should also consider thawing all the cleavage stage embryos and then attempt to grow the embryos to the blastocyst stage (usually for 2-3 days) in culture and then transfer the best 1-2 blastocysts available. It should be noted that some studies of blastocyst transfer suggest there is an increased risk of identical twinning, including situations where the fetuses are in the same fluid filled sac. When the fetuses are in the same sac (monochorionic and monoamnionic) there is an increased risk for miscarriage and late in pregnancy complications such as twin-twin transfusion can occur. Fortunately, this occurs in less that 5% of the cases.

Although the ASRM has not published specific guidelines for the number of frozen embryos to transfer, the following guidelines were recommended by ASRM in 2006 for fresh embryo transfer and we consider them to also be good guidelines for frozen embryo transfer.

1. In patients under the age of 35, <u>no more than two embryos should be transferred</u> in the absence of extraordinary circumstances. For patients with a favorable prognosis, consideration should be given to transferring only a single embryo. The patients having the most favorable prognosis include those who are undergoing their first cycle of IVF, have good quality embryos as judged by morphologic criteria (appearance), and have embryos of sufficient quality and quantity to

warrant cryopreservation (freezing). The patients who have had previous success with IVF should also be considered the most favorable prognostic category.

2. For patients between 35 and 37 years of age having a favorable prognosis, no more than two embryos should be transferred. All others in this age group should have no more than three embryos transferred. After extended culture no more than 2 blastocysts should be transferred.
3. For patients between 38 and 40 years of age with a favorable prognosis, no more than 2 blastocysts or 3 cleavage stage embryos should be transferred. For patients in this age group having a less favorable prognosis, no more than three blastocysts or 4 cleavage stage embryos should be transferred.
4. For most patients greater than 40 years of age, no more than three blastocysts or five cleavage stage embryos should be transferred.
5. For the patients with <u>two or more</u> previously failed IVF cycles and those having a less favorable prognosis, additional embryos may be transferred according to individual circumstances after appropriate consultation.
6. In donor egg cycles, the age of the donor should be used to determine the appropriate number of embryos to transfer.

We understand that we fit into category #_____ listed above. Special considerations for our case, if any, include (none) _____
_____
_____

<u>Option #1</u> - We have selected the following number of cleavage stage embryos to transfer on this cycle (mark one):

____ One intact cleavage stage embryo.
____ Two intact cleavage stage embryos.
____ Three intact cleavage stage embryos.
____ Three intact cleavage stage embryos if only 2 were of good quality when frozen.

The following 5 options are not usually recommended:

____ Four intact cleavage stage embryos.
____ Four intact cleavage stage embryos if only 2 were of good quality when frozen.
____ Five intact cleavage stage embryos.
____ Five intact cleavage stage embryos if only 2 were of good quality when frozen.
____ All surviving cleavage stage embryos.

In addition to the above, for partially surviving cleavage stage embryos (<50% of cells survive) we request:

____ Transfer of up to 2 partial embryos.
____ Transfer all available partial embryos.
____ Discard since the likelihood of pregnancy is very low.

<u>or</u>

Option #2 - We desire to have some or all of our remaining cleavage stage embryos be thawed and then have the lab attempt to grow the embryos to the blastocyst stage (usually for 2-3 days) in culture. We understand that an embryo transfer on the day of the thaw may be recommended if the number of embryos that survive intact is the same as or less than the number we desire to transfer..
We desire to have the following number of embryos thawed for this cycle (mark one):

____ # of cleavage stage embryo(s).
____ # of intact cleavage stage embryo(s) desired for further culture. Embryo(s) will be thawed until the desired number of intact (>50% of the cells surviving) has been achieved or all embryos have been thawed, whichever comes first.
____ All remaining embryos.

We then plan to transfer the following number of blastocysts:

____ One blastocyst.
____ Two blastocysts.
____ Three blastocysts **(not recommended).**

Yes No We understand that refreezing embryos is not usually recommended due to the decreased survival and subsequent pregnancy rates. However, if more good quality blastocysts develop than we desire to transfer, we request that the extra blastocysts be refrozen. We understand that refreezing the embryos will incur additional costs.

or (for patients with frozen blastocysts)

Option #3 - We have selected the following number of blastocysts to transfer on this cycle (mark one):

____ One surviving blastocyst.
____ Two surviving blastocysts.
____ Three surviving blastocysts. **(not recommended)**

We understand that transferring multiple embryos entails the risk of multiple pregnancies, which have much higher risks than single pregnancies. We have had an opportunity to discuss these risks with an RCC physician and accept the risks involved with this decision. We understand that transferring more than two embryos requires physician discussion.

_____ _____
Wife's Signature Date

_____ _____
Husband's Signature Date

_____ _____
Physician's Signature Date

To be completed on the day of embryo transfer:

Based on updated information provided after the thaw on the day of embryo transfer, we desire to change the number of embryos transferred on this cycle to: _____.

We desire that extra embryos of adequate quality (#____) be cryopreserved (refrozen) again today (circle): Yes No

We desire that assisted hatching be performed today (additional cost): Yes No

We desire that extra embryos undergo extended culture (at additional cost) and if at least _____ blastocyst(s) of adequate quality develop we desire that they be cryopreserved again (circle): Yes No

We desire that the embryos be refrozen (circle): In groups (with no more than #____ in a group) Individually

We request that RCC dispose of developmentally arrested, abnormal or undesired embryos. Photographs may be made of any discarded tissues or fluids and may be used anonymously for presentation or publications. We also consent to allow RCC to use any developmentally arrested, abnormal or undesired embryos that would otherwise be discarded, for medical research, quality control, training or teaching purposes.

_____ _____

Wife's Signature Date

_____ _____

Husband's Signature Date

_____ _____

Physician's Signature Date: