National Embryo Donation Academy Reference Manual

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Greetings,

Welcome to the National Embryo Donation Academy and thank you for your interest in embryo donation and adoption. Although still relatively a new option for family building, embryo donation and adoption is rapidly becoming a well known alternative to both patients, fertility clinics, and clinic physicians and staff. With increasing popularity comes increasing volume, making it much more likely that professionals from all the related fields will encounter clients using this option.

As with all new techniques, there are still a lot of unsettled issues. Physicians must learn expected success rates. Embryologists must learn new techniques for thawing embryos. Attorneys will need to know the latest statutory and case law dealing with embryo donation and adoption. Social workers must become aware of the significant differences between working with patients pursuing embryo adoption versus traditional adoption. Theologians and public policy analysts must understand the moral, ethical, and social dimensions of this emerging field.

With all of this in mind, the National Embryo Donation Academy was created. Whatever your discipline, we are confident that you will find this course of study an excellent foundation for your needs and those of your clients. Be sure to book mark www.embryoconnection.org for the very latest weekly updates occurring in the field of embryo donation and adoption.

Again, welcome to the NEDA and thank you for your interest. We wish you the best in your endeavors and are confident that this will be a rewarding and enjoyable learning experience for you!

Sincerely,

Jeffrey A. Keenan, M.D.
NEDA Dean
Director, National Embryo Donation Center
Professor, Dept. of OB/GYN
Univ. of TN Medical Center
Knoxville, TN
Embryo donation and adoption could be the answer for couples who are unable to conceive and for those who have been successful in bearing a child, but are now struggling with the decision of what to do with their remaining embryos. Yet too often, professionals do not mention embryo donation and adoption to their patients or worse, assisted reproductive professionals may be inadequately versed in this new field.

Through a grant from the Department of Health and Human Services a campaign has been established to inform and educate physicians, ART clinics, lawyers, ethicists, and adoption professionals on the awareness of the increasingly popular options of embryo donation and adoption.

The National Embryo Donation Academy is composed of a professional faculty whose mission is to educate individuals in all aspects of EA/ED. Each faculty member will contribute curricula in their respective areas of expertise utilizing a number of educational materials including

- Training manual/reference guides
- Power Point lectures
- Podcasts
- Web-based educational programs
- Educational lectures (either individually arranged lectures or at professional conferences)

Participants will learn the basics of EA/ED through this training. After passing an appropriate exam, participants will earn a “Certificate of Achievement in Embryo Adoption and Embryo Donation” having demonstrated basic competency in the multiple disciplines of embryo adoption and embryo donation.

For more information on the National Embryo Donation Academy please visit www.embryodonation.org/nea
Course Description:

This series of topics includes a spectrum of basic information about embryo donation and adoption. It is intended for a physician, nurse, social worker, or other health or human services professional with a basic knowledge of human reproduction and family life issues. On completion of this material, the professional will be able to handle most basic inquiries about embryo donation and adoption and can explain the most important issues on this topic to learning audiences in clinic, hospital, and professional meeting settings. The professional will also be able to teach and field questions from the general public in media interviews or community forums. The course first covers the scientific and clinical basics of reproductive medicine and infertility in order to explain why embryo adoption is needed and desired. Next, the course deals with a history of the embryo adoption movement and documents its current status including statistical success rates and costs. Then, it turns to the practicalities of the way embryo adoption works, and finally to the issues and problems that confront embryo adoption at this time in its history. Numerous references and resources are documented.

Outcomes: By the end of the training, each participant should:

1. Be able to cite the most common causes of infertility and relate these to the standard treatments for infertility, especially IVF.

2. Be able to cite the reasons why so many frozen embryos exist.

3. Be able to name the choices couples have for their frozen embryos.

4. Describe the success rates and costs of embryo adoption and compare these to those of other infertility treatments.

5. Be able to name at least three problems confronting the embryo adoption movement and describe possible solutions for each.

6. Be able to cite at least four quality on-line resources with information about embryo donation and adoption.
Topics

I. Basics of embryology and reproductive biology
   A. The ovulation cycle
   B. Fertilization
   C. Stages of early embryonic development: 2pn, cleavage, and blastocyst

II. The most common causes of infertility
   A. Tubal factors
   B. Ovulatory factors
   C. Male factors

III. Basic steps of in vitro fertilization
   A. Preparatory medication
   B. Egg retrieval
   C. Fertilization
   D. Embryo transfer
   E. Pregnancy testing and follow-up medication

IV. Factors governing how many embryos are transferred per cycle
   A. Age of the patient
   B. History of previous IVF cycles
   C. Number of embryos available and their observed quality

V. Reasons for large inventories of remaining embryos
   A. Egg retrieval is an expensive ordeal
   B. Freezing of unfertilized eggs is not a good option
   C. Unknown how many embryos it will take to achieve pregnancy
   D. Freezing embryos gives the opportunity to try again

VI. Choices that couples have for disposition of embryos
   A. Keeping for future use
   B. Thawing and disposing
   C. Donation to stem cell research
   D. Donation to other couples

VII. Brief history of embryo adoption practice

VIII. Success rates of embryo adoption and how they are measured

IX. Options for donor and recipient couples
   A. Closed (anonymous)
   B. Semi-open arrangement
   C. Open arrangement
Additional Resources:

Web sites of the primary agencies in the field:
www.embryodonation.org (NEDC)
www.embryoadoption.org (Nightlight)
www.bethany.org (BCS)
www.adoptanembryo.net (Embryo Adoption Services of Cedar Park)
Comprehensive descriptive essay at http://www.cmda.org/AM/Template.cfm?Section=Home&Template=/CM/HTMLDisplay.cfm&ContentID=24205

Bibliography of published medical, legal and bioethical literature at www.embryoconnection.org

See http://www.advancedfertility.com/ivf.htm for more details, this is a very good on-line source of information, it includes an IVF cycle calendar

See other materials listed on embryodonation.org
Embryo Donation & Adoption: A Comprehensive Introduction

This chapter is intended to give the reader a basic, workable command of the key concepts and issues surrounding embryo donation to other couples, also known as embryo adoption. At several points, the reader will be referred to subsequent chapters in this manual, dealing with the clinical, bioethical, legal, and social services aspects of embryo adoption, respectively. We have also included many important literature references. Unavoidably, there will be some overlap in the materials presented, sometimes with slightly different perspectives. As a faculty, we believe that in most cases, it is preferable for the reader to see the different points of view and evaluate those for him- or herself than for an editor to extensively revise each author’s work to eliminate every vestige of disagreement.

In order to understand how embryo adoption works, one must first have a basic grasp of human pregnancy and embryology. If one is familiar in basic terms with the menstrual cycle, ovulation, fertilization, and the stages of pregnancy, one can then appreciate the causes of infertility, which lead couples to seek treatment in the first place.

The American Pregnancy Association website (1) has as much detail as the reader needs regarding the ovulation cycle. Typically, a woman not taking fertility medications produces one egg per month. Natural fertilization usually occurs in the fallopian tube. Following intercourse, sperm swim up the vagina, through the cervix, through the uterus and into the tube where they encounter the egg. Normally, an egg is fertilized by just one sperm of the millions that swim up the female reproductive tract. The fertilization process takes about 24 hours from penetration of the egg wall by the sperm until the DNA from the sperm and egg combine into one genetic code. Even among those who believe that a new human person begins at fertilization, there is debate about exactly when fertilization occurs. For the purposes of this manual, syngamy, the time at which the DNA combines, will be regarded as the time of fertilization. Syngamy is discussed further in chapters 2 and 3.

Once the embryo has been created, it proceeds through a complex series of steps until, if its development is uninterrupted, it becomes a child ready for birth. The LSU Health Sciences Center has created an excellent pictorial series of human embryonic development (2).

It is important to recognize three of the earliest natural stages – 2PN, cleavage (4-10 cells), and blastocyst – because these stages are the same as the ones which occur in the laboratory to cultured embryos being prepared for in vitro fertilization (IVF). The number of days of development in the laboratory need to correspond to the number of days in the woman’s medication cycle since fertilization “would have occurred”. This way, the embryo can be placed in the woman’s uterus at almost exactly the same time that an embryo of that very same developmental stage would have arrived there naturally.

Since embryo adoption is, most often, undertaken as a treatment for infertility, it is important to have some understanding of the causes of infertility. Infertility is defined as the failure to conceive a child after one year of regular, unprotected intercourse. Couples can have difficulty conceiving because of factors involving the man, the woman, or both partners. Most female infertility can be
traced either to a failure to produce viable eggs (ovulatory factors), or a failure of the egg to travel down the fallopian tube where it can encounter sperms (tubal factors). In most of the world, tubal factors, often caused because the tubes are scarred shut from sexually transmitted diseases, are the most common. In the United States, where effective treatment for STDs is usually available, ovulatory factors are more common. The Mayo Clinic attributes about a third of infertility cases to male-only factors and about another third to a combination of factors involving both partners or to unknown causes (3). The likelihood of finding a cause in many cases is limited by a couple’s resources and willingness to undergo complex tests.

In vitro fertilization (IVF) is an effective, but expensive, means of treating infertility. So long as the female can produce one or a few viable eggs, and the male can produce viable sperm, many causes of infertility can be overcome by doing the fertilization in the laboratory, selecting one or more healthy embryos, and placing them into the uterus in a clinical procedure. IVF consists of five basic steps:

- Medication to prepare the ovaries to produce multiple eggs
- Retrieval of eggs from the ovaries by needle
- Fertilization of the eggs with the man’s sperm in the laboratory
- Placement of the resulting eggs into the uterus by plastic catheter under ultrasound
- Pregnancy testing and hormone support of the pregnancy.

Most infertility clinics have web sites explaining the process in more detail – this one from Advanced Fertility (4) is excellent. It includes a calendar depicting the day-by-day tests and procedures that the woman can expect to undergo. There is also more material about IVF in chapter 2 of this manual.

Several factors govern how many embryos are transferred in an IVF cycle. There is a dramatic difference in pregnancy rate by the woman’s age. In the SART table (table 4 at the end of this chapter) one can observe a steep decline in pregnancy rates from left to right as the woman’s age increases (5). Therefore, it makes clinical sense to transfer more embryos to older women than younger, to achieve an acceptable pregnancy rate without an unacceptably high rate of multiple pregnancy. It also makes sense to consider a woman’s prior IVF history. One should transfer more embryos if a patient failed to conceive in a prior cycle, and fewer embryos if a patient was successful previously, again to maximize the chance of success but minimize the chance of multiple pregnancy. Finally, one should consider the quality of the embryos available, as observed in the laboratory. Though it is far from a “sure thing”, an embryologist’s assessment of the embryo under the microscope does correlate to some degree with its chances of implanting. Number of good embryos available may be an additional indicator that the embryos will do well, thus putting the patient into a “favorable” category (6).

Not long after the first IVF procedures were performed in the late 1970s and early 1980s, clinicians learned how to maintain (cryopreserve) embryos in frozen storage and thaw them once again for implantation later, thus, in some cases sparing the woman a second egg harvesting procedure (7,8).
At about the same time, clinicians reasoned that more couples could be helped toward parenthood by substituting donor sperm for men who have no viable sperm, or donor eggs for women who have no viable oocytes – or both. Thus, gamete and embryo donation, as described above, came into being. A careful reading of the 1983 clinical report often cited as the first instance of embryo donation (9) reveals that the donated embryo was actually created for the recipient at the same time that four embryos were made for the donor couple’s own use – if you will, a “make me one while you’re at it” proposition. The menstrual cycles of the donor and recipient women were synchronized using medications, and the transfers occurred on the same day. None of these embryos had been cryopreserved.

Soon thereafter, reports were published documenting successful pregnancies and births from cryopreserved donor embryos. Again, however, these were embryos made from donor gametes specifically for the recipients (10,11).

No one knows for sure when the first true gift of one couple’s remaining embryos to another couple, for clinical transfer into the recipient woman (=embryo adoption) occurred. The term was used as early as the mid-1980s (12,13) in the legal literature. Devroey et al. (14), Bustillo (15), and Jones (16) have reported embryo transfers occurring between 1986 and 1990 that clearly represented adoption of remaining embryos.

The personal story of John and Marlene Strege of California (17), however, brought the idea of embryo adoption to the national stage. Mr. and Mrs. Strege were initially identified as “Zach” and “Elizabeth” (after the parents of John the Baptist, see Luke chapter 1) in order to protect their privacy. Since that time, however, they have become activists for embryo adoption, have testified before Congress, and are identified by name in many news reports and public documents (18,19). John and Marlene, having experienced failure with traditional infertility treatments for some years, learned about the possibility of embryo adoption from their physician. However, this doctor was unable to connect them with a source for a donor embryo. Subsequently, they contacted Focus on the Family for assistance, and as a result were linked with a prospective donor couple from the Midwest, underwent the embryo transfer, and became parents of a daughter, Hannah, on December 31, 1998. Hannah became known as the “first snowflake®” child. Meanwhile, FOTF President Dr. James Dobson, at the urging of his friend, leading pro-life gynecologist Dr. Joseph McIlhaney, came to strongly and publicly support embryo adoption as both a solution for infertility and an opportunity for life for frozen embryos (17). Nightlight Christian Adoptions, directed by adoption attorney Ron Stoddart, facilitated the adoption process for the Strege. Nightlight has since done so for more than two hundred other couples in what is now known as the “Snowflake® Program.”

The Strege story was followed by two other major developments that kept embryo adoption in the public eye. In August 2001, President Bush was confronted with the need to set policy on federal funding for embryonic stem cell research. (Creating cell lines for this type of research results in the destruction of embryos). After much consideration, he decided that although federal dollars could be used for research on existing cell lines, he would not support funding any activity in which further embryos would be destroyed (20) – though this policy has since been reversed by the Obama administration. Soon, embryo adoption came to President Bush’s attention as an
attractive alternative to stem cell research, refuting the argument that “these embryos are only going to be thrown away anyway.” In May 2005, as Congress was challenging the funding policy, the President dramatized the issue by inviting a group of “snowflake” families to the White House (21).

The other development was the 2003 publication of an “embryo census” conducted by the Rand Corporation for the American Society for Reproductive Medicine (ASRM) (22). Although the primary purpose was to find out how many embryos might be available for stem cell research, it was the total number of embryos found to be in frozen storage (just under 400,000) that caught public attention. This was a conservative number, because not every infertility clinic responded to the survey. Nonetheless, the figure was more than double the informal estimates that had been made previously, and highlighted the accumulation of embryos as a difficult problem. A more recent census taken by Snowflakes showed that just over 600,000 embryos are currently stored in clinics and storage facilities in the U.S. To Stoddart and others, these embryos represent frozen lives (23); to infertility clinics, they represent a large expense for storage, tracking, and maintenance. The parents who created them face the often difficult dilemma of what to do with them (24).

It is useful to ask at this point, why are there so many frozen embryos? Several factors contribute. First, egg retrieval is expensive, somewhat painful, and carries some degree of clinical risk to the woman both from the effects of the medications used and from the insertion of the needle into the ovary. Therefore the incentive is to avoid having to go back a second time to retrieve more eggs. At the same time, freezing and thawing of unfertilized eggs is not as favorable an option compared to freezing and thawing of embryos (although this is changing). Indeed, there have been births from eggs that have been frozen, thawed, then fertilized, then transferred (25), and the new technology of vitrification has made this a much more viable option for couples. The cleavage stage embryo, on the other hand, is much more robust than an unfertilized egg, and survives conventional freezing and thawing much more reliably.

Because it is unknown how many embryos will take to achieve pregnancy in an individual woman, it is quite possible for her to have several remaining embryos if pregnancy happens on the first or second cycle of transfers. In this instance, freezing the embryos gives her the opportunity to try again, even years later. It does not matter how long the embryos have been in frozen storage. It only matters how well the embryos withstand the freezing and thawing.

For all these reasons, the procedure in most clinics is to fertilize all the eggs that result from one egg retrieval procedure (that is, create a maximum number of embryos). There are, however, clinics such as Southeastern Fertility Center in Knoxville, TN, that create only the number of embryos the couple is committed to use eventually. Thus, they avoid adding to the accumulation of remaining embryos.
Couples have four realistic choices for the disposition of their embryos. First, they can keep them in frozen storage in case they want to try for another child at a later time. Most of today's frozen embryos are, in fact, still designated this way by the creating couples (22). The history of such embryos in storage does not bear out that most of them will be used, but few clinics are willing to decide on a disposition for embryos without the consent of the couple who created them. Second, a couple can have them thawed and destroyed. This option is acceptable to relatively few couples; moreover, it is not acceptable to those who see the embryo as a life already created (see chapter 3 of this manual for further discussion). A couple could also choose to donate them for research. This option is popular especially among patients who receive their care at research medical centers (26). Most embryos for research go to the creation of cell lines for embryonic stem cell research, though some are used for infertility research or training. In either case, the research results in the destruction of the embryo, so this option runs into the same bioethical objections as outright destruction. The fourth option is to donate the embryos to another couple, to help them achieve pregnancy, as we have been discussing.

Early in the process of considering embryo adoption, a couple will ask, “What are the success rates?” What are the chances that a couple adopting embryos will come home with a live baby? To understand the answer to this question, it is helpful to define a few terms. First: the pregnancy rate. This statistic is the number of pregnancies achieved, per donated embryo transfer cycle performed. The latest data from CDC place this number at 45 percent (27). Second: the live-birth delivery rate. This is the statistic most recipient couples want to know most: it is the number of deliveries of at least one live infant, per donated embryo transfer cycle performed. According to CDC data, this number now stands at 36 percent (27). The difference between 45 and 36 is accounted for by miscarriages, which occur at approximately the same rate as naturally conceived pregnancies. Some clinics achieve consistently higher rates than the national average. The National Embryo Donation Center in Knoxville, TN, for instance, has a pregnancy rate of 57 percent and a live-birth delivery rate of 46 percent. It is important to understand that these rates are per transfer cycle. Each cycle is counted separately, no matter how many cycles a particular woman may have undergone. Typically, a couple will try at least one more time if unsuccessful, so a couple’s eventual chances of a live baby after more than one try will be considerably higher than the figures cited here.

The implantation rate, on the other hand, refers to the individual embryo’s chances of becoming a pregnancy. It is defined as the number of fetal hearts observed on ultrasound, divided by the number of individual embryos transferred to a woman. This rate, nationally, is about 29 percent. The reason this number is lower than the pregnancy rate is that most of the time, more than one embryo is transferred in a cycle. The implantation rate, however, still overestimates an individual embryo’s chances when still frozen. This is because about 30 percent of embryos do not survive the thawing process. The implantation potential is calculated as the number of fetal hearts observed on ultrasound divided by the number of individual embryos thawed. This number, nationally, is about 20 percent. The importance of this number is that it allows one to calculate the potential live births that could occur if all embryos in cryostorage were thawed and transferred. For every 100,000 embryos thawed, about 20,000 babies would be born. Table 1 at the end of this chapter summarizes the outcome statistics.
The live-birth delivery rate for EA of 36 percent compares to about 30 percent for autologous (a couple’s own) frozen cycle IVF (5). Why would a donor embryo frozen transfer cycle be more successful than a frozen cycle using a couples own embryos? This is because of the “selection factor”. More often, embryos employed in a couple’s own frozen cycle IVF come from a cycle where the first embryos have failed to achieve pregnancy. Conversely, embryos employed in an EA cycle most often come from a cycle where the first embryos have been successful. (In this case, the donating couple had as many children as they wanted, and that is why they donated the embryos). Donated oocytes (eggs), on the other hand, because they come from young, healthy donors, produce the highest pregnancy rates. Table 2 at the end of this chapter compares embryo adoption outcomes to those of other fertility procedures.

Couples who wish to donate their remaining embryos have the option to choose an open arrangement, where the donor selects the recipient couple who in turn must accept the donor, each using personal profiles that they have completed. The donors know the recipient couples names, and typically vice-versa. Sometimes, they go on to establish family friendships. Couples choosing this option generally sign an “open donor agreement”, which is mediated by a 3rd party adoption and counseling agency. Couples also have the option to choose an anonymous donation, where neither couple knows who the other is, and all identifying information is kept confidentially at the clinic. It is also possible to opt for a “semi-open” concept where the couples know each other’s profile information except for names and how to locate each other. Donor couples are matched with adopting couple who desire the same degree of openness. At NEDC, approximately 54 percent of matches are anonymous, 45 percent are open, and only one percent of couples select the semi-open arrangement. However, a recent article by Australian authors indicates that more couples would be willing to donate their embryos under a policy of “conditional donation” (28). The wider use of the semi-open concept would seem to facilitate this process.

So what are the legal boundaries governing embryo adoption? In the United States, embryo adoption is governed by contract law rather than by adoption law. This is what has made many in the legal profession uncomfortable with the term “embryo adoption” (see chapter 4 for further discussion). Adoption laws in all the states provide that a child's adoption is only final after birth, usually after a prescribed “waiting period” (29). In embryo adoption, the transfer of ownership of the embryo occurs before the clinical embryo transfer procedure is performed. No state forbids the practice. Uniform Parentage Acts in all states provide that a woman who gives birth to a child is the legal mother. In some states, the UPA is specifically written to include children born from embryo adoption. In the others, the UPA still applies even without specific mention. Legislative initiatives that have been proposed by the Americans United for Life and others, including the statute enacted in Georgia in 2009 and Tennessee in 2012 (30), are with the intent of defending current practice against legal challenge, rather than for the purpose of changing current practice. The Georgia statute allows, but does not require, a couple giving birth to a child by embryo adoption to obtain a confirming court order of adoption after the fact. It is not known, however, what the outcome would be if the validity of an embryo donation contract, under the current statutes, were challenged in court.
Meanwhile, the U.S. Food and Drug Administration regulates the infectious disease screening of embryo donors. Donors are screened for HIV, syphilis, gonorrhea, Chlamydia, HTLV I and II, CMV, and hepatitis B and C. Embryos lacking all the required screening, or having screened positive for an infectious condition, can still be transferred, but only *if the donor and recipient couples are acquainted and only if full disclosure of the embryo’s condition is made.*

Other nations have a variety of legal approaches to embryo adoption. Fourteen nations forbid the practice altogether (see table 3 at end of chapter). In other nations, embryo adoption is either governed by specific laws, or is carried on without any specific legal framework (table 3). In New Zealand, a couple must apply through a national committee in order to become parents by embryo adoption.

So what does embryo adoption cost? In a research study published in 2009 (31), NEDC determined that in seven nationally representative embryo adoption programs, the cost for a first embryo adoption cycle averaged $7,800. This compares to approximately $12,000 for a domestic traditional adoption, $15,000 for an IVF cycle, and about $22,000 for a first egg donation cycle. The study found that embryo adoption is cost-effective compared to egg donation by a factor of 2:1. Stated another way, the average amount a couple pursuing embryo adoption can expect to spend in order to come home with a live baby is half of what they would spend if using an egg donor. Subsequent cycles, regardless of the method used, cost less than a first cycle because much of the medical workup and preparation does not have to be done all over again. The same is true of the counseling and home study, for those embryo adoption agencies that utilize them. These social services involved with embryo adoption will be discussed further in chapter 5.

Though the embryo adoption movement has grown since it began, and has provided heart-warming outcomes for many families, it faces significant challenges, sometimes opposition, from several very different sources. As already mentioned, many attorneys do not like the term “embryo adoption” because the practice is not really adoption as defined in the law. Most of these individuals do not object to the practice, just the terminology. However, there are those in the traditional adoption community who feel strongly that it is unethical to promote embryo adoption when there are already born children living in foster care needing permanent homes. Others counter that the candidates for embryo adoption are looking for an infant to join their family, and are usually not the same people as those interested in undertaking parenting starting from the toddler, school-age, or adolescent stage. If anything, embryo adoption might compete with adoption of already-born newborn infants, but few of these are available for domestic adoption, and the cost of international adoptions was already prohibitively expensive for many even before the doors began to close to adoption from many countries in the past few years.
A second challenge comes from some in the scientific community who see embryo adoption as a competition to the donation of embryos for stem cell research. These individuals see the potential cure for chronic diseases as the priority, and the saving of the life of the embryo a much lower priority since, to them, it is not yet a human person. They may support the right of a couple to choose to donate their embryos, but even then would object to the term “adoption” and place embryo donation within a model similar to that for the donation of tissues or organs (32). It is important to note, however, that despite the promise of “cures within a decade from embryonic stem cell research” (that claim made in 2001), as of yet there are still no cures at all from this technology, and in fact, there is currently only one FDA approved phase III clinical trial using embryonic stem cells. Presently, it appears that iPSC’s (induced Pluripotent Stem Cells) and other technologies, which do NOT use embryos as the source of their cells, are much more promising for a variety of reasons beyond the scope of this text.

Yet another challenge comes from those, particularly in the Roman Catholic community, who assert that the adoption of an embryo creates a new life outside the bonds of marriage. Although it is difficult to see how one can hold this position and also hold that new human life begins at fertilization, several influential Catholic scholars (33-35) do just that. Before the two recent Vatican documents (34,35) were published, Catholic bioethical spokesmen numbered about 2 to 1 in favor of embryo adoption. Those in favor allowed that from their perspective, the creation of embryos outside the body had not been legitimate, but once created, the saving of their lives was a positive act in keeping with the Catholic imperative of sanctity of human life (36,37).

The primary rate-limiting factor to the growth of the embryo adoption movement, however, is not the ideological opposition from the outside, so much as the reluctance of individual couples with remaining embryos to consider donating them. Polls of the general public and of infertility patients conducted by NEDC in 2007 and 2009 in cooperation with Harris Interactive showed that while a relatively large percentage of individuals agreed that embryo adoption was a good practice in the abstract, fewer thought they could consider it for themselves, still fewer had actually considered it, and just a small handful had actually gone through with donating embryos. Sheryl de Lacey in Australia has done the most extensive interviewing of people with embryos to discover why this might be (38,39). Subjects have repeatedly told her that giving up embryos for adoption is too much like parting with one’s own children. Though this might not be good news for the growth of the embryo adoption movement, it does help to negate the arguments of those who do not consider the embryos as human lives. For others, the issue is that they do not like the thought of their children meeting their own genetic siblings unexpectedly. Robert Nachtigall in California has found somewhat similar results (40).

Some prospective donor parents have expressed the concern that they might feel guilty if they “brought a child into the world” to be raised by parents who then divorced or in some way were not satisfactory parents to the child. This point of view resonates with those who believe that the embryo does not yet represent a child.

NEDC undertook a questionnaire study, asking certain questions of those who had inquired with the organization about donating their embryos. The study was done not because the subjects were thought to be typical of those with remaining embryos nationally, but to demonstrate that
there is a subset of patients who feel differently and are much more predisposed to donate, and
to find out why this group of patients believe and feel as they do. Most of the subjects did, as one
would suspect, profess a commitment to donate their embryos to another couple. About half came
from a strict “pro-life” perspective and felt that the right thing to do was to save the life of the
embryo. About another third termed the embryo a “potential child” and wanted to make a gift to
another couple. Subjects in both groups often expressed empathy for the other couple’s infertility
struggle and wanted to help. These findings were similar across religious affiliation groups
represented.

Prospective adoptive parents have expressed some of the same concerns as those seen in
traditional adoption: it is a challenge to raise children that may not look or act like you. Indeed,
parents must decide how to tell the children about the circumstances of their conception. Social
services professionals are recommending transparency from a child's early age as the best course.
This aspect will be covered further in chapter 5.

Two other issues that pose challenges are: 1) that thus far, anyone seeking to adopt
embryos must go to at least two places to receive the needed services (for instance, NEDC offers
everything in-house except the home study, and at Nightlight offers everything in-house except the
clinical services) – and 2) the 2009 Harris Poll found that there are still patients with remaining
embryos who had not heard of embryo donation or adoption by either term. Several agencies are
aggressively addressing this last problem with a public education campaign.

It is true that the subject of embryo adoption is relatively limited in scope, compared, for
instance, to infertility generally, to adoption generally, or to public health issues affecting millions
around the globe, such as human trafficking, HIV infection, or population aging. The numbers of
significant medical, legal, bioethical, and news media publications on embryo adoption are in the
thousands rather than the hundreds of thousands, and if one were to gather all the professionals
whose careers were primarily and specifically devoted to embryo adoption in one place, one would
have a classroom full rather than an auditorium full. However, the issues involved are informative
and can be applied across a wide variety of related health topics. Moreover, embryo adoption is of
incredible importance to those few thousand families who are directly involved, and therefore, of
unquestioned significance to clinicians throughout reproductive medicine, nursing, counseling,
and social work who may encounter them. The best preparation for most such professionals
is to know the right places to find reliable resources. Thus, we especially recommend the web
sites of the NEDC – the nation's only clinic-based national embryo adoption program (41,42),
of Nightlight Christian Adoptions (43,44) and the National Fertility Support Center (45), and of
Embryo Adoption Services of Cedar Park (46) – the nation's only church-based embryo adoption
program. The Embryo Connection web site (42) has several hundred articles, web sites, and other
resources organized by sub-topic, as well as a Forum on which inquirers may ask questions and
dialogue about the issues.

The remaining chapters of this manual – medical issues (Dr. Robert Visscher), bioethical
issues (Dr. William Cutrer), legal issues (Dr. Curtis Harris), and social services issues (Ms. Bonnie
Bernard) will richly complement the overview presented here. We trust you will become a better
informed and skilled health professional as a result of the study you have invested in this topic.
References

1) http://www.americanpregnancy.org/gettingpregnant/understandingovulation.html

2) http://virtualhumanembryo.lsuhscc.edu/HEIRLOOM/Stages/HEP.htm

3) http://www.mayoclinic.com/health/female-infertility/DS01053

4) http://www.advancedfertility.com/ivf.htm

5) https://www.sartcorsonline.com/rptCSR_PublicMultYear.aspx?ClinicPKID=0

6) http://www.asrm.org/Media/Practice/Guidelines_on_number_of_embryos.pdf


15) Personal communication, Maria Bustillo, MD, January, 2007

16) Personal communication, Howard W. Jones, MD, January, 2007

17) Focus on the Family: Breaking New Ground (Panel) (on CD), 1999
18) Focus on the Family: A Closer Look at Stem Cell Research (Panel) (on CD), 2005


27) Centers for Disease Control and Prevention, unpublished data.


29) http://www.4law.net/consentadoption.htm

30) Georgia Code 19-8-40 to 19-8-43 (enacted 2009) 
Tennessee Code Annotated 36-2-401-403 (enacted 2013)


32) The Ethics Committee of the American Society for Reproductive Medicine, American Society for Reproductive Medicine: Defining Embryo Donation, Fertility and Sterility 2009;92:1818-9


41) http://www.embryodonation.org

42) http://www.embryoconnection.org

43) http://www.nightlight.org

44) http://www.embryoadoption.org

45) http://fertilitysupportcenter.org/

46) http://www.adoptanembryo.net
Table 1 - Number of Embryo Donations by Outcomes and Year, USA, 2004-07

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Data Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2004</td>
</tr>
<tr>
<td>Donated Frozen Embryo Transfer Cycles</td>
<td>666</td>
</tr>
<tr>
<td>Number of Embryos Thawed</td>
<td>2773</td>
</tr>
<tr>
<td>Number of Embryos Transferred</td>
<td>1870</td>
</tr>
<tr>
<td>Pregnancies (fetal hearts confirmation by ultrasound)</td>
<td>271</td>
</tr>
<tr>
<td>Pregnancy Rate Per Embryo Transfer</td>
<td>40.7</td>
</tr>
<tr>
<td>Pregnancy losses (sacs lost)</td>
<td>46 (51)</td>
</tr>
<tr>
<td>Implantation Rate</td>
<td>19.2</td>
</tr>
<tr>
<td>Implantation Potential</td>
<td>12.9</td>
</tr>
<tr>
<td>Total deliveries (with at least one live-born)</td>
<td>222</td>
</tr>
<tr>
<td>Delivery Rate Per Transfer</td>
<td>33.3</td>
</tr>
<tr>
<td>Number of clinics</td>
<td>167</td>
</tr>
<tr>
<td>Deliveries with a Twin Live-Born</td>
<td>60</td>
</tr>
<tr>
<td>Deliveries with a Triplet Live-Born</td>
<td>4</td>
</tr>
<tr>
<td>Live Babies</td>
<td>293</td>
</tr>
<tr>
<td>Number of Clinics</td>
<td>167</td>
</tr>
</tbody>
</table>

Written communication with the Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, April 2012.

Table 2 - Comparisons of Embryo Adoption Outcomes to Those of Other Fertility Treatments, 2006-09

<table>
<thead>
<tr>
<th>Treatment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo Donation</td>
<td>36.2%</td>
</tr>
<tr>
<td>Fresh Cycle Autologous IVF</td>
<td>35.8%</td>
</tr>
<tr>
<td>Frozen Cycle Autologous IVF</td>
<td>30.4%</td>
</tr>
<tr>
<td>Fresh Cycle Oocyte Donation</td>
<td>55.0%</td>
</tr>
<tr>
<td>Frozen Cycle Oocyte Donation</td>
<td>31.9%</td>
</tr>
</tbody>
</table>
**Table 3 - Synopsis of Global Laws on Embryo Donation**

Embryo donation is not permitted in the following countries:

1) Austria  
2) China  
3) Denmark  
4) Germany  
5) Israel  
6) Italy  
7) Latvia  
8) Norway  
9) Slovenia  
10) Sweden  
11) Switzerland  
12) Taiwan  
13) Tunisia  
14) Turkey

**Information for other countries:**

1) Afghanistan – do not have ED in country as yet  
2) Argentina -- permitted (doesn’t say how), identifying info can be provided  
3) Australia – governed state by state  
4) Belgium -- permitted by law  
5) Canada – national law states license is required for any creation or use of embryos. Cloning, buying/selling of embryos, creation of chimeras or hybrids, and various forms of genetic manipulation are prohibited by law. Provincial laws do not deal with embryos or embryo donation except to exclude them from tissue/organ donation regulation frameworks. IVF services are excluded from payment under some provincial health plans. Embryo donation is not forbidden by law, but occurs uncommonly  
6) Colombia -- donor embryos used without legislative framework  
7) Finland -- donor embryos used without legislative framework, each clinic makes own policy  
8) France -- permitted by law, adoption is necessary  
9) Greece -- permitted by law  
10) Hong Kong -- permitted by law  
11) India -- permitted by law, offspring and social parents have right to nonidentifying information on donors  
11a) Iran -- permitted by 2003 law  
12) Ireland -- permitted by regulation, “couple must make valid decision not to use own fertilized ova”  
13) Japan -- permitted (doesn’t say how), identifying info can be provided  
14) Netherlands -- permitted by law, but not practiced  
15) New Zealand -- permitted by law, case-by-case approval by ethics committee is required  
16) Portugal -- donor embryos used without legislative framework
17) Romania -- donor embryos used without legislative framework
18) Russia -- permitted by law
19) Singapore -- permitted by law, anonymity required
20) South Africa -- permitted (doesn't say how), identifying info can be provided
21) Spain -- permitted by law, anonymity required, no more than 6 children from each donor
22) Ukraine – permitted by law
23) United Kingdom -- permitted under detailed HFEA law
24) United States – permitted by law, governed state by state
25) Uruguay -- donor embryos used without legislative framework
26) Venezuela -- donor embryos used without legislative framework
27) Vietnam -- permitted by law, anonymity required, no payment permitted

References for specific countries are available on request.
Table 4 - SART Member Clinic statistics for 2007

<table>
<thead>
<tr>
<th>Data Year</th>
<th>Procedure Frequency</th>
<th>Diagnosis Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IVF &gt;99% ICSI 63%</td>
<td>Tubal factor 8%</td>
</tr>
<tr>
<td>GIFT</td>
<td>&lt;1% Unstimulated 1%</td>
<td>Ovulatory dysfunction 6%</td>
</tr>
<tr>
<td>ZIFT</td>
<td>&lt;1% PGD 5%</td>
<td>Diminished ovarian reserve 14%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Other factor 8%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tubal factor</td>
<td>8%</td>
</tr>
<tr>
<td>Ovulatory dysfunction</td>
<td>6%</td>
</tr>
<tr>
<td>Diminished ovarian reserve</td>
<td>14%</td>
</tr>
</tbody>
</table>

|                | Unknown factor 11% |
| Tubal factor   | 8%                |
| Ovulatory dysfunction | 6%            |
| Diminished ovarian reserve | 14%          |

Total Cycles: 132,745

<table>
<thead>
<tr>
<th>Fresh Embryos From Non-Donor Oocytes</th>
<th>&lt;35</th>
<th>35-37</th>
<th>38-40</th>
<th>41-42</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of cycles</td>
<td>38,372</td>
<td>21,707</td>
<td>19,099</td>
<td>8,865</td>
</tr>
<tr>
<td>Percentage of cycles resulting in pregnancies</td>
<td>45.8</td>
<td>37.2</td>
<td>28.2</td>
<td>18.5</td>
</tr>
<tr>
<td>Percentage of cycles resulting in live births</td>
<td>39.9</td>
<td>30.5</td>
<td>21.0</td>
<td>11.7</td>
</tr>
<tr>
<td>(Reliability Range)</td>
<td>(39.4 - 40.4)</td>
<td>(29.9 - 31.1)</td>
<td>(20.4 - 21.5)</td>
<td>(11.0 - 12.4)</td>
</tr>
<tr>
<td>Percentage of retrievals resulting in live births</td>
<td>43.1</td>
<td>34.2</td>
<td>24.4</td>
<td>14.3</td>
</tr>
<tr>
<td>Percentage of transfers resulting in live births</td>
<td>46.1</td>
<td>36.9</td>
<td>27.2</td>
<td>16.4</td>
</tr>
<tr>
<td>Percentage of cycles with elective single embryo transfer</td>
<td>4.5</td>
<td>2.6</td>
<td>1.0</td>
<td>0.3</td>
</tr>
<tr>
<td>Percentage of cancellations</td>
<td>7.6</td>
<td>10.8</td>
<td>14.2</td>
<td>18.1</td>
</tr>
<tr>
<td>Implantation rate</td>
<td>32.6</td>
<td>24.0</td>
<td>15.8</td>
<td>8.6</td>
</tr>
<tr>
<td>Average number of embryos transferred</td>
<td>2.2</td>
<td>2.5</td>
<td>2.8</td>
<td>3.1</td>
</tr>
<tr>
<td>Percentage of live births with twins</td>
<td>32.9</td>
<td>28.4</td>
<td>22.0</td>
<td>14.9</td>
</tr>
<tr>
<td>Percentage of live births with triplets or more</td>
<td>1.8</td>
<td>2.0</td>
<td>1.5</td>
<td>0.7</td>
</tr>
</tbody>
</table>
### Thawed Embryos From Non-Donor Oocytes

<table>
<thead>
<tr>
<th></th>
<th>&lt;35</th>
<th>35-37</th>
<th>38-40</th>
<th>41-42</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of transfers</td>
<td>9,499</td>
<td>4,895</td>
<td>3,240</td>
<td>1,043</td>
</tr>
<tr>
<td>Percentage of transfers resulting in live births</td>
<td>34.0</td>
<td>30.4</td>
<td>25.0</td>
<td>20.7</td>
</tr>
<tr>
<td>Average number of embryos transferred</td>
<td>2.2</td>
<td>2.2</td>
<td>2.3</td>
<td>2.6</td>
</tr>
</tbody>
</table>

### Donor Oocytes (all ages)

<table>
<thead>
<tr>
<th></th>
<th>Fresh Embryos</th>
<th>Thawed Embryos</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of transfers</td>
<td>9,575</td>
<td>5,087</td>
</tr>
<tr>
<td>Percentage of transfers resulting in live births</td>
<td>55.2</td>
<td>31.7</td>
</tr>
<tr>
<td>Average number of embryos transferred</td>
<td>2.2</td>
<td>2.3</td>
</tr>
</tbody>
</table>

Caution: Patient characteristics vary among programs; therefore, these data should not be used for comparing clinics.
Course Description:

The purpose of this course is to engage professionals who have an interest in the practice of donating remaining frozen embryos to other couples with unmet family needs. The first section is designed to help participants: 1) become familiar with the IVF cycle and biology of preimplantation embryos, 2) appreciate the primary and secondary ethical issues associated with IVF and related procedures, 3) know the biological marker events and other facts about human embryos that others use to reference personhood, and 4) review the state of the art of the assisted reproductive technologies and how clinics demonstrate special respect for embryos.

The second session helps attendees: 1) learn the step wise process that couples with cryopreserved embryos go through in the embryo disposition decision making process, 2) become acquainted with the SART informed consent document for IVF, cryopreservation of embryos, and Disposition of Embryos statement, 3) learn the indications for cryopreservation of embryos, 4) become conversant with donor issues and obstacles, 5) become acquainted with the reasons why so few embryos are available for donation, and 6) be cognizant of the language problem that exists between the terms embryo donation versus embryo adoption.

Outcomes: By the end of the training, each participant should:

1. Describe the day to day events of the IVF cycle.
2. Define the primary ethical issue for IVF and embryo donation and determine how you would address the issue.
3. Delineate five secondary ethical issues associated with the assisted reproductive technologies.
4. List five biological markers that people use to reference personhood.
5. Recount six ways how ART clinics demonstrate special respect for human preimplantation embryos.
6. Describe the three essential questions that couples have to address in the embryo disposition decision making process.
7. List four indications for cryopreservation of embryos.
8. Name five issues and obstacles that donating couples have to address before they can decide what to do with their remaining frozen embryos.

9. Describe five reasons why so few embryos are available for donation to other couples in need.

10. Determine what term you favor, embryo donation or embryo adoption, and why.

Topics

I. Introduction
II. First Session: Science, Ethics and Medicine of In Vitro Fertilization (IVF)
III. Biology of IVF
   A. Preimplantation stage of development
   B. IVF cycle
      1. Collect sperm and eggs.
      2. Fertilization process
      3. Day three embryos
      4. Day five embryos
      5. Embryo transfer
IV. Ethical Considerations of the Assisted Reproductive Technologies (ART)
   A. Introduction
      1. Issues surrounding the beginning of life are notoriously controversial.
   B. Primary ethical issue
      1. What is the moral value and status of human preimplantation embryos?
      2. Three positions
         a) Are they “persons”?
         b) Are they “property”?
         c) Are they “nascent human life” with the potential to develop into persons?
      3. Two resources
         a) Scripture
         b) Science
      4. Good ethics should be grounded in both the revelation of scripture and sound science.
      5. Scientific facts about preimplantation embryos
         a) Biologic marker events are used to reference personhood.
         b) Completion of fertilization
         c) Formation of new unique genome
         d) New genome activated on third day.
         e) Sixty percent of embryos are genetically defective.
         f) The central nervous system and the heart start to develop one and two weeks after implantation.
         g) Each embryo has the potential to divide in two (twins), to fuse with another embryo (chimera), or to develop into a tumor (mole).
h) There is the potential for about one-third of the embryos to survive and develop into a live born person.
i) There is a natural selection process in the natural cycle as well as in the IVF cycle.

6. People consider the embryos to be either:
   a) “Persons”
   b) “Property”
   c) “Nascent human life”

C. Authentic ethical pluralism
D. Secondary ethical issues
   1. Stewardship
   2. Right of Privacy
   3. Discrimination
   4. Exploitation
   5. Social Justice
   6. Societal Responsibility
   7. Commodification

V. State of the Art of the Assisted Reproductive Technologies (ART)
   A. Introduction
   B. Fertility Clinic Success Rate and Certification Act
   C. FDA Regulations
   D. ASRM Statement on Moral and Legal Status of the Preembryo
   E. ASRM actions that demonstrate “special respect” for embryos
   F. Dr. R H Asch story
   G. CDC ART Stats and Success Rates
   H. ART complications

VI. Second Session: Embryo Donation
   A. Introduction
      1. Nachtigall study
   B. SART Informed Consent for Assisted Reproduction
      1. 27 page document requires initialing each page, signatures and notarization.
      2. Embryo cryopreservation section requires completion of “Disposition of Embryos” statement.
   C. ASRM /SART Guidelines for Embryo Donation
   D. Embryo Cryopreservation
      1. Introduction
      2. Indications
      3. Number of embryos in storage
      4. Challenge of remaining embryos
   E. Donor Options
   F. Dave and Laurie Story
   G. Embryo Disposition Decisions
      1. Lyerly study
   H. Donor issues and obstacles
   I. Frozen Embryo Transfer Success Rates
J. Embryo Donation/Adoption – Why are so few available?

VII. The Language Problem: Overcoming the language barrier
   A. Introduction
   B. Child Adoption Law
   C. Embryo Donation for Procreation
   D. Parental Roles
   E. Professional Organization Opinion
      1. ASRM / SART
      2. Social Agencies
   A. Government
      1. Federal Legislative Language
      2. DHHS Grant Language
      3. State Statutes
   B. Embryo Donation vs. Embryo Adoption
   C. Develop Consensus

VIII. Embryo Donation/Adoption: Conclusions
Embryo Donation for Procreation / Adoption - Medical Perspective

Introduction

It is not unusual for couples who have undergone in vitro fertilization (IVF) and have accomplished their family goals, to have embryos remaining in frozen storage. Donation of remaining embryos to support the family-building efforts of other infertile couples is an important option for the progenitors of these embryos. However, studies have shown that there is great reluctance on the part of IVF couples to seriously consider donating their embryos to others for their procreative purposes (1-3). The purpose of this presentation is to engage professionals to help potential donors work through the issues and obstacles associated with embryo donation and to work with ART clinics, and social agencies to promote and facilitate embryo donation for procreation / adoption. Embryo donation would likely be more strongly supported if more IVF centers provided ongoing information, facilitation, and support.

To appreciate and understand all the issues associated with the frozen embryo disposition making process, it is necessary to know something of the history, biology, ethics and practice of in vitro fertilization. IVF has become an established treatment for many forms of infertility. It is a medical laboratory procedure that creates human preimplantation embryo by the union of a sperm and egg. The main goal of IVF is to allow a patient the opportunity to become pregnant using her own or donor eggs and sperm from her partner or from a donor. This medical procedure is designed to result in the woman’s pregnancy when other treatments have failed or are not appropriate. It was introduced to the world 30 plus years ago in 1978 by Doctors Steptoe and Edwards with the birth of Louise Brown in Cambridge, England. Reference: Steptoe PC, Edwards RG. Birth After the Reimplantation of a Human Embryo. Lancet 1978 Aug 12;2(8085):366. It no longer is science fiction as depicted by Aldous Huxley in his 1932 novel Brave New World. Huxley, Aldous. Brave New World. New York: Harper & Brothers, 1946. Right from its beginning in 1978, IVF has stirred up significant ethical controversy. Those involved have been accused of “playing god” among other things.

In Vitro Fertilization: Science, Ethics and Medical Practice

Biology of In Vitro Fertilization

Preimplantation Stage of Development

The natural preimplantation stage, which occurs from about the 15th to the 21st day of a woman’s menstrual cycle, is the first seven days of human development. This stage of development happens before a woman can determine that she is pregnant by the use of a urine pregnancy test checking for the presence of human chorionic gonadotropin (hCG). It starts with the release of a mature egg from the ovary. During the first two weeks of a woman’s natural reproductive cycle, four to ten follicles begin to develop under the influence of the pituitary gonadotropins, but usually only one follicle reaches the mature state. In response to the LH surge, a mature egg is released from the follicle. The egg is immediately taken up by the tube and inseminated with sperm residing in the tube. The sperm remain viable in the tube for approximately 48 hours. The fertilized egg (zygote)
spends three and one half to four days in the tube in a shell (zona pellucida) which is 100 microns in diameter. During this time, it undergoes a cell division (mitosis) every 20 to 24 hours. The embryo then moves into the uterine cavity for two days during which it develops into a blastocyst. Late in the sixth day, it hatches from its shell and implants in the wall of the uterus. Assuming the couple does not have an infertility problem, they have a 20 to 25 percent chance every month of becoming pregnant and delivering a live born infant. IVF is the medical laboratory procedure that performs all of these functions that occur during the natural preimplantation stage of development when the embryo is formed in the woman’s fallopian tube and uterine cavity.

IVF Cycle

An IVF cycle starts out with stimulation of the women’s ovaries. The goal is to harvest five to fifteen mature eggs. In patients with an antral follicle count greater than five on ultrasound, a common protocol is to use gonadotropins, in the dose of 100-150 IU per day, starting in the early follicular phase with a GnRH antagonist added after 5-7 days to prevent an LH surge (4). Sometimes clomiphene citrate, 100 mg per day is used for five days before the gonadotropins. Estrogen levels and follicle development are monitored by frequent hormone blood assays and vaginal ultrasound. When the follicles in a woman’s ovaries reach 16 to 18 mm in size, a hormone – HCG is given to mature the eggs in the follicles. About 36 hours later, under light anesthesia, the fluid in the follicles is aspirated using an ultrasound vaginal probe and guided needle, and taken to the laboratory. The mature eggs are identified and put in culture media in the incubator. They have undergone the first reduction division (meiosis) dividing the 23 pairs of chromosomes in two with 23 residing in the eggs’ ooplasm and 23 in the extruded small polar body.
After about 4 to 6 hours, the eggs are inseminated with 10,000 to 50,000 sperm washed from the semen to initiate the fertilization process. The fertilizing sperm is essential for contributing at least three components: 1) the paternal haploid genome, 2) the signal to initiate metabolic activation of the oocyte, and 3) the centriole, which directs microtubule assembly leading to the formation of the mitotic spindles during the initial zygote development. When there is a male factor problem, the eggs are artificially inseminated by picking up a viable sperm with a pipette and injecting the sperm into the egg (intracytoplasmic sperm injection). On average, 75 percent of the mature eggs become fertilized.

After 16 to 18 hours, the eggs are checked to see if the fertilization process has started. If so, a male and female pronucleus will be observed in the ooplasm of the egg. Each pronucleus contains 23 chromosomes. At about 18 to 20 hours, the two pronuclei will fuse together (syngamy) and form a new unique genome with 46 chromosomes and a completely new set of hereditary factors. Shortly thereafter, the fertilized egg (zygote) will divide into two cells (blastomeres) completing the fertilization process. Each cell is capable of developing into an individual (totipotent).

A cell division (cleavage) occurs about every 20 to 24 hours. The first three cell divisions are initiated by the maternal genome of the egg. The new genome of the embryo starts to function on Day 3 when the embryo contains six to eight cells. The current standard practice is to transfer only one or two fresh embryos in favorable-prognosis patients and to limit the number to three in others (4-5). Each embryo has a 20 to 25 percent chance of implanting in the wall of the uterus. Several embryos are transferred to the uterus to improve the chances of a pregnancy. With improved culture media and methods, many IVF programs are now culturing the embryos for five days forming blastocysts which contain an inner cell mass (embryonic stem cells) and trophoblasts around the periphery. One or two fresh blastocyst embryos are transferred to the uterus on Day 5 or 6. Each embryo has a 40 to 45 percent chance of implanting in the wall of the uterus. The remaining embryos are cryopreserved and stored in liquid nitrogen for future use.
Numerous IVF clinics are offering their patients elective single embryo transfer (eSET) of either Day three early cleavage embryos, or Day five blastocyst embryos (6-7). eSET is used more often for younger women and is associated with a slightly reduced likelihood of a live birth, when compared with double embryo transfer (DET), but carries a much reduced likelihood of a multiple pregnancy.

The embryos are transferred to the uterus through the cervix using a small catheter. After two weeks, a pregnancy test is performed to see if the woman is pregnant. Ultrasound is done in four to five weeks to see if there is a gestational sac with an embryo with fetal cardiac activity which confirms a clinical pregnancy. The IVF cycle (in vitro) mimics the natural (in vivo) preimplantation stage of development. The average cost of an IVF cycle in the U.S. is $9,226 (8). Fourteen states have laws that address insurance coverage for infertility.

**Ethical Considerations of the Assisted Reproductive Technologies**

Why is IVF and other related technologies so controversial? Is it because the technology has become a reality and it compels us to focus on “beginning of life” issues? What defines human life? When does it begin? What does it mean to be a person? Is there a consensus on when it begins? Is there a “magic moment” when this happens? Philosophers and theologians have been debating
these abstract issues for 3000 years without any consensus.

Creating human embryos raises other ethical issues. What is the moral value and status of these embryos? Should remaining embryos be donated for adoption? For research? How should society regulate these new technologies to reap benefits and avoid harm?

**Primary Ethical Issue: The moral status and value of human preimplantation embryos**

It has been impossible to develop a consensus in our pluralistic society on “beginning of life” questions. But now that IVF is a reality, it is time for the U.S. to develop some ethical principles to define how to utilize the new technology. Public commissions in many other countries have focused on the moral status of the human preimplantation embryo and have developed public policy accordingly. The Warnock Report in Great Britain (1985) and the Waller Report in Australia (1986) are prime examples of this approach. Therefore, from a practical point of view, the primary ethical issue would appear to be: What is the moral status and value of human preimplantation embryos? The answer to this question will determine how we use the technology.

Depending on a person’s assumptions about when human life begins and when personhood is established, they will usually come to one of three conclusions. Either the embryos are “persons”, or “property”, or are “nascent human life” with the potential to develop into persons. Most people believe that there is a moral obligation to the embryos that are created through the IVF reproductive process. The public expects the IVF clinics to practice “responsible reproduction” and determine to what degree they should show the embryos “special respect”, and to what degree they should protect the embryo’s dignity. Most people do not believe that they are simply raw material like sperm and eggs.

It is helpful to use two very different paradigms to answer this ethical question: the faith paradigm – Judeo-Christian scripture, and the science paradigm – scientific discovery. Both are informative in establishing a bioethical position. Faith and science are partners and complement each other in revealing truth. Both resources are useful in developing an ethical opinion about the moral status of human preimplantation embryos. Good ethics should be grounded in both the revelation of scripture and sound science.

**Biblical References about Human Life**

There are numerous references about human life in the scriptures that people site, some specific and some equivocal. Below are several examples of specific references:

- God creates human beings.
  - “For you created my inner most being; you knit me together in my mother’s womb. I praise you because I am fearfully and wonderfully made.” (Ps 139:13-14)
  - God forms human beings in his image.
    - “God created man in his own image, in the image of
  - God he created him; male and female he created
them.” (Gen 1:27)

God loves all human beings.
- “For great is his love toward us”. (Ps 117:2)
- “His love endures forever”. (Ps 118:1)

Scripture is not specific about when or how the spiritual soul enters the body being formed.
- “As you do not know the path of the wind, or how the body is formed in the mother’s womb (or know how life or the spirit enters the body being formed), so you cannot understand the work of God, the maker of all things.” (Ecc 11:5 – NIV)

Judeo-Christian scripture states that all human beings:
- Are created and loved by God.
- Are marked with God’s image.
- Have a unique nature, status and worth.
- Are dignified but not divine.

Scientific Facts about Embryos

In addition to their personal beliefs and faith, people are inclined to use biological markers as reference points to help define personhood. Some people believe that nascent human life begins with the “organizing principle” that exists when the sperm penetrates the vitelline membrane of the mature oocyte thus initiating the fertilization process. However, the “organizing principle” which is under the control of the maternal genome of the egg, is activated by the LH surge which resumes meiosis (from the first meiotic arrest) in the egg and completes the first meiotic division just before ovulation. So the “organizing principle” is present in the oocyte before it exists in the zygote (fertilized egg). Others believe that personhood is established with the formation of the “new unique genome” and completion of the fertilization process at about 22 hours after insemination. Others believe that personhood is not established until after implantation of the embryo, or after formation of the primitive streak.

There is no question that the completion of fertilization (syngamy) is a significant marker event in the overall continuum of life. It is at this time that a new distinct genetic entity is established with the formation of a new unique genome. This is a common biologic marker cited by many scholars who believe that a new unique genome is the only biologic criteria required to establish personhood. Others people agree that nascent human life begins with the completion of fertilization, but the human self cannot be reduced to the human genome as though genetic completeness were a sufficient condition for the recognition of a person. Therefore, these authors assume that personhood is established after implantation of the embryo, or they believe it occurs after formation of the primitive streak when developmental individuality is established. Another interesting fact is that the new embryonic genome which is morphologically established at about 22 hours after insemination is not activated until two days later. The first three mitotic cell divisions which represent early embryo cleavage are under the control of the maternal genome of the egg. It is also of interest that a high percentage of these embryos have an abnormal genetic makeup (9-
The degree to which this occurs primarily depends on the age of the woman who provides the eggs and can vary from about 20 percent in a woman in her 20’s to about 80 percent in a woman in her early 40’s (9). For a woman 36 to 37 years of age, the average number of genetically defective embryos is about 60 percent. Chromosomal abnormalities (aneuploidies) are one of the main causes behind low pregnancy rates in humans. It occurs during the natural cycle as well as during the IVF cycle.

Aneuploidy is found in both early cleavage stage embryos and first trimester spontaneously aborted fetuses. It can result from: 1) errors at mitotic segregation during the proliferative stage in early oogenesis in the fetus producing aneuploid oogonia, 2) chromosomal nondisjunction during the first meiotic division just before ovulation, 3) premature separation of chromatids prior to the second meiotic division which is initiated by sperm penetration of the oocyte, 4) mitotic errors during early embryo cleavage producing chaotic mosaics. Most of the aneuploidy is due to errors in the first meiotic division during oogenesis; aneuploidy can also occur during spermatogenesis (11) (12). Some of these defects self-correct as the embryo continues to develop (13-14).

Other developmental events are sometimes considered to have significance for determining the status of embryos. For instance, the CNS starts to develop with the formation of the primitive streak on Day 14 and the heart starts to develop on Day 21. Four weeks after IVF, one can usually see fetal cardiac activity on ultrasound. Each embryo also has the potential to divide in two (twins), to fuse with another embryo (chimera), or to develop into a tumor (mole). But, these abnormalities have a much lower occurrence rate. Developmental individuality is established on Day 14 with formation of the primitive streak after which monozygotic twinning no longer can occur. There is the potential for about one third of the embryos to survive and develop into persons. This selection process occurs in the spontaneous natural cycle as well as in the IVF cycle.

From a biologic perspective, human reproduction is a very inefficient process. In general, two-thirds of the embryos do not survive the prenatal period. Only one-third of the embryos appear to implant even after natural conception.

We must recognize that in our pluralistic society, people have different opinions concerning the moral status of human preimplantation embryos. We should try to understand and show respect for other people’s opinions. Depending on one’s personal faith and their understanding and interpretation of the scientific facts about human preimplantation embryos, people are inclined to answer the question as to what is the moral value and status of these embryos in three ways. Either they are “persons”, or simply “property”, or they are “nascent human life” with the potential to develop into persons.

How should we deal with the diversity that exists with this ethical issue? The principles involved with “authentic ethical pluralism” can be a guide. Authentic ethical pluralism respects a person’s right to maintain their particular ethical beliefs and grants that person the freedom to express those beliefs. It demonstrates mutual respect by encouraging dialogue to gain a better understanding of the other person’s beliefs. It presumes that dialogue implies respect and intellectual honesty; it does not presuppose agreement.
In conclusion, human preimplantation embryos have a unique nature, status and worth. They deserve to be treated with “special respect” by all parties involved no matter what ethical status people give them.

**Secondary Ethical Issues**

There are other issues that impact on the practice of the assisted reproductive technologies. Below is a partial list.

1. **Stewardship** – Are we being good stewards of the gift of scientific knowledge and technology? As a society, we are responsible for utilizing the technology in an appropriate manner that is ethically sound, medically indicated, safe and effective, and socially equitable.
2. **Right of Privacy** – Patient’s rights have to be respected. They include:
   a. **Respect for Privacy** – the right to keep decisions private.
   b. **Respect for Procreative Liberty** – the right of couples to determine when and how they want to use their embryos.
   c. **Respect for Patient Autonomy** – the right of couples to make medical decisions in what they consider to be their best interest. Patient autonomy has to be balanced with professional autonomy as sometime patient’s demands can be counterproductive. An example is when patients want to transfer more embryos than is medically indicated according to professional guidelines.
3. **Discrimination** – Showing partiality in selecting which embryos are to be transferred to the uterus.
4. **Exploitation** – Taking advantage of other people for personal gain when using donor gametes.
   This issue primarily comes up when a couple pays an excessive fee to a young woman for egg donation.
5. **Social Justice** – Assuring uniform access and equal opportunity for everyone needing IVF to achieve their family goals. The assisted reproductive technologies are very expensive and usually not covered by insurance. They are out of reach for many couples who require IVF to achieve their family goals.
6. **Societal Responsibility** – Fostering (funding and regulating) the research needed to establish the efficacy and safety of the technology. Most of the IVF research in the U.S. is privately funded.
7. **Commodification** – Transforming medical practice into a commodity market and patenting the technology. Because most research and development has been funded by private clinics and institutions, it is not unusual for them to consider their scientific discoveries as intellectual property and patenting their products and procedures. This has led some people to believe that reproductive medicine is more like a commodity market than medical practice.

**State of the Art of the Assisted Reproductive Technologies**

IVF is a medical laboratory procedure used to create human preimplantation embryos for couples who have unmet family needs and have failed to become pregnant with more conventional forms of therapy. Embryos are created only by the union of a sperm and egg. Embryos are created
only for reproductive purposes. Extra embryos are cryopreserved.

The technology has widespread ramifications because IVF is not only useful as a treatment for infertility per se but has also been a gateway to numerous other biomedical advances. This is a list of some of the clinical applications that use the IVF technique:

- Assisted Reproductive Technologies (ART) use IVF to treat couples with an infertility problem not corrected with more traditional and less expensive forms of therapy.
- Preimplantation Genetic Diagnosis (PGD) is a technology available for couples with a family history of a severe genetic disease. It enables couples at risk for having offspring with a genetic disorder to have a healthy child without having to undergo prenatal diagnosis and possible termination of pregnancy.
- Embryonic Stem Cell Technology (ESCT) is in the basic science research phase, soon to move into the clinical research phase. It produces therapeutic cell lines for regenerative medicine.
- Cancer Stem Cell Research focuses on defining cancer stem cell behavior and finding therapeutic agents that destroy cancer stem cells as well as the other cancer cells.
- Genetic research studies the ESC's obtained from embryos with gene mutations for serious genetic diseases. Embryos with genetic mutations and chromosomal abnormalities that are identified with the PGD technology are valuable resources for medical research.
- Drug development and testing.

Fertility Clinic Success Rate and Certification ACT

The Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA) is the law passed by the United States Congress in 1992 requiring all clinics performing ART in the United States to annually submit their cycle and success rate data to CDC. It took five years to move the bill through Congress. Congressman Wyden of Oregon, as a patient advocate who was concerned about inappropriate utilization of the new IVF technology, initiated the process in his health subcommittee hearings in congress in 1987. The ASRM and SART representatives were concerned about improving their perceived credibility with patients and the public. The process involved the staffs of Congressman Waxman and Wyden in the House and Senators Kennedy, Hatch and later Wyden in the Senate, and the ASRM–SART presidents and staffs. It was signed by President George H. W. Bush in 1992.

The ACT requires the CDC to collect, verify and publish each year, cycle-specific data including pregnancy outcomes on all assisted reproductive technology cycles performed in the United States. It also requires the CDC to report the specific procedures and success rates for each ART clinic. As a quality control measure, 35 of 430 reporting clinics for 2007 were randomly selected for site visits to validate their reports. SART collects the data from its members and passes it on to the CDC. They audit ten percent of the ART programs each year including the outliers. Some ART clinics report directly to the CDC. The law also recommends that each ART embryo laboratory be certified by the College of American Pathology (CAP) or a comparable agency. Programs not responding to these requirements are published in the CDC annual report as
nonresponders.

FDA Regulations

In 2007, the FDA published specific regulations for donor eligibility screening and testing to prevent transmission of infectious disease when donating human tissues and cells including sperm, eggs and human embryos. (http://www.fda.gov/cber/rules/gtp.pdf)

ASRM Statement on Moral and Legal Status of the Preembryo

In 1986, the ASRM Ethics Committee described the moral and legal status of the embryo:

“The (pre)embryo is due greater respect than other human tissue because of its potential to become a person and because of its symbolic meaning for many people. Yet, it should not be treated as a person, because it has not yet developed the features of personhood, it is not yet established as developmentally individual, and it may never realize its biologic potential” (15).

Therefore, the ASRM position is that embryos are deserving of special respect, but they are not afforded the same status as persons. This statement is similar to the position that Great Britain, Canada, Australia and most other countries in Europe have assumed and which is the foundation they have used to develop public policy.

ART Clinic Actions that Demonstrate “Special Respect” for Embryos

Reproductive responsibility and accountability require ART clinics that are ASRM-SART members must treat embryos with “special respect”. Below is a list of some of the ways the clinics demonstrate “special respect” for embryos:

1. ART clinics must have a certified reproductive endocrinologist and certified embryologist on their staff.
2. Embryo laboratories have to be certified by CAP or a comparable agency.
3. All team members must show respect for embryos and exhibit professional integrity.
4. Embryos are created only by the union of a human sperm and egg.
5. Embryos are created only for reproductive purposes.
6. ART clinics must follow FDA regulations to prevent transmission of infectious diseases.
7. ART clinics must abide by the ASRM membership requirements, standards, and guidelines.
8. ART clinics must report all IVF cycle starts and outcomes and the medical director must verify the report.
9. Ten percent of the clinics and all outliers are audited on site every year.
10. Members and clinics that have a criminal record, or do not follow the ASRM-SART professional guidelines, or have persistent adverse results, are expelled from membership.
Dr Ricardo Asch Story

The Dr. Asch story is an example of what can happen when a clinic doctor and other team members do not demonstrate proper respect for the dignity and worth of human embryos. In 1995, Drs. Asch and Balmesada at the University of California, Irvine ART Clinic gave eggs and embryos to other patients without the informed consent or permission of the progenitors. When a whistleblower from the embryology lab informed the university, they did not respond. So, she went to the local newspaper, The Orange County Register. They broke the story. Because of allegations of possible criminal actions, Dr Asch fled to Mexico and Dr Balmesada fled to Chile. Several years ago, the University paid $23 million to the patients involved. In addition, an unknown sum has been paid to the whistleblower. Additional criminal and civil action remains a possibility.

State of the Art

IVF is an established medical procedure with reasonable success rates for couples with an infertility problem not corrected with the more conventional modes of therapy. Both SART and the CDC annually publish a national summary and clinic specific reports on all the ART cycles that are reported for the year. There are approximately 450 clinics in the U.S. doing about 145,000 ART cycles a year producing about 58,000 babies. More than 1% of all babies born in the U.S. are the result of the in vitro fertilization technology. It is estimated that over three million babies have been born worldwide as a result of IVF.

A woman's age is the most important factor affecting the chances of a live birth. This primarily relates to genetic programming in ovarian development and oogenesis. Oogenesis begins soon after the preimplantation embryonic stage of development. Primordial germ cells travel from the yolk sac along the gonadal ridge to the gonads. They go through a proliferative (mitosis) stage increasing from a few thousand to six or seven million. This maximum complement of oocytes exists at 20 weeks of gestation in the female fetus. The number of oocytes in the ovaries then declines naturally and progressively through the process of atresia. The number of oocytes decreases to approximately one to two million at birth, 300,000 to 500,000 at puberty, 25,000 at age 37 years, and 1,000 at age 51 years, the average age of menopause in the United States. As a woman in her reproductive year's ages, the quality of her eggs also deteriorates. Fecundity declines gradually but significantly beginning approximately at age 32 years, and decreases more rapidly after age 37 years. The age-related decline in fertility is accompanied by a significant increase in the rates of aneuploidy and spontaneous abortion (16).
The CDC 2007 Assisted Reproductive Technology Success Rates report states that the standard IVF cycle accounts for 72 percent of the total ART cycles. The average live birth rate per transfer cycle is 36 percent. It varies from 50 percent in young women in their 20’s to 12 percent at age 42. The miscarriage rate is 10 to 15 percent but starts to significantly increase at 37 years of age and is 40 percent at 43 years of age. Frozen embryo transfer cycles make up 16 percent of the ART cycles. The average live birth rate for frozen embryo transfer cycles is 30 percent, but it can vary from 34 percent in young women to 15 percent in older women. Egg donor cycles account for 12 percent of ART cycles. The mean live birth rate for egg donation IVF cycles is 55 percent primarily because egg donors usually are young fertile women in their 20’s. Approximately 32 percent of the pregnancies are multiple pregnancies with 30 percent twins and 2 percent triplets or more (17).

The problems associated with IVF include: 1) ovarian hyper stimulation, 2) multiple pregnancies, and 3) remaining unused stored cryopreserved embryos. The ASRM and its membership are actively involved in addressing these problems.

Percentage of ART Cycles that Result in Pregnancies & Live Births
Embryo Donation to another Infertile Couple for Procreation / Adoption

Introduction

Couples who undergo the in vitro fertilization process frequently end up having remaining embryos cryopreserved and stored in liquid nitrogen. The challenge is, what should be done with the remaining frozen embryos that: 1) Are a by-product of the IVF system? 2) Were originally created for reproductive purposes? 3) Are no longer targeted for the progenitors’ use?

In a University of California, San Francisco interview survey of patients in three large IVF practices, Nachtigall et al., (2) identified 77 families with stored embryos who had not made a disposition decision at the time of recruitment. They averaged two living children per family, seven stored embryos per family, and the mean number of years in storage was seven years. They found that while embryo disposition decision making was influenced by individual life circumstances, embryo quantity/quality, personal values, embryo conceptualization, and clinic information, it was a stepwise process that could be represented as three sequential questions:

1. Will the embryos be used for additional attempts at conception? If not,
2. Will the embryos remain in storage? And if not,
3. Will the embryos be donated to other people or to science, or will they be destroyed?

While most couples reported having little or no discussion about embryo disposition throughout the year, except when the bill arrived, they also regarded the decision as an important one that should be made with adequate time and care. Despite a median annual storage fee of $500, almost two-thirds (63%) of participant families kept their embryos in storage after 5 years, either passively through disagreement or indecision, or actively to maintain embryo potential, avert feelings of loss, or as psychological or genetic “insurance”. They found that IVF clinic support and detailed information about their options motivated families to make disposition decisions.

ASRM Practice Committee 2006 Guidelines for Gamete and Embryo Donation

It is the purpose of these guidelines to provide the latest recommendations for evaluation of potential embryo donors, incorporating recent information about optimal screening and testing for sexually transmitted infections (STI’s), genetic diseases, and psychological assessments. The current document represents an effort to make the screening guidelines for embryos more consistent and incorporated recent information from the US Centers for Disease Control and Prevention (CDC), US Food and Drug Administration (FDA), and American Association of Tissue Banks (AATB). It should be noted that these guidelines represent minimum standards for screening, testing, and counseling of potential donors and recipients (18). The federal government has published minimum requirements for embryo donation (http://www.fda.gov/cber/rules/gtp.pdf). Some states and other localities may have laws or regulations that pertain to embryo donation that may supersede these guidelines.
SART Informed Consent for Assisted Reproduction

SART has a very extensive 27 page informed consent document that many member clinics use. Couples have to fill it out before they enter into an IVF cycle. Part of the form is a 7 page “Disposition of Embryos” statement that couples who chose to freeze eggs must complete before freezing. The statement covers a variety of situations and choices the couple has with regard to the disposition of their embryos that remain in storage. The couple is free to submit a statement at a later time indicating different choices, providing they both agree in writing. The first page of the document requires signatures of the patient, partner, physician/witness and dates. All pages require the initials of the patient and partner. The last page requires their signatures, date of birth, date of signing, and a Notary signature and date.

The first part of the document covers four areas including:
1) In Vitro Fertilization
2) Intracytoplasmic Sperm Injection
3) Assisted Hatching
4) Embryo Cryopreservation

The second part covers:
1) Risks to women
2) Risks to offspring
3) Ethical and religious considerations
4) Psychosocial effects of treatment
5) Alternatives to IVF
6) Reporting outcomes
7) References
8) Disposition of Embryos statement (19).

Cryopreservation of Embryos

Freezing of embryos not transferred after egg retrieval is a common IVF practice in 99% of the clinics. Freezing of eggs is possibly less successful than freezing embryos. The goal is to harvest from 5 to 15 mature eggs. On average, 75 percent of the eggs will fertilize. More embryos are developed than is considered appropriate for transfer to the uterus in the fresh state. The current standard practice is to transfer only one or two fresh embryos in favorable prognosis patients and to limit the number to three in most others. The extra embryos are cryopreserved for future use. Approximately 70 to 75 percent of the frozen embryos survive the process of freezing and thawing.
Indications for cryopreservation are to:

- Reduce the risk of multiple pregnancies. The goal is to transfer no more than two embryos, accepting a 15 percent twin pregnancy rate with no triplet pregnancies.
- Increase the chance of having one or more pregnancies from a single cycle of ovarian stimulation.
- Minimize the medical risk and cost to the patient of repeat stimulation cycles.
- Temporarily delay pregnancy when there is a high risk of ovarian hyper stimulation syndrome (OHSS).
- Preserve fertility potential (cancer, surgery) (19).

The question is often asked whether the problem of accumulation of embryos in frozen storage might be solved by freezing unfertilized eggs and inseminating only those that will be used in a given transfer cycle. In fact, although some investigators have recently reported excellent pregnancy rates from eggs frozen, thawed, and subsequently fertilized (reference: Cumulative ongoing pregnancy rate achieved with oocyte vitrification and cleavage stage transfer without embryo selection in a standard infertility program.


Hum Reprod. 2010 Feb 25. [Epub ahead of print]) this technique remains experimental, requires institutional review board approval, and may not be as reliable as cryopreservation of embryos.

Number of Embryos in Storage

It would be of interest to know how many embryos are stored in liquid nitrogen in the ART clinics and other storage facilities in the United States. One of the initial studies by the SART-RAND team concluded that there were about 400,000 embryos stored in the United States in 2002 (20). 9,225 (2.25%) embryos were available for donation to another couple. Most observers now estimate that there are approximately 500,000 embryos in storage.

Donor Options

The problem exists mostly for couples that have been successful with IVF and have fulfilled their family goals without using all of their embryos. So, they have a difficult ethical dilemma, what is referred to as the “the paradox of blessedness”. What should they do with the remaining cryopreserved embryos that are stored in liquid nitrogen? The couples’ disposition decision is inherently complicated by the variety and disparity of the potential embryo uses and outcomes: 1) They can be used by the couple in further attempts to conceive. 2) They can be donated to other infertile couples who wish to have a baby. 3) They can be used in medical research. 4) They can be abandoned. 5) They can be destroyed with or without a discard ceremony. 6) They can be disposed
of by intentionally transferring them at a time that precludes implantation. 7) Or they can be stored indefinitely. It is important to note that the husband as well as the wife has equal ownership and decision making authority for the embryos.

Dave and Laurie’s Story

David and Laurie’s story is an excellent illustration of the difficulty that couples have with the embryo disposition dilemma. The time line is May 2006. They had an infertility problem (male) that did not respond to conventional therapy. They went through an IVF cycle July 2002 in Grand Rapids, Michigan. Eight eggs were retrieved from Laurie. Six eggs fertilized and developed into good embryos. Two day three fresh embryos were transferred and the other four embryos were cryopreserved and stored in liquid nitrogen. Twins, Michael and Thomas, their pride and joy, were born in March 2003 at 32 weeks weighing 3 and 4 lbs. They are now healthy three year olds.

So, what should they do with the four remaining cryopreserved embryos? They do not want any more children of their own. Dave wants to donate the embryos to another couple but Laurie because of her attachment to the embryos cannot do that. She wants to donate the embryos for research. This partly is because Laurie’s 71 year old mother fell two weeks ago and has a spinal cord injury (quadriplegic) and is a patient in Mary Free Bed Hospital in Grand Rapids. They receive a storage bill every six months, discuss the issue for one to two weeks, can’t decide what to do, pay the bill and repeat the process in six months.

Embryo Disposition Decisions

Both clinical experience and the relevant medical literature have made it abundantly clear that the embryo disposition decision is very challenging for couples with frozen embryos in storage. This is the case even though the informed consent process addresses this subject prior to initiating the first IVF cycle and cryopreserving embryos. Several studies have offered significant insight into why this decision is so difficult. Nachtigall et al., 2005, (1) reported their findings on interviewing 58 couples who had conceived using donor oocytes and had frozen embryos in storage. With an average of 7.1 embryos per couple, and a mean of 4.2 years in storage, 72 percent of the couples had not reached a disposition decision. Most of the couples had not anticipated or appreciated the consequences of having more embryos than they would use. Analysis of the interview tapes identified two major interrelated findings associated with embryo disposition decisions. The first was that the disposition decision process roughly followed four sequential stages:

Stage 1. Reassurance – While undergoing IVF treatment, couples are initially focused on the immediate goal of achieving a pregnancy. They are reassured by having large numbers of embryos. The ability to store surplus embryos is viewed as a bonus. They do not anticipate that having remaining embryos will present a challenge in the future.

Stage 2. Avoidance – Once pregnancy has been successfully achieved and their child bearing is completed, most couples spend little time thinking about their frozen embryos. They avoid the issue by just keeping the embryos frozen in storage, often with the implied
assumption that the decision could be postponed, perhaps indefinitely.

Stage 3. Confrontation – This stage is often prompted by storage bills or reminders from the embryo storage facility. When couples actually begin to confront the disposition decision, their reaction is frequently one of discomfort and uncertainty. Yet couples also felt the importance and weight of the decision and wanted to make a responsible and moral determination. Many couples felt isolated and expressed the desire to talk with other couples who were in the same position.

Stage 4. Resolution – A quarter of the interviewed couples were able to come to a united disposition decision for their embryos and acted on it. Those couples who were able to come to an agreement frequently expressed a profound sense of completeness and resolution.

The second major finding in the Nachtigall et al., 2005 study is that the factor that contributes most significantly to the difficulty of the disposition decision is the complex nature of the couples’ conceptualization of their embryos. They found that not only do virtually all couples recognize their embryos’ potential for life, but their conceptualizations also incorporate a wide variety of deeply personal meanings that complicate their ability to reach a disposition decision. While some couples thought of their embryos as little more than biologic material, some couples envisioned their embryos as living entities with the capacity to experience discomfort and even suffering and were thus unable to contemplate their destruction. Many thought of their embryos as “virtual” children that had interest that must be considered and protected. The thought that the welfare of these “children” might not be under their control was a major issue when couples considered donation to another infertile couple. They were also concerned about the possibility of their living children inadvertently meeting and starting a relationship with a child conceived from one of their embryos.

There were other elements of the parents’ conceptualization that complicated embryo disposition decision making. Some couples considered the potential value of their frozen embryos as a kind of genetic or psychological insurance policy as possible replacements for their living children if any were lost through illness or accident, or that their embryos might provide some medical benefit to their living children at some future time. The authors conclude that parents’ deeply personal conceptualizations of their stored frozen embryos are a major factor in their ambivalence, uncertainty, and difficulty in reaching a disposition decision.

In a multi-institutional U.S. survey by Lyerly et al., published in 2008 (3), 1244 fertility patients’ views about frozen embryo disposition were evaluated. Eighty two percent (1020) of the patients currently had stored embryos. Seventy five percent of the patients with embryos had IVF children previously. Seventy percent of the patients with embryos delayed their decisions five years or more. As one of five response categories in the questionnaire, they found that 54 percent of respondents with cryopreserved embryos were very likely to store them for future pregnancy attempts, 21 percent were very likely to donate the embryos for research, and 7 percent were very likely to choose to donate the embryos to another couple. In another response category, 55 percent were very unlikely to thaw and dispose of the embryos, 31 percent were very unlikely to donate the embryos for research, and 59 percent were very unlikely to donate their embryos to another couple
trying to have a baby. Even though for patients, disposition of remaining cryopreserved embryos is a decidedly private matter requiring difficult and agonizing deliberations, as a public policy matter, this study and the one above clearly define the challenge to professionals and society to promote embryo donation for procreation to another couple with unmet family needs.

Donor Issues and Obstacles

Couples are frequently overwhelmed with the number of issues involved with embryo donation to another couple. Because of equal ownership and decision making authority, the couple has to agree on the decision unless one member defers to the other. Donor issues and obstacles include:

- Options - different options have different consequences for the couple.
- Time factor – how long should they wait before making a final decision?
- Profiling & preferences – to what extent do they want to dictate their desires to the recipient couple? Should the recipient couple be allowed to have preferences?
- Levels of openness – is remaining anonymous in the best interest of the offspring?
- Relationship to recipients and to offspring – do they want to have access and visiting rights with the recipient family and potential offspring?
- FDA regulations – do they want to have all the tests and screens to make sure they are not transmitting any infectious diseases? Who is going to pay for the tests and screens if a recipient couple is not identified right away for the stored donated embryos?
- Psychological assessment – should a psychological assessment and background check be routine for both parties?
- Ethical, legal and risk management issues – they must be aware of these issues and seek council for advice.
- Effectiveness of embryo transfer – is the quantity and quality of their embryos sufficient to warrant going through the donation process?
- Cost – Who is going to pay the medical, laboratory, consultation and legal fees?

Frozen Embryo Transfer Success Rates

The success rate for frozen embryo transfer cycles resulting in live births varies. It is 29 percent for non-donated embryos and 35.5 percent for donated embryos (21). The higher rate for donated embryos appears to be due to better quality of the donated embryos because: 1) Embryos are donated by couples who previously have had successful IVF cycles, and 2) The embryos come from younger women. In a study published by Finger et al. (22), the average cost of embryo donation for seven programs was $7,806.
Embryo Donation/Adoption

Why are so few embryos available for donation to other couples with unmet family needs? Following is a list of the more common reasons:

1. Embryos are highly regarded by progenitors.
2. IVF is arduous, stressful, life altering, and expensive.
3. Excess embryos are just as much the result of love and great sacrifice as the ones they use.
4. Each progenitor has equal ownership and decision making authority. Therefore, they have to be in complete agreement or one has to defer to the other.
5. Counseling, which may not be available, is required with an experienced facilitator to:
   a) Match profile and preferences issues between couples.
   b) Explore the various levels of openness that can exist between the couples and their siblings.
   c) Evaluate psychological, social, legal issues.
6. Risk management is necessary to reduce liability by proper informed consent, background checks and legal contract agreements.
7. Couples must weigh each option against their consciences, personal ethics, religious convictions, and their family values.
8. Each decision is hard won and deserves respect.

The Language Problem: Embryo Donation versus Embryo Adoption

Language matters. It is not just a matter of simple semantics. Distinctions are significant in the context that language defines ethical, legal, and social status which can impact practice, procedures and rights in powerful ways. In “Legal and Ethical Challenges of Embryonic Adoption”, John Mayoue states that, “The greatest challenge to the notion of human embryo adoption stems from fundamental disagreement and uncertainty as to the legal and ethical status of an embryo” (23). How can we overcome this barrier without side-tracking our mission?

Child adoption law applies after childbirth and governs the act of adoption. Birth parents terminate their parental rights to the child born to them. Following a court order, the child is placed with a court approved adoption family. They are granted all legal rights and responsibilities associated with caring for the child.

Embryo donation to another couple for their family building involves the transfer of embryos from a donor couple to a recipient couple. It requires proper informed consent and a legal contract which states the specific conditions and terms of the agreement. The recipient couple to whom a child is born has their names on the birth certificate and is recognized by the State as the infant's legal parents.

Parental roles can be defined in different ways including: 1) biologic (genetic) parents, 2) birth parents, and 3) rearing parents. When embryos are donated to other couples, the donating couples are the genetic and biologic parents, but the recipient couples mother is also a legitimate
biologic parent, and the couple are the “birth parents” and the “rearing parents”.

**Professional Organizations**

Professional organizations can vary as to what language they favor. The American Society for Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology (SART) favor the embryo donation language. Social adoption agencies favor the embryo adoption language.

In a letter to the National Embryo Donation/Adoption Advisory Board, Steve Ory, President (2008) ASRM stated that “… (your) decision to use the term “adoption” creates insurmountable legal, moral, and political difficulties for our patients and membership”.

Sean Tipton, ASRM Director, Public Affairs says “… we are happy to assist efforts which will help patients understand all their options for building their families, including adoption of existing children and embryo donation. However, we cannot be involved in any project which attempts to further the use of the term “adoption” of embryos”.

**Government**

The Federal legislative language in the Senate Committee on Appropriations report uses the term “embryo donation and/or adoption”. The DHHS grant language also uses the term “embryo donation and/or adoption”.

The language in State statutes can be different. Seven States use “adoption” language. Five States use “donation” language. Three States use both “donation” and “adoption” language. All States differentiate “embryo donation for adoption” from child adoption. No State requires a court order except Louisiana whose mandates are ambiguous.

**Embryo Donation versus Embryo Adoption**

The key issue appears to be the moral status of the human preimplantation embryo.

- Those who consider the embryo to be an “unborn child”, favor embryo donation for adoption language.
- Those who consider the embryo to be “nascent human life” with the potential to develop into a person after implantation, favor embryo donation for procreation language.
How is the issue diffused so that it does not detract from the mission which is to increase public awareness and promote the donation of remaining embryos to couples who wish to bear and raise children? We must:

- Recognize that in our pluralistic society, people have different opinions concerning the moral status of human preimplantation embryos.
- Try to understand and show respect for other people’s opinions and dialogue with them.
- Stay focused on our singular mission to promote the donation of remaining embryos to couples with unmet family needs.
- Not get distracted with other controversial issues.
  - The abortion debate.
  - Embryonic stem cell research.
  - Reproductive or therapeutic cloning.
  - Whether IVF is legitimate medical therapy.

### Embryo Donation/Adoption; Conclusions

1. Human preimplantation embryos have a unique nature, status and worth. They deserve to be treated with “special respect” by all parties involved.
2. Couples, who regard the human dignity and worth of their remaining embryos, are interested in the medical, legal, and social aspects of a transfer system that makes it possible to donate their embryos to other couples with unmet family needs.
3. There is a great need for available counseling to help couples make a decision.
4. There is a great need for organizations to act as facilitators to implement the embryo donation - adoption process.
5. It is morally feasible to donate remaining embryos to another couple for procreation / adoption.
6. Saving lives through embryo donation for procreation is morally more compelling than discarding the embryos.
7. It would be ideal if all couples who have cryopreserved embryos stored for three years or more would automatically receive an invitation to meet with a counselor or agency to discuss donation of their embryos to other couples with unmet family needs.
8. We must encourage cooperation and team work between the ART clinics and social agencies.
9. We must recognize that the potential offspring have the most compelling interest when an anonymity versus openness policy is being considered.
10. We must do what is in the best interest of the potential offspring.
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4. Muasher SJ, Garcia JE. Fewer medications for in vitro fertilization can be better: thinking outside the box. Fertil Steril; 2009; 92:1187-1189


17. CDC 2007 Assisted Reproductive Technology Success Rates: National Summary and Fertility Clinic Reports.


23. The Morality of Adoption, Timothy P Jackson, Editor, Chapter “Legal and Ethical Challenges of Embryonic Adoption”, Mayoue JC.
Course Description:

Traditional adoption and custody law has been challenged by clinical advances in Assisted Reproduction Technology (ART), especially as they relate to embryo transfer and adoption. While “embryo custody” cases in divorce proceedings have been widely publicized, changes in family law and child custody law have had more legal impact in embryo adoption practice. Review of relevant case law, statutory law, and legislative initiatives show the areas of concern for donating and adoptive parents, as well as how certain states and court decisions have encouraged stability in the practice. Recommendations for principles that should guide legislative change will be made after a careful review of the current law.

Outcomes: By the end of the training, each participant should:

1. Understand the conflicts in the law governing embryo transfer and adoption

2. Understand the principles by which a court decides custody cases when multiple parties claim maternity or paternity

3. Recognize situations that cause conflict in the law, and predict their outcome

4. Be able to advise prospective parents seeking either embryo donation or embryo adoption of their basic legal rights, and help them anticipate and avoid problems

Topics:

I. The rationale for Embryo Adoption

II. The challenges to developing a consistent public policy toward Embryo Adoption

III. Assumptions for the Discussion

IV. Legislative Response to Embryo Adoption

V. Academic Commentary

VI. An Historic Review of Adoption Law

VII. The Unsolved Problems Created by IVF/ART
VIII. A Review of Recent Case Law Arising from Custody and Support Conflicts for Children Born Using IVF/ART

IX. Embryo Disposition: Case Law

X. Embryo Disposition: Common Themes in the Law

XI. Summaries of Case Law, Statutory Law and Legal Commentary

XII. Model Legislation from Various Sources

XIII. Governing Principles: Suggestions for Model Legislation

XIV. Conclusion/Summary
An Introduction to the History of Family Law

“LAW IS, INDEED, AN HISTORICAL GROWTH, FOR IT IS AN EXPRESSION OF CUSTOMARY MORALITY WHICH DEVELOPS SILENTLY FROM ONE AGE TO ANOTHER.”

-B. CARDOZO


Nothing is more fundamental to the human experience than the quiet enjoyment of family. Traditional family law in the United States derives in large part from English Common Law, which was concerned not only with the sanctity of marriage and family, but also with inheritance of land and property.

The family was considered to be the foundation of a peaceful and lawful society, with children (as the biological offspring) the singularly most important asset of the family. Parents enjoyed both the legally unfettered benefits and the obligations of their children. Before the development of genetics as a science and the recognition of the modern concepts of embryology, the place of children in a family was defined by marriage, socially accepted sexual intimacy, pregnancy and birth. Young children were treated as the “quasi-property” of the family, under the sole control of the parents. Children were not only full members of a family but were also a valued economic resource. Even today, a couple will refer in ordinary English language usage to a child as “our child” in distinction to another’s child, defining the child as somehow belonging to a limited community, and not to society as a whole. In old English Common Law, a dependent child’s soul might belong to God, but his physical being belonged to the family.

Family Law in both England and the United States assumed that the parents of the child would act “in the best interest” of their children, protecting both the physical and mental well being of the child. Until the 20th Century, very few laws allowed a court or any outside party to step between a parent and child in normal or even extraordinary child-rearing decisions. In order to avoid social chaos and to further the best interests of the child, the common law recognized only one father and one mother for any single child. In ordinary circumstances, motherhood was defined by gestation and birth, and fatherhood was defined by the relationship of a man to the mother at the moment of the child’s birth. Prior to genetic typing, paternity was assumed to be that of the husband, without the possibility of a legal challenge absent the husband’s consent.

Legal adoption was not recognized in law until the mid-1800’s in the United States. By the early 1920’s, every state had a statute concerning adoption, some limited and others broad in their scope. All statutory law in the United States incorporated the common law determination of one father and one mother for a child, without the possibility of more than two parents. Further, a mother was assumed to be female, and a father male. With the widespread application of adoption law, it became legally possible for a child to have either a gestational/biological mother or rearing mother, and either a biological father or rearing father. Therefore, a child might have four different
combinations of parents, one of which could have legal custody of the child: a biological/gestational mother and a biological father, a rearing (adoptive) mother and a biological father, a rearing (adoptive) father and gestational/biological mother, and a rearing (adoptive) mother and father. Today, all states have common law and statutory law that deals with each of these situations in well-defined terms.

Following the development of the science of genetics, more detailed information concerning embryology, and the recognition of the biology of human reproduction, the legal determination of paternity no longer relied entirely on the consent of the husband. Genetic typing became available in family law courts (as blood typing) by the middle of the 20th Century, used almost exclusively to determine paternity in cases of non-married parents, and in situations where the husband denied fatherhood. It was not until recent the development and widespread use of in vitro fertilization (IVF) or Assisted Reproductive Technology (ART) as a medical therapy for infertility that traditional family law was forced to change, to assign a single mother and a single father to a child that would not have been born before the science advanced, and to develop law where none was necessary before IVF/ART was available.

Both the common law and the statutory law have changed in an attempt to determine the legal status of putative “parents” in the face of bewildering reproductive technology. However, there is significant disagreement between the states on what law should be applied, and there is no consistency in a number of difficult possible scenarios.

As will be discussed in more detail (below), there are a number of recently recognized ways in which a man or a woman may establish legal parenthood. These changes have increased the number of possible “father” and “mother” pairings or combinations of persons that may claim to be a child’s parents. Where the law previously recognized only 4 possible combinations, 12 now exist. In a state that allows same-sex marriage, the possibility of parenthood for same-sex parents increases the combinations of ways any two persons may be declared to be a child’s parents to 34. Statutory and case law in a few states has dealt as many as 12 of these 34 possible combinations, allowing some and denying others. The remainder have simply not been litigated.

Despite all of the changes we have seen in the last 25 years, certain bedrock principles still remain in the law concerning children and parental rights. First, the a court will find only two legally recognized parents for any one child. Second, with few exceptions, legal parents continue to have a broad latitude in how and where children are raised. Third, gestation (for a woman) and a biological relationship (for a man and a woman) remain the most important factors in custody determinations. Finally, family law has been applied to born children only. Embryo adoption is largely an uncharted area of law that is still developing.

Adoption Law and Custody Law: Response to IVF/ART

Social changes in family structure and family planning have created an increased demand for assisted reproduction. Career building by utilizing family planning and planned fertility have become broadly accepted by young women. Delayed marriage and delayed reproduction have increased infertility rates, at the same time that legal abortion has decreased the number of infants
and children available for adoption by infertile couples seeking a first or additional child later in life. What began as an option for the few has become a necessity for the many.

Until the recent attention focused on surrogacy and the use of embryo implantation for family-building, little conflict with existing family law principles existed. IVF/ART has been treated in the law as part of personal reproductive freedom: private, personal, unregulated as to actual practice, focused on patient safety. The few conflicts with family law that did exist were solved by statute. For example, statutory law controlling semen and oocyte donation, if the donation was done anonymously through a registered facility under the supervision of a physician, severed all claims of paternity based on genetic relatedness. Since both sperm and egg cells were considered pre-conception (pre-embryo) and thus not fully human tissue, uniform tissue donation statutes did not apply.

Some of earlier reported cases established the common law principles used today. People v Sorensen (Supreme Court of California 1968) was an appeal by Mr. Sorensen of his conviction for failing to provide child support for a child he claimed “was not his.” During marriage, his wife became pregnant using artificial insemination (AI) of donated sperm. The procedure was conducted by a physician, with Mr. Sorensen's encouragement and support. The Court ruled that even though the child was not genetically his, “it was lawfully begotten and was not the product of an illicit or adulterous relationship.” By his support, Mr. Sorensen “was directly responsible” for the child's existence, the sperm donor could not be held to be liable, and thus Mr. Sorensen's conviction for lack of child support was upheld. The court mentioned in dicta that had Mrs. Sorensen undergone AI in secret or against her husband's wish, the child would not be his to support. The California legislature codified this case in 1975 (Civil Code sec 7005 Uniform Parentage Act), focusing on the safety of professional involvement in the procedure, the anonymous (and therefore “arms length”) donation of the sperm, and the open participation by both a husband and wife in the procedure as required factors to assign paternity to anyone other than a biological (genetic) father. Jhordan C v Mary K. (California Court of Appeal, 1986) applied the statute to a different set of facts. Mary and Victoria were a lesbian couple that convinced a male friend, Devin, to provide his sperm for an in-home, non-professional artificial insemination (AI). Mary became pregnant, and after delivery of the child (Jhordan), successfully sued Devin for child support. Devin agreed to pay support, but also wanted open visitation as Jhordan's father. When Mary and Victoria refused, Devin brought suit. The court ruled that the fact that the AI was not done within the terms of the statute prevented Mary from blocking Devin's paternity claims, that Devin was the biological and legal father, and that visitation arrangements must be made. Of note, Victoria, who was neither a gestational mother nor biologically related to Jhordan, had no parental rights, and could not interfere with Devin's visitation of Jhordan. This case stands as a reminder that absent a statute governing conception and birth, a sperm donor may assert paternity rights as a biological father, and be held to any financial obligations to raise the child.

In one of the first cases involving embryo transfer, Buzzanca v Buzzanca (California Court of Appeals, 1998) the court reached back to the Sorensen case to decide custody and support. While married, the Buzzanca's arranged for a surrogate to gestate a donated embryo, planning to adopt the child at birth. Before the child was born, they divorced. Mrs. Buzzanca took custody of the child (Jaycee) at birth, and sued her ex-husband, John, for support. He defended on the
grounds that he was not the genetic father, that they had divorced before the child was born, that the child was not born by his ex-wife but rather by a surrogate, and therefore he had no relationship with the child. The court ruled that John had a legal obligation of support because he had “caused Jaycee’s conception every bit as much as if things had been done the old-fashioned way.” The court did not consider the surrogate (gestational) mother nor the gamete donors used to create the embryo as legally responsible, since those three parties were neither making a claim nor were they able to be found.

After the Buzzanca case, California recognized a new standard by which parental rights and obligations could be asserted. “But for the Buzzanca’s intentions, the child would not exist.” If you intend to bring about the birth of a child and your actions are central in causing that birth, you can claim paternity or maternity, and you may be liable for support of that child.

The development of the child custody case law when ART was used for conception built on the underlying principles and assumptions of previous family law as well as social values. Prior to the use of ART, causation (intent to conceive) was imputed to the mother: “You could have said no.” Further, since abortion was legalized by the United States Supreme Court in Roe v Wade (1973), gestation rather than (or in addition to) conception became the implied causation standard for the mother. Causation for the father was imputed by the determination of biological paternity (“You broke it, you bought it”) even when he had no actual intent to conceive a child. Therefore, the concept of intent to cause the birth of a child was not actually new, but was rather a “teasing out” of an imputed principle within previous legal concepts. When gestation and biological paternity were no longer essential elements of parentage due to the practice of ART, the court looked at the actual intent of the parties to determine who would be the responsible parents of the child.

Therefore, under current family law practice, it is possible for a woman to claim maternity by being the biological (genetic), gestational, rearing and intentional mother of a child. A man may claim paternity by being the biological (genetic), rearing or intentional father of a child. However, all of these claims are subject to statutory or common law limitations, and vary widely from state to state. For example, courts in some states have ruled that intent is not enough to establish paternity for an unmarried couple who used semen donation (IVF) to achieve pregnancy. Further, a number of conflicts in the law have not been litigated, and are without a clear answer. For example, in a state that recognizes same-sex marriage, if one partner provides an oocyte, uses an anonymous sperm donor to create an embryo that the other partner gestates, are there two parents (two mothers) or just one? Traditional family law specifically recognizes only one (female) mother and one (male) father. Assume that the same state had adopted a version of the Uniform Parentage Act that provides that a gamete donor cannot be a parent if the donor uses a registered ART clinic. Thus, the partner who gestated the child
would be the only legal mother and parent, thwarting the clear intent of one of the partners, and achieving the illogical result that a genetic parent cannot claim parentage.

The Legal Status of the Human Embryo: Medical Practice and the Law

Against this background of custody law, the ethical practice of embryo creation, preservation and disposal began to develop slowly. Ethical statements by professional organizations that have formed current medical practice began in earnest in the 1980's, and have continued to evolve. Unfortunately, some of the early warnings and concerns were not heeded by all ART clinics, and some additional unexpected problems have arisen over time as the number of ART procedures increased. One significant issue today is the legal and moral status of over 500,000 cryopreserved embryos. While the majority of these embryos remain in storage at the request of the original biological/genetic parents, a significant percentage remain in a frozen state without an obvious future disposition. Recognizing that State and Federal law govern many aspects of the handling of these embryos, and the fact that not every option is available in every state, four dispositions are possible under current law in the United States: (1) Implantation to achieve pregnancy; (2) Experimental use, such as stem cell research; (3) Discarding with the intent to destroy the embryo; (4) Continued and indefinite cryopreservation. One possible use of the embryo increases the possibility of pregnancy: that is, embryo transfer or adoption. It has been estimated that 2% of the current cryopreserved embryo pool would be readily available for donation/adoption. While this is not a large number, it is nonetheless a critically important resource for infertile couples who cannot afford all methods of ART or achieve pregnancy by any other technique.

The practice of embryo donation/adoption has proceeded in limited numbers for more than a decade. One of the best known organizations encouraging the practice is Snowflakes Adoption Agency of Fullerton, California. However, the an obstacle to the more widespread use of embryo donation/adoption has been the perceived legal status of the embryo. “Significant practical roadblocks exist, however, to the application of an adoption model, as the vast majority of states do not permit the pre-birth termination of parental rights....[E]mbryo donation or adoption...is far from being as ‘settled’ as is the law regarding custody or inheritance disputes.”

The courts have struggled with the issue of “Who or What is the human embryo” for nearly 20 years. Is the embryo a person with full protection of the law, property that can be disposed of at will, or “something in between,” neither person nor property, nonetheless due greater respect than mere tissue? Lower court decisions have frequently recognized the human embryo as a legal person, only to be reversed on appeal. While legal commentary and case law has proceeded since 1992, the findings and dicta of the Tennessee Supreme Court in Davis v Davis (1992) have been used to analyze most of the subsequent disputes. There, the court treated the embryo as neither person nor property, threading the difficult path between both extremes. Rather, the human embryo was considered human life subject to “special respect” due to the potential for development into a born human being. Using the principle of “special respect”, and defining the embryo is neither person nor property, various courts for various reasons, based on unique facts, have treated the disposition of the embryo using both family law and property law principles. As in other areas
of law that are ill-defined, courts have used, sometimes manipulated, existing law to reach “fair and just” outcomes, rather than starting out with first principles that compel any one decision.

Certain conclusions have emerged from the case law. First, no court has bared progenitors from agreeing in advance to transfer an embryo to a third party, and will allow the transfer if all parties currently agree. No public policy concerns would therefore prohibit the transfer of an embryo to prospective parents (defined here to mean a couple or woman willing and able to take responsibility for the birth of a child resulting from a pregnancy caused by the embryo), even when the original progenitors are not able to be found or have died. Second, in the case of a dispute between the progenitors, legal arguments protective of reproductive freedom apply equally between men and women. The line of cases beginning with Roe v Wade (1973) that define abortion rights have been ruled not to give a woman unique rights in embryo disposition, since her bodily integrity is not implicated. However, the party who wants to avoid reproduction by disposing of the embryo (destroying the embryo) typically has prevailed. The legal reasoning behind these decisions has focused on the right not to reproduce as fundamental to both men and women: the right to avoid offspring was considered the lynchpin of the current reproductive freedoms law. However, no case has been litigated where the right to procreate has been squarely at issue. Skinner v Oklahoma (1942) established that the right to have offspring is a fundamental right. If it were impossible for either progenitor to have a child other than by the use of their own cryopreserved embryo, would the court’s reasoning change? Finally, no case has addressed a conflict between a (former) husband and wife who both want to use the embryo for reproduction, but cannot agree on who is to gestate the child.

The struggle in the case law has been to develop a language - a vocabulary - that describes what a couple does when they allow another couple (or a person) to take possession of an embryo they have created, for the purpose of conceiving a living child. If the embryo is property, it can be “donated.” If the embryo is a person, it can be “adopted.” By invoking either term in the transfer of an embryo, the parties to the transfer risk that a court will apply one type of law rather than another (property vs family law) to thwart the intent of the transfer. In addition, ART clinics need to know how to apply the law that governs any transfer to avoid liability and provide good informed consent to their patients. Case law has not responded in a consistent manner to solve these problems. Unfortunately, the legislative response has been varied as well.

**The Legal and Political Response**

A number of states have addressed the difficult issues of embryo transfer, adoption and disposition. A brief summary of the various applicable statutes is provided in Appendix A. As is evident from a careful consideration of the available law, the states that have applicable law have chosen to address the various issues of embryo disposition in a “piecemeal” manner, incorporating minor changes into existing Uniform Parentage Act or Medical Practice Act legislation. Most states have lacked either the political will or considered forethought to address the difficult issues raised by this practice, leaving a large degree of uncertainty in the ongoing practice of ART clinics in those states. However, after years of silence, both elected officials and the public are awakening to the need to define embryo donation in a manner that is consistent with traditional public values concerning family law.
The American Bar Association’s Family Law Section has created a model statute that is somewhat useful.\textsuperscript{15} The model legislation is based on contract law principles, but is highly complex and suffers from the fact that it does not adequately address the major political issues raised by embryo donation or adoption. The suggested statute does, however, have useful sections concerning surrogacy, abandoned embryos, limits of civil and criminal liability for ART clinics, and inheritance law. Americans United for Life (AUL) has also developed model legislation that uses family law and adoption law principles, is simple in structure, and is more focused on the practical issues faced by couples and physicians wanting to transfer an embryo for the purpose of giving birth to a living child.\textsuperscript{16} Of note, no direct reference is made to adoption in the AUL model act, but the suggestion is made that if the model statute is used that it be incorporated into the state’s Uniform Parentage Act governing adoption.

Finally, Georgia recently enacted the “Option of Adoption Act 2009” that specifically deals with the issue of embryo transfer.\textsuperscript{17} The statute is an artful blend of contract law and adoption law, creating the ability of an “embryo custodian...to transfer all rights and responsibilities for an embryo to a recipient intended parent,” providing for an expedited adoption or parentage determination upon the birth of the child that “shall be issued and shall be a final order.” While the possibility of fraud or coercion is not considered in the statute, certain ordinary protections against the possibility are included. Georgia has achieved what a number of other states need to achieve: a mechanism by which the ordinary expectations of progenitors and recipients of a cryopreserved embryo can be realized, and clarity in the law that ART clinics can use for good informed consent purposes.

Proposed Concepts To Be Included in Future Legislation

Based on the current model and enacted legislation, traditional family law principles, and the legitimate personal and medical needs of both the adoptive parents and of any child born from such an embryo transfer, I would suggest the following issues be considered in any proposed future legislation:
(1) Adoptive parents need complete protection from paternity or maternity suits brought by embryo custodians or progenitors, and protection from any liability causes of action, either at the moment a cryopreserved embryo is thawed for the purpose of impregnation (preferred) or at the moment of birth of the child the results from such a transfer. Based on current common law and legislative law, this protection can be afforded without the necessity of defining an embryo as either property or person.

(2) The donation should be made with the informed consent of both of the gamete donors, or of the parties who caused the embryo to be created, even if they are not the biological donors. Any such transfer, if made according to any governing statute, should completely sever any rights or responsibilities of the donor parties including any biological donor.

(3) Assuming current intent, the donation of abandoned embryos, or those where only one donor is available, for the purpose of causing a live birth, should be allowed, with the normal legal protections for notice, even in the face of an original agreement by the biological donors that provides otherwise. One or more deceased or unavailable biological donors should not be able to reach out from the abyss to block the possible birth of a human child.

(4) ART clinics should be required to obtain and keep medical records concerning the biological parents of any child born from an embryo transfer until at least the age of majority of that child, and make that information available based on state adoption law.

(5) Finally, the legislation should provide for the state-sponsored development of an informed consent document detailing the possible disposition(s) of an embryo, including the designation of a durable power of health care to any other person (including the ART clinic) for the purposes of such disposition. To encourage the use of the form, the ART clinic could be protected from any direct informed consent liability if it used the form, and followed the terms stated in the form, for embryo disposition at a future date.

Conclusion

The law concerning embryo adoption is under development in the United States. At first impression, important political groups reacted in opposing ways to either encourage or block the process. However, on a more careful analysis of the law, using existing principles of both contract law and family law, it has become apparent that entrenched political views are not necessarily threatened by allowing the “transfer of an embryo for the purpose of causing a live birth.” The widely held value of the peaceful enjoyment of family and children, and the Constitutionally protected personal right of reproduction have began to supersede more narrow concerns involving the (sometimes) technical debate of when human life begins. It is possible to have deeply held views of the sanctity of human life without strongly objecting to a legal definition of an ex utero human embryo that implies that it is less than a fully protected legal person. It is possible to have deeply held views concerning a woman’s reproductive rights without objecting to a legal process that guarantees a woman who wants to bear and raise a child has the opportunity to do so without the intervention of others. Finding a middle ground that allows a legitimate process to continue has only developed recently. The science of IVF/ART proceeded more rapidly than both medical ethics
and law could accommodate. It is only recently that we have been able to both reign in some of the earlier excesses, and to modify our law to protect the legitimate needs of parents and their children. Most of the confusion in our current law concerning embryo transfer/adoption arises from the changing social definition of marriage, divorce and family, not from the idea that it is possible to “carve out” this practice for statutory reform. To the extent that IVF/ART and embryo adoption is considered a social good, it is possible to agree that there are responsible, legal ways to achieve what was impossible until recent times: fertility and family for an infertile, childless couple. We do not need to dramatically change our law to protect the legitimate interests of donor and adoptive couples, just recognize the need.

Endnotes

1 I do not mean to imply that children could be bought or sold as ordinary property. Rather, I am referring to the control a family had over a child in the areas of labor, schooling and apprentice training, and marriage as the functional equivalent of the use of something that can be owned. For example, child labor laws did not (and still do not) apply to work done within and for the benefit of the family. Children were under the exclusive control of the parents, subject to remarkably few restrictions until the 20th Century. See also Stephen B Presser The Historical Background of the American Law of Adoption, 11 J. Family Law 443 (1971). Of note, English law was in stark contract to Roman law, which recognized adoption as if the adopted child were of the same “blood line.”

2 Many states still hold to the common law principle that the husband is the legal father of a child born while he is married to the mother, unless he chooses to challenge that fact. In those states, no man outside the marriage may legally attempt to establish paternity without the husband's consent. Other states have statutory law that presumes a husband’s paternity, subject to an outside challenge within 1 or 2 years of the birth of the child, after which no challenge is allowed absent the husband's consent. The mother of the child may not challenge paternity in either of these situations. Of note, based on recent genetic paternity testing in the United States, 10-30% of children are raised by men who believe they are the biological parent of a child, when in fact they are not.

3 Adoption was first allowed by statute in the United States by Massachusetts in 1851, with most states following by the early 1900’s. See Presser, op cit. Prior to that time, a family might “take in” an orphan under the “apprenticeship” or “putting out” traditions of England, normally after the age 7. The younger children were raised by a number of organizations, including local city governments in “foundling asylums” and “maternity hospitals” using female convicts; or religious groups and Foundling Societies. The remarkable historical observation is the lack of abuse of the children, other than the few consigned to the State. Private placements were virtually without reported problems, largely due to the “intense religious devotion” of the organizations that ran them. There are also records of wealthy Southern families that raised and trained over 20 orphaned children, who later were able to claim some of the estate of the patriarch under a will. However, unless an illegitimate child (a bastard) was acknowledged by his father, he had no legal claim on his father’s time or estate, and no way to publically become an integral part of any family without a potential cloud over his place in that family. One of the stated purposes of early adoption law was to no longer penalize an innocent (illegitimate) child for the sins of his parents, and to give the child inheritance rights. It is important to note that adoption was and is a creation of statute and not the
common law. Adoption is a state law issue with the exception of two federal statutes: the Indian Child Welfare Act (ICWA), 25 USC 1901-63 ((1978), and the Multi-ethnic Placement Act (MEPA), 25 USC.

I will use the terms “biological” and “genetic” interchangeably. Most of the legal literature uses the term biological to mean genetic, which is the more precise medical terminology.

I will use the terms “rearing” and “adoptive” interchangeably, as it applies to family law. It is of course possible for a man or a woman to rear a child without adoption, even calling the child “my own”and using the same last name. However, for the purposes of this discussion, I will not consider that situation.

The evolution the professional ethical policy statements is still ongoing, as recognized uses and abuses of ART occur. One of the emerging issues is eugenics or “designer babies.” Couples in general want a child that is “like them” in terms of race, but beyond that consideration there have been few reported abuses. It is interesting to note that during the historical debates on adoption during the 19th Century, a major issue was familial determinism vs socialization, or “Nature vs Nurture.” Religious groups emphasized nurture, with every human made in the image of God, capable of his or her own destiny. Organizers of state or city run programs often considered the children of “inferior breeding” and thus in need of structured housing and discipline, removed from ordinary society, not placed with families for adoption. (See the debates between Rev. Charles Loring Brace and William H. Whitmore, Presser op cit.) Current ART guidelines are protective of the individual embryo and its potential to become a unique human being under the support of loving and protective parents. However, at another level, some organizations offering oocytes and semen have long advertised the source of the tissue as from “college educated, healthy” donors. Social and disease profiling of embryos is simple, and has been considered, though currently rejected. Some of the major organizations and their statements are: American Society Reproductive Medicine “Defining Embryo Donation” Fertil Steril (December 2009); 92(6): 1818-9; Christian Medical and Dental Associations Ethical Statements (1992).

The estimated number of ART procedures in 1996 was 64,681 with 14,507 live births, compared to 134,260 procedures in 2005 with 52,041 live births. (U.S. Center for Disease Control and Prevention).

See page 616 for estimates of cost and availability of frozen embryos in comparison to other ART techniques. One of the attractive aspects of embryo adoption is the substantially lower cost and complexity associated with the procedure, compared to the de novo creation of an embryo. Much of the limitation placed on embryo donation/adoption using the current pool of cyropreserved embryos involves the screening of human tissue for infectious diseases, but this is less of an issue for ART clinics using current technology. See also Elizabeth E Swire “The Disposition of Cryopreserved Embryos: Why Embryo Adoption is an Inapposite Model for Application to Third-Party Assisted Reproduction” Will Mitchell L R 35:520 (2009)

Swire, id at 495. It is interesting to note that Snowflakes Adoption Agency models its contracts
between donating and adopting parents using both family law/adoptive law and contract law principles. Most centers that store embryos operate as if the law concerning embryo donation/adoption is settled. When both the donor and adopting parties agree on the outcome, case law has recognized the legitimacy of the arrangement. Only when a challenge occurs is the weakness in the current law obvious.

10 Most of the case law involves divorce or death of a spouse, with the disposition of cryopreserved embryos in dispute. See Davis v Davis (TN 1992); Kass v Kass (NY 1998); A.Z. v B.Z. (MA, 2000); J.B. vs M.B. (NJ 2001); Litowitz v Litowitz (WA 2002); In re: Marriage of Witten (IA, 2003); Roman v Roman (TX, 2006); and In re Marriage of Dahl and Angel (OR, 2008).

11 Some legal commentators have argued that a woman has a superior claim to the ultimate disposition of an embryo based on the difficulty of harvesting an oocyte compared to obtaining sperm (a form of “sweat equity” by the woman) and some vague, unique property of being female as opposed to male, treating the man as a mere “sperm donor.” See Judith Daar Am J Law and Med (1999 and 2001). These views have been heavily influenced by feminist philosophy and are thus not politically neutral. As such, they have been rejected by the courts thus far.

12 This conflict would implicate legal principles more important to the area of embryo adoption. If both progenitors (or causative putative parents) sought reproduction, traditional family law principles might apply. Here the issues would be custody of any child born outside marriage, defining the role of gestation prior to implantation or transfer, deciding if the interests of an embryo as a potential human child should be considered, and determining support obligations. The most intriguing questions to be answered would be: (1) Should the “best interests” of an unborn child (even prior to pregnancy) be considered? That is, would it matter which parent would be the most “fit” parent? (2) Would it matter that the female progenitor could gestate the embryo herself, as opposed to using a surrogate? (3) Would it matter if there were two women capable of gestation (the progenitor and the (now) wife or partner of the man), but the anticipated success rate for a live birth was far greater for one of them? (4) Would it matter that either progenitor was in a same-sex relationship in a state that recognized same-sex marriage or rejected same-sex marriage?

13 Provided by Reginald Finger, National Embryo Donation Center (2010)

14 Several states have attempted to pass such legislation without success. Most recently, Tennessee introduced SB 2136/HB 2159 in the 2009-2010 session, but the bill did not pass the hearing stage. See www.capitol.tn.gov/billinfo/BillSummary.aspx?BillNumber SB2136. The Tennessee legislation would have created a binding contract for embryo transfer for the purpose of a live birth, expedited adoption upon birth, possible visitation agreements between transferring and adoptive parents, and record keeping requirements for ART clinics. In contrast, Louisiana has statutory language defining the embryo a legal person, allows for embryo adoption, prohibits embryo research when such research does not benefit the embryo directly, and limits IVF using embryos to ACOG and ASRM certified clinics. For a more in depth discussion of the legal and liability implications of a strict definition of an embryo as a person or as property, see Katheryn Katz “The Legal Status of the Ex Utero Embryo: Implications for Adoption Law” Cap Univ L Rev 35:303-340 (2006); Donna M Sheinbach “Examining Disputes Over Ownership Rights to Frozen Embryos: Will Prior Consent
Documents Survive If Challenged by State Law and/or Constitutional Principles? Cathol Univers Law Rev 48:989-1027 (1999). Finally, the variability in the law is not a unique characteristic of the United States. See Appendix B for a summary of embryo donation practices in other nations.


16 Embryo Adoption: Model Legislation and Policy Guide for the 2007 Legislative Year. Contact AUL, 310 S Peoria St, Suite 500, Chicago, IL 60607 or www.AUL.org or legislation@AUL.org.

17 See www.legis.state.ga.us/legis/2009_10/fulltext/hb388.htm, HB 388, to amend Chapter 8 of Title 19 of the Official Code of Georgia.
Table 1 - Number of Embryo Donations by Outcomes and Year, USA, 2004-2007

Alabama
- Find no mention of embryos or cloning in statute search

Arkansas (2003) 20-16-1001-4
- Has cloning ban

California (year of passage not given) Health & Safety Code, 125315
- Requires IVF practices to outline options for disposition of embryos
- Requires disposition form to outline options in case of death, divorce, or abandonment of embryos

Colorado (2008) 19-4-106
- Provisions of uniform parentage act are specific to IVF, donor egg, and donor sperm but not to embryo donation per se
- Provides that a sperm or egg donation is not a parent of the resulting child; that a former spouse (deceased or living) is not a parent unless he/she consented in record to be so

Connecticut (2005) 19a:32d-g
- A provision that couples must be told the options for remaining embryos; provides for ESC research, prohibits cloning

- Uses the word “donor” generally
- Provides that a donor is not a parent of a child of assisted reproduction
- Provides that a former spouse (deceased or living) is not a parent unless he/she consented in record to be so

Florida (year of passage not given, but law was on books in 2000) 742.11-742.18
- Provides that gestating woman and her husband are parents of children resulting from egg donation or embryo donation, provided they have consented in writing to the donation
- Provides that donors have no rights or obligations of parenthood
- Only “reasonable compensation” is permitted to donors

Georgia (2009) 19.8.40-43
- Permits, but does not require, a couple becoming parents through embryo adoption to obtain a court order confirming them as legal parents of the child
- Confirms in statute the standard practice of contracting for the donation of embryos prior to embryo transfer
- Provides that if a donor embryo was created from donor gametes, the gamete donors are not entitled to notice of the embryo donation
Louisiana (1986) 9:121-133
- Defines embryo as juridical person
- Forbids sale of embryos
- Forbids destruction of embryos
- Provides for adoption of abandoned embryos
- Restricts practice of IVF to physicians and facilities who meet ACOG and ASRM standards

Massachusetts (2005) Chapter 111L, Section 4
- Requires IVF practices to provide information to patients sufficient for them to make an informed choice about embryo disposition (law specifies continued storage, donation to research, donation to another person, and destruction as options)

Michigan (2008) state constitution 1-27; statutes 333.26401-3
- ESR provided for, cloning prohibited

- Requires counseling and medical evaluation for IVF
- Restricts embryo culture to 14 days
- Forbids embryos donated for research to be used for reproduction

- Requires IVF practices to provide information to patients sufficient for them to make an informed choice about embryo disposition (law is just one sentence)

New Mexico (2007) 24-9A-1
- Provides that IVF to treat infertility is not considered clinical research, so long as embryos created for IVF are transferred to a human female (by my reading, the restrictions on clinical research would preclude ESC research)

New York (1992) 8:121-124
- No mention of embryos except briefly in surrogacy law

North Dakota (2000) 14-20
- Specific to all forms of ART including donor embryos
- Donor is not a parent of ART child
- Provides that a former spouse (deceased or living) is not a parent unless he/she consented in record to be so

Ohio (2006) 3111.97
- Has parentage law written specifically for embryo donation
- Has provision that husband can rebut presumption of parenthood by clear and convincing evidence if he did not consent to the ED
- Donors not considered parents of children born of ED
Oklahoma (2000) 10.556
- Requires ET be performed by a licensed physician (general provision, donated embryo or otherwise)
- Requires written consent of donor and recipient couples for donated ET
- Consents filed with court and are confidential
- Children born of donated ET are children of recipient couple; donor couple relieved of rights and responsibilities
- Oklahoma also has Freedom of Conscience Act (2008) which protects professionals from discrimination, for refusing to destroy an embryo

Oregon (2009 HB 2598)
- Stated – funded embryonic stem cell research program enacted

South Dakota (2000) 34-14-17
- ESR and cloning prohibited

Texas (2007) 160.102, 160.701-707, 160.793
- Term “assisted reproduction” used generally – not specific to donor embryos
- Donor not a parent of ART child
- Provides that a former spouse (deceased or living) is not a parent unless he/she consented in record to be so

Utah (2008) 788-15
- Specific to all forms of ART including donor embryos
- Donor not a parent of ART child
- Provides that a former spouse (deceased or living) is not a parent unless he/she consented in record to be so

- Covers ART procedure, not specific to ED
- Donor not a parent of ART child
- Similar provisions as Colorado (Provides that a former spouse (deceased or living) is not a parent unless he/she consented in record to be so), with technical exception related to timely notification of death or divorce to physician performing procedure

- Specific to all forms of ART including donor embryos
- Donor not a parent of ART child
- Provides that a former spouse (deceased or living) is not a parent unless he/she consented in record to be so
- Has provision that husband can rebut presumption in court if he did not consent to ED, if he commences proceedings within 2 years of learning of the birth of the child
Wyoming (2003) 14-2-901 et seq.
- Term “assisted reproduction” used generally – not specific to donor embryos
- Donor not a parent of ART child
- Provides that a former spouse (deceased or living) is not a parent unless he/she consented in record to be so
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<thead>
<tr>
<th>Nation</th>
<th>Reference</th>
<th>Link to Abstract</th>
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</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Attested on the following websites: IVF Canada and The Life Program</td>
<td><a href="http://www.ivfcanada.com/services/index.cfm">http://www.ivfcanada.com/services/index.cfm</a></td>
</tr>
<tr>
<td></td>
<td>Beginnings Family Services – Embryo Adoption</td>
<td><a href="http://www.beginnings.ca/contact-us">http://www.beginnings.ca/contact-us</a></td>
</tr>
<tr>
<td>India</td>
<td>Described in news media article India is hot ground for embryo adoption. Redcliff India Abroad January 08, 2007</td>
<td><a href="http://in.rediff.com/news/2007/jan/08embryo.htm">http://in.rediff.com/news/2007/jan/08embryo.htm</a></td>
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<td>Nation</td>
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(Update 04-12-2010)
Course Description:

Embryo Adoption Program: The Adoption Assessor/Counselor component of the curriculum provides a professional overview of the key components associated with assessing and preparing donors, recipients, and their respective children for embryo donation. The function of this presentation is to inform and educate professional audiences about the preparation and counseling aspects of embryo donation and adoption. It provides comprehensive training for health, social services, legal, and other involved professionals (e.g., physicians, nurses, embryologists, counselors, clinic staff, etc.). The curriculum addresses the differences between embryo donation and traditional adoption, the importance of identity, the various levels of openness, and how to prepare donors and recipients for the process involved.

Outcomes: By the end of the training, each participant should:

1. Explore how embryo donation and traditional adoption differ from one another.
2. Gain an understanding of the importance of genetic and medical histories.
3. Determine if traditional adoption practices are relevant to embryo donation.
4. Examine the importance of identity.
5. Define “openness” and how it can be integrated into embryo donation.
6. Examine the importance of education and psychological assessment prior to and in conjunction with embryo donation.
7. Learn how to prepare embryo donors for embryo donation.
8. Learn how to prepare embryo recipients for embryo adoption.
9. Gain access to resources and support materials that can assist patients with the embryo donation process.
The Embryo Donation Process

Embryo donation is much more complex than simply receiving a bunch of cells from another person that might result in the birth of a child for the embryo recipient. All children born through the process of embryo donation will forever hold a genetic relationship to their embryo donors; likewise, the embryo donors and their children will forever hold a genetic relationship to any child born to the embryo recipients. Not only will the child born hold these relationships but the generations of children born to them and their genetically related siblings will hold these relationships with one another as well. Relationally, this is most akin to that of traditional adoption.

HOW DOES EMBRYO DONATION DIFFER FROM TRADITIONAL ADOPTION?

<table>
<thead>
<tr>
<th></th>
<th>Embryo Donation</th>
<th>Traditional Adoption</th>
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</thead>
<tbody>
<tr>
<td><strong>Embryo Donation</strong></td>
<td>A child born through embryo donation:</td>
<td>A child placed through traditional adoption:</td>
</tr>
<tr>
<td><strong>Genetics</strong></td>
<td>forever shares the genetic background of their embryo donors.</td>
<td>forever shares the genetic background of their birth parents.</td>
</tr>
<tr>
<td><strong>Medical History</strong></td>
<td>will always be directly in need of and may be impacted by the past, current and the on-going health history of their donors and their donors extended family members.</td>
<td>will always be directly in need of and may be impacted by the past, current and on-going health history of their birth parents and their birth parents' extended family members.</td>
</tr>
<tr>
<td><strong>Future Generations</strong></td>
<td>may later give birth to children of their own. These children (and any future generations to come) will also forever be connected to and/or directly influenced by the medical and genetic histories of their parents’ donors and extended family.</td>
<td>may later give birth to children of their own. These children (and any future generations to come) will also forever be connected to and/or directly influenced by the medical and genetic histories of their parents’ birth parents and extended family.</td>
</tr>
<tr>
<td><strong>Genetic Siblings</strong></td>
<td>will always share a genetic and medical relationship to the children of their donors.</td>
<td>will always share a genetic and medical relationship to the children of their birth parents.</td>
</tr>
<tr>
<td>Nature vs. Nurture</td>
<td>may be significantly influenced or impacted by their genetic make-up as scientific evidence suggests that personality make-up, natural abilities, interests/hobbies, and talents are influenced by a combination of both nature and nurture.</td>
<td>may be significantly influenced or impacted by their genetic make-up as scientific evidence suggests that personality make-up, natural abilities, interests/hobbies, and talents are influenced by a combination of both nature and nurture.</td>
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<tr>
<td>-------------------</td>
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</tr>
<tr>
<td>In Utero Experience</td>
<td>is typically gestated in the womb of the mother that will raise him/her.</td>
<td>is typically gestated in the womb of the birth mother.</td>
</tr>
<tr>
<td>Birth</td>
<td>will be placed with their non-genetic family before birth and will be born from the mother that will raise him/her.</td>
<td>will be born from the birth mother who will adoptively place them with another family following birth.</td>
</tr>
<tr>
<td>Post-Birth</td>
<td>will be raised by the parents to whom they were born following embryo donation.</td>
<td>will be raised by the parents with whom they were placed following adoption.</td>
</tr>
<tr>
<td>Parents</td>
<td>will forever, legally and relationally, be the child of the parents that birthed and raised them. However, medical, genetic and self-identity questions may lead them to having an interest in communicating or one day meeting their embryo donors, as well as any genetic siblings they may have.</td>
<td>will forever, legally and relationally, be the child of the parents that raised them. However, medical, genetic and self-identity questions may lead them to having an interest in communicating with or one day meeting their birth parents, as well as any genetic siblings they may have.</td>
</tr>
</tbody>
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THE IMPORTANCE OF GENETIC AND MEDICAL HISTORIES

What is so important about genetics and/or medical histories and how do these relate to embryo donation?

In order to understand the importance that genetics play in the lives of people all across the world one must ask this question: Over the past 30+ years, why has there been a significant increase in:

- websites such as ancestry.com
- acclaimed hit television shows and movies that explore heritage and genetic topics
- specialty DNA focused medical clinics

Furthermore, why do the National Institutes of Health, the Centers for Disease Control and Prevention (CDC), and the Office of the United States Surgeon General promote and reinforce the concept that every American should maintain an up-to-date and thorough medical history dating back at least three generations? In fact, the CDC states the following:

“Family members share genes, behaviors, lifestyles, and environments that together may influence their health and their risk of chronic disease. Most people have a family health history of some chronic diseases (e.g., cancer, coronary heart disease, and diabetes) and health conditions (e.g., high blood pressure and hypercholesterolemia). People who have a close family member with a chronic disease may have a higher risk of developing that disease than those without such a family member.

Family health history is a written or graphic record of the diseases and health conditions present in your family. A useful family health history shows three generations of your biological relatives, the age at diagnosis, and the age and cause of death of deceased family members. Family health history is a useful tool for understanding health risks and preventing disease in individuals and their close relatives. Family health history information may help health care providers determine which tests and screenings are recommended to help family members know their health risk.”

http://www.cdc.gov/genomics/famhistory/index.htm

This begs the question: If medical and genetic histories are so important and play such an invaluable role in the life of every American, what must life be like for an adopted person or a person born following embryo donation if they are never provided with the means by which to update their own genetic and medical history?
Medical histories do not stay static. While gathering and receiving a medical update at a certain point in time is helpful, the benefit becomes constrained if it is not updated and maintained over time.

Embryo donor, Jerry, developed prostate cancer at the age of 49, five years after his embryo donation resulted in the birth of three little boys. Would the ability to receive a medical update regarding Jerry’s diagnosis and treatment not be considered essentially valuable and vital to the long-term care and well-being of all three of these children and their parents?
If so, how might an open or closed embryo donation plan influence the ability of these genetically connected parties to pass on and/or receive this information? And how might receiving or not receiving this medical update influence the level or type of medical care that may be provided to these three children in the future?

A person’s direct and extended family medical background and history is of such importance and significance that medical doctors require updates at every physical exam that is given.

Simply put, genetic history helps provide people with a sense of “who they are” and it assists them in understanding those to whom they are connected. Many recipient parents express concern about the possibility of their child inadvertently meeting and falling in love with an unknown genetic relative. While the statistical odds of this are small, having access to a more open genetic record may emotionally help relieve this worry and help prevent related parties from inadvertently marrying one another.

Therefore, if genetic history is of growing importance to the masses and medical history is significantly important to every individual seeking out medical care, it makes sense that each would be equally important to those individuals born through embryo donation. The American Society for Reproductive Medicine (ASRM) recommends that “a mechanism must exist (in embryo donation programs) to maintain the (donor’s medical) records, as a further medical resource for any offspring produced.”

The American Society for Reproductive Medicine (ASRM) recommends that “a mechanism must exist (in embryo donation programs) to maintain the (donor’s medical) records, as a further medical resource for any offspring produced.

It is also interesting to consider that, according to the policies kept by most medical clinics in the United States, if medical records are not fully known or up-to-date, an individual is automatically disqualified from being accepted as an egg or sperm donor by the clinic. Therefore, if a current medical history is of this importance in order to be accepted and approved by the medical community as a gamete donor, how is it fair to deny access to this same information for children born from embryo or other forms of gamete donation?

ARE TRADITIONAL ADOPTION PRACTICES RELEVANT TO EMBRYO DONATION?

Many professionals have limited experience in the area of adoption practice. While some are familiar with the basic concepts and constructs of traditional adoption, most professionals have limited knowledge or expertise about adoption’s lasting impact on birth parents (or first parents), adoptive parents, and their respective children. While embryo donation is certainly different from traditional adoption, research has demonstrated that issues pertaining to genetic/medical history, embryo donation/adoption are quite similar. When it comes to questions about the importance of self-identity, research findings have also demonstrated that client needs and desires of those going through embryo donation and adoption are often of similar relevance and importance to one another.
THE IMPORTANCE OF IDENTITY

According to the Center for Adoption Support and Education, deficits in information about birth parents, birthplace, etc. may impede integration of identity causing a child to seek identity in early pregnancies or extreme behaviors in order to create a sense of belonging. http://www.adoptionsupport.org/res/indexcorea.php

In spite of the substantiated evidence about the importance of self-identity in traditional adoption, many prospective parents and parents continue to be counseled by some medical and mental health professionals that it is not necessary to share the circumstances of the child’s conception with their child and that it is not necessary for the child to know the truth about how he came to be part of his family. The rationale for this position includes respect for the infertile parents’ privacy, as well as the desire to protect the child from emotional harm in light of those people in our society who are opposed to assisted reproductive technologies. This argument holds many similarities to opinions previously held by professionals in the field of adoption. However, such viewpoints have clearly been debunked and are now considered to be both outdated and in opposition to professional practices that support the best interest of the child.

Agencies offering traditional adoption have now begun to embrace and accept the importance of allowing an adopted child, through mutual openness agreements, to have on-going access to information about their birth/genetic family for more than thirty years. Traditional adoption is a well-developed, well researched, and studied form of family building practice that thoroughly recognizes and provides a continuum of life-long support services for all family members impacted by the adoption experience.

While in the past, closed or anonymous adoption was the norm in traditional adoption, the Adoption Identity Movement (which advocated and eventually allowed for openness between birth and adoptive parents and their children) became a demanded practice in the field of traditional adoption in the 1980’s. First greeted with uncertainty, openness is now embraced as best practice in traditional adoption. Openness options and the encouragement of on-going communication between birth parents and adoptive parents is recognized as bringing emotional and relational value to all members of the traditional adoption triad. And, just as that former wall of secrecy in traditional adoption brought many challenges and sometimes pain to children placed through traditional adoption (and their families), a system of secrecy is often detrimental to children born through donor conception or embryo donation. Medical and mental health professionals are beginning to embrace, understand, and support the benefit of openness when building a family through all forms of donor conception, including embryo donation.

There is a now an active and growing movement for openness associated with the field of donor gametes that mirrors that of the Adoption Identity Movement in traditional adoption.

Laws passed in both Australia and England allow a child born through gamete donation to have access to their genetic records at the age of majority. Medical clinics that facilitate the placement of donor eggs and/or sperm and later, embryos, are required and/or strongly encouraged to maintain genetic parentage records forever. In addition, they now must develop policies that
allow for the sharing of this information in accordance with the laws established should a child be interested in obtaining records at the age of 18 or older. This means that organizations facilitating donor gamete matching or transfers must build long-term counseling and psychological services into their organizations in support of the children who will eventually be born, grow up, and come back to them seeking information about their genetic parents. The psychological needs and informational requests of these individuals will most likely mirror that of the traditionally placed adopted child. Furthermore, the clinic/organization should develop policies and procedures for addressing the long-term needs of its embryo recipients, as well as its embryo donors, related to genetic record-keeping, information sharing, medical updates, and support services about how to discuss and share the topic of embryo donation with their child.

Because most medical professionals understand the importance of knowing their patient’s medical history and receiving regular updates, professionals should never recommend to an embryo recipient that it is an option as to whether or not they tell their child about their true genetic and medical background.

Practically speaking, it is becoming increasingly difficult to maintain a wall of secrecy around a child’s biological identity as the world is becoming more interconnected through advancing technology, the internet, and DNA databases. As stated, several countries outside of the United States have created legal mandates that allow children of donor conception access to their genetic records at the age of majority. Within the United States, the state of Washington recently passed legislation that addresses the importance of and provides a mechanism for the release of genetic records to children born through donor conception when they reach the age of majority.

So, to what is a family blended by donor conception best compared? In practice, the relationship in open donation is comparable to that between extended relatives such as aunts and uncles. In donor conception, the recipient family and donor family make a commitment to stay in contact because they realize that the donor family is an important part of the child’s identity. As with extended relatives, relationships vary. Some open donor relationships develop into friendships while others are more distantly involved. All, however, recognize that they are connected to one another and are important in the life of each of their respective children.

Barry Stevens, a Toronto-based filmmaker, learned after his father died that he and his sister were donor conceived. Now, more than 20 years later, he says he knows parents think they are sparing their children by keeping the truth from them. ”The issue of disclosure is often framed as a question of whether or not it’s good for the offspring. But I don’t think it’s anyone’s concern but mine whether the truth hurts or helps. It’s a question of rights. Nobody has the right to withhold key information about my origins from me,” he says. “ The saddest thing for me is that so many parents insist on secrecy because they fear that if their children knows, they won’t love them. I suspect that was true of my father. But that’s so unfounded. Children love the people who nurture them.”

It can then be argued that fully constructed semi-open communication plans allowing for confidential exchanges of on-going medical and other updates (or ideally, more open plans when both parties desire such) provide the greatest short and long-term benefit to all.

All children, regardless of conception beginning, should be affirmed with the truth about their biological uniqueness, medical history, and the miraculous story of how they each came to be.

**WHAT DEFINES “OPENNESS” AND HOW CAN IT BE INTEGRATED INTO EMBRYO DONATION?**

The following statements reflect the reality of how openness impacts non-genetic families formed through adoption, refuting some of the most commonly held myths about openness. In fact, most of the commonly held negative assumptions about openness have been disproved by adoption research. Validated research in the field of adoption has demonstrated that:

- Parties in open adoptions are NOT confused about their parenting rights and responsibilities.
- Birth mothers do NOT attempt to “reclaim” their children.
- Children in open adoption are NOT confused about who their parents are. They do understand the different roles of adoptive and birth parents in their lives.
- Differences in adolescent adoptive identity or degree of preoccupation with adoption are NOT related to the level of openness in the adoption.
- Adoptive openness does NOT appear to influence an adopted person’s self-esteem in any negative way.
- Adoptive parents in an open adoption do NOT feel less in control and, indeed, have a greater sense of permanence in their relationship with their child.
Openness is best pictured as a continuum of communication possibilities that allow for a vast array of individually tailored options and possibilities.

Below is a short summary of three differing levels of openness communication:

<table>
<thead>
<tr>
<th>Open Donation</th>
<th>Semi-Open Donation</th>
<th>Closed Donation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allows the donor(s) and recipient(s) to be:</td>
<td>Allows the donor(s) and recipient(s) to be:</td>
<td>Closed Donation:</td>
</tr>
<tr>
<td>known to one another by first and last names;</td>
<td>be known to one another by first names only; and,</td>
<td>denies the donors and recipients the opportunity to be known to one another by either first or last name; denies the donors and recipients the ability to share or exchange medical updates with one another that can benefit their respective children and/or the generations to come;</td>
</tr>
<tr>
<td>connected to one another through a mutually accessible communication portal that they have individually chosen and agreed to share with one another;</td>
<td>connected to one another by way of a communication portal that they have individually chosen and both agreed to share with one another;</td>
<td></td>
</tr>
<tr>
<td>open donation may or may not include the possibility of the couples talking by phone;</td>
<td>semi-open donation may or may not include the possibility of the couples talking by phone;</td>
<td>denies the donors the opportunity to receive any information about the disposition or outcome of their embryo donation;</td>
</tr>
<tr>
<td>open donation may or may not include the option or requirement of meeting one another;</td>
<td>semi-open donation may or may not include the option or requirement of meeting one another;</td>
<td>denies the respective children of the recipients and the donors the ability to easily contact one another as adults.</td>
</tr>
<tr>
<td>open donation allows the possibility for the connected families to communicate with one another in a manner that is mutually agreeable;</td>
<td>semi-open donation allows the possibility for the connected families to communicate with one another in the manner that is mutually agreeable;</td>
<td></td>
</tr>
</tbody>
</table>

Embryo Adoption Program the Assessor / Counselor Component
the donors and recipients can exchange medical and/or other updates with one another, benefiting both sets of children;  

allows the respective children and families a developed and controlled pathway to connecting with one another as adults;  

knowing each other’s last names allows the opportunity for both families to stay connected over-time and it makes it easier for the respective children to seek one another out should they desire to do so.

The donors and recipients can exchange medical and/or other updates with one another, benefiting both sets of children;  

allows the respective children and families a developed and controlled pathway to connecting with one another as adults at which time, last names can be exchanged.

**THE IMPORTANCE OF EDUCATION AND PSYCHOLOGICAL ASSESSMENT PRIOR TO AND IN CONJUNCTION WITH EMBRYO DONATION**

Embryo donation is a complex process medically, legally, and relationally. Embryo donation will produce an on-going, life-long impact for the embryo donors, embryo recipients, and their respective children. Therefore, a thorough psychosocial assessment is strongly encouraged before a donor donates and before a recipient moves forward with embryo donation. Because the embryo donation process is multi-faceted in nature, a thorough educational process that helps prepare both embryo donors and recipients by exploring communication options and choices, psychological risks and benefits, and “what if” scenarios is essential.

**PREPARING EMBRYO DONORS AND RECEPIENTS FOR EMBRYO DONATION**

The ASRM recommends that all embryo donors and recipients should undergo a thorough psychosocial assessment process and receive detailed education, preparation, and support services prior to proceeding through embryo donation. Some clinics collect embryo donation paperwork from potential donors without anyone on their staff personally contacting the donor to provide comprehensive, individually-based education and psychological assessment services. Education and assessment should address legal, medical, emotional, ethical, and relational issues/needs associated with embryo donation.

However, some clinics currently allow embryo recipients to voluntarily sign a waiver exempting them from participating in a psychosocial assessment or the educative counseling process.
process prior to moving through embryo donation. This practice is not professionally recommended as it provides no assurance that a patient truly understands or is adequately informed about the numerous relational, emotional, and psychological risks associated with embryo donation. The assumption that a patient can effectively self-educate themselves about a subject as complex as embryo donation may not be wise as it could open a potentially wide door of liability for the organization. Therefore, it is recommended that medical clinics and organizations either directly offer education and psychosocial services or provide it through an external referral to a mental health professional who holds expertise in the areas of traditional adoption, embryo donation, and family relationship counseling.

**PREPARING EMBRYO DONORS**

The ASRM recommends that the embryo recipients should at minimum be individually assessed and prepared as follows:

A. All potential donor couples should be informed about all aspects of their medical treatments and the relevant psychological and ethical issues inherent in donating embryos.

B. There should be a discussion of embryo disposition options before cryopreservation. After couples have concluded their own reproductive attempts, embryo disposition options should be re-evaluated.

C. The decision to proceed with embryo donation is complex, and patients may benefit from psychological counseling to aid in the decision. Psychological consultation with a qualified mental health professional is strongly recommended for all patients considering donating embryo(s). The assessment should include a clinical interview and, where appropriate, psychological testing. The clinician should require psychological consultation for patients in whom there appear to be factors that warrant further evaluation. In circumstances involving known donors, psychological evaluation and counseling is strongly recommended for the donors. The potential impact of the relationship between the donor and recipient should be explored. It is important to ascertain whether the donor is informed about any plans that may exist relating to future contact. The assessment should occur after couples have concluded their own reproductive attempts and have clearly indicated their desire to donate embryos.

D. The clinical interview (at minimum) should include a psychosocial history of both partners, which addresses:

1. Family history.
2. Educational background.
3. Assessment of stability.
4. Motivation to donate.
5. Current life stressors and coping skills.
6. Difficult or traumatic reproductive history.
7. Interpersonal relationships.
8. Sexual history.
9. History of major psychiatric and personality disorders.
10. Substance abuse in donor or first-degree relatives.
11. Legal history.
12. History of abuse or neglect.
13. Emotional attachment to embryo(s).

E. If indicated, psychological testing is recommended to document and validate in a standardized objective manner the information gathered from the clinical interview and should include an objective personality test and other self-report measures to assess potential instability or psychopathology. http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Guidelines_and_Minimum_Standards/2008_Guidelines_for_gamete%281%29.pdf

Psychosocial assessment and counseling revealed that Ken and Sue, prospective embryo donors, were still struggling with the aftermath of an abortion that they experienced while childhood sweethearts in high school. The assessment process brought to light that they still retained grief and guilt over having ended that pregnancy. Emotionally, both expressed individually that releasing their unused embryos was triggering in them the same feelings that they had experienced after their earlier abortion decision. Ultimately they were able to honestly express to each other that neither felt truly ready to release their embryos for donation. Following further assessment and counseling, Ken and Sue opted to go through another transfer themselves with their remaining embryos.

It is recommended that, following embryo donation, embryo donors should receive:

- grief and loss support services
- communication exchange support services
- access to support services that will assist them in answering questions about embryo donation that may arise in the future
- referral to “search and/or reunion support services” to assist them should future contact occur between the respective families and/or children

The embryo donors should also receive education about how to discuss their donation decision with their children and/or family members. They should receive support services that assist them in learning how to answer questions and/or address feelings and emotions that may arise for their children related to their embryo donation decision, particularly if a child is born through the donation process.

PREPARING EMBRYO RECIPIENTS FOR EMBRYO ADOPTION

The ASRM recommends that the embryo recipients should at minimum be individually assessed and prepared as follows:

A. Recipients of donor embryos and their partners should receive counseling about the
potential psychosocial implications.

B. The assessment should include a clinical interview and, where appropriate, psychological testing. The physician should require psychological consultation for patients in whom there appear to be factors that warrant further evaluation.

C. The recipient and her partner should be counseled about their subsequent feelings concerning the medical conditions that made necessary the use of donor embryos.

D. The impact of treatment failure also should be addressed, including coping with treatment termination, the grieving process, and developing alternatives for the future.

E. Relative issues, such as the impact of the relationship between known donors, recipients, and offspring, should be explored.

F. This assessment should attempt to exclude significant psychiatric illness and current substance abuse and to evaluate their ability to cope with the stress of Assisted Reproductive Technology.

G. Recipients of donor embryos should be advised of screening and testing requirements and be prepared either to not use or to assume the risks related to the use of donor embryos.

It is also advantageous for embryo recipients to be thoroughly assessed for their ability and readiness (financially, emotionally, and psychologically) to parent a child. Criminal and child abuse background checks are required for prospective adoptive parents and should be equally important when screening a patient for embryo donation. In addition, an assessment should explore if there is any history related to domestic violence, sexual assault/trauma, sexual abuse, substance abuse, and mental health treatment.

Bob and Jane presented as recipients for embryo donation. The assessment process uncovered that several months prior to application for embryo donation, Jane had been treated for an active cutting disorder. In addition, the assessment revealed an extensive history of multiple incidents of sexual assault, rape and sexual abuse that began at the age of 5. Jane was taking both anti-depressants and anti-anxiety medications. Prior attempts to wean her of such had resulted in the need for hospitalization. A recommendation was made that additional counseling would be necessary prior to making a determination if embryo donation should be approved. In addition, a medical consultation between Jane’s REI and psychiatrist was recommended to further assess and discuss the possible emotional implications that could impact Jane related to the potential interactions between the hormonal medications required for embryo donation and those being used to treat her depression and anxiety.

It is vitally important that recipients also be assessed for their willingness and capability to
accept the responsibility of parenting a child that may be born to them through embryo donation, regardless of any physical, educational, developmental, and emotional challenges their child may face.

Following embryo donation, embryo recipients should also receive:

- grief and loss support services, as necessary
- pregnancy and bonding assessment and support services
- communication exchange support services
- access to support services that will assist them in answering questions about embryo donation that may arise in the future
- referral to “search and/or reunion support services” to assist them should future contact occur between the respective families and/or children

In addition, embryo recipients should receive education about how to discuss their donation decision with their children and/or family members. They should receive support services that assist them in learning how to answer questions and/or address feelings and emotions that may arise for their children related to their embryo donation decision, particularly if a child is born through the donation process.

According to the Donor Sibling Registry, when counseling a recipient who fears the idea of telling their child about their genetic origins the following questions may be helpful:

1. If a parent is ashamed about infertility, how will that underlying sense of shame be hidden from the child?

2. If genetics is viewed as such an essential aspect of parenting that a non-biological connection is seen as harmful for the parent-child bond, will the parents be able to disguise that bias?

3. If it is unimportant how the child was create (since the raising is the crucial definition of a parent), then why keep it a secret?

Essentially, telling and not telling often comes down to a question of whether one or both parents are ashamed or afraid of something. Not addressing the larger issues of the parent’s emotions does not do the child any favors.

Resources

American Society for Reproductive Medicine

Centers for Disease Control and Prevention (CDC)

Child Gateway

Donor Sibling Registry

Embryo Adoption Awareness

National Fertility Support Center

National Institutes of Health

Office of the United States Surgeon General

RESOLVE
A study of bioethical issues concerning cryopreserved embryos and their disposition. Topics include theories of knowledge (epistemology assumptions), worldview presuppositions, diverse ethical systems, and principles. Analysis will include both secular and theological constructs pertaining to Embryo Donation /Embryo Adoption (ED/EA).

Outcomes: By the end of the training, each participant should:

1. To become familiar with the field of bioethics; definitions and approaches to the morality of healthcare as it relates to the status of the cryopreserved embryo.

2. To analyze secular bioethical constructs, comparing and contrasting with several theological viewpoints regarding the value of preimplantation human life.

3. To catalyze constructive conversation within the diverse opinions and approaches regarding this complex result of technological advances.

4. To foster a more functional consensus regarding the fate of the frozen embryos.

Topics:

I. Defining the Ethical Conflict (ED/EA)
   A. Overview of the problem
      1. Statistics regarding cryopreserved embryos
      2. Status of the cryopreserved embryo
         a. Legal
         b. Moral
         c. Humanity/Personhood
   B. Possible Solutions for the Cryopreserved Embryos
      1. Donation/Adoption
      2. Designation for research
      3. “Compassionate Transfer”
      4. Indefinite Storage – “Frozen Limbo”
      5. Terminal “Thawing”
   C. Ethical Constructs Pertinent to the Cryopreservation Crisis
      1. Epistemology: Theories of Knowledge
         a. Empiricism – Material
b. Metaphysical – Material + Immaterial

c. Theological – Material + Immaterial + God

2. Worldview Approaches
   a. Naturalism, Scientism
   b. Environmental Biocentrism
   c. Theological (sampling)
      i. Jewish – Torah
      ii. Roman Catholic – Biblical Revelation; Papal Authority;
      iii. Natural Law
      iv. Protestant – Biblical Authority; Holy Spirit Illumination

II. Bioethical Approaches (Secular)
   A. Ethical Systems
      1. Utilitarian
      2. Kantian (Deontological)
      3. Rights Based
      4. Communitarian
   B. Principlism
      1. Beneficence
      2. Non-maleficence
      3. Autonomy
      4. Justice

III. Bioethical Approaches (Theological)
   A. Image of God (Biblical Authority)
   B. Human Dignity – Sacred – Worthy of respect
   C. Human Life vs. Living Tissue
   D. Deserve protection; opportunity to develop
      1. Personal rights
      2. Community Benefit
      3. Principles
         a. Autonomy
         b. Justice
         c. Beneficence
         d. Non-maleficence
   E. Additional Principles
      1. Natural Law
      2. Totality
      3. Finality

IV. Controversy within Theological Camps
   A. Roman Catholic
      1. Procreative Unitive Principle
      2. Papal opposition; “inherent evil of in vitro making the situation beyond
         redemption”
      3. Diversity within Catholic Ethical views; totality, finality
      4. “Suspension of agreement”
Bioethics: Embryo Donation and Embryo Adoption

B. Protestant perspectives
   1. Good neighbor, sacrificial love
   2. Procreative Unitive Principle
   3. One Flesh Principle
   4. Orphan Care – Imperative of “True Religion”
   5. Adoption Imagery

C. Jewish thought
   1. “Fetal Matter”
   2. Research and Medical Advance
   3. Good Neighbor Imagery

V. Secular Analysis: Scientific; Naturalism
   A. No dignity issue, no inherent value to a cryopreserved embryo before:
      implantation; primitive streak; period of twinning; neurological development;
      sentience; consciousness; self-consciousness
   B. No species advantage
      1. Personhood based on qualities or characteristics, ability to “do.”
      2. These are not possessed by embryo.
      3. Human origin but not person deserving of rights/protection.
      4. Therefore, thaw, discard, experimentation acceptable, for science sake even
         laudable in scientific endeavors.
      5. Utilitarian: for the good of the many, research on embryos, embryonic stem
         cells a positive good, a moral, ethical solution.
      6. Kantian: No duty or law to non persons; thus, no moral obligation
         imperative.
      7. Rights based: Non persons have no rights to consider; rights of parents
         could be taken into consideration.
      8. Communitarian: for the good of the community such research holds
         potential benefits and no ethical obstacles.

VI. Disposition of Cryopreserved Embryos: Analysis with Theological Perspective
   A. Construct One:
      1. Biological Life vs. Functional Personhood.
      2. Cryopreserved Embryos, while alive, are NOT persons with legal/moral
         standing.
      3. No law, duty, or obligation to intervene on behalf of embryo.
      4. Destruction and/or experimentation presents no ethical obstacle. BUT
         ED/EA likewise no ethical obstacle, seen as donor tissue, transplant model

   B. Construct Two:
      1. Life is SACRED from Syngamy (living zygote).
      2. Destruction/Experimentation rejected
      3. ED/EA is NOT an ethical response to cryopreserved embryos
      4. In Vitro Fertilization is an “inherent moral evil” – nothing can redeem
      5. Embryo Transfer results in a pregnancy which “controls” the mother in a
         way that would violate the one flesh union of marriage.
** Other Roman Catholic Theologian/Ethicists have “suspended agreement” with the papal position regarding organ donation/transfer, taking exception to the totality/finality principles, allowing for Charity and Self Sacrifice to be more compelling arguments permitting the discussion of Embryo Donation and Adoption.

- Center for Thomistic Studies

C. **Construct Three:**

1. Life is SACRED from Syngamy.
2. ED/EA IS an ethical response to cryopreserved embryos.
3. Destruction and/or experimentation represents an assault on innocent human life.
4. Supported by Biblical revelation, biological continuity, natural law appreciation for the humanity and personhood of the embryo even in the cryopreserved state.
5. Permanent “frozen limbo” is neither a solution nor a compassionate response to human life at its earliest, weakest and most vulnerable stage.
6. While the developing embryo certainly impacts the maternal body, it does not “control” it.
7. The Covenant bond of marriage is NOT violated when both husband and wife agree to provide an opportunity for life and development to a cryopreserved embryo.
8. Adoption of tiny human being pictures a sacrificial Christlike love. (Laying down one’s life/yielding one’s rights for another)
Bioethics: Embryo Donation and Embryo Adoption

Introduction

Rapid advances in assisted reproductive technologies have resulted in an unanticipated ethical dilemma. From the first successful IVF-ET procedure in 1978 until now, the efficiency and availability of such high-tech procedures has resulted in an estimated 500,000 cryopreserved embryos without a definitive plan for disposition. By no means is all of this vast number available for donation/adoption, but the ethical, legal and social framework needs further elucidation for these embryos and for the Assisted Reproductive Technologies (ARTs) as well.

Cryopreserved embryos, though containing only a few cells, are clearly living – as evidenced by their further development and ultimate delivery of viable offspring. But now, in their present “frozen limbo,” do these living cells represent merely human tissue or an individual human being, persons worthy of dignity, respect and legal protections? How are these decisions impacted by worldview perspectives in order to analyze and determine a future, both right and moral, for these tiny human beings? Who will make these determinations?

This session will explore several prominent worldviews and the resultant ethical constructs that yield an understanding of the moral value of these embryos. Consideration will be given to the possible dispositions of the embryos, including the following:

1. Designation for research/experimentation – Death of the Embryo
2. “Compassionate transfer” where the frozen embryos are returned to a womb at a time when implantation is virtually impossible – Death of the Embryo
3. Terminal thaw allowing the frozen embryos to return gradually to room temperature and “die naturally” in a Petri dish – Death of the Embryo
4. Permanent storage – the frozen limbo of indecision
5. Donation and adoption by screened parents willing to accept transfer of the embryos with the goal of development, delivery, and adoption into the family. – Life of the Embryo

Clearly not all of these solutions have equal moral merit, but each has support among certain segments of society, the scientific and the theological community.

Bioethics

Building bioethical understanding and consensus requires more basic understanding on theories of knowledge (epistemology), worldviews, and available bioethical systems of thought. Thus the building blocks for meaningful discussion demand an unpacking of personal, social, medical, and legal factors that predispose the analysis and predetermine the outcome for these embryos.
Epistemology – Theory of Knowledge: How do we know what we know?

Initial foundational reasoning begins with the determination of what constitutes “truth” and how one can know it. For most postmodern thinkers, knowledge is relative, determined by societal norms and paradigms. Thus there exists no absolute truth that conforms by definition to reality. Knowledge is rather fluid, flexible, and determined by different needs in different places and situations. This worldview has lost traction in the arena of philosophic discussion because the endpoint of “whatever is moral/right for you as an individual is “moral” results in an impotent argument when considering societal norms. If everyone’s perspective is correct but relative, then there will be no impetus to find common ground or workable solutions where perspectives differ.

Currently the bioethical debate has centered in a worldview of scientific naturalism or empiricism that declares that true knowledge represents what can be determined and tested scientifically, with repeatable, empiric studies. From this perspective, issues of ethics, humanities, and theology cannot be “known” because they cannot be tested and therefore cannot be applied to bioethical determinations. However, the underlying premise that “the only things that can be known are those that can be empirically tested” is a statement of premise that itself cannot be tested! One cannot draw a bioethical conclusion if one's worldview concludes ethics is not “knowable.” Attempts to reject opposing worldviews before the discussion even begins cannot be endorsed. Science, with its reputable empiric studies, holds great value to the discussion, but the rapid expansion even of scientific knowledge should generate caution before declaring “current knowledge is all that can be known.” Thus, openness to future research and discovery remains essential to the development of the biomedical field.

Another currently popular worldview known as radical environmentalism elevates nature to the highest level of determinism. For those holding this perspective, the human species has no particular advantage, has no special claim over any other living thing. Most holding to biological determinism would favor a scientific/empiric view of knowledge, while firmly encamped in the evolutionary hypothesis. Decisions are then based on what is best for the world as a whole, a community of living organisms, putting cryopreserved embryos on an equal footing with cryopreserved flora and fauna, without particular bias or preferred status. This view generally rejects high-tech medical interventions on behalf of the embryo, and favors instead that effort, energy, and resources be directed toward general environmental concerns.

Finally, the theistic perspectives, which in this session will be limited to the various Judeo-Christian worldviews, can accept good scientific research as knowledge without conceding that such results are the only truth, the only things knowable. Many holding to a theistic worldview appeal also to natural law, a truth of conscience written in human hearts that reveals what is right and what is wrong. This metaphysical approach, which appreciates a reality beyond the physical sphere, has ancient historical roots.
A solidly monotheistic worldview, dependent upon a creator God and revelation of absolute truth that conforms to reality contained within the Hebrew Bible (Torah, prophets, Psalms) and later the Christian Bible (Old Testament and New Testament), contains statements of truth by way of divine revelation. Such absolute truth, taken as the inspired word of God, does not conflict with scientific research, but rather precedes and informs it, when properly interpreted.

Each of these worldview presuppositions leads to a different ethical analysis and will be considered as regards the cryopreserved embryos.

**Bioethical Systems**

On the background of epistemology and diverse world views, moral theories were developed to integrate and systematize ethical principles into functional arguments. Such abstract moral reflection should undergird argumentation, using the resulting constructs to analyze and reach conclusions about complex ethical dilemmas. A brief review of several of the prominent ethical systems will prove beneficial in analyzing the cryopreservation crisis.

**Utilitarianism**

Utilitarianism, also called “consequentialism”, allows the determination of morality, the “right and wrong” of a situation according to the balance of good and bad results. Thus, morality becomes the “most good for the most people” or the best overall result. In this system the majority opinion or advantage rules; the minority submit and experience the consequences.

**Deontological – Kantianism**

Morality in this system is based on duty or law. That is, there must be an obligation that can be generalized to all cultures and society. This view is closely associated with Immanuel Kant who utilized the term “categorical imperative” as the basis of duty, and hence morality. Acts are not ethical because of concern for individuals, compassion or empathy, but rather a duty or law requires such an act. Theists likewise appeal to the Law of God and the duty to obey as pivotal in the decision making process. Conflict may well arise when the Law of God conflicts with the law of the land. Those adhering to a Kantian ethic would have opposing perspectives of duty and authority. The legality and morality of slavery and abortion highlight conflicting views with regard to law and ethics.

**Rights Theory**

Rights Theory, a relatively new system that has been adopted in America to a great extent, involves a powerful, liberal individualism which makes the individual’s rights supreme in all decision-making as regards morality. The government is to protect the individual against the society, protecting and preserving the right to not only “life, liberty and the pursuit of happiness”
but the right to privacy, to die, to universal health care, etc. Theists generally look to the rights of others, concepts of sacrifice, and a duty to preserve and protect others.

**Communitarianism**

In contrast to the personal rights in view in Rights Theory, Communitarianism understands morality as it relates to the “common good.” In other words the rights of the community supersede the rights of an individual. Advocates would support as moral those actions which benefit the community as a whole and the relationships therein, even at the expense of individual rights. Such issues as mandatory vaccination and perhaps rationing of expensive health-care modalities would distinguish this school of thought. While considering the common good, theists are more inclined to focus on the glory of God and obedience to divine revelation.

**Virtue-based Ethic**

Virtue-based Ethics poses the question, “What would a person of virtue do in this situation?” and it uses virtuous character traits to analyze the dilemma. The problem arises in selecting who would such a person be, and what traits are truly virtuous. Many theologians are drawn to this system because it appeals to character issues beyond the individual’s self absorption or advancement as well as the centrality of community prosperity. Some foundational principles, such as the sanctity of human life, outweigh other concerns.

**Principalism**

A useful system based on a grid of principles, outlined by Beauchamp and Childress in Principles of Biomedical Ethics, includes Beneficence, Non-maleficence, Autonomy and Justice. In short Beneficence is to do the good; Non-maleficence is to avoid the harm; Autonomy gives the individual the right to make decisions concerning himself, that is, self determination; and lastly, Justice demands for all what is right or due. By using these principles and weighing them, each bioethical situation can be seen as regards the good, the harm, the rights of the individual, and the rights of the community.

It is readily apparent that these systems, each useful in many respects, have areas of overlap and areas of conflict. The principles listed above can be seen in each of the other systems as dominant in decision-making, or less central. Each of these paradigms springs from a worldview that is predominantly empirical and science-driven. None accounts for or even includes the spiritual realm of the theists. However, the theists, as noted, certainly appreciate and appropriate the strengths and logic of these systems without yielding that such analysis brings the only weight to the discussion.
Theistic Perspective

From a purely theistic standpoint, based on the sacred writings of the Torah (Hebrew Bible) and the Old and New Testaments of Christianity (foundational in both law and ethical thinking historically and culturally), human life emerges from the Creator God who spoke the universe into creation. The biblical record states unequivocally that God created mankind, male and female. Hence, from the beginning, from the outset of maleness and femaleness, God was at work. The Bible stated that male and female, humanity, was created in the “image of God.” Theologians have struggled for centuries to unpack the fullness of what this “image” means, recognizing that God is Spirit, immaterial and infinite, whereas humanity is material, finite and temporal. Differing approaches include a “substantive” understanding of image, whereby humans share certain characteristics with God, including reason, ability to contemplate the future, to worship and respond to the creator. Others hold to a “relational” view of image, whereby as God is relational (revealed as Father, Son, Spirit; a triune interanimated, interpenetrating One, that lives in perfect relationship as God) and desires relationship with His creation. As creatures, humans long for relationship with God and thrive in relationship to others—this being the reflection of “image of God.” Still others look to the eschatological or future fulfillment of “image” when God brings this creation to consummation and humans, see Him as He is, and become like Him. The purpose of this session is not to exhaustively explore the theological constructs or implications, but merely to introduce by way of overview several main viewpoints that bring theists to a strong belief in the value of the life of the unborn, even to the embryos in cryopreserved limbo because they are created in the image of God.

Maleness or femaleness is determined at syngamy, the one-cell stage, where the presence of either two “X” chromosomes signals the identity of a female, or one “X” and one “Y” chromosome identifies the one-celled male. Any other combination represents a serious anomaly. Thus, male/female image of God begins at the very first cell. No genetic material is naturally added from that moment on. Rather gradual expression of the genetic blueprint for that person continues to unfold, and that human becomes what he or she already is, at the microscopic level. The progressive differentiation and various milestones are “programmed” into the DNA, make any other distinction quite artificial, not in terms of function, but in terms of the essence of human personhood. Of crucial importance from the theistic perspective is the principle of the sanctity of human life and this understanding provides essential understanding as regards the value of the frozen embryo. Most Roman Catholic and Protestant bioethicists will argue for personhood and dignity of the one-celled human being. Thus, the cryopreserved, multi-celled embryos warrant appropriate protection and dignity.

Jewish bioethicists bring both Torah (written law) and Talmud (oral law) to bear on these discussions. Foundationally, the approach is one of duties within the context of relationships: physician-patient; husband-wife; parent-child. Central principles include the foundational belief that human life has infinite value, the body belongs to God, and that humans are stewards or caretakers of the body. Thus, there is a duty for the individual and the “neighbors” to save human life. These tenets shape the approach to all human life.
One rabbi serving at the Yeshiva University Center for the Jewish Future reasoned that there would be no issue with embryo donation for scientific research. An embryo external to the womb has no viability or potential viability to mature into a human being in its present location. Additionally, according to this rabbi, embryos of less than 40 days of age would classify as “fetal matter” without concern for destruction. The usefulness of embryos for medical research would “celebrate our responsibility to be God’s junior partners in finding ways to cure disease and improve the world. Adoption of such embryos would be a possibility, but the lack of clarity as to actual parental connections would be a concern.¹

Therefore, even within the Judeo-Christian bioethical community, issues pertaining to unique individual human life, personhood, and rights lack consensus. A variety of positions on the handling of cryopreserved embryos have advocates within the faith community.

Sanctity of Human Life

From the perspective of most theists, every human life is sacred, worthy of dignity and respect, from syngamy, in the hours following fertilization, in my view. Different theologians and secular ethicists try to pinpoint the moment the human life becomes a human person deserving not only of respect but having the rights attributable by law to persons. Personally, I am convinced by the theological and biological evidence that a new human life and person begins when the chromosomes of the sperm align with the chromosomes of the egg, and activate – a process called syngamy. Thus, the one-celled embryo, the zygote, is indeed and in truth a person.

Others attribute personhood to a stage of embryological development: implantation, the formation of the primitive streak, the end of the period of twinning, particular neurological development, sentence or a level of consciousness. Others would withhold the label of “person” until a point of self-consciousness, or self-awareness (when the infant knows himself to be a person) as prerequisite to personhood. While these scholars allow that the embryo is human in origin, genetics and development merely by being of human parentage, personhood with the right to protection requires a functional capacity or maturity. Thus, humans with certain developmental handicaps or intellectual shortcomings, along with the embryos, could be humans without being persons with rights.

Obviously, particular principle of personhood becomes the essential dividing point as regards the value and fate of the cryopreserved embryo. For many theists, and the secular ethicists who attribute full personhood for the zygote, the cryopreserved embryos represent human persons, frozen, yet worthy of full dignity and respect. This decision dictates in large extent the possible ethical disposition of the hundreds of thousands of currently cryopreserved embryos. For those holding to an ethical construct that denies full personhood until certain functional or anatomical milestones are met, destruction of or experimentation upon the frozen embryos presents no moral conflict.
In summary, the principle of the Sanctity of Human Life declares that each and every human being is of inestimable value by “being” - not by “doing” or achieving certain maturation levels. Every human being is a person, worthy of honor and respect and an eternally significant part of God’s plan to glorify Himself through creation, whether that life exists for one day or exceeds one hundred years.

Other principles have been invoked within this debate regarding personhood and the value of the cryopreserved embryo. Once embryos are declared to be “persons,” significant implications follow. Certainly one cannot legally destroy a person or experiment on said person without informed consent, but neither can one donate another person. So the very language of donation and adoption become potential legal hurdles within the current discussion. For some, using the analogy of tissue transplantation and organ donation circumvents this particular issue, but considering embryos as “donated tissue” raises issues of its own.

For those contributing to this field from the perspective of Roman Catholic Theology unique hurdles may arise. The papal position on in vitro fertilization (the ultimate source of the currently cryopreserved embryos) considers IVF-ET an “inherent moral evil” which cannot be redeemed. So, though these theologians would hold to the sanctity of human life, even at the one cell stage, and strongly oppose the destruction of or experimentation upon these embryos, they may be left without an ethical solution, but rather only able to support indefinite cryopreservation at this time.

Additional theological principles that have contributed to this discussion include the procreative-unitive principle within marriage. This principle requires that every act of marital intercourse must be open to procreation, and every conception must rightfully and naturally result from sexual union. In vitro fertilization, along with many of the other assisted reproductive technologies, fails to adhere to this procreative-unitive principle, foundational for many Roman Catholic theologians. Thus, in addition to opposing many high-tech procedures, adherents to this view believe the resulting embryos at the center of this discussion have no rightful place to be “created” by an inherently immoral process.

Also, some have argued that in marriage, the womb of the wife “belongs” to the husband in the sense that no other man’s child may be gestated there. Labeled as the principle of “Finality,” meaning that only the person born with the organs has the right to use them, thus organ transplantation is unethical, and in an extrapolated sense, embryo transfer likewise would fail the moral standard based on marital unity and exclusivity. Others reject this line of argumentation but rather invoke the principle of “Totality,” which states one cannot harm the
“whole” of one person for the good of another person. These would argue in the organ transplant arena that it would be immoral to harm or “mutilate” the donor, even with full knowledge and consent for the good of the organ recipient. Viewed from the perspective of the embryo-donation question, the “harm” would be to the recipient woman, whose body would in some sense be damaged or “controlled” by the pregnancy transferred there into. Personally, I find neither Totality nor Finality compelling arguments in the discussion of embryo donation and adoption.

Some appeal to the one-flesh principle of marriage, which states that the Bible declares husband and wife to be one flesh, not limited to the moments of intercourse but from the moment the marriage covenant is sealed until one or both depart this life. Within this construct the husband and wife together could prayerfully decide to make the womb available to gestate and rescue these frozen, orphaned embryos. Thus, for adherents to this line of thinking, an openness to Holy Spirit-led decisions that could allow for the transfer, gestation and adoption of an embryo conceived in vitro.

Strong theological arguments have been made from the basis of so-called natural law, a paradigm associated with Thomas Aquinas and influential even to this day, suggesting that a moral law has been “written on the human conscience” giving a knowledge of right and wrong. A more uniform consensus would seem to be required to give credence to this hypothesis, but there is general agreement on certain societal basics of right and wrong behavior, good and bad character. So, if one uses the secular general definitions of ethics as recorded by Beauchamp and Childress, ethics is “a generic term covering several different ways of examining and understanding the moral life.” And morality “refers to norms about right and wrong human conduct that are so widely shared that they form a stable (although incomplete) social agreement.” The basics of natural law are in place. That is, “norms are so widely shared” would suggest and support a natural law ethic.

From this natural law ethic, Roman Catholic theologians conclude that human life is sacred and deserving of protection, whereas most secular ethicists conclude that human persons are deserving of protection, but few will extend that protection to the cryopreserved embryo. Interestingly, for most secular ethicists, embryo donation/adoptive does not present a moral obstacle. Neither does discarding or experimentation. Some Catholic theologians reach an impasse because of the morality questions regarding assisted reproductive technology in general, and in vitro fertilization/embryo transfer specifically. To move the debate further, theologians have suggested the law of charity, whereby making a sacrifice for the good of another may be a stronger argument. Some have “suspended agreement” with the papal position on the morality of embryo adoption. Others have appealed to the clear teaching of the New Testament writings regarding true religion being evident in the care of orphans. (If one ascribes personhood to cryopreserved embryos and they are abandoned, these embryos are, by definition, orphans). Others have invoked the imagery of the parable of the Good Samaritan wherein one had a responsibility to care for a “neighbor,” equating the tiny frozen humans with neighbors. Old Testament teaching on hospitality, and the Golden Rule of doing to others what one would wish have done to/for oneself suggests that the frozen embryos are deserving of an opportunity to grow, whether seen as neighbors, fellow humans in need, or orphans needing care.
From this sketch of the major worldviews and ethical systems foundationally, the crisis of existence for the cryopreserved human embryos can be seen in at least three major constructs.

**Construct 1:**

Presuppositions: Cryopreserved human embryos are biological life, human in origin and destination, but not persons in any sense, having failed to achieve sufficient maturity and functional ability to qualify. (Be that sentience, consciousness, neurological development etc.) Predominant view among Scientific Naturalists.

- Cryopreserved embryos have no legal or moral standing since, while alive, they are not living persons.
- Destroying, discarding, allowing to thaw and die, using in medical research, and leaving embryos frozen presents no ethical obstacle.
- Transferring embryos upon thawing to a willing recipient likewise presents no ethical obstacle. If such embryos develop and reach selected milestones, they become persons deserving of protection.
- The author rejects this construct.

**Construct 2**

Presuppositions: Life is sacred from the one-cell stage (following syngamy). Cryopreserved embryos are persons deserving of protection, not destruction or experimentation. Predominant view among Roman Catholic ethicists.

- Embryo Donation/Adoption is not an ethical response for cryopreserved embryos.
- In vitro fertilization represents an “inherent evil,” and nothing can redeem it.
- ARTs such as in vitro/embryo transfer violate the procreative-unitive principle of marriage.
- The process of embryo-transfer and gestation in a surrogate womb controls the woman in a way that violates the one-flesh union and sanctity of marriage.
- Unethical medical procedures have resulted in human beings without an ethical option for survival.
- Cryopreserved embryos must be left frozen to avoid compounding the immoral procedure.
- Neither the totality principle, finality principle nor charity principle can redeem this situation.
- The author rejects this construct.
Presuppositions: Life is sacred from the one-cell stage (following syngamy). Cryopreserved embryos are persons, human beings created in the image of God, deserving of protection, not destruction or experimentation or consignment to frozen limbo indefinitely. Predominant view among Protestant theologians; 14 of 21 published Catholic scholars writing prior to the 2008 and 2009 Vatican pronouncements also agreed with this position.

- Embryo Donation/Adoption is the moral response to cryopreserved embryos.
- Destruction, experimentation, “compassionate transfer,” and terminal thaw each represent an assault on innocent human life.
- Supported by biblical revelation, biological continuity, natural-law appreciation for the humanity and personhood of the embryo.
- The covenant bond and sanctity of marriage are not violated by the mutual consent of husband and wife to offer abandoned, orphaned embryos the opportunity of life and development.
- The developing fetus certainly has an impact on the maternal anatomy and physiology but does not “control” it.
- Adoption of embryos, tiny human beings, pictures sacrificial Christ like love, yielding one’s rights and comfort for the sake of another.
- The author strongly supports this position.

Summary:

An appreciation for the present crisis regarding the half million or so cryopreserved embryos resulting from assisted reproductive technologies generates conversation and debate in bioethical spheres and literature. Various approaches to the complex topic are considered and different conclusions presented. For scholars viewing the issue from the viewpoint of philosophical naturalism, (the “scientific materialist”) there is no compelling empirical evidence for the personhood of the cryopreserved embryo. The value attributed to a collection of cells, numbering from a few to the approximately hundred in the blastocyst, while organized and self-determining cannot think, feel, reason or respond to external stimuli, and thus are merely precursors to persons in this mindset. As such these embryos are available for experimentation (utilitarian, communitarian) for the good of the many. Destruction, terminal thawing, and “compassionate transfer” likewise are acceptable (rights based on when maternal rights are in view, no rights are ascribed to the non-person embryo). Likewise, there would be no moral objection to embryo adoption, just no ethical imperative to act on behalf of cryopreserved embryos.

Those, whose worldview fits more within the radical environmentalism approach, with its biocentric focus, see no particular importance or special significance to the species of “human” above any other living order. In fact, living organisms with a higher degree of differentiation would be more deserving of attention and protection than the early human embryo. For scholars
holding to this view, the resource allocation involved in high-tech reproductive technologies would probably be better served elsewhere, and the cost/benefit ratio pertinent to EA/ED make this debate a peripheral concern.

For the theists who understand creation as a gift from God for His ultimate glory, the value of the unborn, preimplantation embryo is immeasurable. Each cryopreserved embryo represents a tiny human, made in the image of God, worthy of dignity, respect and protection. Questions about ensoulment, surrogacy, charity, and sacrifice still remain to be clarified. However, once one ascribes full human personhood to the embryo, even in its cryopreserved state, such options as destruction, terminal thaw, and experimentation, become an affront to human life in that they constitute the wilful death of a fellow human being. Such theism energizes the debate on behalf of the embryos, bringing an urgency and significance to the ultimate disposition of these tiny lives.

Even as a recognition and appreciation of the differing approaches to the embryo crisis are outlined and understood, additional issues surface, worthy of concentrated bioethical thought. As we look to the future of reproductive technology and the good desire to procreate, invasive medical procedures must be considered in light of the ethical quandaries that might result. Such issues as limiting the number of eggs inseminated in IVF, perfecting the freeze/thaw of human eggs, cryopreservation versus number of embryos transferred in a particular cycle become essential foci of discussion. Once embryos are formed, their grading, growth, and disposition become an ethical issue of central importance. And, finally, legal consideration relate to designation of these embryos as tissue to be donated and transplanted, or embryos to be adopted and transferred. How then are adoptive parents selected and screened? How will embryos be selected and matched for adoption? Much work remains to be done to resolve the moral, legal and social issues arising from the “epidemic” of cryopreservation and storage of human embryos.
Glossary:

EA – Embryo Adoption

ED – Embryo Donation

IVF-ET – in vitro fertilization – embryo transfer

Ethical Systems

Utilitarian – consequentialism; most good for most people

Kantian – deontologic – duty or law based – categorical imperative

Rights Based – individual has right over his own well being

Communitarian – what benefits the community is the moral option

Ethical Principles

Beneficence – to do good

Non-maleficence – to avoid harm

Autonomy – right of self determination

Justice – giving to all their right or due

Epistemology – theory of knowledge; How can you know what is true – truth corresponding to reality

Totality – cannot harm the “whole” for the good of another person, dignity of the person

Finality – only person born with the organs can use them – EA does not belong
Uterus can only be “used” to gestate offspring of husband
**Natural Law** – written on human conscience knowledge of right and wrong
Valuable in establishing dignity and personhood of embryo

**Personhood** – human being with rights (legal-moral)
Functional definition – ability to “do” sentient, conscious, self-conscious
Ontological definition - human being equates to personhood regardless of size, mental or physical capabilities

**Syngamy** – Union of gametes, alignment and activation of chromosomes from sperm plus egg.
Result is one celled human being (zygote).

**Suggested Resources:**

- Principles of Biomedical Ethics, Beauchamp and Childress
- Human Dignity in the Biotech Century, Colson, Cameron
- At the Beginning of Life, Hui
- Clinical Ethics, Jonsen, Siegler, Winslade.
- Bioethics: A Primer for Christians, Meilaender
- Biotech and the Human Good, Mitchell, Pellegrino, et.al.
- Bioethics, Rae and Cox

**Conference Centers**
- Center for Thomistic Studies; University of St. Thomas, Houston, Texas
- Center for Bioethics and Human Dignity, Deerfield, Illinois

1 Personal communication; Rabbi Kenneth Brander, The David Mitzner Dean, Yeshua University Center for the Jewish Future, December 27, 2009.


3 Conference discussion: Center for Thomistic Studies; University of St. Thomas, Houston, Texas; March 27, 2009.
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Bonnie J. Bernard, MEd, PC, NCC is the founder and executive director of Embryos Alive. She has worked with children and families for over 30 years, and has been the executive director and founder of several adoption-related agencies. She is a member of Chi Sigma Iota, a national professional honor society which recognizes scholastic and professional excellence in her field, a member of the American Counseling Association, and a member of the Ohio Association of Youth and Child Care Professionals. She is an acclaimed writer, speaker and presenter in the field of embryo adoption, and has pioneered several advances in methods for defining the terms of transparency and anonymity in adoptions. Her work has been featured in dozens of media venues, including television, newspapers, professional journals and internet articles.

William R. Cutrer M.D. practiced Obstetrics and Gynecology in Dallas for fourteen years, pastored for 4 years, and he now serves as the Gheens Professor of Christian Ministry at The Southern Baptist Theological Seminary in Louisville, Kentucky as well as the Director of the Gheens Center for Marriage and Family. Dr. Cutrer is married with three children, and six grandchildren. He has published a number of books and articles. Among them are the following:
The Church Leader’s Handbook, (Kregel 2009) Sexual Intimacy in Marriage, (Kregel, 1998, 2001, 2007); The Contraceptive Guidebook (Zondervan, 2005); and The Infertility Companion (Zondervan, 2004). He contributed to the Biobasics Series (Kregel) and his interest in bioethics has also led to a series of fictional medical-thrillers about stem cell research (Lethal Harvest, Kregel, 2000), end-of-life-issues (Deadly Cure, Kregel, 2001), and sanctity of life issues (False Positive, Waterbrook, June 2002).

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