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Introduction

IVF with donor eggs has become an increasingly important option for fertility patients in the USA. Approximately 93 % of US clinics offering IVF also offer egg donation, and, across all age groups, nearly 10,000 donor-conceived fresh-embryo transfers were reported for 2010 [1]. Egg donors, under current constructs, may be anonymous to their recipients, share some degree of identification, or may be fully identified donors, either known to the recipients through family or friendship or chosen from among recruited donor candidates who permit their identities to be shared with the recipients of their eggs. A fertility treatment plan that includes a donor (or a surrogate) may be referred to as “collaborative” or “third-party” reproduction.

History

The first report of a live birth from “egg donation” was in February 1984 and actually involved transfer of an embryo conceived by the donor woman after insemination with the sperm of the intended father. On the fifth day following the insemination, Dr. John Buster, at

the University of California at Los Angeles School of Medicine, removed the embryo from the donor woman’s uterus by lavage and placed the embryo into the uterus of the intended mother [2]. Shortly thereafter, a group from Monash University (Australia) reported a live birth from a single, donated, unfertilized ova procured through an IVF procedure [3].

The earliest egg donor arrangements in the USA evolved in the days before cryopreservation techniques were refined and widely accepted in the ART community. A patient, undergoing IVF for her own reproductive purposes, would sometimes produce an unusually large number of eggs, which, if they were all to be inseminated, would create the expectation of more embryos than would be transferred in a single treatment cycle. The patient might have been approached by her physicians and asked if she would donate the supranumerary eggs to another cycling patient whose response to stimulation was poor. These earliest arrangements were almost always anonymous, there was rarely psychological counseling involved, payment was not generally part of the plan, and no particular, established protocols were in place [personal observation of the author, at the time a registered nurse working in a hospital-based fertility practice, circa 1984–1986]. This source of donated eggs was relatively short-lived, since, with improved methods of cryopreservation, fertility patients increasingly requested fertilization of all of their usable eggs and then froze those resultant embryos not transferred fresh.

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Without an identified and accessible supply of donor eggs, absent a friend or relative willing to donate, the opportunity to benefit from this type of ART was extremely limited. Then, sometime in the late 1980s, fertility centers began recruiting donors from the community at large, rather than from among their population of fertility patients. At this time, the donation was contemplated as simply that, with reimbursement only for actual expenses and recipient payment for the medical procedures. However, donor participation was sparse, and beginning around 1990, a few fertility centers began advertising for paid donor candidates, offering compensation for time, inconvenience, and other intangibles. Typically, the payments were approximately \$2,000–\$2,500 for a completed cycle. In 1991, one of the first commercial egg donor recruiting/matching groups was started in California [4].

Since the 1990s, with the notable exception of egg freezing, the basic science involved in egg donation has not dramatically changed, although treatment protocols continue to be refined and improved. The complex practical and legal aspects of egg donation have shifted dramatically, though, as the need for donors continues to grow.

The Legal Landscape

An egg donor is a woman who contributes her genetic material, usually for reproductive purposes, to another. A donor does not intend to be a parent of any resultant child and waives any rights she may have to the eggs upon the donation. The term “donor” is a very specific legal term: a woman who provides eggs for her own reproductive purposes and who intends to parent the resultant child should never be referred to as a donor.

Examining the commonalities of sperm and egg donation helps identify the rationale of the shared legal and policy development in gamete donation. Sperm donation, with its decades of utilization as a solution for male infertility, informed the early development of approaches to egg donation. For instance, the concept of anonymity in egg donation follows the usual paradigm in sperm donation. Sperm donation paved

the way for, perhaps, easier acceptance of the concept of genetic material from a third party in the conception of a child for a genetically unrelated intended parent. Whether or not the use of donor gametes should be disclosed to a donor-conceived child, how that is best done, when the topic should be approached, and other disclosure issues are pertinent (and controversial) whether the donation is of egg or sperm. Additionally, since a majority of the states have codified various aspects of sperm donation (including parental rights for the intended father, donor rights and procedural requirements, among other things), a model for asserting equal rights protection for women receiving donated eggs has been established. While these state laws can be used as models for egg donation laws, it is important to note that the state laws regarding donor sperm are varied. Some of these laws only offer protection if the intended father is married to the mother; some, but not all, specifically terminate the rights of the donor; a number of them require professional medical participation or supervision; and several require consent of the intended father to the procedure, while others allow for implied consent.

While the framework of sperm donation has been helpful in the development and analysis of egg donation issues, there are obvious and significant differences between the two. The time commitment required and the complexity of medical participation for an egg donor have no parallel in sperm donation. While unlikely, if the donor develops a medical complication, it can represent a serious risk to the egg donor, a scenario that is not applicable to the sperm donor. The cost of an egg donor cycle, which can easily exceed \$20,000 (when using a recruited, compensated donor), further distinguishes the egg donation process from that of donor sperm. Further, payments to the egg donor far exceed those paid to the sperm donor, raising questions of coercion and commodification. Accordingly, in response to the special concerns raised by egg donation, professionals in this area have developed medical and psychological screening guidelines for all participants, considered and formally commented on myriad ethical issues,

and suggested legal protections for participants and medical providers [5, 6].

Currently, fewer than 15 of the states in the USA have laws addressing egg donation.¹ In jurisdictions without statutory or precedential case law that establishes parental rights, there is no absolute assurance that the intended mother would be considered a legal parent. Fortunately, in the vast majority of cases, there is not litigation generated by controversy among the parties in these arrangements. (Worth noting is that while the paucity of case law reflects a general contentment with the practice of donation, its absence does not allow for reliable prediction of the outcome of any disputes.) Arguably, the reason that so few donor arrangements give rise to dispute and litigation is the application of carefully drawn safeguards, now practiced with regularity. These include recommendations for psychological evaluations and careful and thorough informed consent discussions. Another factor that serves not only the intended parents and the donor but also the clinician is a legal consultation for both donors and intended parents, with independent representation for the parties. This process allows a frank discussion of the legal risks and an explanation of rights and responsibilities by an expert who acts as an advocate for his or her client. The additional step of drafting and negotiating a direct agreement between the parties assures that they have reviewed the salient legal points; that a blueprint, agreed upon by all parties, outlines everyone's understanding of intent, contractual duties, and problem solving; and that this negotiated instrument memorializes that meeting of the minds.

While recommendations, current law, guidelines, and process may address some of the potentially troublesome aspects of egg donation, other issues may not be encompassed by existing protections. For example, in states where there is no law, the process for determination of the parental status of the intended mother and whether that determination will withstand a challenge are questions that continue to be debated. A medical provider's professional liability when facing, for example, an accusation of misuse of

donor eggs or improper informed consent is also a topic that remains largely unsettled and is only resolved on a fact-specific, state-by-state basis.

Survey of Case Law

Parentage law varies widely from state to state, but most states' laws provide that the parental status of a natural mother can be established by some proof that she is the woman who has given birth to the child. However, not every state has a statute that defines the term "mother," although all codify a definition of "father." Exceptions to this understanding of the legal meaning of "mother" are particularly strained by gestational surrogacy arrangements and will be discussed further in the chapter on surrogacy. At a minimum, though, because of the various ART methods, there can now be up to five definitions of "mother": a woman who has both the genetic and gestating connection to the child, a woman declared by legal process to be the mother (as in adoption), a woman with a genetic but not gestating connection to the child, a woman who has given birth to the child, or a woman who has the intention, usually contractual, to be the mother, although this final definition is not always dispositive. (For instance, in a situation where an intended mother has contracted with a traditional surrogate [i.e., the woman giving birth is also the genetic mother], without the rare statute or case law that permits otherwise, the intended mother cannot be a legal parent without an adoption.)

Disagreements between donors and recipients that lead to a lawsuit about the maternity of a donor-conceived child are rare. Furthermore, in situations where donor-conceived babies are gestated by the (married) intended mother, the overwhelming trend is to recognize the gestating woman as the legal parent of the child. Notwithstanding, one of the first disputes involving egg donation addressed this very issue. In *McDonald v. McDonald* [7], a divorcing husband asserted that, since he was the only available genetic parent of the children born to him and his soon-to-be ex-wife through egg donation, he possessed a superior right to custody. The court,

¹ At the time of this writing, states that have statutes are CO LA, ND, OK, OR, TX, UT, VA, WA, WY, CA, NY, and FL.

having noted that the parents had entered into a written egg donation agreement that documented their intentions to both be parents, went on to declare that the father had no superior claim to the twin girls. In 1997 and, more recently, in a 2008 Tennessee case, the courts reached the same conclusion under similar circumstances [8].

More problematic is the scenario of the lesbian couple using ART to build their family, when one of the partners provides the eggs and the other gestates. A California case exemplifies challenges faced by fertility centers working with these patients. In *K.M v. E.G.* [9], the clinic provided the partner from whom the eggs were obtained with a consent form that labeled her a “donor,” which she dutifully signed. There was no written parentage agreement between the two women, and the genetic mother did not subsequently adopt the twins who were born from the arrangement. Later, when the partners separated, they became ensnared in a custody dispute, with the gestating mother claiming that her former partner was simply a donor and that there was no intent for her to parent. Initially, the trial court ruled that a woman who gave her oocytes to her lesbian partner, who, with donated sperm, conceived and gave birth to a child, was not a parent. The court reviewed the preconception intentions of the parties, as reflected in the standard “oocyte-donor” consent forms used by the medical facility, and noted that no further action was taken by the plaintiff to establish her maternity. The lower level appeals court also found in favor of the birthing mother. The ruling was overturned at the California Supreme Court level, and the court remarked that “...when partners in a lesbian relationship decide to produce children (by one partner providing her ova for IVF, with resultant embryos implanted into the other partner), both the woman who provides her ova and her partner who bears the children are the children’s parents” [9]. The court also recognized that the two women intended to raise any resultant child together.

In a convoluted case involving an intended father who was also the genetic father and was unmarried, his unmarried partner and intended mother, a married gestational carrier and her husband, and an egg donor, an Ohio appeals court

ruled that an oocyte donor had parental rights to triplets born to the carrier. The carrier had refused to release the triplets to their genetic father, and the donor asserted her claim of parental rights upon the request of the father [10]. This ruling challenged a prior Pennsylvania court’s decision that the gestational carrier of the boys was entitled to primary custody. Eventually, applying a test established by the *Belsito v Clark* case (parental rights established by genetic link, but since donor had waived her rights, the only parent is the father), custody of the triplets was awarded to the father [11].

Other areas where problems occur in the context of egg donation are donor screening and mix-ups of gametes/embryos created with donor gametes. Screening of egg donors for communicable diseases and heritable disorders requires careful interviewing of the donor, review of her medical records, follow-up of test results, and reporting to the patient as well as to the anticipated recipients of her eggs. Adherence to the ASRM guidelines is also a critical component of the testing regimen [6]. In a 2003 case, an egg donor tested positive as a carrier of the cystic fibrosis gene mutation, but the test result was not reported to the recipients, who proceeded with the egg donation process and went on to give birth to a child with the disease. The medical practice did not test the intended father for carrier status. While the court disallowed the child’s claim for wrongful life, it permitted the parents to proceed with their malpractice case against the medical practice [12].

Cases involving mix-ups of donor eggs appear to be uncommon, but can be particularly complex. For instance, a married couple, Denise and Robert, underwent IVF with an egg donor and sperm of intended father, while Susan, a single woman in the same practice, arranged to receive a donated embryo. Some of the embryos were inadvertently switched, and Susan received one of the embryos created with the husband’s sperm and the donor’s egg. The parties learned this from the clinic 10 months after a child was born to both Susan and to the wife, Denise. Denise and Robert filed a parentage action. The court determined that Robert had standing, that he was not a

“donor,” and after ordering a paternity test, declared him the father. However, since Denise had no genetic or gestational connection to the child, the court dismissed her from the case, noting that her situation was distinguishable from cases where an intended mother contracts with an egg donor and a gestational surrogate. The gestating mother retained custody of the child and was declared to be the mother [13]. Although not involving donor egg, in a similar, widely publicized occurrence, two married couples underwent IVF at the same fertility center, but only one of them, Carolyn Savage, became pregnant. Four days later, the couples learned that Carolyn had received the embryo of the other couple, Shannon and Paul Morell. Carolyn decided to carry the child and, upon delivery, to place the baby with the genetic parents. The parties resolved the parentage issue among themselves, but not without tremendous strain on both couples. At least one of the couples negotiated a settlement with the fertility center [14]. In an interesting twist, in August 2011, the Savages went on to have twins via a gestational carrier [15].

In egg donor/recipient agreements, the usual understanding is that the donor’s eggs are to be used by one particular recipient. If the arrangement is to vary from this basic understanding, then it must be clear that the donor had been informed, and did not object to, this variance. Proceeding with egg sharing or subsequent donation to another recipient, without the donor’s prior notification and authorization, resulted in the downfall of at least one egg-matching organization and a messy lawsuit for the physicians involved. Several years ago, a donor believed that she had donated her eggs to particular recipients at a Texas fertility center but later learned that the eggs were being shared with another couple without her authorization. Ultimately, the fertility program and its physician were found liable for, among other things, failing to comply with their agreement with the egg donor agency. Amid allegations of other misdeeds, the agency folded shortly thereafter [16].

Egg donor arrangements involving gestational carriers further complicate the determination of which woman is the mother and, in some

situations, determination of who is the father. In the early 1990s, a California couple received an embryo created with donor gametes and contracted with a gestational carrier to carry the pregnancy. During the pregnancy, the intended parents separated. During subsequent divorce proceedings, the husband contested any claim that the child was a child of the marriage, a determination that would implicate him in child support. The trial court agreed with him, but on appeal, the court ruled that the husband signing the surrogacy agreement was enough to determine the husband to be Jaycee’s father, as he had been married to Jaycee’s legal mother at the relevant time, and that he would be liable for child support [17].

Always a controversial area, egg donation has been the subject of much scrutiny and negative publicity regarding excessive payments to egg donors, reputed to be, in some cases, up to \$50,000. While actual instances of such inflated compensation were exceedingly unusual, ASRM and SART, along with respected professionals in the related fields of fertility counseling, ethics, and law, recognized the importance of a careful analysis of donor recruitment practices and examination of the rationale and justification for donor payment. While recognizing that payment should fairly reimburse the donor for her time, risk, and inconvenience, the reviewers also expressed concern that payment should be limited, so that it does not represent undue inducement to participate in an activity that holds risk, both physical and emotional, for the participant [5]. Accordingly, ASRM suggested a cap on payments to egg donors, and SART instituted a policy that any recruitment organizations that wished to be listed on its website must agree to comply with the compensation suggestions [18]. In 2011, ASRM, SART, and the Pacific Fertility Center were all named defendants in an antitrust lawsuit filed in California by an egg donor. The donor, Lindsay Kamakahi, who also asks that she and other similarly situated donors be certified as a class, claims that the defendants engaged in impermissible price fixing by establishing and enforcing guidelines on payments that may be paid to donors by fertility centers. The case is still in preliminary stages [19].

Recent Developments in Egg Donation

Technological advances over the past several years have given rise to reliably consistent results in egg freezing, warming, and fertilizing, opening new doors for women who wish to preserve their own eggs for future use and for banking of donated eggs. In mid-September 2012, ASRM recommended removing the “experimental” modifier from the process, concluding that reliable research demonstrates that egg freezing, with subsequent thaw and fertilization, works just as well as fertilizing fresh eggs [20]. As with many innovations, egg freezing, particularly for donation, raises ethical and legal challenges for medical practices and banking organizations. Current practices of sperm banks and egg donation recruitment and matching services offer the rudiments of process and application for the practitioner, but differences among these options drive the need for development of specific policies and procedures.

An issue receiving renewed attention is that of donor-conceived children seeking out their genetic progenitors. Sperm banks now routinely ask their donors if they would consent to future contact by a child born from their donation, but this practice has not been so commonly practiced with egg donors. A direct contract between donor and recipient (which can be prepared while preserving immediate anonymity) may address this issue and provide a mechanism for such future contact. However, medical practices that do not refer these patients for legal consult and rely instead on their internal forms, usually an informed consent document, may not have the capacity or the framework to address these issues. Fertility practices are encouraged to develop written policies addressing these situations. Of course, future contact by a child assumes that the donor will then understand that a child has been born of her donation, information that is typically not shared with the donor. Newest research in this area, though, suggests that most donors would like this information and that some practices now, with permission by recipients, do share the out-

come [21]. The degree of information provided (whether eggs fertilized, whether a pregnancy occurred, whether a child was born) varies. Hand in hand is the related topic of disclosure of his/her origins to the donor-conceived child. While the decision is left to the discretion of the parents, mental health professionals and other experts continue to recommend disclosure at an appropriate age, but research suggests that parents, even those who indicate that they intend to disclose, often do not [5, 21]. At least one state has recently adopted a law governing the release of donor-identifying information to children. While disclosure of identity is not mandatory, and the law provides that the donor may opt out of disclosure, it is silent as to what entity shall serve as the repository of donor information, how records are to be maintained, who will underwrite associated costs, and related issues [22].

Debate concerning the establishment of a national donor registry continues, and such discussion crystallizes the logistical issues that such an undertaking would face. Reasonable questions include the following: would registration be mandatory; would the registry provide full, identifying information; how would the information be protected; who would have access and how; would mandatory registration negatively impact the supply of donor eggs; where would such information be housed; who would administer the registry; what would be the cost; and how would it be funded? At present, privately created and managed registries such as the Donor Sibling Registry perform this function, charging a registration fee for recipients and donors, but participation in these arrangements is totally discretionary in most donor arrangements [23].

Implications for the Clinician

The overarching principle is that clinicians should review and follow professional guidelines in this area. Absent otherwise established standards of care, guidelines, although lacking real enforceability, are *de facto* standards of care against which practitioners will be judged. Even in light of the current threat imposed by the loom-

ing egg donor class action suit [19], this principle remains solid. Local laws and policies, as well as internal regulations, may allow for variances in the application of guidelines, but the importance of their use in day-to-day practice is well recognized.

Areas of general concern for the practitioner may include the following.

Informed Consent for Egg Donation Participants

During the last 25 years, as American bioethics and medical technology increasingly merged, but were often in discord, informed consent became a touchstone doctrine. The amount and complexity of information to be offered and discussed grew exponentially, and nowhere is this more apparent than in ART, most especially in collaborative reproduction, and particularly with respect to egg donation. The informed consent process primarily, although not exclusively, deals with risks to the patient. In egg donation, the risks pertain to the primary patient, to the potential offspring and to the donor patient, whose behavior is outside the control of the primary patient but for whom the primary patient is assuming some level of financial liability.

The exact requirements for the informed consent process itself and the depth and breadth of the information to be offered differ from state to state (and sometimes even among cases within a state). However, certain core elements are essential to any informed consent process, including for the egg donation patient:

1. The physician, not a physician-designee, conducts the informed consent discussion.
2. The patient consent is documented. Proving consent without written evidence of the patient's agreement is difficult, at best, so, generally, the patients should be asked to sign documentation of the discussion.
3. The consent should occur after a review of the essential elements, including:
 - (a) Diagnosis, to the extent known.
 - (b) Nature and purpose of the proposed treatment or procedure.

- (c) Benefits and risks and the likelihood of success.
- (d) Alternatives to the proposed treatment or procedure and their benefits and risks, including a discussion about the risks and benefits of doing nothing.
- (e) An assessment of that particular patient's ability to understand and documentation that he/she does evidence understanding of the topics discussed.

Additional areas of discussion for the intended parent participant include:

1. Financial obligations and specific costs—what the patient is expected to pay, what those charges are for, and when they are to be paid
2. Information regarding treatment options not available from the current provider
3. Disclosure of the federal reporting requirements and release of information about the patient to the report (nonidentifying)
4. Information about nonmedical options
5. Adoption and foster care as alternatives to family-building through fertility treatment
6. Living without children [24]

The medical aspects of each particular fertility treatment are complex and involve steps that are extraordinary in most realms of patient care. ASRM revised guidelines on gamete donation and its practice guideline on informed consent provide additional direction for the clinician [25].

Egg Freezing for Donation

It is reasonably anticipated that eggs banked for donation might not actually be provided to the eventual recipients/intended parents until, perhaps, years after the retrieval of those eggs. Under the current paradigm of egg donation, the donor usually relinquishes her rights to those eggs and any eventual embryos to a directed recipient. With egg banking, the relinquishment will likely be to the medical practice or other business entity, giving rise to a host of practical and liability concerns. For instance, does the practice have an obligation to provide updated medical information, which then would necessitate continuing contact with the donor? Should the practice entertain a

donor's "change of mind" as to unused, banked eggs? Another concern is structure of payments to the donor. As in traditional egg donation, any payment should be based on her time, inconvenience, and risk, and not in any way associated with the number or quality of eggs. In order to avoid running afoul of existing and possibly relevant organ donor laws, charges to the recipients of those eggs should not be based on number of eggs that they will receive. Rather, those fees should reflect clinic expenses, such as storage, laboratory fees, and the payment to the donor (apportioned among the various recipients according to a written policy), as well as the practice's customary charges for the medical services involved in the egg donation cycle. Also, different types of laws and standards apply to the sale of products as opposed to the provision of services, and these theories of liability can attach if practice materials suggest that the center is selling eggs [Remarks by N. Desai at the ABA Family Law Conference, Section on ART, FL, April 2012]. Quite clearly, suggested fee structure, marketing materials, and patient information should all be developed with, or at minimum, referred to, the practice's legal counsel before beginning any egg banking program.

Conclusion

ART with third-party collaboration forever changed the face of family formation. Egg donation, while still a comparatively new process, has undergone any number of procedural changes and medical protocol improvements since it was first introduced in the mid-1980s. The need for donors continues to grow, as does the technology: egg freezing is poised to break new barriers and allow for greater convenience, affordability, and choice for patients. However, developing treatments are burdened with the responsibility of extra diligence, measured application, and careful disclosures to patients about their risks and benefits. The law is slow to respond to rapid advances in medical technology, but practitioners may be guided by the lessons of the past in their visions for the future.

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