Establishing and Managing Donor Oocyte Banking

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Learning Objectives

- Array of resources required to establish a donor oocyte bank
- Strategy for oocyte donor recruitment and compensation
- Processes for screening and acceptance of prospective oocyte donors
- Validated and effective clinical and scientific standard operating procedures for donor ovarian stimulation and method for oocyte cryopreservation (vitrification), respectively
- Federal regulations regarding donor reproductive cells and tissue
- Utility and advantages of donor oocytes in family building for some patients
- Development of marketing of inventory to recipients

59.1 Introduction

For almost four decades following the birth of the first IVF baby in 1978 [1], in vitro fertilization (IVF) and the array of assisted reproductive technologies (ART) have made it possible for countless individuals to realize the dream of having a family. Remarkable technical advances in IVF were rapidly made to enhance fertilization and optimize embryo implantation and utilization. The catalogue of ART evolved to include freezing (cryopreservation) of cleavage-stage embryos [2] as well as zygotes (fertilized eggs) and blastocysts, assisted hatching [3], intracytoplasmic sperm injection (ICSI) [4], and embryo biopsy for preimplantation genetic testing for single-gene mutations and/or chromosome copy number (aneuploidy screening) [5, 6]. What eluded inclusion in this repertoire for many years was the ability to cryopreserve eggs despite an early report of a live birth [7].

Multiple advantages are afforded by egg freezing. In providing an alternative to freezing *embryos* in a treatment cycle, the patient who elects to freeze her supernumerary eggs and her partner can avoid the ethical dilemma of the disposition of potential "surplus" embryos, i.e., more embryos than are needed to build their family. In instances when sperm are not available on the day of retrieval, the eggs can be frozen, deferring the insemination. Egg cryopreservation, importantly, offers the prospect of fertility preservation to reproductively aging women as a strategy to manage ovarian loss or function from gonadotoxic treatments such as surgery or chemo- or radiotherapy and potential loss or injury during military service or from an accident or against declining ovarian reserve with age.

A significant contribution to ART is the success of egg freezing in fulfilling an obvious need in third-party reproduction, or family building requiring donor gametes and gestational carriers. While the availability of frozen donor sperm through commercial banks or private clinics had been well-established for treatment with home insemination, or intra-uterine insemination (IUI) or ART, infertility therapies requiring donor eggs were realized with the advent of IVF and the use of eggs from "fresh" donation, i.e., ovulation induction of and egg retrieval from the egg donor [8]. Treatment was comprised of the selection of an egg donor from those available through specialized agencies or clinics by the recipient, the egg donor's ovarian stimulation and egg retrieval in a treatment cycle hormonally synchronized with the egg recipient's, and, finally, transfer of the resultant embryo(s) to the recipient's uterus with optimal endometrial preparation.

Fresh egg donation offered excellent prospects for clinical pregnancy and live birth rates for recipients as reflected in the annual infertility clinic reports of the Society of Assisted Reproductive Technology (► https://www.sartcorsonline.com) but entailed a high cost per treatment cycle or attempt (typical total fees for one attempt can be approximately $35,000), the contracting with an anonymous donor through an agency or clinic, and coordination of the donor's stimulation and monitoring of hormonal and ovarian follicular response to achieve synchronization with the recipient's. Given the significant commitments of time and effort by the donor to the cycle, the recipient was necessarily dependent on her availability to undergo the stimulation and retrieval, introducing inconvenience and potentially, a protracted waiting time. Cost-efficiency and convenience were not hallmarks of this treatment modality: there was a clear need to have donor egg availability achieve better access.

Effective egg freezing opened the door to egg "banking." The advantages are multiple: (1) with the advantage of distributing eggs from a single retrieval cycle among multiple recipients, cost-efficiency for each donor stimulation is achieved; (2) the temporal burden of donor and recipient cycle synchronization is eliminated, offering significantly greater convenience; and (3) greater access afforded by frozen egg banks increased the opportunity to many more patients whose reproductive treatments required donor eggs [9–13].

The availability of a reliable egg cryopreservation method readily fulfilled two clinical needs: the ability of reproductively aged women to preserve their fertility and the creation of donor egg banks analogous to sperm banks. The latter was an obvious opportunity to provide a significantly more convenient and affordable option and greater access to individuals desiring donor eggs for family building compared to identifying a suitable donor whose stimulation and retrieval cycle was dependent on her availability as well as possible synchronization with the recipient's cycle to afford optimal timing for embryo transfer. While egg freezing and storage for a clinic's patient for her own use (autologous egg freezing) follow the same model as that applied for cryopreserved embryos created through a treatment cycle, commercial *donor* egg banking entails more resources.

The establishment and management of a cryopreserved donor egg bank are multifactorial processes and require an array of expertise and operations. The establishment must include (1) a laboratory that has acquired, validated, and implemented the laboratory methodologies of egg vitrification and inventory management, is registered with and accredited and licensed by all appropriate regulatory agencies, and has an electronic database that captures and tracks

outcomes for each donor's eggs from number of eggs acquired to number of live births to achieve quality assurance and control; (2) a systematic approach for (a) recruiting, screening, and accepting appropriate egg donors; (b) the medical and clinical expertise for appropriately and thoroughly evaluating the donor candidates; and (c) managing the donors from ovulation induction cycle through egg retrieval; (3) an organizational plan that provides (a) an administrator and manager who oversee the development of the bank and its catalogue by building and nurturing relationships with its donors and clients and (b) a business director responsible for the financial and fiduciary management of the bank and oversight of its contracts and agreements with partners; and (4) a multidisciplinary leadership team attuned and attentive to the bank's continued development and quality.

This chapter provides a framework for establishing and managing a donor egg bank by addressing each of these elements, presented in ◘ Table 59.1.

59.2 The Science, the Technology, and Laboratory Requirements

Identifying a consistent and reliable method for freezing eggs, unlike sperm, was a challenge. Although a report of a pregnancy from thawed eggs frozen by slow cooling appeared in 1986 [7], the method could not be immediately replicated.

The slow-cooling method that proved successful for the freezing of zygotes (di-pronucleated fertilized eggs), embryos, and blastocysts involved equilibration of the samples with cryoprotectants and cooling in programmed freezing machines to achieve gradual reduction in temperature, e.g., rates such as 0.3° per min. Thawing or warming was achieved with a brief exposure to room temperature followed by equilibration in thawing or warming solutions to achieve stepwise rehydration of the zygote, embryo, or blastocyst.

Encouraging outcomes from egg freezing by slow cooling were reported [14–16], but it was the application of the ultrarapid freezing achieved by vitrification that catalyzed the emergence of a reproducible methodology for freezing and warming eggs with acceptably high recovery, survival, and potential for fertilization and embryo development.

Vitrification, in contrast to slow cooling, entails the equilibration of the egg with much higher concentrations of cryoprotectants followed by immediate immersion (plunging) of the sample into liquid nitrogen. The effective freezing rate with vitrification is the ultrarapid −20,000° per min, producing a glassy or vitreous intracellular environment and avoiding all ice crystal formation and its attendant damage to the cell [17, 18]. This technique was successful in addressing the unique challenges posed by eggs owing to their large diameter, high water content, and intracellular architecture, i.e., the meiotic spindle, requiring protection against disruption and the result risk of aneuploidy [19–22].

Warmed eggs do require fertilization by ICSI [23], reflecting potential low-temperature-induced changes to the zona pellucida precluding fertilization by conventional insemination.

Meticulous technique in vitrification must also be applied to achieve the desired post-warming survival, fertilization, and developmental potential for effective egg banking. Cryopreservation-related damage can result from nonadherence to the technical protocol that is specific in duration of equilibration intervals in cryoprotectant solutions and the loading of the eggs onto the carriers (the plastic appliances holding the vitrified eggs for storage). In addition, appropriate handling of the carriers must be achieved during transfer from storage vessel to vessel, e.g., storage tank to shipper, and shipper to storage tank. Best practices will prevent unintended warming of the eggs that will negatively affect their integrity, survival after warming, and ability to be fertilized and develop into embryos. Effective and validated training in conjunction with a solid foundation in reproductive biology and the principles of cryobiology will foster the quality assurance and quality control that contribute to the success of the bank. Thus, the prospective laboratory of the egg bank must ensure mastery of the technology with a structured training plan documenting practice by and validation of each scientist who will participate in egg retrieval, evaluation of maturity, and vitrification of mature (Metaphase II) eggs for addition

◘ **Table 59.1** Organizational and checklist chart for establishment and management of an egg bank

Scientific/laboratory	Medical/clinical	Administrative/business
Effective and validated egg freezing methodology Training for quality and consistency Appropriately equipped laboratory Storage facilities System for distribution Licensure and accreditation Registration with FDA Quality assurance/quality control programs	Compliance with ASRM guidelines Medical, psychological, and social history criteria for acceptance as an egg donor Application database Donor candidate evaluation and vetting (genetic screening, ovarian reserve screening) Risk factor assessment, infectious disease testing, physical examination Achieving safety for the egg donor and recipient	Egg bank's mission and values Development of contracts and business agreements Financial management of bank Provision of guarantees to recipients Development of business for growth and enhanced services to recipients/clients

to the bank's inventory. These professional scientists are likely to be clinical embryologists, well-versed in collecting eggs from ovarian follicular fluid, enzymatically removing the cumulus cells surrounding the eggs and evaluating the eggs for nuclear maturity. The mature eggs, that is, eggs at Metaphase II, are those that will be frozen.

With the burgeoning of favorable clinical experience and reports of pregnancies and live births from vitrified eggs in the medical literature, the American Society for Reproductive Medicine lifted the qualifier, "experimental," from egg vitrification in 2013 [24]. Subsequent reports reflect that egg freezing by vitrification has become firmly incorporated among the ART available to patients [25, 26] and has been deployed to commercial as well as autologous egg banking.

59.2.1 Storage and Distribution

An egg bank must have adequate storage capacity and meticulous maintenance of the storage containers, a redundant system for inventory management, e.g., both electronic and hardcopy versions, and a system for tracking inventory and accounting for the disposition of all samples – eggs that are in storage, shipped to other sites, or removed and discarded.

A database containing details of egg warming, specifically number of eggs surviving thaw and undergoing ICSI and number fertilized; number of embryos or blastocysts that developed and were transferred, cryopreserved, or discarded; and the clinical outcomes of any transfers, whether fresh or from a frozen embryo transfer (FET) cycle, must be in place for quality assurance and control. These data are central in the management and development of the bank's inventory, administering any guarantee programs and rendering decisions on the recycling of the egg donors, or conversely, the discontinuation or withdrawal of donors.

For shipment of eggs to other centers, dry shippers that have been validated through a program documenting that appropriate internal temperature is maintained over multiple days are used. If recipient centers send their tanks to the egg bank for loading of the samples, then the bank must inspect these to ensure they are fully functional. The use of colorimetric markers to reflect maintenance of the internal temperature over time is an excellent tool for routine use during shipping.

59.3 Compliance with Regulatory Agencies

The US federal government is clear in its rules for bank or establishment registration with the Food and Drug Administration (FDA) and the procurement, processing, storage, and distribution of donor cells and tissues: these are provided in the Federal Register, 21 CFR Part 1271 [27]. Donor eggs are considered and regulated as reproductive HCT/P – human cells, tissues, and tissue-based products. The ultimate objective of the regulations is to prevent the transmission of infectious disease by treatments using the cells or tissue. Fulfillment of these rules is achieved by the infectious screening of blood samples drawn from the candidate donor and the medical review of the outcomes that underpins whether an individual is eligible or ineligible as a donor.

The donor egg bank must register each year as an HCT/P-producing center, describing each type of product from the bank, and is subject to unannounced inspections by FDA officials. Included in the inspection are a survey of all the documents, procedures, and policies of the bank, interviews with its personnel, inspection of its facilities, and review of all donor records. Penalties for failures in compliance can be severe, with the possibility of closing of the bank's operations.

Complementing the federal regulations are the requirements by individual states that the egg bank must apply for a license as a tissue bank. Each state's application will vary in the breadth of information that must be provided to qualify for initial and renewed licensure.

While an egg bank could have an independent laboratory dedicated solely to egg retrieval, processing, vitrification, and storage, it is more frequently the case that the bank exists within and is part of an IVF clinic. While the egg donors can undergo ovulation induction and cycle monitoring at remote physician's offices or other centers, egg retrieval will occur at the bank where the eggs can be vitrified in its laboratory. ART laboratories for egg banks must have licenses as tissue banks, be registered with the FDA, and be certified as compliant with CLIA 88, the Clinical Laboratory Improvement Amendment of 1988, as well as the American Association of Tissue Banks (AATB), depending on state-specific requirements. As well, the laboratory is likely to be a member of the Society for the Assisted Reproductive Technologies (SART) of the American Society for Reproductive Medicine (ASRM).

59.4 Donor Recruitment, Evaluation, and Selection

In addition to the laboratory component, a donor egg bank requires both administrative and clinical staff working in conjunction toward bringing in young, healthy egg donors for ovarian stimulation. Administrative personnel and nurses work together to advertise to and recruit donors, review donor applications for clinical contraindications, accept applications contingent upon donors passing screening tests, coordinate screening tests, and ultimately stimulate the egg donor to produce a large cohort of oocytes.

A key component in establishing and maintaining a donor oocyte bank is the recruitment and screening of egg donors [28–30]. This is best accomplished through online advertising, social media, and local recruitment efforts. Knowing the target audience is crucial. The ideal age of donors is 21–30 years of age. Recruitment strategies must be focused toward healthy, young women, with a sense of altruism who would benefit from the compensation. They must be healthy, motivated, compliant, eager, and, ideally, educated. Initial online screening should be focused on the following areas: age, body mass index, health status, family history, and level of education. If the prospective donors do not meet

these basic criteria, it is not worthwhile to expend additional energy. If the prospective donors do meet these criteria, a much more extensive online application is the next step. Donors must submit demographic information, specific personal and relationship information, lifestyle information, detailed medical and surgical history for the donor, detailed medical history for first and second degree family members, as well as subjective information such as favorite subjects in school, hobbies and interests, and a personal statement about why they are interested in egg donation.

Donors may be disqualified at this second level of screening for poor lifestyle choices, personal or family history of autoimmune disorders, cancers at young age, or any other host of medical or social concerns. It is important to remember the attributes that donor recipients may be looking for when they undertake the donor selection process. If a recipient is not likely to choose a donor, then it does not make sense to continue further testing for that prospective donor.

Once the donor application has been vetted, it is then imperative for the nurse(s) to coordinate and perform ovarian reserve testing, genetic screening, psychological screening, infectious disease screening, risk factor screening, and physical examination including a detailed list of the donor's piercings and tattoos. Ideal egg donors will have a high normal ovarian reserve, not be carriers of common or high impact genetic diseases, be psychologically sound, be free of infectious diseases, and possess no limiting risk factors. All rules and regulations with respect to tissue banking must be adhered to in accordance with FDA policies.

Donor screening must be stringent. It is estimated that only 1–2% of women applying to be egg donors will actually meet all of the criteria set forth. Once the donors have been vetted, it is necessary to provide appropriate, detailed information about the egg donation process, including risk and benefits, time commitment, and compensation. All egg donors will need to complete informed consent. All prospective donors must be thoroughly educated about how to administer medications and subcutaneous injections, expected side effects, expected schedule for testing by blood draw and ultrasound, as well as the egg retrieval procedure and related anesthesia or sedation used to perform the egg retrieval.

It is the role of the nurse to provide the majority of the education regarding the treatment plan and medications used to stimulate the donor's ovaries. Ovarian stimulation protocols may vary, but must take into account the age and relatively high ovarian reserve potential of donors. Also, it must be remembered that these women are not considered infertile. As is the case in most IVF treatment cycles, the nurse(s) will provide overall education and day-to-day contact with the egg donor for medication instructions as the ovarian stimulation progresses. Detailed written medication and injection instructions are strongly recommended and will allow the donor to follow along and reduce medication errors on the part of the donor. Many donors will appreciate receiving their daily instructions via email, rather than verbally. Most donors have email accounts on their cellular phones and prefer this method of communication. Although most stimulation medications are now given by subcutaneous injections, minimizing the number of injections and length of time the donor will be subjected to medications and injections is imperative. The nurse will also provide preoperative instructions prior to the egg retrieval and postoperative follow-up after the egg retrieval. Nurses must ensure that donors feel well-cared for throughout the process if they hope to retain donors for subsequent donation cycles. Meeting with the donor on the day of the egg retrieval or soon after, thanking her for the donation and gift, and providing her with the compensation are strongly recommended.

According to guidelines set forth by the American Society for Reproductive Medicine, donors may participate in up to a maximum of six donation cycles [31]. It is financially beneficial for donor egg banks to utilize donors multiple times to offset the time and financial costs inherent in repeated screening.

59.5 Development of the Egg Bank and Future Prospects

The successful development of a donor egg bank must include the continual replenishment and expansion of the catalogue to offer potential recipients a greater array of donor phenotypes. As some ethnicities and mixed-ethnicities may be underrepresented among donors, an effort to recruit among these groups may fill potential voids in availability.

Every clinical and scientific technique should be subject to constant effort to achieve improvement, measured in terms of efficiency and/or efficacy. The safety of the donor during ovulation induction can be realized from innovations in controlled hyper-stimulation. With respect to the freezing method, constant revisions in cryoprotectant formulations or the technical steps of processing the eggs to achieve even higher survival, fertilization, and embryo development rates could lead to a reduction in the number of eggs needed to comprise a "lot" (the number of eggs purchased for a single treatment) consistent with leading to embryo transfer and live birth and potential supernumerary embryos for cryopreservation and future FET cycles. Potential improvements in design or function of cryopreservation storage tanks or shipping containers would also be advantageous to an egg bank for efficient operation.

59.6 Conclusion

The advent of effective egg freezing through vitrification with high survival and developmental potential offered significant advantages to individuals seeking fertility preservation as well as an improved model for patients using donor eggs. Advantages of lower cost, higher convenience, and greater access compared to the established model of fresh donor eggs were realized. The establishment and effective management of a donor egg bank is the result of careful planning and organization to ensure solid technology underpinned by committed quality assurance and control, a program of medical, genetic,

and psychological screening that is both regulation compliant and dedicated to the safety and protection of both donor and recipient, and a responsible and accountable administrative and business infrastructure for optimal donor and consumer relationships and financial management. A committed and dedicated team comprised of business, administrative, clinical/medical, laboratory, and marketing personnel is central to achieving success in the area of donor egg banking.

Review Questions

1. List the components that comprise a donor oocyte bank.
2. Describe the strategy for recruiting oocyte donor candidates.
3. Outline the processes for screening and acceptance of prospective oocyte donors.
4. Describe the clinical and scientific methods involved in creating an inventory of donor oocytes.
5. Identify the federal legislation that covers donor reproductive cells and tissues and summarize how a donor egg bank complies with this law.
6. Outline the advantages of cryopreserved donor eggs to a recipient.
7. Propose a viable marketing plan for the donor oocyte bank.

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