

## Recruitment and screening policies and procedures used to establish a paid donor oocyte registry

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**We have reviewed the demographic characteristics of, and report abnormalities noted in, the de-novo growth and development of a paid oocyte donation programme. The personal profiles of all prospective oocyte donors were reviewed. Acceptance or rejection of candidates was based upon screening the results of medical, genetic and psychological testing. A total of 603 candidates initially responded to our advertisement. From this pool, 313 individuals were considered suitable and contacted by telephone. Following further conversation, 176 women were scheduled an entry interview. On completion of the formal screening process, 17.6% ( $n = 31$ ) of those actually interviewed were denied entry. Thus, from the initial interested parties, only 23% of women wishing to participate in oocyte donation were considered suitable candidates. Given the high attrition rate, we concluded that the need for rigorous and thorough medical, psychological and genetic testing is mandatory for the establishment of a donor registry. Furthermore, professional counselling of prospective donors with respect to the results of tests and the implications of test results with respect to their future medical and reproductive health, are important parts of providing comprehensive care.**

*Key words:* donor registry/oocyte donation/pathology/screening

### Introduction

The demand for donors has increased dramatically as indications for oocyte donation continue to evolve. Today, women with hypergonadotrophic hypogonadism, natural menopause and women failing attempts at assisted reproduction commonly choose to pursue oocyte donation. As a result, the number of clinics performing oocyte donation has risen and currently more than half of all centres reporting to the Society for Assisted Reproduction claim to offer this method of assisted reproduction (ASRM, 1996).

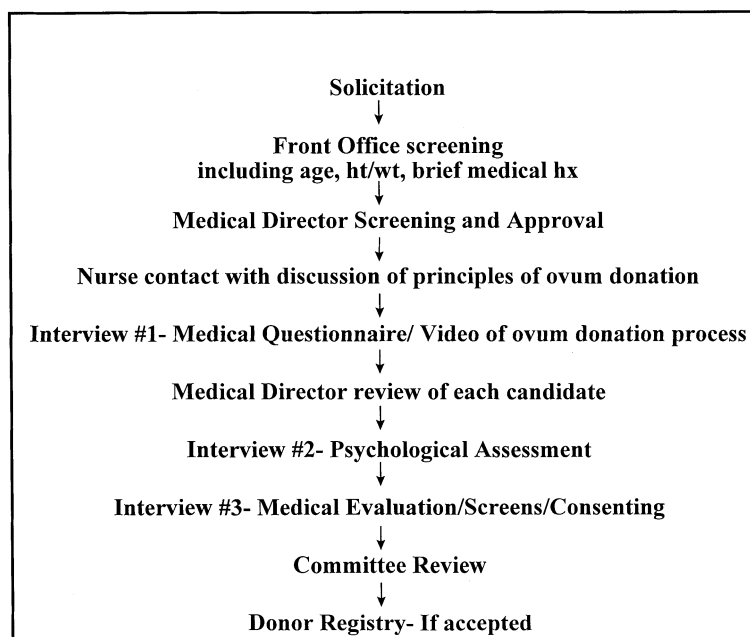
In most United States programmes, donors are recruited and

given financial compensation for services rendered. However, internationally, programmes are often restricted in the amount of payment permitted or cannot utilize paid participants at all. For instance, in the UK, the Human Fertilisation and Embryology Authority mandates that all payments to gamete donors, other than reasonable expenses, would be disallowed (HFEA, 1993). Similarly, French law forbids in its 'general principles' any payment for organ donation or 'parts of products of the human body' (l'assistance médicale, 1994). In contrast, in the USA, statutory law has not restricted payments. In general, practitioners have considered financial remuneration acceptable since the complexity of the process, the risks assumed, and the time required of donors, who must use parenteral drugs for ovarian stimulation and undergo follicle aspiration and anaesthesia to donate oocytes, are substantial (Sauer, 1997).

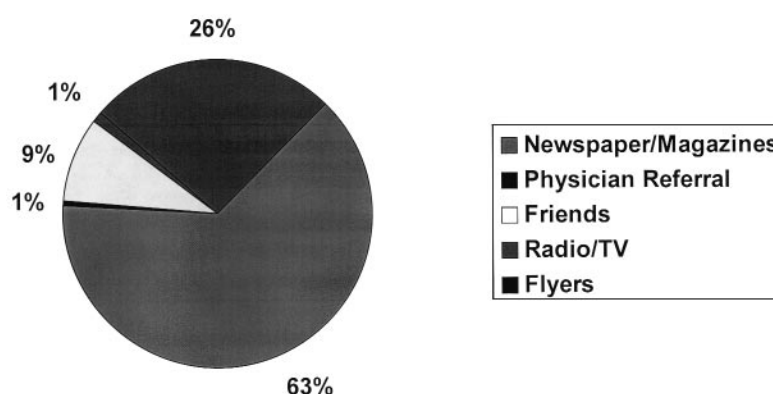
To satisfy the ever-increasing demand for donor services, most programmes solicit young women for participation. Participation may occur in a variety of ways. In the case of non-anonymous donation, extensive psychological counselling is required prior to initiating treatment in order to identify and prevent conflicts between known parties that may occur later in their relationship. Several groups have reported their experience of using friends or relatives of recipients who donate gametes for them or even another couple (Frydman *et al.*, 1990). In other instances, eggs may be procured from patients undergoing in-vitro fertilization who anonymously share oocytes with recipient couples in exchange for discounted or free IVF services (Check *et al.*, 1994), while other programmes provide oocytes from a single donor for two recipients (Abdalla *et al.*, 1997).

Our programme has primarily utilized the services of anonymous donors obtained through direct solicitation. Although the task of maintaining an active donor pool is challenging, solicitation permits the continual recruitment of large numbers of young women and allows for the rapid establishment of a registry necessary to meet the ever-present needs of a busy programme.

We originally reported on the establishment of an oocyte donation programme at the University of Southern California (Sauer *et al.*, 1994). Over the years, in excess of 500 potential donors were screened and over 300 women were recruited for entry without advertisement. In building a new oocyte donation programme at Columbia University, a need to quickly attract women to perform services, balanced by the ethical treatment of healthy young women undergoing medical procedures for the benefit of others than themselves, was required. This report profiles our experience in the de-novo growth and development of this new programme. Reported are the demographic charac-



**Figure 1.** Steps in establishing a donor registry. A summary of the process of screening potential applicants for an oocyte donation programme.



**Figure 2.** Distribution of donor response. The pooled enquiries of applicants contacting our programme.

teristics of women responding to our advertisements, as well as abnormalities discovered in this population during the screening process.

### Materials and methods

The programme for oocyte donation was reviewed and approved by the Institutional Review Board of Columbia University, College of Physicians and Surgeons, Columbia-Presbyterian Medical Centre. All oocyte donors underwent screening between July 1995 and July 1997.

Advertisements and flyers were placed in local newspapers and magazines typically read by younger women and posted on the medical and university campus bulletin boards. Advertisements were directed at healthy women between 21 and 34 years of age, and offered \$2500 financial remuneration for services. Prospective candidates were asked to contact our office nurse co-ordinator by telephone. All calls were initially received by the front office staff, who administered a standardized questionnaire to ascertain the age, height, weight, ethnic background and brief medical history of interested candidates. Questionnaires were later reviewed by a physician (medical director) and

candidates deemed appropriate (aged 21–34 years and without medical conditions) were then contacted by the nurse co-ordinator. The nurse presented the applicants a 10- to 15-min review on the principles of oocyte donation, outlining the necessary time commitment, number of required visits to the office, use of parenteral medication, and potential risks and liabilities of participation. Additionally, a preliminary medical history was taken. After this, if the prospective donor still appeared suitable (without significant medical, genetic or psychological problems) and did not convey major concerns over injections and time commitment, they were invited for a series of interviews, as previously described (Sauer *et al.*, 1994). These interviews are designed to extract key aspects of their medical, familial, social, reproductive and psychological history.

The prospective donor was asked to allot 2–3 h for their initial face-to-face consultation. During this time, the candidate completed a detailed questionnaire which included information on her sexual, reproductive, gynaecological, medical, surgical, social and family history. A videotape was viewed which demonstrated and reviewed practical aspects of egg donation, including injections, monitoring and oocyte retrieval. A review of the donor's history and a discussion

**Table I.** Personal characteristics and demographic background of screened oocyte donors ( $n = 166$ )

Characteristic	Mean $\pm$ SD	Range
Age (years)	26.4 $\pm$ 3.6	21–36
Gravidity	0.7 $\pm$ 0.8	0–5
Parity	0.4 $\pm$ 0.6	0–3
Elective abortions	0.2 $\pm$ 0.4	0–3
Spontaneous abortions	0.1 $\pm$ 0.3	0–2

of all aspects of ovum donation were conducted with each candidate by the medical director to ensure the good health of the applicant and to assess her personal characteristics, motivation and compliance. An interview with the nurse co-ordinator was performed to obtain information regarding the donor's ability to comply with injectable medications.

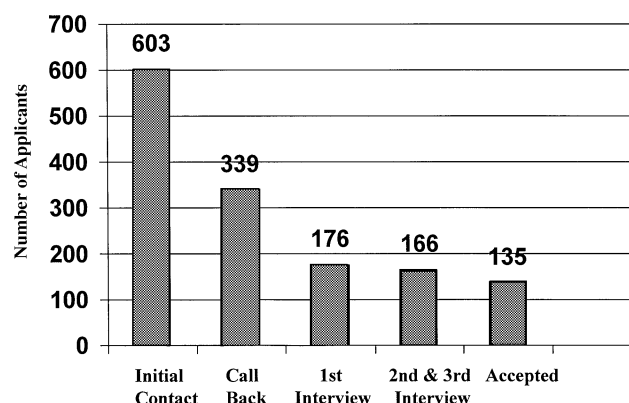
For those considered healthy and motivated, a second appointment was set up for an interview with psychiatry to discuss underlying motivations and better assess her psychological make-up. After this, a third visit was required to perform a full physical examination, including pelvic ultrasonography. Finally, tests for toxicology, sexually transmitted diseases and carrier status for genetic diseases including cystic fibrosis, Tay–Sachs disease, thalassaemia and sickle cell disease was conducted. On completion of all screening requirements, the prospective donor's file was presented to our ovum donation committee, a group composed of physicians, psychiatrists and nurses, for formal review. All screening results were reviewed with each donor. If deemed medically and psychologically suitable, she was registered in our active donor pool. Figure 1 reviews the steps in establishing a donor registry.

Donors were consented according to established SART guidelines (Guidelines for oocyte donation, 1994). Financial remuneration was provided to the donor at a rate of \$2500 per completed cycle, and \$500 if she did not complete the cycle. This fee is the direct responsibility of the recipient, who pays the programme this sum in advance of the initiated cycle.

## Results

Between July 1995 and July 1997, 603 candidates contacted our office. The majority of enquiries resulted from responses to newspaper/magazine advertising ( $n = 382$ , 63.3%) (Figure 2). Others were recruited through university flyers ( $n = 157$ , 26.0%), friends ( $n = 53$ , 8.8%), radio/television segments on infertility ( $n = 8$ , 1.3%) and physician referral ( $n = 3$ , 0.5%). After preliminary review, 339 potential candidates were contacted by the nurse by telephone. Following this interview, 176 candidates were scheduled for an entry interview. Of the other 163 women, 94% were discovered to have reservations about the time commitment and/or injections and said they would contact us if they had a change of mind, 4% were either too young or too old for the programme, and 2% had existing medical conditions which precluded them. All but one donor admitted that they were initially enticed by monetary gain, but they also stated their desire to help others as a strong reason for participation. Tables I and II summarize the characteristics and demographic data for screened applicants.

Of the 176 candidates, 10 donors (5.7%) elected not to participate after their interview with the medical director. Of

**Figure 3.** The attrition rate from initial contact through final committee approval.**Table II.** Demographic background of screened oocyte donors ( $n = 166$ )

<i>Marital status</i>	
Married	12
Divorced	3
Never married	85
<i>Anonymity</i>	
Anonymity preferred	95
Non-anonymity preferred	5
<i>Education</i>	
College educated	90
Graduate degree	21
<i>Occupation</i>	
Full-time students	22
Employed	75
Unemployed	3

the remaining 166 donors, 31 (18.7%) who completed their second interview were later dropped from entry. Reasons for exclusion included 13 with perceived psychopathology (three with previous sexual abuse and failure of resolution, three with depressive disorders, two with eating disorders, two with sexual dysfunction and chronic pelvic pain, two considered to be misrepresenting their personal histories and one with marital discord); nine for active 'recreational' drug use including two using opiates and seven using marijuana; two with hyperprolactinaemia; two with chronic active hepatitis-B and hepatitis-C; one with renal dysfunction; one with lupus-like syndrome; one with Cushing's disease; one with polycystic ovarian disease; and one with a complex adenexal mass.

Carrier status for sickle-cell trait was detected in 15% (2/13) of Afro-American donors; thalassaemia in 2% (1/40) of Afro-American, Asian and Mediterranean donors; Canavans and Tay–Sachs diseases in none of eight Eastern European Jewish donors; and cystic fibrosis in 2.1% (3/139) of women of Northern European descent.

Transvaginal ultrasound findings during physical examination led to the identification of 60 (36%) women with polycystic-appearing ovaries (PAO) which have previously been described to be associated with metabolic alterations (Carmina *et al.*, 1997) compared with 106 donors (64%) with normal-

appearing ovaries (NAO). Furthermore, 16 of the 166 donors (9.6%) had asymptomatic uterine myoma, six had Müllerian anomalies confirmed by sonohysterography (three bicornuate uteri and three septate uteri), five had intrauterine devices, three had hydrosalpinges, two had intrauterine polyps and one had a complex cystic mass later referred for surgical evaluation. When pathology was encountered, a lengthy discussion of the significance of the finding(s) was provided to clarify the significance regarding possible future gynaecological, obstetric and reproductive consequences. Those with uterine anomalies were referred for an intravenous pyelogram, although no urological malformations were discovered. The patient found to have a complex cystic mass did not return for follow-up.

Figure 3 depicts the attrition rate from initial contact through final committee approval. Approximately one in four initial enquiries resulted in participation. However, 43% who responded to a call back were approved and subsequently placed into active service.

## Discussion

Establishing a registry of oocyte donors requires a team of health care professionals to carefully screen applicants in order to expedite entry into a programme that is constantly changing. Similarly, attention to maximizing the donor's experience by only requiring necessary visits helps ensure compliance, while minimizing frustration. However, office visits do provide an opportunity for the physicians and nursing staff to ascertain the donor's willingness to participate in the programme. A minimum of three visits are required to screen and teach donors, prior to matching them with recipients.

It is interesting to compare our present donors with those of other programmes. In previous years, as reported at University of Southern California (USC) (Sauer *et al.*, 1994), donors were commonly non-anonymous, multiparous, married and in their thirties—characteristics quite different from our current donor pool. However, the earlier experience evolved without the use of advertisements. The selection bias inherent to our current programme is largely attributable to direct solicitation, though other differences may relate to characteristics of an anonymous versus non-anonymous programme. In the USC report, over 25% of participants were known donors (friends, siblings, relatives). We speculate that as the majority (65%) of recipients were aged over 40 years, the donor sibling's age was likewise higher, which also increased their likelihood of marriage and offspring.

Currently, our programme is predominantly anonymous (95%) and is similar to Yale's programme where donors are typically students (Greenfeld *et al.*, 1995). Thus, donors are more likely to be single, nulliparous and in their twenties. Not surprisingly, initial interest centres on financial remuneration. However, donors also claim that their motives for participation are driven by compassion which enables them to endure better the inconvenience and discomfort of a donor cycle and probably explains why many accept the medical risks.

Interestingly, pathology in the seemingly 'normal' donor

is not uncommon. Psychopathology and drug use in 9.3% underscores the need for collaborative evaluation by trained professionals in psychiatry or psychology. The discovered carrier status for Mendelian pattern inheritable diseases does not necessarily exclude a donor, but does require further genetic counselling and screening of the recipient couple. To date, three couples have chosen a donor known to be a carrier for one of the many cystic fibrosis gene mutations. However, in these cases informed consent and genetic counselling is required of recipients and must include testing of the husband to exclude a carrier state.

Pelvic sonography demonstrated that 16% (28/176) of donors had abnormalities. The presence of uterine leiomyomas is in accord with estimates from clinical studies placing the incidence of disease in reproductive aged women at 15–25% (Buttram and Reiter, 1981; Wallach, 1992). Although 20–50% of women commonly complain of myoma-related symptoms, all donors were symptom-free. In a review of the literature (Strassmann, 1966), the reported range of uterine anomalies in reproductive aged women is 1.1 to 3.5%, consistent with the 3.4% (6/176) seen in our donor population. The clinical significance of PAO remains unclear, although data suggest alterations in the insulin-like growth factor/binding protein axis (Carmina *et al.*, 1997). Responses to ovarian hyperstimulation by PAO donors and their pregnancy outcomes are similar to NAO donors. Because of the incidence of pathology and its possible impact on future fertility, proper informed consent of donors is imperative in detailing how discovered pathology may impact on future reproductive potential.

In summary, a commitment to recruitment and screening enables a programme rapidly to develop a donor registry. We feel that financial remuneration is requisite for establishing a programme, although altruism does play a secondary role. Though seemingly healthy, candidates are not without psychological, endocrinological and pelvic pathology, and may also be carriers of common genetic disorders. This underscores the need for rigorous and thorough medical evaluations. While information gathered in screening is important in determining optimal candidates, it also mandates follow-up counselling as women must be given proper care regarding potential medical and gynaecological illnesses discovered.

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Received on September 25, 1997; accepted on February 27, 1998