

# Oocyte donors' comprehension as assessed by the EDICT (Egg Donor Informed Consent Tool)

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**Objective:** To assess oocyte donors' comprehension of the process and potential risks of oocyte donation using the EDICT (Egg Donor Informed Consent Tool).

**Design:** Prospective cohort study.

**Setting:** University-based, tertiary reproductive health practice.

**Patient(s):** Prospective oocyte donors.

**Intervention(s):** Donors (N = 65) participated in an audiovisual informational session, and met with a reproductive endocrinologist individually. Donors then completed the Subjective EDICT and Objective EDICT.

**Main Outcome Measure(s):** We report scores on Subjective and Objective EDICT, scores stratified for demographic variables, relationship between Subjective and Objective EDICT scores, and the effect of counseling on scores.

**Result(s):** In general, our cohort of oocyte donors performed well on both objective and subjective portions of the EDICT. We verified the effect of counseling on EDICT scores by comparing before and after counseling scores and demonstrating significant gains. There was no significant correlation between Subjective and Objective EDICT scores.

**Conclusion(s):** For the first time, we report oocyte donors' comprehension of oocyte donation as assessed by the EDICT. Reassuringly, we demonstrate that oocyte donors have adequate subjective and objective comprehension of the process and risks associated with oocyte donation. We also demonstrate that oocyte donor comprehension is significantly impacted by physician counseling efforts. In addition, scores on perceived understanding (Subjective EDICT) did not predict scores on performance-based comprehension (Objective EDICT). The lack of correlation between the two scores further underscores the utility of a performance-based tool, as relying on a donor's self-report (e.g., simply signing a consent form to indicate understanding) may not reflect her actual understanding. (Fertil Steril® 2014;101:248–51. ©2014 by American Society for Reproductive Medicine.)

**Key Words:** Oocyte donation, informed consent, third-party reproduction

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Oocyte donation is an area of assisted reproduction that is of particular ethical concern, as donation has attendant risks, while not directly benefiting the donor (1–4). Thus, the informed consent process for donors must be held to an even higher standard than that for other

patients who assume risk in exchange for direct potential benefit. In the United States, oocyte donors are financially compensated, which may limit information seeking and impair decision making (5). Furthermore, the physician or recruiting agency may be externally motivated to have a

potential donor agree to proceed with the donation (6). It is thus incumbent on those who serve this patient population to ensure the adequacy of informed consent in these potentially vulnerable young women.

Prior research in the area of oocyte donor informed consent and comprehension has been limited. Previously, Kenney and McGowan (7) described relatively poor understanding of the risks of oocyte donation on the part of oocyte donors. For example, only 33.8% of their sample noted awareness of ovarian hyperstimulation, 20% noted awareness of bleeding or infection, and 15% noted awareness of ovarian torsion or damage before oocyte donation. However, the

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principal caveat of this study (7) is that data were collected retrospectively AFTER donation, and therefore are subject to recall bias. In an effort to improve the informed consent process for oocyte donors, we previously reported on the development and validation of the EDICT (Egg Donor Informed Consent Tool) (1). The EDICT was designed to assess both the perceived (subjective) and performance-based (objective) understanding that oocyte donors have of the process and risks of oocyte donation after the informed consent process, but *before* oocyte donation. Here we report on the first implementation of the EDICT, and to our knowledge, the first standardized assessment of the adequacy of informed consent for oocyte donors. The purpose of this study was to assess the objective and subjective understanding that oocyte donors have of the process and potential risks of oocyte donation using the EDICT.

## MATERIALS AND METHODS

### Subjective and Objective EDICT: Content and Scoring

We have previously reported on the development of the EDICT (Egg Donor Informed Consent Tool) a novel, valid informed consent questionnaire specific to oocyte donors (1). Specifically, we developed the EDICT in two parts—Subjective EDICT and Objective EDICT—to interrogate oocyte donors' subjective and objective understanding of the process of oocyte donation. Subjective understanding is a measure of how well informed the donor *feels* about the process of oocyte donation. Objective understanding is a performance-based measure of the donor's comprehension of the facts and concepts relevant to oocyte donation (1).

In brief, the Subjective EDICT contains 13 questions designed to assess perceived (subjective) understanding. These questions ask participants to rate how well they felt they understood elements of the oocyte donation process. Responses are on a 5-point Likert scale anchored by "I didn't understand this at all" to "I understood this very well". The summary score for the Subjective EDICT ranges from 0–100. This score is calculated by averaging the responses for the 13 questions to obtain a raw average ranging from 1–5, then scaling the raw average to a summary score using the formula: Summary score = (Raw average - 1) × 25.

The Objective EDICT consists of 20 items designed to interrogate objective understanding. Responses elicited to each item are "true," "don't know," and "false". Example questions are, "There is no chance that I can become pregnant during the process of egg donation" and "If I do not want to donate my eggs, I can change my mind now." Correct responses for items on the Objective EDICT are assigned a score of 100 points. Incorrect answers are given 0 points and the "don't know" response is scored as 50 points, giving preference to the acknowledgment of uncertainty over the assertion of false belief (1). These scores are simply summed and divided by the number of items to achieve a summary score ranging from 0–100.

### Participants

Institutional Review Board approval for this study was obtained from the University of California, San Francisco.

Prospective oocyte donors (N = 65) who presented to the University of California, San Francisco Center for Reproductive Health for an initial screening visit between February 1, 2012 and May 31, 2013, were invited to participate in the study. Inclusion criteria were aged 20–32 years, presence of both ovaries, and no known major medical or genetic problems. As all of our prospective oocyte donors are screened by telephone before their clinic visits, all of the 65 women met these inclusion criteria. All 65 of these prospective donors agreed to participate, both verbally and in writing.

### Counseling

All prospective oocyte donors attended an hour-long audiovisual presentation conducted in person by one psychologist and one of two reproductive endocrinologists (either A.A.S. or H.G.H.). The presentation covers the following areas: process of oocyte donation including stimulation and oocyte retrieval, medications and side effects, medical risks, psychological aspects, legal aspects, logistics and time commitment. The reproductive endocrinologist encouraged questions throughout the presentation and was available immediately afterward for questions. Donors then met with a reproductive endocrinologist (A.A.S. or H.G.H.) individually for approximately 30 minutes in conjunction with their medical screening visits. Medical risks were again reviewed and donors were encouraged to ask questions during these visits. Donors then completed the Subjective EDICT, followed by the Objective EDICT.

### Statistical Analysis

Data were analyzed using STATA 11.0. Paired *t*-test was used to compare EDICT scores before and after counseling. Spearman correlation and multivariate regression analyses were used as appropriate.

## RESULTS

Our cohort of potential oocyte donors consisted of 65 women, presenting to our center between February 1, 2012 and May 31, 2013. Demographic information was self-reported by the prospective donors on intake forms (Table 1). The mean (± SD) age of the cohort was 25.7 (± 3.2), consistent with our clinic's inclusion criteria for oocyte donation. The racial and ethnic backgrounds of our donors were largely consistent with the population served by our clinic. Specifically, the cohort was comprised of 32 whites, 8 Asians, and 8 women of mixed ancestry. Examples of mixed ancestry include Irish/Cuban/Native American and Chinese/Mexican/white. Prospective donors in our cohort were largely well educated. Mean years of post-high school education was 3.9 (± 1.7), with all donors reporting at least 1 year of post high-school education.

In general, our cohort of oocyte donors performed well on both objective and subjective portions of the EDICT (Fig. 1). Specifically, the mean score on the Subjective EDICT was 96.1 (SD = 4.6). In addition, the bottom quartile score for the Subjective EDICT (Q1) was 94.7, indicating that the vast majority of oocyte donors feel very well informed after counseling. The mean score on the Objective EDICT in our cohort

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