
Risk Disclosure and the Recruitment of Oocyte Donors: Are Advertisers Telling the Full Story?

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Introduction

In vitro fertilization (IVF) using donated oocytes has proven to be an effective treatment option for many prospective parents struggling with infertility, and the usage of donated oocytes in assisted reproduction has increased markedly since the technique was first successfully used in 1984.¹ Data published by the Centers for Disease Control and Prevention (CDC) on the use of assisted reproductive technologies (ARTs) in the United States indicate that approximately 12% of all ART cycles in the country now use donated oocytes.² The increased use of oocyte donation in the United States has prompted discussion regarding risks associated with the process and how best to ensure the safety of oocyte donors.³

Physical risks associated with oocyte donation include bleeding, infection, ovarian hyperstimulation syndrome and a potential, although unconfirmed, increased risk of developing various forms of cancer, such as uterine, colon, breast, ovarian, and endometrial cancers.⁴ A number of anecdotal reports recount donor experience of some of these unconfirmed physical risks and also recount experience of psychological risks, including donor concerns about potential long-term physical risks and a variety of concerns associated with offspring resulting from the IVF procedure.⁵

Accurately estimating these risks is complicated by the dearth of long-term studies that evaluate the risks specifically associated with oocyte donation by healthy, presumably fertile, volunteers.⁶

Payment to oocyte donors also raises ethical concerns, including the perceived commodification of oocytes and the potential exploitation of oocyte donors.⁷ Suzanne Holland claims that many find their sense of human dignity disturbed when parts of our bodies that we “associate with our personhood” are viewed as property and “sold off on the market for whatever the market will bear.”⁸ Similarly, Radhika Rao notes that compensation could be criticized because “it treats the sacred components of human life as a form of property, engendering an attitude of disrespect for actual persons.”⁹ However, others argue that payment to oocyte donors is justified as a means for compensating donors fairly for their time and physical commitments and for ensuring an adequate supply of donated oocytes for those who suffer from infertility.¹⁰ Excessive compensation levels, however, raise concerns about “undue inducement” and the exploitation of donors.¹¹ The concern is that very high compensation may manipulate women into making rash decisions to proceed with donation without adequate consideration of the associated risks.¹²

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There is also a broader set of ethical concerns about decision making by potential donors in light of the known and unknown risks. As with any individuals who decide whether to undergo a medical procedure, it is important that oocyte donors understand both the benefits and risks of the donation process and that they have adequate opportunity to consider and weigh both before they decide whether to proceed. This concern is anchored in the ethical principle of autonomy and the practice of informed consent that aims to vindicate this principle. This imposes obligations on professionals involved in the oocyte recruitment and donation process to inform potential donors of the benefits as well as risks and to ensure that they understand and consider both before they decide whether to proceed.

There has been only limited investigation of the effectiveness of current informed consent procedures in ensuring donor understanding and consideration of the benefits and risks of donation. One retrospective survey of oocyte donors concluded that most donors did not adequately understand the physical risks — including the risks of bleeding or infection and ovarian hyperstimulation syndrome — before deciding to engage in the donation process.¹³ Nancy Kenney and Michelle McGowan found that donors' retrospective self-reported awareness of the risks associated with the donation process did not correspond with the risks they actually experienced.¹⁴ In a 2013 prospective study, Amanda Skillern, Marcelle Cedars, and Heather Huddleston found that the potential donors in their study population showed very good subjective (perceived) and objective (performance-based) understanding of the risks of donation as measured by their informed consent assessment instrument. They conclude that it is possible to achieve fully informed consent under the conditions reflected in their study, which included intensive counseling. Potential donors attended an hour-long audio-visual presentation conducted by a psychologist and a reproductive endocrinologist, with encouraged questions during and immediately following the presentation. Each donor then met individually for 30 minutes with a reproductive endocrinologist for medical screening and additional review of risks with questions again encouraged.¹⁵

In the absence of more extensive studies of current informed consent procedures, the adequacy of current procedures in ensuring that potential donors understand and consider the benefits and risks of oocyte donation is uncertain. This uncertainty is of significant concern in the distinctive context of oocyte donation in which the risks, benefits, and incentives to undertake risks differ from those in the typical medical context. The oocyte donor undertakes medical risks in the

absence of any medical benefits to the donor,¹⁶ and with the incentive of significant financial benefit and, for many, the additional incentive of providing altruistic help to others in achieving an important and deeply desired result.¹⁷ Concerns about incentives to undertake medical risks in the absence of medical benefits might be mitigated by reliance on the safeguards of the ordinary physician-patient relationship in ensuring adequate opportunity to consider the risks. The physician-donor relationship, however, is atypical.

Judith Daar argues that the nature of the physician-donor relationship is problematic for accomplishing informed consent. In the usual physician-patient relationship, the physician is concerned with the medical benefits and risks for her patient and in ensuring that her patient understands and has an adequate opportunity to consider the benefits and risks before deciding whether to proceed. In the oocyte donation process, however, it is the recipients of the donated oocytes who will realize the medical benefits of the donation process if they are successfully treated for infertility.¹⁸ Sharon Lerner's experience posing as a potential oocyte donor exemplifies the potential problematic effects.¹⁹ In the course of attending five appointments, which included medical exams, tests, and counseling, Lerner observed that concern was focused primarily on the infertile recipients of her oocytes rather than on her as a patient.²⁰ The Ethics Committee of the American Society for Reproductive Medicine (ASRM), the self-regulatory association for ART professionals, has recognized and issued guidelines directed to the potential concerns posed by the distinctive context:

Once the donation process begins, oocyte donors become patients owed the same duties present in the ordinary physician-patient relationship. Programs should ensure that every donor has a physician whose primary responsibility is caring for the donor. Oocyte donor program staff should recognize that physicians providing services to both donors and recipients could encounter conflicts in promoting the best interests of both parties and should create mechanisms ensuring equitable and fair provision of services.²¹

Another potentially problematic feature of the decision-making context is the recruitment process for potential donors, which proceeds in a series of stages. In some cases, there is a delay of weeks or months between the time a potential donor is recruited and receives information about the donation procedure and the time the donor is contacted to proceed with donation and give formal consent.²² This prompts the question of what, if any, risk disclosures should be

included at various stages of the recruitment process to ensure that the potential donor adequately understands and considers the risks at the time she decides whether to proceed.

Carson Strong argues for risk disclosure before the potential oocyte donor attends her first office visit and begins to invest a significant amount of time and energy in the process because potential donors may rely on the initial information they are provided in deciding whether to proceed.²³ Andrea Gurmankin posed as a potential oocyte donor in placing 19 preliminary phone calls to IVF clinics and oocyte donor agencies that advertised for oocyte donors in college newspapers.²⁴ Gurmankin noted that, in these phone calls, five percent of the programs volunteered information associated with the risks of donation and 21 percent avoided her questions regarding risk and referred Gurmankin to information that would be mailed to her. This study was criticized for its small sample size and for assuming that risks associated with oocyte donation should be discussed over the phone; Gregory Stock observed, for example, that in advertisements and preliminary phone calls recruiting individuals for cosmetic surgery or weight-loss treatments, it is uncommon to include full disclosure of risks.²⁵ One response to the Gurmankin study was support for providing a standardized risk statement to all potential donors early in the recruitment process.²⁶

We consider here the question of risk disclosure at the earliest stage of the recruitment process: in recruitment advertisements. Potential donors may learn something about the donation process from a variety of sources, but advertisements are the earliest source of information provided by IVF clinics and oocyte donor agencies, and Kenney and McGowan's survey study found that advertisements provided the first introduction to the donation process for more than a quarter of respondents.²⁷ The first point to consider is whether any risk disclosure should be included at this earliest stage of recruitment or whether, instead, it need only be included in later stages to ensure understanding of and adequate opportunity to consider both benefits and risks before potential donors decide whether to proceed.

To advance consideration of this first point, we note that oocyte donor recruitment advertisements are relevantly similar to advertisements recruiting participants for clinical research. In both decision contexts, individuals are recruited to undergo medical procedures that pose medical risks to them and that are intended to provide medical benefits to others. In both contexts, individuals may receive financial compensation and perhaps other benefits including a sense of altruistic satisfaction in helping others.

Franklin Miller and Andrew Shorr note that the U.S. Food and Drug Association (FDA) recognizes advertisements as the initial introduction to the informed consent process and argue that advertisements that list any benefits of participation should also include potential risks and/or burdens associated with participation.²⁸ Miller and Shorr argue that omission of risks and burdens from advertisements when the benefits of participation are presented could cause potential subjects to develop misconceptions based primarily on the benefits of participation listed in the advertisements.²⁹

A 2008 study by Robert Klitzman and colleagues of the website recruitment of human subjects notes the "anchoring heuristic" described in the work of Daniel Kahneman and Amos Tversky: the effect of initial information in establishing a framework that influences individuals' understanding and weighing of subsequent information. Klitzman observes that website recruitments to clinical trials "may provide the first information that a potential research subject sees about a study, and anecdotal information suggests that some individuals decide to enroll in a study before they have even seen the informed consent document or participated in the informed consent process."³⁰ His study found extensive noncompliance with guidance from FDA and from the Office for Human Research Protections (OHRP) regarding inclusion of risk disclosure in recruitment advertisements for clinical trials.³¹

In the context of oocyte donation, similar concerns arise with respect to recruitment advertisements. Advertising is the first occasion when recruiting entities provide information to potential donors about the donation procedure and, as such, they effectively initiate the informed consent procedure. Failure to note the existence of risks may cause potential donors to develop misconceptions and may frame their subsequent receipt of information in ways that are inconsistent with ensuring informed consent. Given the heightened concerns about ensuring informed consent in the distinctive context of oocyte donation and in the absence of assurance that current informed consent procedures adequately ensure understanding of and opportunity to weigh the benefits and risks, we conclude that, at a minimum, when advertisements note the benefits of donation, they should also note the existence of risks.

The ASRM Ethics Committee has addressed the question of risk disclosure in oocyte donor advertisements in its guidelines. The ASRM guidelines provide that "if financial or other benefits are noted in advertisements, the existence of risks and burdens also should be acknowledged."³² In addition, more generally, the guidelines provide that "programs offering financial incentives

should ensure that advertisements for donors are accurate and responsible.”³³ The rationale for these ASRM guidelines was to help ensure that potential donors had good information about the donation procedure and were aware that there were some risks associated with the procedure before they proceeded.³⁴

These ASRM self-regulatory guidelines are the only current source of regulation of oocyte donor advertisements of national scope. Their self-regulatory force extends to ASRM members; IVF clinics that are members of the Society for Assisted Reproductive Technology (SART), which is an organization of ART professionals affiliated with ASRM; and to oocyte donor agencies that register with SART, signing an agreement to abide by ASRM guidelines.³⁵ Several studies have examined compliance with various ASRM guidelines,³⁶ and two studies have evaluated risk disclosure on clinic and donor agency websites.³⁷ However, to our knowledge, no studies to date have examined compliance with the ASRM guidelines regarding risk disclosure in recruitment advertisements.

No federal law specifically addresses oocyte donor recruitment advertisements,³⁸ although these adver-

tisements are subject to the prohibitions against false or deceptive advertising under the Federal Trade Commission Act.³⁹ Other federal law regulates oocyte donation and IVF but does not address oocyte donor advertisements. The FDA regulates donated reproductive tissue that is intended for implantation in human recipients and requires that all donors provide a medical history and be free of certain infectious diseases.⁴⁰ And the Fertility Clinic Success Rate and Certification Act (FCSRCA) of 1992 requires the CDC to collect data from IVF clinics for its annual report to Congress on ART success rates.

California is the only state that specifically regulates risk disclosure in recruitment advertisements for potential oocyte donors. The California law (Cal. Health & Saf Code § 125325), enacted in fall 2009 (AB 1317), requires that all entities that post oocyte donor advertisements offering “financial payment or compensation of any kind” for oocyte donation also include a notice indicating that there may be risks associated with donation and requires that the donor receive specific information on the known risks before agreeing to proceed (see Table 1 for the spe-

Table 1

Laws and Self-Regulations Relevant to Oocyte Donor Recruitment Advertising

Law/Self-Regulation	Relevant Language
FTC Act [15 U.S.C. §§ 41-58]	“The term ‘false advertisement’ means an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual.”
ASRM Ethics Committee: <i>Financial Compensation of Oocyte Donors</i> (2007)	“If financial or other benefits are noted in advertisements, the existence of risks and burdens also should be acknowledged.” “Programs offering financial incentives should ensure that advertisements for donors are accurate and responsible.”
California Law (Cal. Health & Saf Code § 125325)	(a) “The person or entity posting an advertisement seeking oocyte donation associated with the delivery of fertility treatment that includes assisted oocyte production and a financial payment or compensation of any kind, shall include the following in a clear and conspicuous manner: <ul style="list-style-type: none"> • ‘Egg donation involves a screening process. Not all potential egg donors are selected. Not all selected egg donors receive the monetary amounts or compensation advertised. As with any medical procedure, there may be risks associated with human egg donation. Before an egg donor agrees to begin the egg donation process, and signs a legally binding contract, she is required to receive specific information on the known risks of egg donation. Consultation with your doctor prior to entering into a donor contract is advised.’ (c) “Persons or entities that certify compliance with the American Society for Reproductive Medicine (ASRM) guidelines by registering with ASRM are exempt from the notice requirements set forth in subdivision (a). Use of the exemption when the guidelines are violated shall constitute false advertising.”

cific language required in the notice). Alternatively, the entity may certify compliance with the ASRM guidelines by registering with ASRM (see Table 1 for the ASRM guidelines). Thus, all donor recruitment advertisements placed in California that offer compensation to oocyte donors must include either the risk disclosure specified in the California law or a risk disclosure that complies with the ASRM guidelines. According to the author of the original version of the bill eventually enacted in revised form, the purpose of the California law was “to help women make an informed donation decision” in light of concerns that financial incentives “may unduly influence the judgment of young women.”⁴¹ To our knowledge, there are no published studies that have examined compliance with this law.

Assuming that the policy approach adopted both in the ASRM guidelines and in California law appropriately advances the goal of ensuring that potential donors understand and have adequate opportunity to consider both the benefits and risks before deciding whether to proceed with oocyte donation, the second point to address is whether, in practice, oocyte donor advertisements that list benefits also include risk disclosures. In this study, we address this question by analysis of a collection of oocyte donor recruitment advertisements posted on Craigslist in November 2011.

We examine, first, all advertisements in the collection to determine whether those that list benefits also include risk disclosures. We next examine whether there is a difference in risk disclosure between those entities that are subject to the self-regulatory force of the ASRM guidelines and those entities that are not. Finally, we examine whether there is a difference in risk disclosure between those entities that are subject to the regulatory force of California state law and those that are not.

Materials and Methods

Data Collection

The oocyte donor recruitment advertisements analyzed in this study were collected from Craigslist, an online classifieds and forum community. To ensure advertisements from different cities were comparable, all advertisements were collected during the week of November 28, 2011. The 2010 U.S. Census Report was used to identify the top 50 metropolitan statistical areas (MSAs), defined by population, from which the advertisements were collected. Due to the classification and inclusion of specific cities on Craigslist, a total of 48 cities were searched for oocyte donor recruitment advertisements. We performed a pilot study using a variety of terms associated with oocyte

donation and found that “egg donation” and “egg donor” were most relevant and inclusive. We recognize that it is possible that this search strategy missed some relevant advertisements but believe our dataset includes the vast majority of oocyte donor recruitment advertisements placed on Craigslist during this time period. The majority of the advertisements collected fell within the following Craigslist categories: Jobs, Services, For Sale/Wanted, and Gigs. Because the same advertisement could be posted multiple times, only those advertisements that had a unique title or text in the body of the advertisement were evaluated. A total of 435 advertisements were collected.

Coding and Analysis

A content analysis was completed for all advertisements. Each advertisement was evaluated for any benefits listed and for advertiser characteristics, including the type of entity posting the advertisement (IVF clinic, oocyte donor agency, personal, or unspecified), the name of the entity, the state in which the entity was located, and the city and state in which the search was completed. Most coding was completed directly from the advertisement, but, when necessary, we conducted Internet searches using information from the advertisement (e.g., an email address or phone number) to complete the coding as thoroughly as possible. The SART membership status of each IVF clinic as of June 2012 was determined from the SART website, and the registration status of each oocyte donor agency as of June 2012 was determined by reference to the list of registrants available on the ASRM website.⁴²

Several coding approaches were explored to develop a coding system that accurately evaluated whether an advertisement included risk disclosure language that would comply with the minimum requirement of the ASRM guidelines by acknowledging the “existence of risks.” Our goal was to identify language that reasonably might convey to the reader the concept of “risk” in connection with the oocyte donation process. Before describing this process, we should note that, although full compliance with the ASRM guidelines would require disclosure of both risks and burdens, we limited our analysis to disclosure of risks. This choice reflects our belief that disclosure of risks is a more central ethical concern than disclosure of burdens, such as the time commitment involved in the process or the need to undergo injections. For this reason, in our examination of compliance with the ASRM guidelines by those entities subject to their self-regulatory force, we considered an advertisement compliant if it acknowledged the existence of risks associated with the oocyte donation process even if it omitted acknowledgment of relevant burdens.

To develop our coding strategy, we considered general terms reasonably likely to convey the concept of risk to the reader, and we reviewed the advertisements to determine whether any of these general terms appeared. We also carefully reviewed the advertisements looking for other specific language that reasonably might convey ideas of risk even if these advertisements did not include any of these general terms (see Table 2). With the exception of the word “risk” (including “risks”) and “complication” (including “complications”), none of the general terms we considered (e.g., “dangerous” or “side effect”) appeared in any of the advertisements. The word “complications” appeared in a single advertisement that used the term to indicate that there was a “low risk of complications.” We also identified specific language (e.g., “injectable medication” and “egg retrieval surgery”) that arguably might trigger ideas of risk. Ultimately, however, we concluded that, while these phrases reasonably conveyed ideas of burdens associated with the donation process, they did not reasonably convey the concept of risk associated with the process. There were no cases in which advertisements that included these phrases conveying ideas of burdens also included the general term “risk.”

These considerations led us to develop a straightforward coding system that assessed whether or not advertisements contained the word “risk” and, for those advertisements that did include the word “risk,” whether or not the term was used in reference to risks to donors in connection with the oocyte donation process. In all, 69 advertisements included the word risk, and 68⁴³ of these uses were in reference to risk

to oocyte donors. We coded each of these 68 advertisements as containing a risk disclosure that would comply with the minimum requirement set forth in the ASRM guidelines. While one of these advertisements minimized the potential risks, indicating that there was a “low risk of complications,” we nonetheless coded this advertisement as containing a risk disclosure that would satisfy the ASRM guidelines because it might reasonably convey to the reader the concept of risk associated with the oocyte donation process.

Results

Disclosure of Risk Nationwide

A total of 435 oocyte donor recruitment advertisements were collected from Craigslist and analyzed. We determined that 424 (97%) of these advertisements listed benefits. In each case, the benefits listed included financial compensation to the oocyte donor. A total of 11 (3%) of these advertisements did not list benefits to the donor. These 11 advertisements did not trigger risk disclosure requirements under either the ASRM guidelines or the California law and were excluded from the remainder of the analysis. The 424 advertisements that included benefits were then analyzed to determine whether they included a risk disclosure that would satisfy the minimum requirement set forth in the ASRM guidelines by inclusion of the term “risk.” Of the 424 advertisements, 68 (16%) did include reference to “risk” and 356 (84%) did not.

For the 68 advertisements that would satisfy the ASRM guidelines, there were two unique uses of the term “risk”:

1. “As with any medical procedure, there may be risks associated with human egg donation. Before an Egg Donor agrees to begin the Egg Donation process, and signs a legally binding contract, she is required to receive specific information on the known risks of Egg Donation.”
2. “Low risk of complications.”

All but one of the 68 advertisements included the first disclosure, which matches the specific risk disclosure language set forth in paragraph (a) of the California law. Of the 67 advertisements that included this specific risk disclosure language, only 26 (39%) were posted in California and, hence subject to the requirements of the California law. We also note that, with respect to the one advertisement that instead referred to a “low risk of complications,” although we coded the language as containing a risk disclosure that would satisfy the ASRM guidelines because it acknowledges the existence of risks even while minimizing them, its

Table 2

Risk Terminology

Terms Related to Risk Disclosure	Number of Advertisements
Risk	69
Injection/Injectable Medication	29
Egg Retrieval Surgery	3
Blood Drawn	1
Complication	1
Ultrasound	1
Dangerous	0
Hazardous	0
Injury	0
Side effect	0
Warning	0

adequacy in communicating the existence of risks at the start of the recruitment process — for example, while there may be a low likelihood of risks, they may be of high magnitude — is questionable.

To determine whether the high rate of nationwide nondisclosure of risk (84%) was driven by advertisements placed by a specific type of entity, the advertisements were categorized by entity type. Oocyte donor recruitment advertisements are typically placed by IVF clinics or oocyte donor agencies, although individuals also place some of these advertisements, termed “personal” in this analysis. Because they are not subject to the ASRM self-regulatory guidelines and are not professionals who otherwise might be expected to provide minimal risk disclosure regardless of whether they are subject to the self-regulatory ASRM guidelines, we excluded the 19 personal recruitment advertisements from this analysis.⁴⁴ We also excluded 4 advertisements that could not be assigned to a specific source and 8 advertisements that were placed by clinics or agencies that we could not identify by name. Entities that placed the remaining 393 advertisements were classified as “partially compliant” if they placed at least one advertisement that would satisfy the ASRM guidelines and “fully compliant” if all of their advertisements would satisfy that standard.

Although a slightly larger percentage of agencies were either partially or fully compliant compared to clinics, the difference in the distribution of agencies and clinics into the three compliance categories was not statistically significant. Overall, 65 of 71 entities in our dataset placed at least one non-compliant advertisement (Table 3).

Disclosure of Risk by Entities Subject to ASRM Guidelines

We next examined the influence of the ASRM guidelines for risk disclosure on those entities subject to their self-regulatory force: IVF clinics that are members of SART and oocyte donor agencies that register with SART. Entities placing advertisements were clas-

Table 3

Comparison of Oocyte Donor Agency and IVF Clinic Compliance (Full Sample)

	Agency	Clinic
# Entities	43	28
% Fully Compliant	12% (5)	4% (1)
% Partially Compliant	7% (3)	0% (0)
% Non-Compliant	81% (35)	96% (27)

Table 4

Comparison of SART and Non-SART Compliance in OC Advertisements

	SART	Non-SART
# Advertisements	246	56
% Advertisements Compliant	15% (38)	5% (3)
% Advertisements Non-Compliant	85% (208)	95% (53)

sified as SART (IVF clinic SART member or oocyte donor agency SART registrant) or non-SART and a comparison of risk disclosure was completed.

In performing this comparison, we excluded from the analysis advertisements posted by SART and non-SART entities in California. Both SART and non-SART entities are subject to the California law when posting advertisements in California. The California law requires either compliance with the specific language provided in paragraph (a) of the law or compliance with the ASRM guidelines pursuant to paragraph (c). Thus, if advertisements posted by SART or non-SART entities in California include risk disclosure, this presumably, should be attributed to the formal regulatory force of California law rather than to the self-regulatory influence of ASRM guidelines.

A total of 302 advertisements were placed outside of California (OC) by entities whose SART status could be ascertained. Most of these advertisements (81%) were placed by SART entities with the remainder placed by non-SART entities. A majority of advertisements placed both by SART and non-SART entities were classified as non-compliant, although SART entities included risk disclosures in a higher percentage of their advertisements (15% vs. 5%) (Table 4). This difference was statistically significant (P <0.05).

Disclosure of Risk by Entities Subject to California Law

We next examined both the direct and indirect influence of California law on risk disclosure. By “direct” influence, we mean evidence of compliance with the California law by entities posting advertisements in California. By “indirect” influence, we mean evidence of influence by the California law on either the extent or nature of risk disclosure by entities posting advertisements OC; advertisements posted OC, whether by California or non-California entities, are not subject to the regulatory requirements of the California law.

We first compared advertisements posted in California and those posted OC. There were a total of 100 California advertisements of which 95 (95%) listed benefits. There were a total of 335 OC advertisements of which 329 (98%) listed benefits. All benefits listed included financial compensation to the oocyte donor.

Of those advertisements that listed benefits, a majority of both California and OC advertisements included neither the specific risk disclosure language of paragraph (a) of the California law nor other risk disclosure language that would satisfy the ASRM guidelines (Figure 1). Of those California advertisements that did include risk disclosures, all included the specific risk disclosure language set forth in paragraph (a) of the California law. In all but one case, all OC advertisements that included risk disclosures also included the specific risk disclosure language set forth in paragraph (a) of the California law. There was a significant difference ($p < 0.01$) between the 27% of California advertisements that included risk disclosures and the 13% of OC advertisements that included risk disclosures (Figure 1). It should be noted, however, that the percentage of California advertisements including risk disclosures was still quite low.

To capture the possible indirect influence or “halo effect” of California law on advertisements posted OC, the 304 advertisements placed OC by identifiable California and non-California entities were compared

Table 5

Influence of California Law on OC Advertisement Compliance

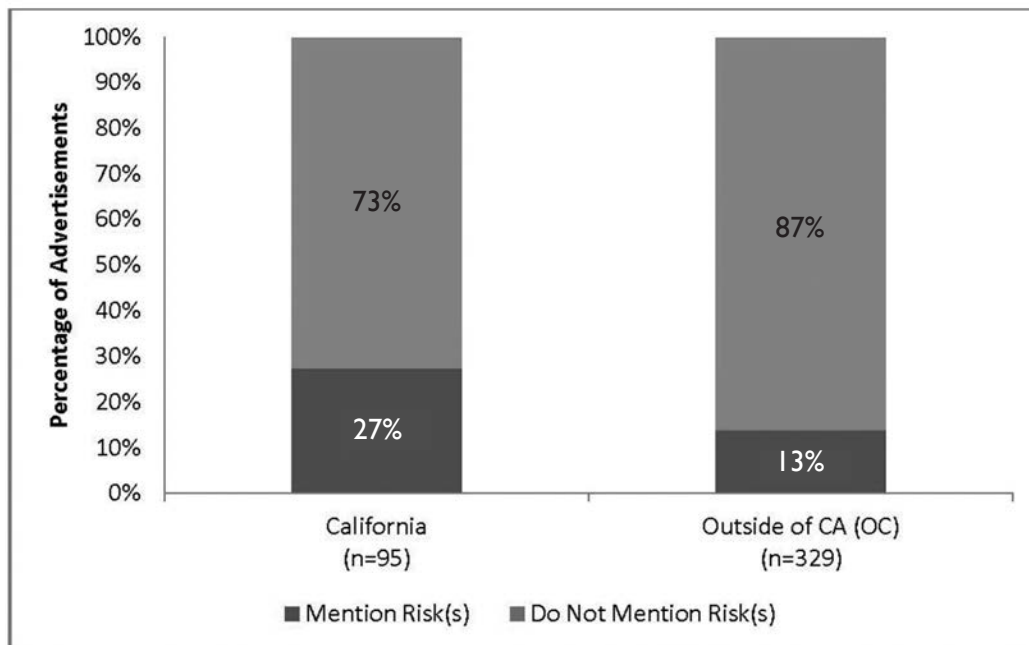
	CA Entities	Non-CA Entities
# OC Advertisements	132	172
% Advertisements Compliant	30% (39)	1% (2)
% Advertisements Non-Compliant	70% (93)	99% (170)

(Table 5). We found that advertisements placed OC by California entities were significantly more likely to disclose risks than advertisements placed OC by non-California entities (30% vs. 1%, $p < 0.01$). This effect was driven by 2 of the 14 California entities that disclosed risks in all of their advertisements (both in California and OC). These results suggest that enactment of the California law may have encouraged a small subset of California entities to disclose risks when advertising OC.

We note further that, in all but one case, risk disclosure by California and non-California entities in advertisements posted in California and OC consisted of the specific risk disclosure language set forth in paragraph (a) of the California law. Thus, in our collection of advertisements, the California law heavily influenced the nature of risk disclosure.

Figure 1

Comparison between California and OC Advertisements



Discussion

In our evaluation of nationwide risk disclosure in oocyte donation advertisements, we find that the vast majority of the advertisements in our dataset that include reference to benefits do not include risk disclosures. Although disclosure rates are low for both groups, we find that risk disclosure is significantly more common in advertisements placed by SART entities than in advertisements placed by non-SART entities. We do not find a significant difference in rates of risk disclosure between IVF clinics and oocyte donor agencies. Our results indicate that risk disclosure in oocyte donation advertisements placed by all enti-

tus quo regarding risk disclosure in advertisements, there is also a significant problem with the efficacy of current ASRM guidelines in influencing risk disclosure among SART entities.

Our results indicate that risk disclosure in California advertisements is significantly greater than risk disclosure in advertisements posted OC, indicating that formal regulation does exert a meaningful influence on risk disclosure. However, the regulatory force of the California law still yields risk disclosure in less than 30% of advertisements posted in California. There is also evidence of an indirect influence or “halo effect” of California law. This indirect influence is observed in

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Although SART entities include risk disclosures in their advertisements more frequently than non-SART entities, the low rate of risk disclosure observed in advertisements placed by SART entities suggests that ASRM risk disclosure guidelines currently exert little influence on entities subject to their self-regulatory force. While we have no basis for determining whether risk disclosure was even more rare prior to publication of the ASRM guidelines, our analysis of a set of advertisements collected in 2011 shows very low rates of risk disclosure among SART entities, including both IVF clinics that are SART members and oocyte donor agencies that registered with SART. Hence, if there is a significant ethical and policy problem with the sta-

the higher rate of risk disclosure by California entities (as compared to non-California entities) in advertisements placed OC and in the nature of risk disclosure language included in the minority of advertisements placed OC that do disclose risks.

The very low overall rate of risk disclosure in advertisements cannot be attributed to non-disclosure by unregulated entities, i.e., entities that are not subject to the self-regulatory force of the ASRM guidelines or to the formal regulatory force of the California law. Non-disclosure of risks was across-the-board, among entities that were and were not subject to the ASRM guidelines or California law. There was, however, significantly greater although still very low risk disclosure among entities subject to the self-regulatory force of the ASRM guidelines and to California law.

Other possible explanations for the very low rate of risk disclosure include low awareness of the ASRM guidelines and the California law or ineffective enforcement of them or both. ASRM’s self-regulatory

guidelines are published in *Fertility and Sterility* and the guidelines on the compensation of oocyte donors, which include the risk disclosure requirement, appeared most recently in 2007.⁴⁵ These guidelines are also available on the ASRM website.⁴⁶ The risk disclosure requirement is not highlighted within these publications, however, and some readers of the guidelines may not have noted it or may not have fully comprehended what it requires. Concerns have also been voiced about insufficient efforts to monitor or enforce compliance with other ASRM guidelines and with the California risk disclosure law.⁴⁷ For those entities that are aware of the risk disclosure requirements of the ASRM guidelines and the California law, there may be a willingness to risk non-compliance both due to lack of monitoring and enforcement and to lack of the threat of significant penalty even if non-compliance came to light.

The primary conclusion of our study is that inclusion of risk disclosure language in advertisements that refer to benefits is very low as evidenced in our collection of advertisements. If, as we have argued, disclosure of the existence of risks should be provided at the earliest stage of recruitment if benefits are noted, then there is a significant ethical and policy problem. The results of our study indicate that neither current self-regulatory nor formal regulatory efforts are succeeding in addressing this problem.

This points to the following significant policy questions arising from the findings of our study:

(1) We have asserted that risk disclosures should be included in oocyte donation advertisements, if benefits are noted in the advertisements, to help ensure informed consent by oocyte donors. Inclusion of risk disclosure requirements in the ASRM guidelines and the recent adoption of the California risk disclosure law reflect the same policy conclusions and rationales. Assuming that this policy stance is appropriate, there is an apparent need to address the ineffectiveness of current self-regulatory and formal regulatory efforts. Widespread noncompliance with the ASRM guidelines and somewhat better compliance with the California law may indicate that formal regulation is necessary to achieve improved compliance. Very low compliance even with the formal regulation set forth in California law may indicate the need for enhanced enforcement effort or revision of the law to better specify the enforcement mechanism and penalties for noncompliance.

However, future studies might address whether the primary explanation for noncompliance consists in a lack of awareness of the guidelines and the law — or a lack of awareness of their rationale — inviting a different response to achieve meaningful compliance. If, for

example, those responsible for directing the advertising practices of these entities were persuaded that risk disclosure at later stages of recruitment is wholly adequate to ensure informed consent, this would encourage noncompliance in the absence both of formal regulation in all but one state and in the absence of vigorous enforcement efforts. It may be that the most effective response to the results of this study would include greater attention by ASRM to explaining the rationale for including risk disclosure in advertisements and to publicizing that explanation.

It may also be helpful to include recommended risk disclosure language in the ASRM guidelines. The indirect influence of the language included in the California law on OC advertisements is noteworthy. It may be that compliance with ASRM guidelines would be improved if standard risk disclosure language were included in its risk disclosure guidelines. The effect may be both to improve awareness of the requirement and its rationale and to provide a convenient and readily replicated means for satisfying the requirement.

(2) It may be that the assumed need to include risk disclosure in oocyte donation advertisements should be examined more closely. The net effect may be to reduce the effectiveness of recruitment efforts and the corresponding capacity of IVF clinics and oocyte donation agencies to meet the needs of people suffering from infertility without any significant gains in ensuring that potential oocyte donors understand the risks and benefits of oocyte donation before they decide whether to proceed.

We note that there has been relatively little study either of the long-term risks of oocyte donation or of the effects of risk disclosure at various stages in the recruitment process. Studies on the effects of risk disclosure might draw on the experience with risk disclosure in oocyte donation advertisements in other countries and on the experience with risk disclosure in other contexts involving risks to donors and benefits to others, including human subjects experimentation and organ donation. In the absence of these studies, it is difficult to assess the value of risk disclosure relatively earlier or later in the recruitment process, and this assessment might well be influenced by better understanding of the known and unknown but potential risks of the donation process. Pending further study and analysis, we conclude, as has ASRM, that it is appropriate to assume that inclusion of risk disclosures in oocyte donation advertisements is important to ensuring informed consent by oocyte donors. But the results of these studies might be persuasive in revising this assumption, which may justify revising the ASRM requirement for risk disclosure in advertisements in light of the effects on donor recruitment

and our capacity to address the needs of those suffering from infertility.

(3) It is also possible that the results of further studies would yield a different conclusion warranting more extensive, formal regulation of risk disclosure in advertisements. If, for example, the known and unknown but potential risks of the donation process are significantly greater than we now know, far more comprehensive risk disclosure and enforcement of risk disclosure may be called for. This possibility informs our assumption that the minimal risk disclosure set forth in the ASRM guidelines is currently warranted and our conclusion that there is a significant ethical and policy problem with the status quo. It also informs our conclusion that it is important to remedy the current widespread noncompliance with ASRM and California risk disclosure requirements and to study both the effects of risk disclosure at various stages of the recruitment process and the long-term risks of oocyte donation.

We recognize that this study is limited by the single advertisement source at a single time period and by a strict coding mechanism employing the term “risk.” In addition, it is limited by the absence of analyses of the results of the studies called for above, including the practices and effects of risk disclosure at later points in the recruitment process. Despite these limitations, the study does suggest widespread noncompliance with current risk disclosure guidelines for oocyte donation advertisements set forth in ASRM guidelines and California law and the need for more effective current regulation pending future studies and future policy-making in response to their results.

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35. When collection of advertisements for this study was undertaken in November 2011 and when analysis of entities placing these advertisements was undertaken in 2012, ASRM made publicly available on its website a list of oocyte donor agencies that had registered with SART, signing an agreement to abide by ASRM guidelines. At the time of preparation of this article, ASRM no longer makes this list publicly available on its website. Our determination of the SART registration status of oocyte donor agencies that placed advertisements collected in November 2011 is based on the list that was publicly available on the ASRM website in June 2012.
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43. The one advertisement that contained the word "risk" and was coded as non-compliant with the ASRM guidelines used the term in reference to the possibility that a donor who had received a tattoo or body piercing in the last twelve months might pass infectious disease on to the intended mother or future child.
44. We note that, by its terms, the California law would require these "persons" to provide the specific risk disclosure set forth in the California law if they post the advertisements in California. We did not separately analyze whether or not these "personal" advertisements were posted in California and, if so, whether they included the risk disclosure required by California law.
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