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Compliance with donor age recommendations in oocyte donor recruitment advertisements in the USA

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Abstract IVF using donated oocytes offers benefits to many infertile patients, yet the technique also raises a number of ethical concerns, including worries about potential physical and psychological risks to oocyte donors. In the USA, oversight of oocyte donation consists of a combination of federal and state regulations and self-regulatory guidelines promulgated by the American Society for Reproductive Medicine. This study assesses compliance with one of these self-regulatory guidelines – specifically, ASRM’s preferred minimum age for donors of 21. To assess compliance, 539 oocyte donor recruitment advertisements from two recruitment channels (Craigslist and college newspapers) were collected and evaluated. Of these, 61% in the Craigslist dataset and 43% in the college newspaper dataset listed minimum ages between 18 and 20, which is inconsistent with ASRM’s preferred minimum age recommendation of 21. Advertisements placed by oocyte donor recruitment agencies were more likely than advertisements placed by clinics to specify minimum ages between 18 and 20. These results indicate that ASRM should evaluate and consider revising its donor age guidelines. 

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Introduction

IVF using donated oocytes has proved to be an important and effective treatment option for many women (Tarlitzis and Pados, 2000), and annual reports on assisted reproduction treatment in the USA indicate that usage of donated oocytes is increasing (Centers for Disease Control and Prevention, 1998, 2011). While the benefits of oocyte donation for recipients are well recognized, concerns have been raised about potential physical risks for donors (Althuis et al., 2005; American Society for Reproductive Medicine, 2008a; Bodri et al., 2008; Jayaprakasan et al., 2007). These risks include ovarian hyperstimulation syndrome, a complication associated with the medications donors take to induce ovulation (American Society for Reproductive Medicine, 2008a; Bodri et al., 2008; Jayaprakasan et al., 2007; Institute of Medicine and National Research Council, 2007), potential links between fertility medications and various forms of cancer (Althuis et al., 2005; Institute of Medicine and National Research Council, 2007; Schneider, 2008) and concerns about the potential impact of the donation process on a donor's future fertility (Kramer et al., 2009; Stoop et al., 2012). Assessing these risks is difficult, as long-term studies of the risks associated with fertility medications and the oocyte retrieval process are few in number and generally focus on women undergoing IVF rather than oocyte donors (Althuis et al., 2005; American Society for Reproductive Medicine, 2008a; Institute of Medicine and National Research Council, 2007; also see Bodri et al., 2008; Maxwell et al., 2008 for exceptions).

Concerns have also been raised about potential psychological harm to donors and the broader social impact of oocyte donation. These concerns derive in part from the differences between oocyte and sperm donation with respect to the medical risks of the procedures, the compensation donors typically receive, the degree of physical 'investment' by oocyte donors and the characterization of oocyte donation as an altruistic deed (Almeling, 2009; Rao, 2006). The distinctive features of oocyte donation have led to concerns about the potential exploitation of oocyte donors (Steinbock, 2004) and the perceived commodification of oocytes (Almeling, 2009; Holland, 2001; Rao, 2006) and have triggered debates about appropriate compensation of oocyte donors (Levine, 2010; Steinbock, 2004).

In contrast, relatively little attention has been paid to the implications of these physical, psychological and social concerns for the ages at which it is appropriate for women to donate oocytes. Since female fertility declines with age, it would be expected that younger donors, all else equal, would provide healthier oocytes to their recipients and thereby increase their recipients' chances for successful IVF cycles. Several studies support this contention (Barton et al., 2010; Cohen et al., 1999; Faber et al., 1997).

However, these benefits should be weighed against any potential for increased physical or psychological risks for younger donors. For example, several studies and an Institute of Medicine report have noted that younger oocyte donors are at greater risk of ovarian hyperstimulation syndrome (Delvigne and Rozenberg, 2002; Institute of Medicine and National Research Council, 2007; Jayaprakasan et al., 2007). The potentially lesser maturity of younger donors

raises additional concerns about their decisions to assume the physical and psychological risks associated with oocyte donation.

In the USA, oversight of oocyte donation includes Food and Drug Administration (FDA) rules designed to prevent the transmission of communicable diseases, Centers for Disease Control and Prevention (CDC) rules requiring the reporting of success rates and a handful of state laws addressing various aspects of the practice. As far as is known, current regulation of gamete donation does not address the permissible ages for donors. However, the American Society for Reproductive Medicine (ASRM) – an organization consisting primarily of healthcare professionals and dedicated to advancing the field of reproductive medicine – and the Society for Assisted Reproductive Technology (SART) – an affiliated organization dedicated to promoting and advancing assisted reproduction treatment – have developed self-regulatory guidelines that address this issue. In a 2008 report, ASRM states that sperm donors 'should be of legal age and, ideally, less than 40 years of age' and that oocyte donors 'should be of legal age, and preferably between the ages of 21 and 34 years' (American Society for Reproductive Medicine, 2008b). Oocyte donors 'less than 21 years of age should have psychological evaluation by a qualified mental health professional, and the decision to proceed with such a donor should be determined on an individual basis' (American Society for Reproductive Medicine, 2008b).

Given the voluntary nature of these guidelines, the extent to which they affect the recruitment and enlistment of oocyte donors aged 18–20 is unknown. Although few studies have specifically addressed this issue, one recent study analysed 102 oocyte donor agency and clinic websites and found that 41% indicated acceptance of donors under age 21 (Keehn et al., 2012). Studies examining compliance with another set of ASRM self-regulatory guidelines – guidelines for oocyte donor compensation – have found evidence of low compliance with the compensation limits specified in the guidelines (Levine, 2010; Luk and Petrozza, 2008).

The present study focuses specifically on evidence of compliance with the ASRM oocyte donor age guidelines and uses two datasets of oocyte recruitment advertisements – one collected from college newspapers in April 2006 and one collected from the Craigslist website in November 2011. Although advertisements cannot provide definitive evidence about the enlistment of oocyte donors aged 18–20 or about the practices of psychological evaluation and case-by-case determination for these donors, they can provide insight into the recruitment of these potential donors.

Materials and methods

The oocyte donor recruitment advertisements analysed in this study were collected from the internet and college newspapers. The online advertisements were collected from the US section of Craigslist, a classified advertisements website (www.craigslist.org/about/sites/#US). To ensure the data were consistent from one city to the next, all Craigslist advertisements were collected during the week of 28 November 2011. The 2010 US Census Report was used to identify the 50 most populous metropolitan statistical areas, and 48 of these with a distinct Craigslist

site were searched using the search terms 'egg donor' and 'egg donation', resulting in the collection of 434 advertisements. An advertisement was counted as unique if either the text or title of the advertisement differed from others.

The college newspaper advertisements were collected in April 2006, as described in a previous study by Levine (2010). Briefly, letters were mailed to student newspapers at 975 colleges and universities requesting copies of two recent issues. A total of 366 newspapers responded and 105 oocyte recruitment advertisements were found in newspapers from 63 different universities. Although the newspaper advertisements are older, the same guidelines for oocyte donor age were in effect when they were collected and their inclusion allows us to examine compliance at two points in time in two different recruitment channels.

The same content analysis was performed on both datasets. To develop the coding approach, all three co-authors performed a preliminary analysis on 20 advertisements randomly selected from the Craigslist sample. This analysis was used to develop a coding book, which a single coder then used to evaluate the advertisements in both datasets for the minimum and maximum donor age listed and specific advertiser characteristics, including advertiser type (i.e. agency, clinic, personal or unspecified) and name of the advertising entity.

The compliance of each advertisement with the minimum age threshold (18) and preferred minimum age (21) for oocyte donors was evaluated based on the ages, if any, specified in the advertisement. For example, a clinic advertisement that listed a minimum age of 18 was treated as evidence of the clinic's compliance with the minimum age threshold of 18 and as evidence of the clinic's noncompliance with the preferred minimum age of 21. Some advertisements did not specify a minimum age. These omissions were viewed neutrally, rather than as evidence of either compliance or noncompliance with the age guidelines.

For the Craigslist data, the SART membership status of each clinic placing an advertisement was ascertained (www.sart.org/find_frm.html). Similarly, each agency identified in the Craigslist dataset was evaluated to determine if the agency had signed an agreement with SART to follow ASRM oocyte donation guidelines (www.sart.org/egg_donor_agencies).

Results

In all, 105 advertisements were collected from college newspapers and 434 were collected from Craigslist. The percentage of advertisements in each dataset that complied with the minimum age threshold (18) and preferred minimum age (21) for oocyte donors was determined (Figure 1). Of the college newspaper advertisements, just under a quarter listed a minimum donor age of 21 or higher, in compliance with the preferred minimum age specified in the guidelines, 43% listed a minimum donor age between 18 and 20 years, complying with the minimum age threshold but not the preferred minimum age, and 35% did not list any minimum age. In the Craigslist dataset, compliance with the preferred minimum age was slightly higher, with 35% of advertisements listing a minimum age of 21 or higher, and almost all of the

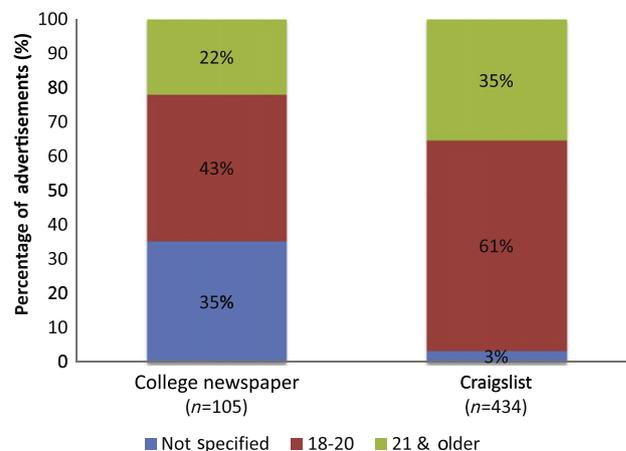


Figure 1 Minimum donor age specified in college newspapers and Craigslist advertisements. Due to rounding, percentages may not sum to 100%.

remaining advertisements listing a minimum age between 18 and 20 years, with only 3% listing no minimum age.

To assess whether the type of entity placing the advertisement was a factor in the minimum age listed, the advertisements were grouped by entity type, including specific individuals or couples ('personal') (Figure 2). A small number of advertisements could not be assigned to a specific source and were excluded from the analysis. Donor agencies placed a majority of the advertisements in both datasets.

Of advertisements placed in college newspapers by agencies, 47% listed a minimum age between 18 and 20 (Figure 2A), 42% did not specify a minimum donor age and the remaining 12% listed a minimum age of at least 21. The advertisements placed by clinics in college newspapers showed higher compliance with the preferred minimum age recommendation, with 80% listing a minimum age of at least 21 and only 20% listing a minimum age between 18 and 20. The difference between agencies (47%) and clinics (20%) in non-compliance with the preferred minimum age of 21 was statistically significant (t -test, $P < 0.1$). Of the Craigslist advertisements, 67% placed by agencies and 35% placed by clinics recruited donors between 18 and 20 years (Figure 2B), a statistically significant difference (t -test, $P < 0.01$).

There were broad similarities between the advertisements placed in college newspapers in 2006 and on Craigslist in 2011 (Figure 2). In both datasets, advertisements placed by agencies were more likely to list minimum ages between 18 and 20. Clinics were more likely to comply with the preferred minimum age of 21. However, approximately one-fifth to one-third of clinic advertisements recruited donors aged 18–20.

To assess if this observed non-compliance with the preferred minimum age recommendation was driven by a small subset of clinics or agencies, advertisements were next grouped by the clinics or agencies placing the advertisements. This permitted an assessment of non-compliance with the preferred minimum age of 21 by individual clinics and agencies (Figure 3). The analysis did not include personal advertisements because it was not possible to ascertain the identities of these advertisers. Results were broadly similar to the results of the assessment by adver-

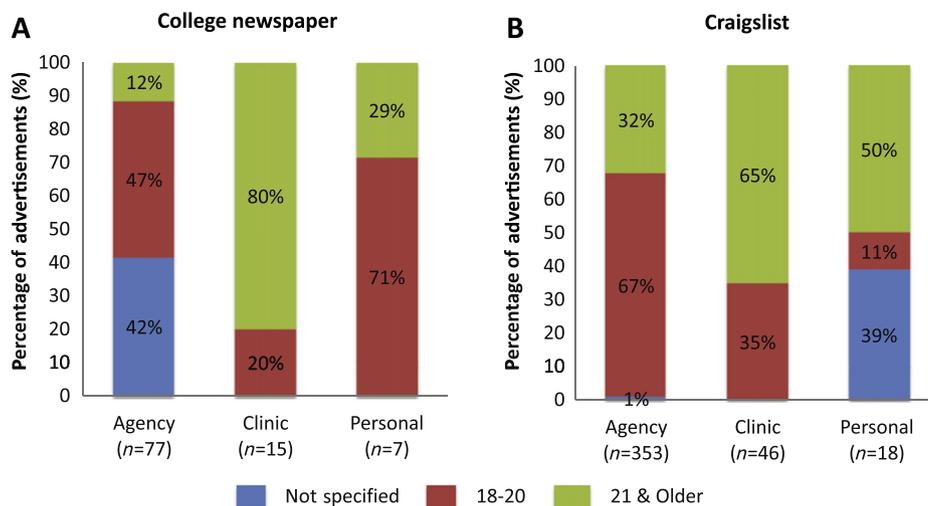


Figure 2 Minimum donor age specified in college newspapers (A) and Craigslist (B) advertisements by type of advertiser. Due to rounding, percentages may not sum to 100%.

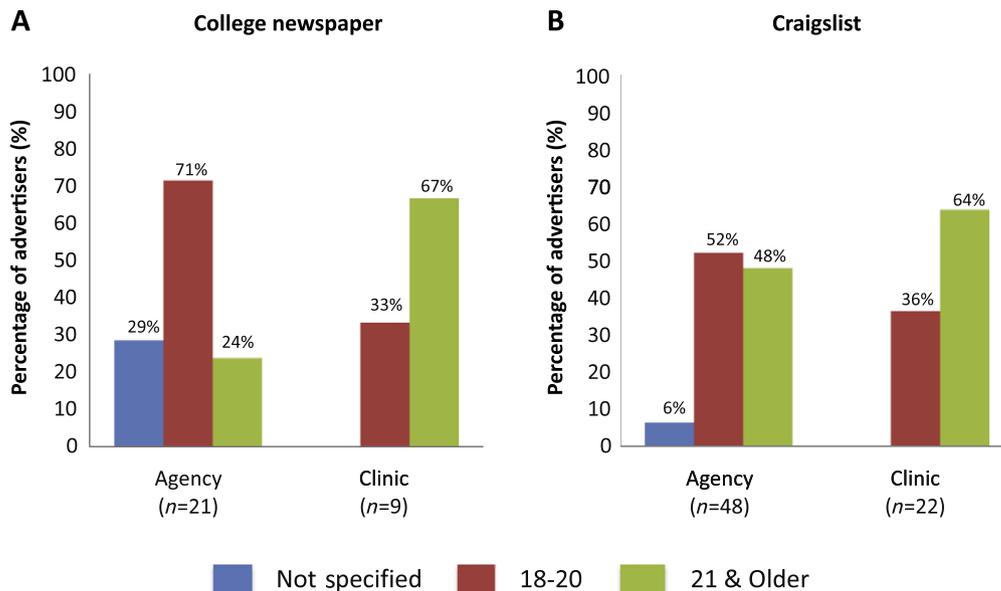


Figure 3 Minimum donor age specified in college newspapers (A) and Craigslist (B) advertisements by agencies and clinics. Entities that placed multiple advertisements with different minimum age specifications are counted in each appropriate category.

tisement and entity type in **Figure 2**. In both datasets, a majority of agencies and approximately one-third of clinics placed advertisements specifying a minimum age between 18 and 20. These results suggest that non-compliance with the preferred minimum age recommendation was not driven by a small subset of clinics or agencies, but rather distributed throughout the datasets.

Clinics were then grouped by their SART membership status and agencies by their participation in SART's donor agency registry to test whether these affiliations were related to the minimum age specified in donor recruitment advertisements. This analysis was limited to the 2011 Craigslist dataset because only current SART affiliation status was available. The analysis showed that 23 SART agencies were more likely

to follow the preferred minimum age recommendation than 24 non-SART agencies (57% versus 38%) and 18 SART clinics were less likely to comply with the preferred minimum age recommendation than four non-SART clinics (61% versus 75%). Neither difference was statistically significant.

Discussion

None of the advertisements examined listed a minimum age younger than 18, suggesting that advertisers typically comply with the ASRM minimum age threshold of 18 for oocyte donors. However, numerous advertisements listed ages below the preferred minimum age of 21, suggesting noncompliance with the preferred use of donors who are

at least 21 years of age. Recruitment of donors between 18 and 20 was found in agency, clinic and personal advertisements in both datasets. These results indicate that ASRM's self-regulatory guidelines do not deter at least some advertisers from recruiting oocyte donors between the ages of 18 and 20.

The type of entity placing the advertisement was a factor in the minimum age listed. In both datasets, clinic advertisements were more likely to list the preferred minimum age of 21 and agency advertisements were more likely to list minimum ages between 18 and 20. Donors recruited by agencies must ultimately donate at clinics, however, and the extent to which clinics that list the ASRM preferred minimum age in their own advertisements utilize younger donors recruited by noncompliant agencies remains an important open question.

Although the focus of this analysis is compliance with the oocyte donor age guidelines, the results raise broader questions about the efficacy of self-regulation in the industry. The donor age guidelines are presumably among the easiest of ASRM's self-regulatory guidelines for clinics and agencies to monitor and follow. Yet advertising for donors under the age of 21 appears widespread, suggesting that noncompliance with the preferred use of donors age 21 and older may also be widespread. Tolerance of widespread noncompliance may, over time, weaken the legitimacy of the current self-regulatory regime.

Not all clinics, agencies or individual couples advertise for donors on Craigslist or in college newspapers and the extent to which these results generalize to advertisements placed by other clinics or agencies, through other channels or at different times is unknown. The results reported here are consistent, however, with those found in a recent study of clinic and agency websites (Keehn et al., 2012).

In addition, although listing a minimum age below 21 in an advertisement is a strong indicator that the entity placing the advertisement is willing to work with such donors, the age listed may not reflect the actual practices at fertility clinics. This study cannot indicate whether, for example, after agencies and clinics recruit donors aged 18 and older, they then exercise a preference for using donors who are at least 21, as recommended by the guidelines. Furthermore, ASRM recommends that, if donors under 21 are to be used, the decision to proceed should be made only after psychological evaluation by a mental health professional. This study does not offer any indication of whether or what kinds of psychological evaluations of younger donors are performed.

These results highlight the importance of deciding whether and why it is important for oocyte donors to be at least 21 years old. Because the current ASRM guidelines do not provide the rationale for the preferred minimum age of 21, it is not clear which parties the guideline aims to benefit or protect or which values it aims to uphold. A 2006 ASRM report for parents involved in third-party reproduction suggests that concerns about the maturity of donors motivated the current age recommendations: the report explains that the older oocyte donor age of 21 is designed to 'ensure that the donor is mature enough to provide true informed consent' (American Society for Reproductive Medicine, 2006). Opinions on this issue appear to vary among fertility specialists: some reject all donors under 21 (Fox

News Associated Press, 2012) and others accept them, indicating that they believe some 18–20-year-old women have the maturity to make the decision to donate their oocytes (Sweet, 2012).

One approach to addressing concerns associated with oocyte donation by younger women might consist in revising the ASRM guidelines to specify a minimum age threshold of 21, with no allowance for case-by-case evaluation and enlistment of women aged 18–20. This approach would protect younger women from the risks associated with oocyte donation, but would deny them financial or other benefits of donation and deprive recipients of the benefits of oocytes from younger donors. The exclusion of all women aged 18–20 would raise the question – more pointedly than the current case-by-case approach – of whether differential treatment of female and male gamete donors is justified or, instead, reflects stereotypical beliefs about gendered differences surrounding reproduction or about the capacity of younger women to make the choice to undertake risks. The rationale for this differential treatment would need to be addressed in the revised guidelines.

Another approach would consist in retaining the current age guidelines but specifying the criteria for case-by-case recruitment and enlistment of 18–20-year-old women. And, to facilitate application of the criteria by agencies and clinics, a standardized protocol for case-by-case psychological evaluation capturing these criteria would be developed. A related alternative approach would be to eliminate the preferred minimum age of 21 and substitute a required case-by-case psychological evaluation for all potential donors, regardless of age, applying a standardized protocol that captures all concerns, including those related to the maturity of the potential donor.

If ensuring compliance with self-regulatory guidelines is considered too problematic, a more formal regulatory structure for the oversight of oocyte donation might merit consideration. Such an approach could potentially integrate current regulations – such as FDA rules mandating screening for infectious diseases and CDC rules requiring the reporting of success rates – into a more coherent regulatory system. This more formal approach, variants of which have been adopted in the UK, China and numerous other countries (e.g. Ahuja, 2012; Cai et al., 2012), may offer donors greater protection and promote consistency in application of the rules, but, depending on the specific regulations, may reduce the availability of donated oocytes (Levine, 2011).

Approximately 10% of advertisements in the combined dataset did not list a minimum age. Because many of these advertisements, especially those placed in college newspapers, were likely to reach an audience that included significant numbers of women under the age of 21 and some under the age of 18, the omission of any minimum age raises questions about compliance both with the preferred minimum age of 21 and the minimum age threshold of 18.

Finally, the results of this study highlight the need for better knowledge of the actual practices of clinics and agencies in the screening and enlistment of donors. Simply requiring the reporting of the ages of oocyte donors in the annual data collection for the assisted reproduction

treatment success rates report would yield useful data regarding the frequency of donation by women under age 21 and help quantify the concerns raised by this study. Collecting and reporting data on the ages of oocyte donors would also increase the transparency surrounding the process of oocyte donation in the USA and provide potentially useful information to recipients, donors, and the general public, and the data would likely prove valuable when the ASRM donor age guidelines are next reviewed and revised.

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