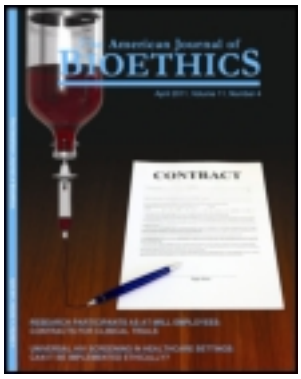

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Reconsidering Risk to Women: Oocyte Donation for Human Embryonic Stem Cell Research

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and refers treatment. Yet certain areas demand enforceable regulation, such as the recruitment tactics and exploitation of vulnerable populations for oocyte donation.

OHSS is a potential and significant risk for any woman undergoing ovulation induction. New techniques allow a lessening of this risk and should be applied liberally to reproductive and research donors. When using donor oocytes (or sperm) and embryos for reproduction or research, we must guarantee nonexploitive recruitment, minimal stimulation protocols with OHSS prevention tools, true informed consent, and long-term follow-up of donors. ■

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Reconsidering Risk to Women: Oocyte Donation for Human Embryonic Stem Cell Research

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Ellison and Meliker (2011) direct our attention to ethical problems concerning risk that arise from the use of human eggs (ooctyes) in stem cell research involving somatic cell nuclear transfer (SCNT). The authors identify that the chief risk associated with ovulation induction is ovarian hyperstimulation syndrome (OHSS). They challenge anti-SCNT arguments informed by risk to women by demonstrating that if risk of OHSS is low for women undergoing in vitro fertilization (IVF) and if risk of OHSS is low for healthy women donating oocytes for research purposes, then risk cannot reasonably be used to support continuing ethical objections to SCNT. The authors claim that anti-donation arguments using data on the risks of ovarian stimulation collected from women already experiencing fertility commit the fallacy of unrepresentative sample, because these data may not be applicable to the population of oocyte donors for SCNT. Moreover, the authors emphasize the importance of shifting "the body of literature away from women undergoing assistive reproductive technologies to the population relevant to oocyte donation, specifically" (Ellison and Meliker 2011). As they acknowledge, a study conducted in Spain showing that "a low rate of serious complications can be expected following oocyte retrieval" (Bodri 2008, 241) is one of the few currently available in the growing body of literature focused specifically on the case of women donating ooctyes for research purposes. As Ellison and Meliker also acknowledge, these women occupy a special status that is distinct from research subjects on the one hand and oocyte donors for infertility purposes on the other.

The authors' argument is, in significant part, dependent upon the same unrepresentative sample: women experiencing fertility problems. This is evident in their claim that OHSS, risk of clinical complications, and death cited by donation-opposing arguments may be challenged on the basis of clinical evidence. First, they appeal to evidence (i) from Klemetti and colleagues (2005) showing that there is a lower rate of clinical complications in patients undergoing simple ovulation induction than in patients undergoing ovulation induction and IVF, (ii) to evidence from Venn and colleagues (2001) suggesting a lack of correlation

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between incidence of OHSS and incidence of death in the relevant population of IVF patients, and (iii) to evidence from Papanikolaou and colleagues (2005), who claim that severe OHSS—more strongly correlated with death than the less severe forms of the syndrome—almost always occurs more than a week following retrieval and in conjunction with endogenous secretion of gonadotrophins following implantation in pregnancy. The authors show that the evidence from Papanikolaou and colleagues (2005) is in line with that from Klemetti and colleagues (2005), and further strengthen their case by making an additional connection between these studies and Bodri's (2008) claim that risk of clinical complications is lower in the case of women undergoing the process of oocyte donation than in the case of women undergoing the process of ovulation induction for IVF. However, their argument does not thereby avoid dependence on an unrepresentative sample. In developing these points, the authors use data from studies conducted in Finland and in Brussels. It is not evident that these data are sufficient to be as broadly applicable worldwide as they appear to intend, meaning that the authors are being too hasty in generalizing about OHSS risk on the basis of these specific studies.

The authors also contend that while data on the risks of ovarian stimulation have come from a population already experiencing infertility problems, donation-opposing arguments based on these data neglect to factor in a correlation between incidence of polycystic ovarian syndrome (PCOS) and incidence of OHSS. The authors' evidence concerning the correlation between incidence of PCOS and OHSS is taken from a retrospective study of clinical complications in a Dutch IVF program by Roest and colleagues (1996) involving 2495 IVF cycles. Although the authors are correct to point to the need for future research studies to "include ... rates and risk proportions [and] statistically adjusted rate ratios of getting OHSS, given the exposure of ovulation induction medications," and to recommend screening for "immunological responses to ovarian stimulation drugs, medical history, and type of drugs used" (Ellison and Meliker 2011), in making this claim by appealing to Kenney and McGowan's (2008) analysis of data collected from reproductive (rather than research) oocyte donors, they invoke the same error in reasoning. The problems of hasty generalization and unrepresentative sample thus also apply here.

There is a gap in the authors' analysis of the risk of exploitation of economically disadvantaged women. On the basis of their argument concerning OHSS risk to oocyte donors, the authors claim that "the risk for OHSS for women of any socioeconomic status does not appear to be so great as to warrant policies preventing women from donating eggs" (Ellison and Meliker, 2011). The authors support their claim with the following rationale: (i) Donors are likely to be motivated by altruistic rather than financial reasons; (ii) society supports risks such as clinical trials and forms of manual labor involving greater risks at far greater rates than ooctye donation; (iii) the degree of risk in oocyte donation for SCNT research is outweighed by research potential. They conclude that a small risk to women should be acknowledged yet accepted as implicit in the pursuit of research progress.

However, this rationale gives insufficient consideration to types of exploitation. As Dickenson and Idiakez (2008) point out, exploitation may include trafficking in oocytes alongside sex trafficking in Europe, commercial egg brokerage such as is done by the DNA-Bank agency in Korea, which provides ooctyes for research, and the emerging possibility of a global ooctye trade where the poorest nations are the major suppliers. Baylis and McLeod (2007, 730) develop the problem of global oocyte trade in relation to economic disadvantage as follows: To avoid undue inducement of women from poor nations to undergo ovulation induction and oocyte retrieval, payments would have to be kept small, thereby opening up the possibility of exploitation; however, increasing payment size to eliminate exploitation would reintroduce undue inducement. In light of this problem, Baylis and McLeod recommend (i) altruistic donation with compensation for direct, receipted expenses, and (ii) acceptance of a short supply of oocytes for stem cell research if women choose not to donate. Dickenson and Idiakez further problematize the notion of altruistic motivation for donation in Ellison and Meliker's rationale by arguing that one-way altruism, in which benefits flow from donors to researchers, "smacks of exploitation" (2008, 139). Dickenson and Idiakez ground this claim in uncertainty in the available evidence about possible risk to women and underestimation of risk that may take decades to become fully evident, such as possible premature menopause. More recently, Klitzman and Sauer (2009) have produced evidence suggesting that Ellison and Meliker may not be correct to accept that U.S. oocyte donors are more likely to be motivated by altruism. Relatedly, Ellison and Meliker identify proper informed consent and information exchange as a central demand for policy. However, Dickenson and Idiakez point out that uncertainty in the available evidence may make it impossible for women to give properly informed consent to donation. The authors should have acknowledged these points and made a more modest claim concerning altruism and exploitation of economically disadvantaged women.

Ellison and Meliker also neglect to weigh psychosocial, racial, and ethnic factors in their analysis of the risk of exploitation of economically disadvantaged women. Predicting the emergence of the global oocyte market, Dickenson (2002) reasoned that race blindness of enucleated eggs with no genetic content may promote oppression in that if "race ... does not matter," women of the South could be targeted as potential donors (60). As she claims, "The South has the women who might be 'contracted' to do the job, if legal protections are not set in place quickly in the poorer countries to protect their female population" (60). Baylis and McLeod (2007) reaffirm Dickenson's point on oppression relative to geography in light of the December 2006 release of the International Society for Stem Cell Research (ISSCR) *Guidelines*

for the Conduct of Human Embryonic Stem Cell Research. They contend that because undue inducement is context dependent, both with regard to female economic inequality within a nation and with regard to such inequality across nations, the ISSCR stipulation that there be no undue inducement to women who provide oocytes outside of a clinical context may amount to endorsement of a policy in which some women are paid less for oocytes than others. Baylis and McLeod consider that one explanation for the ISSCR policy may be to reduce risk of additional psychological harm to, and undue inducement of, infertility patients who donate oocytes for research purposes by discouraging these women from doing so. They also point out that the guidelines create two classes of payees by encouraging oocyte providers who are not receiving fertility treatment to supply oocytes. Klitzman and Sauer (2009) rightly call for more attention to the medical and psychological impact that providing oocytes has on donors.

Ellison and Meliker are correct that more research needs to be done on this issue; this is precisely why their policy recommendations are too hastily drawn. ■

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Harmony and Compensation for Oocyte Providers

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The law, science, and ethics surrounding the practice of compensating women who provide oocytes for research and reproductive purposes have incorporated the belief that ovulation induction posed the same medical risk of harm associated with fertility treatment. Ellison and Meliker (2011) offer an updated analysis suggesting an important difference between the risks of one particularly serious harm, ovarian hyperstimulation syndrome (OHSS), as it arises in reproducing and non-reproducing oocyte providers. This new medical reality that women who provide oocytes for others, be it for research or reproductive purposes, are at less risk for OHSS than women who undergo ovulation induction for their own reproductive purposes invites a reexamination of the disparate compensation policies currently governing reproductive and research oocyte donation. We first examine the medical significance of Ellison and Meliker's contribution, and then turn to legal and ethical matters.

MEDICAL PERSPECTIVES

In accessing the risk of OHSS in oocyte donation cycles for use in critical research endeavors, there are several key elements of the medical procedure that differ from most reports of OHSS occurrence. OHSS is a rare iatrogenic complication

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