

Virtual Mentor
American Medical Association Journal of Ethics

January 2014, Volume 16, Number 1: 1-88.
Ethics and Assisted Reproductive Technology

From the Editor

- ART and the Art of Medicine** 3
Katie Falloon

Educating for Professionalism

Ethics Cases

- Assisted Reproduction for Postmenopausal Women** 5
Commentary by Senait Fisseha and Natalie A. Clark
- Physician Responsibility When a Surrogate Mother
Breaks her Contract** 10
Commentary by Saima Rafique and Alan H. DeCherney
- Are IVF Risk-Sharing Programs Ethical?** 17
Commentary by Leslie P. Francis
- Shared Decision Making about IVF for Savior Siblings** 24
Commentary by Emily S. Jungheim

The Code Says

- AMA Code of Medical Ethics' Opinions on
Assisted Reproductive Technology** 30

Journal Discussion

- Health and Development of Children Conceived through
Assisted Reproduction** 34
Clinton Wang

State of the Art and Science

- Expanded Genetic Testing in Assisted Reproduction:
Lessons Learned from Prenatal Testing** 38
Susan Klugman and Siobhan M. Dolan

Law, Policy, and Society

Health Law

**Physician Duties in the Face of Deceitful Gamete Donors,
Disobedient Surrogate Mothers, and Divorcing Parents** 43
Judith Daar

Fully Informed Consent for Prospective Egg Donors 49
Naomi Cahn and Jennifer Collins

Policy Forum

**Egg-Donor Price Fixing and *Kamakahi v. American Society for
Reproductive Medicine*** 57
Kimberly D. Krawiec

Medicine and Society

**Who Pays? Mandated Insurance Coverage for Assisted
Reproductive Technology** 63
Katie Falloon and Philip M. Rosoff

Resources

Suggested Readings and Resources 70

About the Contributors 86

Upcoming Issues of *Virtual Mentor*

February: Unwarranted Variation in Health Care

March: The Problem of Mistreatment in Medical Education

April: Third Parties in the Clinical Encounter

May: Ethical Issues in Geriatric Care

Virtual Mentor

American Medical Association Journal of Ethics
January 2014, Volume 16, Number 1: 3-4.

FROM THE EDITOR

ART and the Art of Medicine

On a summer night in 1978, as the hour approached midnight, Dr. Patrick Steptoe prepared himself for surgery [1]. A veteran obstetrician and gynecologist nearing retirement, Dr. Steptoe had delivered many babies by caesarean section, and he performed the surgery flawlessly [1]. At 11:47 pm, Louise Joy Brown came into the world, perfect and exquisite and vulnerable in that way only babies can be, though Louise Joy Brown was no ordinary baby [1]. To her parents, she was an unexpected and yearned-for gift after almost 10 years of trying to conceive; to Dr. Steptoe and his colleague, Robert Edwards, she was the culmination of countless years of research; and, to the world, she was a mixture of scientific triumph and medical marvel. She was the first so called “test tube baby,” or, in the correct scientific parlance, the first baby born following in vitro fertilization (IVF), which entails extracting eggs from a woman using a needle, fertilizing one or more with sperm, and then inserting one or more of the embryos into her uterus with the hopes that one implants. This year, a pregnant Louise celebrated her thirty-fifth birthday, with her husband and their first child [2].

In those 35 years since Louise’s birth, the field of assisted reproductive technology (ART) has flourished. What was on that July night a scientific breakthrough has become commonplace. Couples who are carriers for devastating genetic conditions they don’t want to pass on, gay and lesbian couples, women with anatomic abnormalities that prevent them from conceiving, men with abnormalities in their sperm, and countless others have found ART to be a kind of savior science, a way to have children when nature has denied them that option. ART has helped millions of people desperate for babies, like the Browns, to conceive, and, to date, more than 5 million babies have been born with the help of assisted reproductive technology [3].

But ART is not without controversy, as is generally the case in any rapidly expanding field. As the technology has powered ahead, questions about its ethical and moral implications, along with the appropriate regulation to protect the rights of all parties involved, remain unresolved, and its high cost and, hence, limited availability raise questions of distributive justice.

In many ways, ART highlights ethical dilemmas that exist, in more subtle forms, throughout all of medicine. What does a doctor do when he or she questions the decisions a patient is making? Can a doctor’s personal values ever trump those of the patient? When two of the physician’s patients have different interests in the same outcome (as can happen in surrogacy arrangements, for example), where do the physician’s loyalties lie? What obligations do physicians have to an unborn fetus and to a future child?

ART also raises questions about how medical technology should be regulated. Should regulation be in the hands of the government or in the hands of ART practitioners themselves? Should there be recommendations or laws? How much regulation is too much, and how much is too little? And are there limits on how far this technology should be allowed to progress?

So too does ART raise questions that are uniquely related to reproductive technology itself. What compensation should there be for egg donors? Is it ethical for fertility clinics to offer risk-sharing programs to their patients? What social impact, if any, does ART have on the children that result from it?

Ultimately, at the heart of the ethical dilemmas surrounding ART is our understanding of reproductive choice. How do we define this term, what do we value most about it, and how do we protect it?

Through a series of articles written by physicians, scientists, lawyers, public health experts, and students and a podcast with Thomas Price, MD, this issue of *Virtual Mentor* explores these questions thoughtfully. They are difficult ones, with no absolute answers and, sometimes, no obvious practical solutions. But as new techniques develop and use of ART grows, as it undoubtedly will, we are obliged to consider what that growth means, what aspects of procreation we as a society value most, and, perhaps most importantly, how we can best serve the interests of all future parents and their future children. This issue honors that obligation.

References

1. The world's first test tube baby. *American Experience*. PBS. <http://www.pbs.org/wgbh/americanexperience/features/general-article/babies-worlds-first/>. Accessed November 10, 2013.
2. Levin A. World's first test tube baby pregnant again—Louise Brown, 35, reveals her joy at expecting a second child six years after giving birth to a son. *Daily Mail*. July 20, 2013. <http://www.dailymail.co.uk/news/article-2371716/Worlds-test-tube-baby-Louise-Brown-pregnant-second-child.html>. Accessed November 10, 2013.
3. Five million babies born with help of assisted reproductive technologies [press release]. Washington, DC: American Society of Reproductive Medicine Office of Public Affairs; October 14, 2013. http://www.asrm.org/Five_Million_Babies_Born_with_Help_of_Assisted_Reproductive_Technologies/. Accessed October 15, 2013.

Katie Falloon
MS-2
Duke University School of Medicine
Durham, North Carolina

Acknowledgment

The theme issue editor would like to acknowledge Philip M. Rosoff, MD, MA, for his guidance and assistance in editing this issue of *Virtual Mentor*.

The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.

Copyright 2014 American Medical Association. All rights reserved.

Virtual Mentor

American Medical Association Journal of Ethics
January 2014, Volume 16, Number 1: 5-9.

ETHICS CASE

Assisted Reproduction for Postmenopausal Women

Commentary by Senait Fisseha, MD, JD, and Natalie A. Clark, MD

Dr. Deans, a fertility specialist, is meeting Lily and her husband Bill for the first time. As Dr. Deans gets to know her, he learns that Lily has wanted to have children since she was a little girl, but work—she lists her occupation as a corporate CEO—always seemed to get in the way. Now, at 53, she and her husband have decided to have a child before it is too late. Lily, who has undergone menopause, realizes that she no longer is able to have a child that will be genetically related to her, but she is willing to use donor eggs and her husband’s sperm to carry the child to term herself.

Dr. Deans carefully takes a complete history and does a thorough workup and physical exam. As he finishes, Lily looks up at him hopefully. “So,” she says, “can you help me to become a mother?”

Under Lily’s expectant gaze, Dr. Deans realizes he has conflicting responses to her request. Pregnancy is always riskier the older a woman is, but, if he’s being honest with himself, there’s really no medical reason why he shouldn’t help Lily get pregnant. Lily is 2 years younger than the age at which the American Society for Reproductive Medicine’s guidelines say IVF should be “discouraged” [1], and she has no comorbidities, such as hypertension or diabetes, that would make her a poor candidate for IVF. Indeed, Lily is in excellent health.

What’s making Dr. Deans uncomfortable doesn’t have much to do with the clinical situation at all—it’s the image of a 63-year-old mother cheering on her 10-year-old during school plays and soccer matches, or a 68-year-old telling her 15-year-old that she’s been diagnosed with cancer, or a devastated 17-year-old sitting on a hard wooden pew at his or her mother’s funeral.

Dr. Deans knows that the future is unpredictable regardless of a parent’s age, and, had Lily become pregnant without ART, he recognizes that he would not have the same hesitation. Still, he can’t help feeling that using ART resources in this case is not quite right, and he finds himself wanting to advise Lily against a procedure.

Commentary

How old is too old to be having a baby? No case illustrates the ethical dilemmas faced by Dr. Dean better than the case of Maria Bousada, a single mother who conceived and delivered twins using donor-egg IVF at age 66 and died 3 years later, leaving her 2-year-old twins orphaned [2]. Shortly after that, Omkari Panwar, a 70-year-old woman from India, gave birth to twins [3]. Such cases have gotten

substantial media attention, bringing to light the ethical issues that surround postmenopausal reproduction.

The central ethical issue is balancing the patient's interest in reproductive autonomy and the welfare of the children born from that person. Although the decision to provide reproductive services to women of advanced reproductive age in the United States falls to individual practices and clinicians, most infertility doctors use the American Society for Reproductive Medicine's (ASRM) practice and ethical recommendations as a guide.

Arguments in Favor

The ASRM ethics committee describes the main arguments in favor of making donor-egg IVF available to postmenopausal women: that not to do so would contradict societal values of equality and personal freedom [1].

1. It is not uncommon for grandparents to raise children; according to the ASRM ethics committee opinion, they "often bring economic stability, parental responsibility, and maturity to the family unit" [1]. If our society considers it acceptable for grandparents—postmenopausal women and men of the same age—to raise children, then it follows that for older people (who are not physically or psychologically incapable) to raise their *own* children should likewise be considered acceptable.
2. It is prejudicial to disallow older women to have children if it is considered acceptable for men to procreate very late in life. One could argue that allowing men and women to have equal reproductive possibility would contribute to a more egalitarian society.
3. Our society recognizes individuals' rights to make reproductive choices regardless of their life expectancy or age; there is no prohibition placed on people, for example, with terminal illnesses that shorten their life spans or careers that jeopardize their safety. Therefore, it would be discriminatory to deny only older women the opportunity to fulfill their desire to become parents by procreating.

Additional arguments can be made in favor of allowing postmenopausal reproduction. From a consequentialist viewpoint, if no considerable damage is to be expected, the full right to reproductive freedom can justifiably be exercised without limitation even at advanced age. From a macroeconomic perspective, women who conceive later can focus on working and contributing to society for a longer uninterrupted period of time, and the costs of parenting can be postponed until financial security has been achieved.

Furthermore, the societal norm for heterosexual women to marry men of the same age or older is fading, and it is not inconceivable for women to marry men even two to three decades younger. Thus, the concern that children born to postmenopausal

mothers would be harmed because they would have two parents who are likely for age-related reasons to die while the children are young may not apply in all cases. Certainly, regardless of gender, when patients have similarly aged partners or are considering single parenthood, thought certainly needs to be given to the support system that will be available until that child reaches adulthood.

Arguments Against

The arguments against postmenopausal reproduction described by the ASRM ethics committee invoke the “natural” limit on reproductive capacity, concerns about the child-rearing ability of older parents and possible harm to their children arising from their age, and the medical risks involved in pregnancy after menopause [1]:

1. Natural reproduction takes place in women in the years between the onset of menstruation and its end. In this sense, because it transcends the natural limit of reproductive capacity, postmenopausal reproduction can be termed “unnatural,” which some view as morally wrong.
2. Despite the social acceptance of grandparents raising children, parenting poses significant emotional and physical demands that some people of advanced age may not be able to handle. Additionally, there is a high likelihood that the children may experience the loss of one or both parents before reaching adulthood [1]. Given the evidence that children who experience the loss of a parent have a greater chance of depression and drug abuse [4], knowingly subjecting children to the probable loss of both parents early in life is to expose them to likely harm.
3. Postmenopausal pregnancy poses a greater risk of obstetrical and neonatal complications to both mother and child [1, 5]. A study that stratified maternal age demonstrated that mothers older than 49 had statistically significantly more maternal morbidity, including risk of diabetes, cardiac disease, and preeclampsia, as well as increased neonatal mortality and morbidity, than mothers 49 or younger [5].

Additional arguments can be made against allowing postmenopausal reproduction. Considerations of a child’s best interests are indicated in matters of reproduction, particularly when those matters require intervention and fall outside societal and biological norms. From the standpoint of the child’s welfare, it can be argued that the possible harm to a child who is likely to suffer the loss of a parent at an early age may outweigh the harm to parents of not being able to exercise reproductive autonomy. And, if resource limitations demand that society make decisions about allocating them, one can argue that it might be difficult to justify denying assisted reproduction technologies to a young woman with premature ovarian failure while granting it to an older woman past her natural reproductive life cycle.

Analysis

Certainly, guidelines provide a framework for physicians making difficult decisions, and the values of an individual physician can differ from this framework, as evidenced by the trepidation of Dr. Deans. In this particular case of caring for Lily, an otherwise healthy 53-year-old woman, after appropriate medical screening and assessment of social support, we would invoke respect for patient autonomy and uphold the ASRM guidelines by offering Lily donor-egg IVF. While physicians should indeed be aware of the greater sociocultural implications of their care, their decisions are made on an individual basis while caring for individual patients, not for society as a whole.

Conclusion

Cases like that of Lily and Dr. Deans bring to light the ethical dilemmas routinely faced by infertility doctors. While the donation of oocytes and embryos to women of advanced age is undeniably a charged issue, compelling arguments exist on both sides. Physicians are bound by ethics to uphold beneficence and nonmaleficence, and they must ensure the welfare of the child and the mother and protect their patients from harm. Women should be extensively counseled about the potential adverse health risks of pregnancy at an advanced age as well as the potential health risks to their future offspring.

References

1. Ethics Committee of the American Society for Reproductive Medicine. Oocyte or embryo donation to women of advanced age: a committee opinion. *Fertil Steril*. 2013;100(2):337-340.
2. Oldest woman to give birth dies, leaving twins. *USA Today*. July 15, 2009. http://usatoday30.usatoday.com/news/world/2009-07-15-spain-oldest-woman-birth_N.htm. Accessed November 25, 2013.
3. Indian woman gives birth at age of 70. *Telegraph*. <http://www.telegraph.co.uk/news/worldnews/asia/india/3683289/Indian-woman-gives-birth-at-age-of-70.html>. Accessed November 25, 2013.
4. Melhem NM, Walker M, Moritz G, Brent DA. Antecedents and sequelae of sudden parental death in offspring and surviving caregivers. *Arch Pediatr Adolesc Med*. 2008;162(5):403-410.
5. Salihu HM, Shumpert MN, Slay M, Kirby RS, Alexander GR. Childbearing beyond maternal age 50 and fetal outcomes in the United States. *Obstet Gynecol*. 2003;102(5 pt 1):1006-1014.

Senait Fisseha, MD, JD, is an associate professor of obstetrics and gynecology and chief of the Division of Reproductive Endocrinology and Infertility at the University of Michigan in Ann Arbor.

Natalie A. Clark, MD, is a third-year obstetrics and gynecology resident at the University of Michigan in Ann Arbor who is applying to fellowships in reproductive endocrinology and infertility.

Related in VM

[Health and Development of Children Conceived through Assisted Reproduction](#),
January 2014

[Assisted Reproduction and *Primum Non Nocere*](#), September 2007

The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental.

The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.

Copyright 2014 American Medical Association. All rights reserved.

Virtual Mentor

American Medical Association Journal of Ethics
January 2014, Volume 16, Number 1: 10-16.

ETHICS CASE

Physician Responsibility When a Surrogate Mother Breaks Her Contract

Commentary by Saima Rafique, MBBS, DGO, and Alan H. DeCherney, MD

Dr. Kerr greets Stacy, who is in her first trimester of pregnancy, for her second prenatal visit. Stacy's situation is still relatively rare in Dr. Kerr's obstetric practice: after extensive counseling, Stacy decided to become a surrogate mother for a gay couple. During her first visit, Stacy told Dr. Kerr about the surrogacy contract she had entered into, which detailed the compensation she would receive for her time and medical bills and stipulated that she would report for all prenatal visits, refrain from risky behavior such as smoking or alcohol consumption, and keep an open medical record, so the couple could know directly how the pregnancy was progressing.

Stacy tells Dr. Kerr that, apart from a little morning sickness, she has no complaints. Dr. Kerr goes through her examination as usual. "Everything looks great," she tells Stacy. "Do you have any questions for me?"

Stacy hesitates for a moment, but after an encouraging look from Dr. Kerr, she begins to speak. "When I signed the surrogacy contract," Stacy says, "I didn't think I'd have any trouble not drinking alcohol. But I'm finding it really hard to give it up. I did some research online and read a little alcohol won't hurt the baby, so I've started drinking a glass or two of wine a week. I know I said I wouldn't, so please don't put anything in my record, but what I'm doing is OK, right?"

Commentary

This clinical vignette describes a unique and ethically sensitive scenario that is likely to become more common in the near future as the techniques for assisted reproduction steadily advance and the incidence of surrogate pregnancy continues to rise. The matter of surrogacy is complex and challenging due to the multidimensional physical, ethical, emotional, financial, social, and legal impacts it has on all those involved. In addition to all these considerations, the added ethical dilemma here is that Stacy is asking the doctor to condone and participate in her violation of the surrogacy contract.

Surrogacy is an arrangement in which a woman (the surrogate) bears and delivers a child for another couple or person. It is further classified as traditional or gestational. In traditional surrogacy, also known as straight or partial surrogacy, the surrogate is impregnated with the sperm of the intended father or a sperm donor, usually by artificial insemination (AI). Gestational surrogacy, also known as full surrogacy, is a more sophisticated procedure in which, with the help of in vitro fertilization, gametes

from both the intended parents or from sperm or oocyte donors are used to create an embryo that is then implanted in the surrogate's uterus [1]. Surrogacy can be commercial, in which a financial compensation is provided to the surrogate and delivering the baby, or altruistic, motivated purely by an intention to help.

The first report of a baby born as a result of gestational surrogacy came from the United States in 1985 [2]. The topic of commercial (compensated) surrogacy arrangements has remained controversial since then, and individual states in the US have different laws and policies regarding these arrangements [3]. In states where commercial surrogacy is allowed, professional legal organizations assist couples in finding a surrogate. This is followed by a detailed discussion among the surrogate, the intended parents, and the clinician about different aspects of surrogacy, including medical risks, benefits, alternatives, and the treatments involved. It is highly recommended that both parties undergo in-depth counseling by an independent counselor to help them understand the process and its consequences [4]. The legal aspects are separately discussed under the guidance of a lawyer with expertise in the field.

Following the completion of the counseling and legal procedures, many fertility centers that manage surrogacy cases present a combined report to an independent ethics committee for review and approval [1]. Any physician who facilitates a surrogacy arrangement needs to be aware of the policies and the laws on surrogacy in his or her state. It is the physician's responsibility to make appropriate arrangements to protect the prospective child, the potential surrogate mother, and the intended parents from medical, psychological, and legal harms [5].

Patient First

In the current clinical scenario, although the contract Stacy signed asked her to refrain from risky behavior like alcohol and smoking, she is finding it hard to give up alcohol and has started consuming a couple of glasses of wine per week. Her concerns about alcohol consumption and willingness to discuss them with Dr. Kerr should be taken as an opportunity to appreciate her responsible behavior—this will strengthen the patient-physician relationship and facilitate further communication. According to the recommendations of the 2008 American Congress of Obstetricians and Gynecologists (ACOG) committee opinion,

While caring for a surrogate mother it is the professional obligation of the obstetrician to support the well-being of the pregnant woman and her fetus, to support the pregnant woman's goal for the pregnancy, and to provide appropriate care regardless of the patient's plan to keep or relinquish the child. The obstetrician must make recommendations that are in the best interests of the pregnant woman and her fetus, regardless of prior agreements between her and the intended parents [6].

Dr. Kerr's first ethical obligation, then, is to provide Stacy with information and recommendations that safeguard Stacy and the fetus, the contract aside.

Although there is strong evidence that high alcohol consumption during pregnancy can lead to a spectrum of damaging effects on the fetus [7], data regarding the effect of low-to-moderate alcohol consumption on fetal growth and development is not so clear [8]. Recent studies evaluating the neurodevelopmental outcomes of children exposed to low-to-moderate alcohol consumption during gestation do not demonstrate any significant effect on intelligence [9], behavior [10], executive function [11], attention [12], or balance [13]. Dr. Kerr should discuss with Stacy the potential dose-related effects of alcohol on the fetus and provide the published evidence on which the discussion is based.

Despite the findings mentioned above, since there are no clear guidelines on the acceptable levels of alcohol in pregnancy and Stacy is in the sensitive situation of surrogacy, the conservative approach of avoiding alcohol in pregnancy would be safest. Further, that Stacy is finding it hard to give up alcohol means she may benefit from additional resources like counseling and behavioral interventions. Following the ethical principle of respect for patient autonomy and patient's right to know, all the pros and cons should be clearly discussed so that Stacy is able to make a responsible decision. Knowledge of the state laws on the rights of surrogate mothers would help Dr. Kerr to further assist Stacy in understanding her options.

The Child's Welfare

Along with her obligation to Stacy, Dr. Kerr has a responsibility to the unborn child. Since the conception of the first surrogate baby, child welfare in this context has been a topic of ongoing and intense debate. The regulatory framework on children born through surrogacy and assisted reproduction is still in the process of solidification [14]. Advocates of child welfare argue that, because of the desire of the intended parents to procreate and the motivation of the fertility specialist to deliver a baby to the intended parents as quickly as possible, the welfare of the child involved does not receive appropriate attention [14]. These advocates argue for a heightened focus on the best interests of the child. Vulnerability and dependency are the two important characteristics of children around which most of the sociocultural and legal safeguards are framed, and they should be applied here [15].

It is imperative to recognize that children's rights cannot be adequately protected without the participation of the adults who have been vested with the responsibility to make decisions that affect them [16]. While most adults can safeguard their own rights and interests, the health of children, especially unborn children, is significantly dependent on the choices and actions of their parents. Parental decisions may influence the child's future capacities, health status, and quality of life. A physician's responsibility is to give those parents information about avoiding risks to their children's lives, guide them to appropriate resources, and assist them in making decisions that are in the best interest of their children.

Although novel techniques for assisted reproduction have been successful in filling voids in the lives of infertile couples and have led to the birth of many healthy children, the risks associated with these techniques cannot be completely overlooked. For the mother, these risks range from those that are inherent to pregnancy and delivery to those that occur as side effects of medications and procedures used in assisted reproduction. The higher incidence of multiple fetuses in assisted reproduction adds to the obstetric risk.

Studies analyzing the development and performance of children conceived by IVF suggest that, in the long term, they are generally healthy and do not differ in cognitive development and performance from children conceived without assistance [17, 18]. However, there are reports of significantly higher rates of low- and very-low-birth-weight babies in both multiple and singleton pregnancies achieved through assisted reproduction [19], as well as a higher rate of major birth defects [20], childhood cancers [21], genomic imprinting disorders [22], cerebral palsy, and developmental delay, the last two often caused by prematurity [23]. Having a child with any of these disorders not only creates an environment of psychosocial, emotional, and financial distress for the parents but also limits the child's future potential. Hence all the parties involved in such an arrangement have a responsibility to avoid any predictable risk that would compromise the health and welfare of the child. Advocates of child welfare have repeatedly said that "children born through assisted reproduction have a right to expect that their parents received appropriate information about risks and the actions that might be taken to prevent or reduce them, and that a fair balance was struck between their parents' liberty rights and their rights to protection" [24].

In this particular situation Dr. Kerr should initiate a discussion with Stacy to get an idea of Stacy's knowledge about the potential risks associated with assisted reproduction, filling in any missing gaps in information and addressing any queries. She should explain to Stacy that, even after appropriate planning and precautions, unforeseeable consequences do arise, but all foreseeable risks associated with surrogate pregnancy, assisted reproduction, and alcohol consumption—for example a disability that could lead to the rejection of the infant by the intended parents or the diminishment of his or her capacities—should be avoided as far as possible through appropriate planning. Dr. Kerr should also highlight that Stacy's difficulty giving up alcohol might augur a tendency to drink more or be unable to control her drinking. If needed, arrangements should be made to counsel Stacy to adopt responsible behavior for her own health as well as to make informed decisions that safeguard the health of the fetus.

Hiding Information

The third important issue that Dr. Kerr must address is Stacy's request that she not put anything in the medical record regarding Stacy's recent alcohol consumption. Having an open medical record allows the other party to the surrogacy contract access to the surrogate's medical information. It would not be appropriate for Dr. Kerr to withhold information from the medical record, even if she were doing it to

remain faithful to Stacy. Lying to Stacy by saying that she will not put anything on record and later updating it would not be suitable either. Dr. Kerr has to approach this issue in a tactful way that honors her various professional obligations. An appropriate way to address the concern would be to repeat that the health and well-being of Stacy and her child are Dr. Kerr's first priority and that she will do everything in her capacity to protect them. Dr. Kerr could then explain that she is bound by medical practice rules that mandate accurate and complete record keeping, but that she will be by Stacy's side as her physician and health advocate in any situation. Dr. Kerr should strongly encourage Stacy to communicate with the prospective parents and could also offer to mediate such a discussion during which she could provide the parents with evidence about low alcohol consumption and fetal health. She could highlight that Stacy's not hiding her alcohol consumption is responsible behavior and that Stacy is willing to participate in counseling and other resources on behavioral modification if needed.

Conclusion

Dr. Kerr is facing a clinical and ethical dilemma unique to surrogate pregnancy. She has to take an approach that puts Stacy's health and that of her child first regardless of the contract. Dr. Kerr should safeguard their health by providing appropriate information on the dose-related effects of alcohol and encouraging Stacy to make informed and responsible decisions for herself and the future child by avoiding any foreseeable risk. She should honestly convey to Stacy that her ethical responsibilities do not allow her to hide medical information but assure Stacy that she will be by her side at all times and would be happy to mediate an evidence-based discussion with the intended parents to give them a complete picture of the situation, make arrangements for appropriate follow-up, and provide additional resources.

References

1. Brinsden PR. Gestational surrogacy. *Hum Reprod Update*. 2003;9(5):483-491.
2. Utian WH, Sheean L, Goldfarb JM, Kiwi R. Successful pregnancy after in vitro fertilization and embryo transfer from an infertile woman to a surrogate. *N Engl J Med*. 1985;313(21):1351-1352.
3. Gugucheva M. *Council for Responsible Genetics Special Report: Surrogacy in America*.
<http://www.councilforresponsiblegenetics.org/pagedocuments/kaevej0a1m.pdf>. Accessed September 1, 2013.
4. Boivin J, Appleton TC, Baetens P, et al. Guidelines for counselling in infertility: outline version. *Hum Reprod*. 2001;16(6):1301-1304.
5. American Congress of Obstetricians and Gynecologists Committee on Ethics. ACOG committee opinion number 397, February 2008: surrogate motherhood. *Obstet Gynecol*. 2008;111(2 Pt 1):465-470.
6. American Congress of Obstetricians and Gynecologists Committee on Ethics, 469.
7. Sokol RJ, Delaney-Black V, Nordstrom B. Fetal alcohol spectrum disorder. *JAMA*. 2003;290(22):2996-2999.

8. Patra J, Bakker R, Irving H, Jaddoe VW, Malini S, Rehm J. Dose-response relationship between alcohol consumption before and during pregnancy and the risks of low birthweight, preterm birth and small for gestational age (SGA)-a systematic review and meta-analyses. *BJOG*. 2011;118(12):1411-1421.
9. Kesmodel US, Eriksen HL, Underbjerg M, et al. The effect of alcohol binge drinking in early pregnancy on general intelligence in children. *BJOG*. 2012;119(10):1222-1231.
10. Skogerbo A, Kesmodel U, Denny C, et al. The effects of low to moderate alcohol consumption and binge drinking in early pregnancy on behaviour in 5-year-old children: a prospective cohort study on 1628 children. *BJOG*. 2013;120(9):1042-1050.
11. Skogerbo A, Kesmodel US, Wimberley T, et al. The effects of low to moderate alcohol consumption and binge drinking in early pregnancy on executive function in 5-year-old children. *BJOG*. 2012;119(10):1201-1210.
12. Underbjerg M, Kesmodel US, Landro NI, et al. The effects of low to moderate alcohol consumption and binge drinking in early pregnancy on selective and sustained attention in 5-year-old children. *BJOG*. 2012;119(10):1211-1221.
13. Humphriss R, Hall A, May M, Zuccolo L, Macleod J. Prenatal alcohol exposure and childhood balance ability: findings from a UK birth cohort study. *BMJ Open*. 2013;3(6). Epub June 17, 2013.
14. Rosato JL. The children of ART (assisted reproductive technology): should the law protect them from harm? *Utah Law Rev*. 2004:57-110.
15. Solnit AJ, Schowalter JE, Nordhaus BF. Best interests of the child in the family and community. Social, legal, and medical implications for pediatricians. *Pediatr Clin North Am*. 1995;42(1):181-191.
16. Solnit AJ. The bioethics of children's rights. *Isr J Psychiatry Relat Sci*. 2004;41(1):4-16.
17. Ludwig AK, Sutcliffe AG, Diedrich K, Ludwig M. Post-neonatal health and development of children born after assisted reproduction: a systematic review of controlled studies. *Eur J Obstet Gynecol Reprod Biol*. 2006;127(1):3-25.
18. Mains L, Zimmerman M, Blaine J, et al. Achievement test performance in children conceived by IVF. *Hum Reprod*. 2010;25(10):2605-2611.
19. Schieve LA, Meikle SF, Ferre C, Peterson HB, Jeng G, Wilcox LS. Low and very low birth weight in infants conceived with use of assisted reproductive technology. *N Engl J Med*. 2002;346(10):731-737.
20. Hansen M, Kurinczuk JJ, de Klerk N, Burton P, Bower C. Assisted reproductive technology and major birth defects in Western Australia. *Obstet Gynecol*. 2012;120(4):852-863.
21. Kallen B, Finnstrom O, Lindam A, Nilsson E, Nygren KG, Olausson PO. Cancer risk in children and young adults conceived by in vitro fertilization. *Pediatrics*. 2010;126(2):270-276.
22. Paoloni-Giacobino A. Implications of reproductive technologies for birth and developmental outcomes: imprinting defects and beyond. *Expert Rev Mol Med*. 2006;8(12):1-14.

23. Stromberg B, Dahlquist G, Ericson A, Finnstrom O, Koster M, Stjernqvist K. Neurological sequelae in children born after in-vitro fertilisation: a population-based study. *Lancet*. 2002;359(9305):461-465.
24. Larcher V. The health of children conceived by assisted reproduction technologies. *Arch Dis Child*. 2007;92(8):669.

Saima Rafique, MBBS, DGO, is a clinical researcher at the Program in Reproductive and Adult Endocrinology at the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health in Bethesda, Maryland. She completed her medical study and residency in obstetrics and gynecology at Jawaharlal Nehru Medical College in Aligarh, India. Her research interests include women's health, infertility (including primary ovarian insufficiency) and assisted reproductive techniques, and community-based participatory research.

Alan H. DeCherney, MD, is head of the Program in Reproductive and Adult Endocrinology at the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health in Bethesda, Maryland. His medical degree is from Temple University School of Medicine, his internship in medicine was at the University of Pittsburgh, and his residency in obstetrics and gynecology, at the University of Pennsylvania. His interests include both basic and clinical endocrinology in the areas of endometriosis, infertility and assisted reproductive techniques, leiomyoma, polycystic ovarian syndrome, ectopic pregnancy, implantation and oocyte physiology, and health policy in reproduction.

Related in VM

[Physician Duties in the Face of Deceitful Gamete Donors, Disobedient Surrogate Mothers, and Divorcing Parents](#), January 2014

The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental.

The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.

Copyright 2014 American Medical Association. All rights reserved.

Virtual Mentor

American Medical Association Journal of Ethics
January 2014, Volume 16, Number 1: 17-23.

ETHICS CASE

Are IVF Risk-Sharing Programs Ethical?

Commentary by Leslie P. Francis, PhD, JD

Dr. Rearden, the head of a fertility clinic in Philadelphia, called a meeting with his staff to discuss budgeting for the coming year. During the meeting, Dr. Rearden proposed implementing a “risk-sharing” program. Patients selected for such programs would initially pay a higher fee to the clinic. If a patient had a successful pregnancy, then the clinic would keep her entire fee. If the patient did not become pregnant, a previously specified proportion of the fee would be returned to her.

In his presentation to the staff, Dr. Rearden explained that the program would be beneficial to both the clinic and patients. The program represents a safety net for patients who pay for IVF out of pocket by leaving them money to pursue other options should their treatment fail. Moreover, the higher fee paid by patients who become pregnant ensures that the clinic will have money to reimburse the patients for whom treatment is unsuccessful.

At the conclusion of Dr. Rearden’s presentation, Dr. Whipple, a long-time ob-gyn physician in the clinic, asked to speak. “I can appreciate wanting to offer a safety net for patients, especially given that IVF is not covered by insurance,” Dr. Whipple began. “But I have some serious reservations about implementing such a program. First, it seems that those who would be selected as candidates for the program are also those most likely to become pregnant, so we would be taking advantage of patients in a moment of substantial emotional stress by essentially overcharging them. Second, and more importantly, if medical payment is based on outcome, our focus will inevitably shift from doing what is best for our patients to trying to get the desired outcome, in this case pregnancy, regardless of what that means for the people we’re treating. I just don’t think we should go down this road.”

Commentary

As use of IVF continues to increase, risk sharing [1] has emerged as a potential financing method, with some commentators estimating that such programs are in fact quite common [2]. A survey of the websites of the 10 fertility clinics top ranked for achieving pregnancy by *Parents* magazine indicated that 3—University Fertility Consultants at Oregon Health & Science University, Portland (AttainIVF), Nevada Center for Reproductive Medicine, Reno (AttainIVF), and Florida Institute for Reproductive Medicine, Jacksonville (Guarantee Program)—advertise risk sharing [3-13].

IVF is an expensive procedure that, in the United States, is typically not covered by insurance and thus is paid for out of pocket by patients. It appears unlikely that coverage for the procedure will increase in the near future, given cost pressures on the US health care system. Because patients seeking IVF are highly motivated to become parents and may wish to preserve resources for surrogacy or adoption should IVF be unsuccessful, risk sharing is appealing to them, which makes these high costs especially problematic.

Risk-sharing programs also appear to be advantageous to clinics because they promise higher fees (albeit with the possibility that a percentage of at least some of these fees will need to be returned), coupled with the ability to provide at least some recompense to understandably disappointed patients. Risk-sharing programs thus appear to be a “win-win” for patients and clinics—but are they? Whether Dr. Whipple’s concerns are well founded depends on how the clinic structures its program.

Insurance Coverage for IVF

Many health insurance plans offered through the individual market or provided by employers do not include IVF. In response, a few states (Connecticut, Illinois, Massachusetts, New Jersey, and Rhode Island) have put in place statutes mandating the coverage, although these mandates do not apply to the plans offered by most large employers who self-insure [14].

Under the Affordable Care Act, individuals and small businesses will be able to purchase plans offered through exchanges that opened in late 2013, and the requirement for individual coverage will go into effect in 2014. Plans offered through the exchanges must provide “minimum essential benefits,” including those in the following categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and “habilitative” services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care [15]. Notably, infertility care is not included in this list (although management of a chronic disease such as diabetes may improve fertility for some patients). More specific requirements for each state are set by the selection of “benchmark” plans in that state. States may choose their benchmarks; if they don’t, they are assigned as a default benchmark the largest plan by enrollment in the largest product in the state’s small-group market [16].

Of the currently listed benchmark plans, only a few include IVF. Connecticut covers two cycles of IVF [17]; Nevada covers six [18]; Hawaii covers IVF after five years of unsuccessful efforts at achieving pregnancy or for specified indications such as endometriosis [19]; Illinois covers four cycles with two more for a subsequent pregnancy [20]; Massachusetts, Michigan, and Rhode Island cover IVF without specified exclusions [21-23]; and Texas includes an option to purchase IVF services [24]. Benchmark plans in all other states either offer no coverage for infertility or

cover limited services such as diagnostic interventions but specifically exclude IVF [25]. This limited coverage of IVF means that most patients are likely to continue to pay entirely for the procedure in at least the near future.

Conflict of Interest

The overarching ethical problem raised by risk-sharing programs is conflict of interest [26]. Clinicians and practices have financial interests in these programs that may not always align with the interests of their patients. If patients enter the programs and become pregnant, they pay more for the service than they would pay in a clinic that did not have risk sharing. Patients who do not become pregnant receive partial refunds, but the refunds may not adequately reflect the degree of unlikelihood that those patients could achieve pregnancy. For example, if the patient had a very low chance of achieving pregnancy (say, 10 percent), and received a refund of 65 percent of the initial fee instead of 90 percent, her refund would not reflect the slim chance she had of becoming pregnant. Patients who are unlikely to become pregnant through IVF may be encouraged to pursue it by the possibility of a refund, even when it is not a good option for them. Moreover, having to refund money to patients who do not conceive may be an incentive for clinicians to engage in risky practices such as multiple-embryo transfers even when in appropriate. In light of these conflicts, the American Society for Reproductive Medicine (ASRM) emphasizes the importance of informed consent and adherence to practice guidelines in structuring refund programs [26].

Informed Consent

Despite the importance placed on informed consent documents, however, achievement of genuinely autonomous consent can be difficult. Though patients seeking reproductive assistance are highly likely to have decision making capacity and clear wishes, they may also be emotionally vulnerable and under stress [27]. They may be so desperate to become pregnant that they do not evaluate risks rationally. Cognitive biases such as anchoring (overreliance on a particular piece of information), attentional bias influenced by emotion, confirmation bias (focus on the information that confirms rather than refutes existing beliefs), framing effects (the impact of whether the decision is structured in terms of the likelihood of success or failure), or sunk cost bias (the desire to continue down a path when costs already incurred cannot be recovered) may complicate patients' decision making.

In light of these challenges to reasoned decision making about risk sharing, several aspects of the informed consent process are especially worth noting. Patients should be given sufficient time to consider risk programs and alternatives to them. They should be given clear explanations of their chances of achieving pregnancy, of what they would pay if they did not enroll in the program, and of payments retained by the program if pregnancy is not achieved. Patients should be given clear explanations of whether "success" is defined by achieving pregnancy or by live birth and should also understand what costs are covered by the risk-sharing payment and whether any additional costs may be billed to them.

Patients may overestimate their chances of success; clinics should guard carefully against encouraging cognitive biases that influence this tendency. For example, giving patients examples of others who have been highly satisfied by risk-sharing programs—either because they achieved pregnancy or because they were able to adopt a child using funds received as a refund—could inappropriately invoke cognitive biases favoring the decision to use risk sharing. Clinicians must convey only accurate information to patients in a manner intended to counteract likely cognitive biases.

Because of the difficulties with fully informed and carefully reasoned consent to risk sharing, and because of the significant financial and health risks involved, risk-sharing programs must also be structured in ways that protect patients who enter into them.

Adherence to Practice Guidelines

Programs that offer risk sharing must take care to adhere to practice guidelines in the care they provide in order to protect their patients. The ASRM Ethics Committee opinion cites several ways in which conflicts of interest that result from risk-sharing may encourage inappropriate care [26]. Clinicians should guard against recommending ancillary procedures such as sonohysterograms unless they are clearly indicated, especially if the costs of these procedures are extra and significant. In order to bring about pregnancy and avoid refunds, physicians may try procedures with higher risks than guidelines recommend, such as stimulation protocols that produce more oocytes or embryo transfers in numbers that could result in multiple gestations. The ASRM Practice Committee presently recommends offering single-embryo transfer to women under 35 who are likely to become pregnant and transferring at maximum two embryos [28]. The committee also advises practices to monitor their outcomes continuously to adjust transfer numbers to avoid undesirable pregnancy outcomes [28]. To keep the patient's best interest at the forefront, it is especially important to assess patients according to appropriate diagnostic criteria [29].

Pricing

A common objection to risk-sharing programs is that they constitute illicit contingent fees—that is, pay based on results. The ASRM opinion determining that risk sharing is permissible suggests that these programs pool patients' risks and allow the practice to earn a modest return for assuming the risk [26]. The refund program should be structured so that it does not undermine this analysis. Of particular importance are the fee increase for the program, the percentage of the fee refunded, the exclusion of ancillary costs from the risk-sharing fee so that patients must incur these costs in addition, and the number of IVF cycles included in the program. If fees or ancillary costs are excessive, if refunds are low, or if only limited services are included in the program, patients may reasonably complain that the program's intent appears primarily to benefit the practice rather than to share risks fairly.

Conclusion

Dr. Whipple is right to raise concerns about risk-sharing programs. However, these concerns can be alleviated by careful attention to informed consent, adherence to practice guidelines, and fair pricing structures. Clinics considering these programs must be especially vigilant in assessing whether their actions avoid conflicts of interest. Under such circumstances, risk-sharing programs may indeed be beneficial to both providers and patients—but only under such circumstances.

References

1. Refund programs typically include up to 6 IVF cycles, impose specified medical criteria for participation, include all standard services within the fee, and return a minimum of 70 percent of the original fee. Attain IVF. What do the Attain IVF programs include? <http://attainivf.attainfertility.com/attain-ivf-includes>. Accessed November 18, 2013.
2. Levens ED, Richter KS, Levy MJ. Money-back guarantees. *Semin Reprod Med.* 2013;31(03):198-203.
3. Cico K. Ten best fertility centers. *Parents.* <http://www.parents.com/getting-pregnant/infertility/treatments/best-fertility-centers/>. Accessed November 18, 2013.
4. This clinic runs its own “guarantee” program with an extensive list of exclusion criteria and requirements. Florida Institute for Reproductive Medicine. IVF guarantee program. <http://www.fertilityjacksonville.com/costs/cost-information/ivf-guarantee-program/>. Accessed November 18, 2013.
5. Colorado Center for Reproductive Medicine. Basic infertility services. <http://www.colocrm.com/Services/BasicInfertilityServices.aspx>. Accessed November 21, 2013.
6. The Ronald Perelman and Claudia Cohen Center for Reproductive Medicine at Weill Cornell Medical College website. <http://www.ivf.org/>. Accessed November 21, 2013.
7. Oregon Health Sciences University. Fertility services at OHSU. <http://www.ohsu.edu/xd/health/services/women/services/fertility/>. Accessed November 21, 2013.
8. NYU Langone Fertility Center website. <http://www.nyufertilitycenter.org/>. Accessed November 21, 2013.
9. Infertility Center of St. Louis website. <http://www.infertile.com/>. Accessed November 21, 2013.
10. Nevada Center for Reproductive Medicine website. <http://www.nevadafertility.com/nevada/>. Accessed November 21, 2013.
11. Texas Health Presbyterian website. <http://texasivf.com/>. Accessed November 21, 2013.
12. Southern California Reproductive Center website. <http://www.scrxivf.com/>. Accessed November 21, 2013.
13. Center for Reproductive Medicine of New Mexico website. <http://infertility-ivf.com/>. Accessed November 21, 2013.

14. American Society for Reproductive Medicine. State infertility insurance laws. <http://www.asrm.org/detail.aspx?id=2850>. Accessed November 18, 2013.
15. Centers for Medicare and Medicaid Services. Glossary: essential health benefits. <https://www.healthcare.gov/glossary/essential-health-benefits/>. Accessed November 18, 2013.
16. National Conference of State Legislatures. State health insurance mandates and the ACA essential benefits provisions. <http://www.ncsl.org/issues-research/health/state-ins-mandates-and-aca-essential-benefits.aspx>. Accessed November 21, 2013.
17. Centers for Medicare and Medicaid Services Center for Consumer Information and Insurance Oversight (CCIIO). Connecticut EHB benchmark plan. <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/connecticut-ehb-benchmark-plan.pdf>. Accessed November 19, 2013.
18. CCIIO. Nevada EHB benchmark plan. <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/nevada-ehb-benchmark-plan.pdf>. Accessed November 19, 2013.
19. CCIIO. Hawaii EHB benchmark plan. <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/hawaii-ehb-benchmark-plan.pdf>. Accessed November 19, 2013.
20. CCIIO. Illinois EHB benchmark plan. <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/illinois-ehb-benchmark-plan.pdf>. Accessed November 19, 2013.
21. CCIIO. Massachusetts EHB benchmark plan. <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/massachusetts-ehb-benchmark-plan.pdf>. Accessed November 19, 2013.
22. CCIIO. Michigan EHB benchmark plan. <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/michigan-ehb-benchmark-plan.pdf>. Accessed November 19, 2013.
23. CCIIO. Rhode Island EHB benchmark plan. <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/rhode-island-ehb-benchmark-plan.pdf>. Accessed November 19, 2013.
24. CCIIO. Texas EHB benchmark plan. <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/texas-ehb-benchmark-plan.pdf>.
25. CCIIO. Additional information on proposed state essential benefits benchmark plans. <http://www.cms.gov/ccio/resources/data-resources/ehb.html>. Accessed November 19, 2013.
26. Ethics Committee of the American Society for Reproductive Medicine. Risk sharing or refund programs in assisted reproduction: a committee opinion. *Fertil Steril*. 2013;100(2):334-336. Accessed November 19, 2013.
27. Wu AK, Elliott P, Katz PP, Smith JF. Time costs of fertility care: the hidden hardship of building a family. *Fertil Steril*. 2013;99(7):2025-2030.

28. Practice Committee of American Society for Reproductive Medicine; Practice Committee of Society for Assisted Reproductive Technology. Criteria for number of embryos to transfer: a committee opinion. *Fertil Steril*. 2013;99(1):44-46. Accessed November 19, 2013.
29. Practice Committee of American Society for Reproductive Medicine. Diagnostic evaluation of the infertile female: a committee opinion. *Fertil Steril*. 2012;98(2):302-307. Accessed November 19, 2013.

Leslie P. Francis, PhD, JD, is Distinguished Alfred C. Emery Professor of Law and Distinguished Professor of Philosophy at the University of Utah in Salt Lake City. She is a member of the ethics committee of the American Society of Reproductive Medicine and is editing the *Handbook on Reproductive Ethics* for Oxford University Press.

Related in VM

[Balancing Practice Economics with Patient Need](#), August 2011

The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental.

The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.

Copyright 2014 American Medical Association. All rights reserved.

Virtual Mentor

American Medical Association Journal of Ethics
January 2014, Volume 16, Number 1: 24-29.

ETHICS CASE

Shared Decision Making about IVF for Savior Siblings

Commentary by Emily S. Jungheim, MD, MSCI

When Joe and Dana brought home their son Carl from the hospital, they were overjoyed. He quickly became their everything. Together, they lovingly captured Carl's "firsts"—his first bite of solid food, his first steps, the first time he put on his Thomas the Tank Engine backpack to head off to preschool. When Carl began to fall asleep earlier and earlier, they attributed it to all the activity of preschool. They thought his pallor was due to a wintertime lack of sun. They became concerned though, when they noticed swelling in his abdomen and face. Not long afterward, bruises began blooming over his skin, especially on his trunk and abdomen, and they knew that something was wrong.

They were devastated when, at just five years old, Carl was diagnosed with acute myeloid leukemia (AML). They vowed to do everything they could to save their son. And when it became clear that a stem cell transplant was the best option, and no one they knew was a match, they decided to have another child to supply stem cells for Carl. They went to see Dr. Preed, a reproductive endocrinologist, and began the process of in vitro fertilization (IVF) with preimplantation human leukocyte antigen (HLA) typing in earnest.

After a series of hormone injections, ova were taken from Dana and fertilized in vitro with Joe's sperm. Resulting embryos were biopsied and tested for aneuploidy and they were HLA-typed. Only euploid embryos that were HLA matches for Carl were transferred, but they were few, and, after three cycles and \$40,000 spent, Joe and Dana had not conceived. The hormones and appointments, on top of caring for a child who was quite sick, began to take a toll on the whole family. The course had also started to take its toll on Dr. Preed. Dana and Joe were impatient and frustrated. They called Dr. Preed many times each week, and he returned the calls, though he had nothing new to tell them. When Dana failed to conceive after a fourth cycle, Dr. Preed decided it was time to raise his concerns with the family.

When he started to do so, Joe stopped him. "We're not going to give up," he said, his eyes flashing, whether with anger or sadness Dr. Preed could not tell. Dana grasped her husband's hand and nodded her assent. "If Carl were your child, you'd do anything you could to save him too. If you won't continue to help us, we'll find someone else who will."

Commentary

Clinical application of preimplantation genetic diagnosis (PGD) was first announced in 1990 in a case series in which PGD was used to select female embryos to eliminate the risk of transmission of recessive X-linked diseases [1]. Today most IVF centers in the United States offer PGD for a variety of reasons, including embryonic screening for aneuploidy, elimination of single-gene disorders, medically indicated sex selection, and, despite much controversy, sex selection for nonmedical reasons.

Application of PGD for HLA matching was first reported in 2001 [2]. A couple in Colorado underwent four cycles of IVF-PGD before they conceived an HLA-matched sibling for their child who was affected with Fanconi anemia and needed a stem cell transplant. Similar cases have followed. To date, most data on PGD for HLA typing comes from Dr. Semra Kahraman and colleagues in Turkey [3]. Their 2011 report summarizes the results of 327 IVF-PGD cycles undergone by 171 couples—from one to nine cycles each—between 2003 and 2010. The rate of pregnancy was 34.9 percent, a total of 59 HLA-compatible children were born, and 21 siblings had undergone successful stem cell transplantation at the time of the report.

Such published experience on IVF-PGD for HLA matching demonstrates that it is indeed “not a quick fix,” as Willem Verpoest, medical co-director at the Centre for Reproductive Medicine at UZ Brussel, put it in a recent commentary on Dr. Kahraman’s report [4]. Dr. Verpoest cautions that couples with sick children may have unrealistic expectations of their chances of successful IVF-PGD. Thus, he proposes a multidisciplinary approach incorporating psychological counseling and support and emphasizes the need for open communication with the medical team caring for the sick child. Furthermore, he stresses the importance of considering the laboratory personnel’s IVF-PGD experience when deciding whether to pursue IVF with HLA matching, because that experience overwhelmingly determines the chance of a successful outcome.

Joe and Dana’s case illustrates the importance of Dr. Verpoest’s perspective and raises a number of issues, including the future of a child born as a savior sibling, the fate of extranumerary embryos created during the process, the mounting costs this couple is facing, the resources dedicated to their care that may be detracting from the care of other patients in Dr. Preed’s clinic, and more. Ultimately, Dr. Preed must determine whether he will offer additional IVF-PGD treatments to Joe and Dana. If he chooses to do so, he must also determine at what point the treatments will stop and when and if he should offer them an alternative, for example, a referral for another opinion. It is the path to making these decisions that is not clear.

The Ethics Committee of the American Society for Reproductive Medicine (ASRM) offers some guidance on cases like this [5]. The committee states that “clinicians may refuse to initiate a treatment they regard as futile or having a very poor prognosis” [5]. In Joe and Dana’s case however, Dr. Preed has already initiated treatment, and, while they haven’t conceived, they have had HLA-matched, euploid

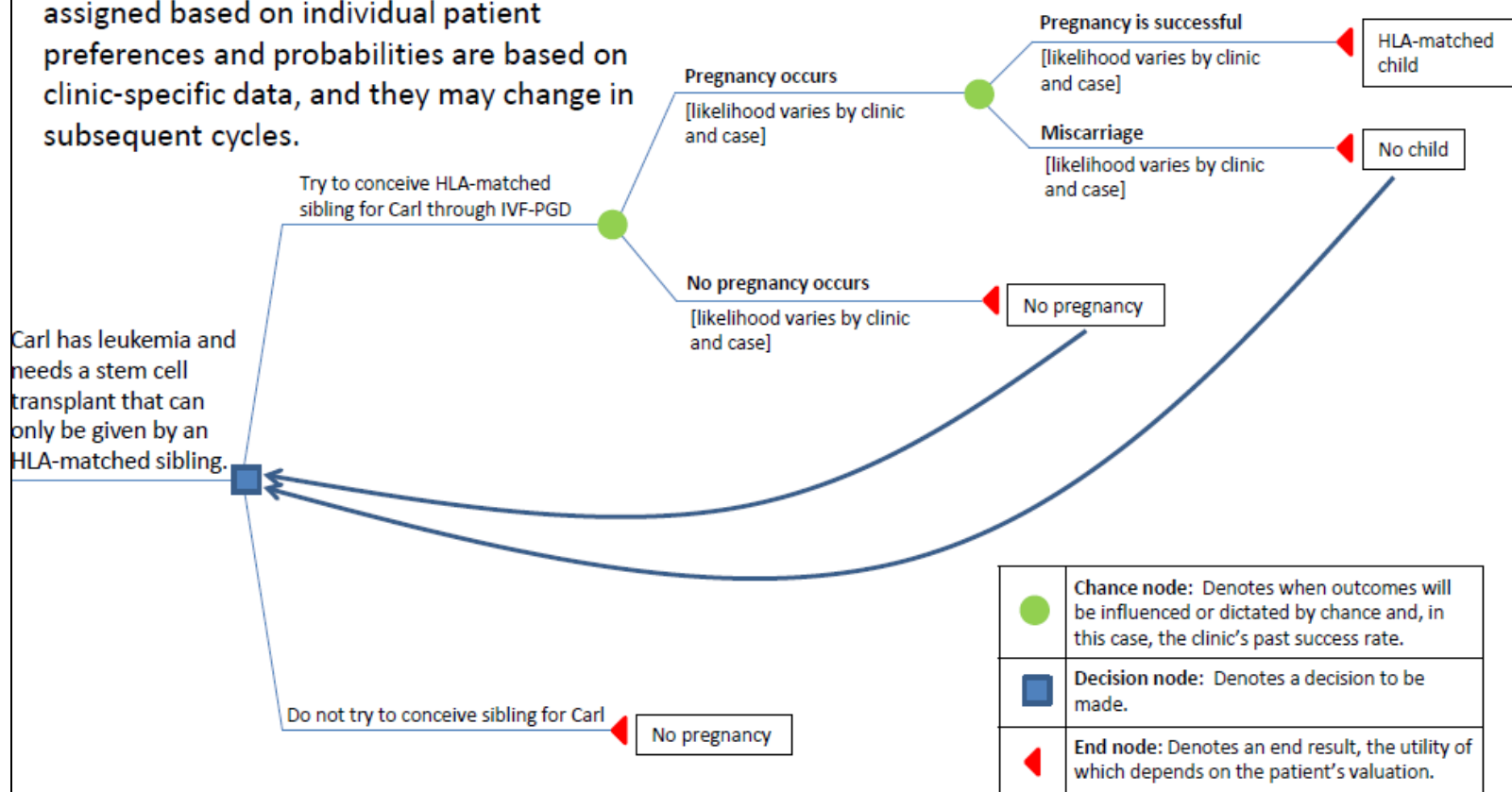
embryos available for transfer in their previous cycles. Given this, the published experience on PGD for HLA matching and data regarding cumulative success from IVF suggests the couple still has a chance of a successful outcome [3, 6]. On the other hand there is no guarantee [6]. Further, the committee states that “decisions about treating or refusing to treat couples and/or individuals always should be patient-centered” and they “should be made in cooperation with couples” [5]. They advise clinicians to revisit the treatment plan with couples. This is an ideal time for Dr. Preed to do so.

Clearly the situation is painful, and the couple’s need for psychological counseling has likely exceeded Dr. Preed’s skills in this arena. If he hasn’t already done so, Dr. Preed should insist that Joe and Dana seek the services of a mental health professional (MHP). Many fertility treatment centers have MHPs on staff or refer to licensed MHPs with expertise in reproductive counseling and the issues raised by infertility [7]. Although the Mental Health Professional Group of the ASRM recommends counselors have training in medical and psychological aspects of infertility, this is not required, and indeed Joe and Dana are not using these treatments for infertility.

The ASRM Ethics Committee also states that “fertility centers should develop evidence-based policies to guide decisions about treating couples and/or individuals” [5]. But, outside of the experience published by the group in Turkey described above, there is little evidence on which to base policy for decision making; reports of these cases are sporadic and hard to generalize from. The question at hand is really what to do when the outcome is uncertain and patient desire is of great importance. Thus, this is a case in which medical decision making (MDM) techniques may help reduce conflict and lead to a mutually agreeable decision.

In 1983, in a medical news piece for *JAMA*, medical writer Terra Ziporyn reported on a session entitled “Ethical Issues in Medical Decision Making” at the fourth annual meeting of the Society for Medical Decision Making. Ziporyn discusses how an uncertain case such as the one presented here could be approached systematically using techniques such as decision analysis. Decision analysis would allow Dr. Preed to incorporate each of the issues at hand into one “decision tree” factoring individual likelihoods and utilities or patient preferences into the ultimate decision [8, 9]. Decision trees are constructed as follows: squares represent “decision nodes” outlining the choices; circles represent “chance nodes” breaking down the possible outcomes of those decisions [10]. The probabilities of and utility scores for each outcome can be entered into software programs like TreeAge to help assign a value to each of the choices [11, 12]. Figure 1 represents a simple decision tree.

Figure 1. Simple example of a decision tree that may aid in making patient-centered decisions. The utility values of end results are assigned based on individual patient preferences and probabilities are based on clinic-specific data, and they may change in subsequent cycles.



In the example outlined in Figure 1, the choices include moving forward with another IVF-PGD cycle and ceasing treatment. Other choices that could be considered and expanded upon include pursuing treatment at another clinic or trying to conceive spontaneously. Those choices would make for a more detailed tree with additional decision nodes and chance nodes. Probabilities can come from historical clinic data, published data, or from Dr. Preed's expert knowledge [11]. Utility scores would be informed by Dana and Joe [11]. If nothing else, constructing a decision tree would allow Dr. Preed to work with Joe and Dana to weigh all options in light of the facts, the available evidence, and their preferences [9].

Dr. Preed needs to consider whether there are other clinics that may be able to offer Joe and Dana a better chance of a successful outcome. The ASRM Ethics Committee recommends that, when the prognosis is very poor or futile, "individuals should be fully informed and offered information about referrals, especially if other clinics have had greater success with similar medical indications" [5]. Another opinion may be of great benefit for this couple and for Dr. Preed alike. Dr. Preed most likely has a number of resources for identifying a clinic to which to refer this couple and for arranging for timely consultation through his professional relationships with

individual clinicians, through professional organizations like the American Society for Reproductive Medicine, the Society for Assisted Reproductive Technology, and international organizations like the European Society for Human Reproduction and Embryology.

The undeniable facts of the case are as follows: IVF success plateaus after four to six cycles, and optimal results from IVF-PGD cases are obtained “by a dedicated teams and by highly skilled laboratory technicians and embryologists” [13]. While the majority of clinics in the United States offer PGD, individual clinic success rates with procedures used in ART including PGD are often variable [14]. Decision analysis could be used in a shared decision-making process to include these facts along with individual preferences —Joe’s, Dana’s, and Dr. Preed’s—to help the stakeholders come to a mutually agreeable conclusion regarding what steps to take next [15].

References

1. Handyside AH, Kontogianni EH, Hardy K, Winston RM. Pregnancies from biopsied human preimplantation embryos sexed by Y-specific DNA amplification. *Nature*. 1990;344(6268):768-770.
2. Verlinsky Y, Rechitsky S, Schoolcraft W, Strom C, Kuliev A. Preimplantation diagnosis for Fanconi anemia combined with HLA matching. *JAMA*. 2001;285(24):3130-3133.
3. Kahraman S, Beyazyurek C, Ekmekci CG. Seven years of experience of preimplantation HLA typing: a clinical overview of 327 cycles. *Reprod Biomed Online*. 2011;23(3):363-371.
4. Verpoest W. PGD and HLA matching: not a quick fix. *Reprod Biomed Online*. 2011;23(3):271-273.
5. Ethics Committee of American Society for Reproductive Medicine. Fertility treatment when the prognosis is very poor or futile: a committee opinion. *Fertil Steril*. 2012;98:e6.
6. Malizia BA, Hacker MR, Penzias AS: Cumulative live-birth rates after in vitro fertilization. *N Engl J Med*. 2009;360(3):236-243.
7. Blyth E. Guidelines for infertility counselling in different countries: is there an emerging trend? *Hum Reprod*. 2012;27(7):2046-2057.
8. Ziporyn T. Medical decision making: analyzing options in the face of uncertainty. *JAMA*. 1983;249(16):2133-2135, 2138-2141.
9. Detsky AS, Naglie G, Krahn MD, Naimark D, Redelmeier DA. Primer on medical decision analysis: part 1--getting started. *Med Decis Making*. 1997;17(2):123-125.
10. Detsky AS, Naglie G, Krahn MD, Redelmeier DA, Naimark D. Primer on medical decision analysis: part 2--building a tree. *Med Decis Making*. 1997;17(2):126-135.
11. Naglie G, Krahn MD, Naimark D, Redelmeier DA, Detsky AS. Primer on medical decision analysis: part 3--estimating probabilities and utilities. *Med Decis Making* 1997;17(2):136-141.

12. Krahn MD, Naglie G, Naimark D, Redelmeier DA, Detsky AS. Primer on medical decision analysis: part 4--analyzing the model and interpreting the results. *Med Decis Making*. 1997;17(2):142-151.
13. Hornslet M, Danielsen S. *Adoptionsloven*. Copenhagen, Denmark: Juristforbundet Forlag; 1974.
14. Society for Assisted Reproductive Technology. SART national summary. IVF success rates: find a clinic. http://www.sart.org/find_frm.html. Accessed November 20, 2013.
15. Politi MC, Lewis CL, Frosch DL. Supporting shared decisions when clinical evidence is low. *Med Care Res Rev*. 2013;70(1 Suppl):113S-128S.

Emily S. Jungheim, MD, MSCI, is a scholar in the Women's Reproductive Health Research program and an assistant professor of reproductive endocrinology and infertility at the Washington University School of Medicine in Saint Louis. Dr. Jungheim completed her residency training in obstetrics and gynecology at Duke University, followed by a fellowship in reproductive endocrinology and infertility at Washington University in Saint Louis, where she also completed a master's of science in clinical investigation. Her research focuses on lifestyle and reproductive health.

Related in VM

[Assisted Reproduction for Postmenopausal Women](#), January 2014

[Sex Selection for Nonhealth-Related Reasons](#), February 2012

[Sex Selection for Nonmedical Reasons](#), June 2007

The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental.

The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.

Copyright 2014 American Medical Association. All rights reserved.

Virtual Mentor

American Medical Association Journal of Ethics
January 2014, Volume 16, Number 1: 30-33.

THE CODE SAYS

AMA Code of Medical Ethics' Opinions on Assisted Reproductive Technology

Opinion 2.055 - Ethical Conduct in Assisted Reproductive Technology

The following guidelines are intended to emphasize the value of existing standards to ensure ethical practices in assisted reproductive technology (ART):

- (1) The medical profession's development of technical and ethical guidelines for ART should continue. Education of the profession and patients should be pursued through widely disseminated information. Such material should include information on clinic-specific success rates.
- (2) Fertility laboratories not currently participating in a credible professional accreditation program are encouraged to do so. Professional self-regulation is also encouraged through signed pledges to meet established ethical standards and to comply with laboratory accreditation efforts. Physicians who become aware of unethical practices must report such conduct to the appropriate body. Physicians also should be willing to provide expert testimony when needed. Specialty societies should discuss the development of mechanisms for disciplinary action, such as revocation of membership, for members who fail to comply with ethical standards.
- (3) Patients should be fully informed about all aspects of ART applicable to their particular clinical profile. A well-researched, validated informed consent instrument would be useful for the benefit of patients and professionals. Payment based on clinical outcome is unacceptable.
- (4) Physicians and clinicians practicing ART should use accurate descriptors of available services, success rates, and fee structure and payment obligations in promotional materials.

If legislation on regulation of ART laboratories, advertising practices, or related issues is adopted, it should include adequate financial resources to ensure the intended action can be implemented. Improved legislative protection may be needed to protect physicians and their professional organizations when they provide testimony on unethical conduct of colleagues.

Issued December 1998 based on the report "Issues of Ethical Conduct in Assisted Reproductive Technology," adopted June 1996.

Opinion 2.14 - In Vitro Fertilization

The technique of in vitro fertilization and embryo transplantation enables certain couples previously incapable of conception to bear a child. It is also useful in the field of research directed toward an understanding of how genetic defects arise and are transmitted and how they might be prevented or treated. Because of serious ethical and moral concerns, however, any fertilized egg that has the potential for human life and that will be implanted in the uterus of a woman should not be subjected to laboratory research.

All fertilized ova not utilized for implantation and that are maintained for research purposes shall be handled with the strictest adherence to the Principles of Medical Ethics, to the guidelines for research and medical practice expressed in the Council's opinion on fetal research, and to the highest standards of medical practice.

Issued June 1983.

Opinion 2.04 - Artificial Insemination by Known Donor

Any individual or couple contemplating artificial insemination by husband, partner, or other known donor should be counseled about the full range of infectious and genetic diseases for which the donor or recipient can be screened, including communicable disease agents and diseases. Full medical history disclosure and appropriate diagnostic screening should be recommended to the donor and recipient but are not required.

Informed consent for artificial insemination should include disclosure of risks, benefits, and likely success rate of the method proposed and potential alternative methods. Individuals should receive information about screening, costs, and procedures for confidentiality, when applicable. The prospective parents or parent should be informed of the laws regarding the rights of children conceived by artificial insemination, as well as the laws regarding parental rights and obligations.

Sex selection of sperm for the purposes of avoiding a sex-linked inheritable disease is appropriate. However, physicians should not participate in sex selection for reasons of gender preference. Physicians should encourage a prospective parent or parents to consider the value of both sexes.

If semen is frozen and the donor dies before it is used, the frozen semen should not be used or donated for purposes other than those originally intended by the donor. If the donor left no instructions, it is reasonable to allow the remaining partner to use the semen for artificial insemination but not to donate it to someone else. However, the donor should be advised of such a policy at the time of donation and be given an opportunity to override it.

Issued June 1993; updated December 2004.

Opinion 2.05 - Artificial Insemination by Anonymous Donor

Thorough medical histories must be taken of all candidates for anonymous semen donation. All potential donors must also be screened for infectious or inheritable diseases which could adversely affect the recipient or the resultant child. Frozen semen should be used for artificial insemination because it enables the donor to be tested for communicable disease agents and diseases at the time of donation, and again after an interval before the original semen is used, thus increasing the likelihood that the semen is free of blood-borne pathogens. Physicians should rely on the guidelines formulated by relevant professional organizations, such as the American Society of Reproductive Medicine, the Centers for Disease Control and Prevention, and the Food and Drug Administration, in determining which disorders to screen for and which procedures to use in screening. Physicians should maintain a permanent record which includes both identifying and non-identifying health and genetic screening information. Other than exceptional situations where identifying information may be required, physicians should release only non-identifying health-related information in order to preserve the confidentiality of the semen donor.

Physicians should maintain permanent records of donors to fulfill the following obligations: (1) to exclude individuals from the donor pool who test positive for infectious or inheritable diseases, (2) to limit the number of pregnancies resulting from a single donor source so as to avoid future consanguineous marriages or reproduction, (3) to notify donors of screening results which indicate the presence of an infectious or inheritable disease, and (4) to notify donors if a child born through artificial insemination has a disorder which may have been transmitted by the donor.

Informed consent for artificial insemination should include disclosure of risks, benefits, likely success rate of the method proposed and potential alternative methods, and costs. Both recipients and donors should be informed of the reasons for screening and confidentiality. They should also know the extent of access to non-identifying and identifying information about the donor. Participants should be advised to consider the legal ramifications, if any, of artificial insemination by anonymous donor.

The consent of the husband is ethically appropriate if he is to become the legal father of the resultant child from artificial insemination by anonymous donor. Anonymous donors cannot assume the rights or responsibilities of parenthood for children born through therapeutic donor insemination, nor should they be required to assume them.

In the case of single women or women who are part of a homosexual couple, it is not unethical to provide artificial insemination as a reproductive option.

Sex selection of sperm for the purposes of avoiding a sex-linked inheritable disease is appropriate. However, physicians should not participate in sex selection of sperm for reasons of gender preference. Physicians should encourage a prospective parent or parents to consider the value of both sexes.

In general, it is inappropriate to offer compensation to donors to encourage donation over and above reimbursement for time and actual expenses.

Issued June 1993; updated December 2004.

Related in VM

[Physician Duties in the Face of Deceitful Gamete Donors, Disobedient Surrogate Mothers, and Divorcing Parents](#), January 2014

[Egg-Donor Price Fixing and *Kamakahi v. American Society for Reproductive Medicine*](#), January 2014

[Who Pays? Mandated Insurance Coverage for Assisted Reproductive Technology](#), January 2014

Copyright 2014 American Medical Association. All rights reserved.

Virtual Mentor

American Medical Association Journal of Ethics
January 2014, Volume 16, Number 1: 34-37.

JOURNAL DISCUSSION

Health and Development of Children Conceived through Assisted Reproduction

Clinton Wang

Bos H, van Balen F. Children of the new reproductive technologies: social and genetic parenthood. *Patient Educ Couns.* 2010;81(3):429-435.

Reproductive technologies have provided infertile couples, gay couples, and single women with the opportunity to bear children. As this Bos and van Balen article describes, families in which only one parent is genetically related to the children are increasingly popular, particularly among lesbian couples and single women who seek pregnancy by artificial insemination with donated semen (AID) [1].

The Bos and van Balen review “Children of the New Reproductive Technologies: Social and Genetic Parenthood” responds to some observers’ concerns about the quality of the parent-child relationship in such families [2, 3]. These commentators suggest that the social parent—the parent who is not genetically related to the child—may feel more distant from the child than the genetic parent and hence have a less intimate parent-child relationship. Communication and trust may be hindered when the parents have not informed a child about the circumstances of birth, while children who know that they are unrelated to one parent may experience identity conflicts that interfere with their psychosocial adjustment. In addition, some worry that single mothers may face difficulties rearing a child without the support of a partner [4].

The review by Bos and van Balen challenges those concerns. They cite nine European studies [5-13] that, taken together, suggest that the parent-child relationship is even stronger in families with only one genetic parent than in “natural-conception families,” and that the psychological adjustment of children with one genetic parent is unaffected [14]. The studies found that heterosexual parents who had children using AID or oocyte donation were more involved, competent, and warmer, that they took more pleasure in childrearing, and that their children’s psychosocial adjustment was comparable to that of other children. The parental effect was not merely limited to the genetic parent; in both AID families (in which the father is the social parent) and oocyte-donation families (in which the mother is the social parent), both the social and genetic parents were more invested in childrearing than the parents of children conceived without medical assistance. The review article suggests that this difference may be due to the extra burdens experienced by these parents in their efforts to achieve parenthood [14]. Moreover, couples who cannot reproduce without assistance would be unlikely to seek technologic help if they were not particularly enthusiastic about parenting [14].

The review article cites other studies [15, 16] that report evidence that mothers in father-absent families (i.e., lesbian and single mothers) are more emotionally involved with their offspring and that their children felt more securely attached to the mother than in father-present families. Although children in these families were reported to have slower cognitive and physical development at age 6, this difference from children conceived without assistance disappeared by age 12, and they showed relatively low levels of anxiety, depression, hostility, and alcohol abuse at age 19 [17]. Gay and lesbian couples share responsibility for childcare more fairly than do heterosexual couples, making them happier with the division of childrearing [14]. For families with gay fathers, there are no differences in the child's psychosocial adjustment from children conceived without assistance [18].

Evidence from this overview suggests that social parents and single AID mothers are no less capable and invested in childrearing than parents who conceived their children without assistance, nor do their children generally face more difficulties in psychosocial development. However, this does not imply that social parenthood brings no particular difficulties. A survey of social parents in AID families revealed that, because social parents are not recognized as legal parents in some states, they face disadvantages in certain situations such as custody disputes [19]. Another study Bos and van Balen cite found that single mothers often expressed concern about their children growing up without fathers and felt they needed to find a male role model for their children [20].

Some of the article's conclusions should be interpreted cautiously. While the authors point to one study that found children with surrogate mothers showed no difference in psychosocial development from sexually conceived children at age three, another study found that children born of surrogate mothers faced greater adjustment difficulties at age seven [21]. The latter study hypothesized that a genetic surrogate mother who remains in contact with the family rearing the child may undermine family relationships and that a seven-year-old child would understand biological inheritance and perhaps feel the absence of a biological connection to his or her social parents—factors that would not be captured at age three. Thus, while the Bos and van Balen review presents considerable evidence that social parenthood or the absence of a father is not an inherent disadvantage in parent-child relationships and child development, it may not reveal important factors that impact childrearing or child development in certain situations.

As Bos and van Balen describe, future research should examine factors that influence childrearing quality and psychosocial adjustment in families engaging in reproductive treatment. Researchers might, for example, study perceptions of AID children by their peers and teachers and examine how social stigma may hinder psychosocial development. Future studies should also clarify whether the difficulty of obtaining reproductive donations in fact accounts for the difference in parental motivation between parents who use them and parents who can reproduce without using them, which implies that one might expect to see a decrease in parental warmth when the barriers and costs of reproductive treatment are lower. Larger sample sizes

and more controlled conditions may be needed to tease out smaller differences between particular family structures. Greater research into new family models facilitated by reproductive technology will ensure that prospective parents can be fully informed in their decision to raise children and be prepared for any difficulties that they or their children may face.

References

1. Bos H, van Balen F. Children of the new reproductive technologies: social and genetic parenthood. *Patient Educ Couns.* 2010;81(3):429-435.
2. Baran A, Pannor R. *Lethal Secrets.* New York, NY: Amistad; 1993.
3. Clamar A. Psychological implication of the anonymous pregnancy. In: Offerman-Zuckerberg J, ed. *Gender in Transition: A New Frontier.* New York, NY: Plenum; 1989.
4. Bos, van Balen, 430.
5. Golombok S, Cook R, Bish A, Murray C. Families created by the new reproductive technologies: quality of parenting and social and emotional development of the children. *Child Dev.* 1995;66(2):285-298.
6. Brewaeys A, Ponjaert I, van Hall EV, Golombok S. Donor insemination: child development and family functioning in lesbian mother families. *Hum Reprod.* 1997;12(6):1349-1359.
7. Golombok S, Brewaeys A, Cook R, et al. The European study of assisted reproduction families: family functioning and child development. *Hum Reprod.* 1996;11(10):2324-2331.
8. Golombok S, MacCallum F, Goodman E, Rutter M. Families with children conceived by donor insemination: a follow-up at age twelve. *Child Dev.* 2002;73(3):952-968.
9. Golombok S, Brewaeys A, Giavazzi MT, et al. The European study of assisted reproduction families: the transition to adolescence. *Hum Reprod.* 2002;17(3):830-840.
10. Golombok S, Lycett E, MacCallum F, et al. Parenting infants conceived by gamete donation. *J Fam Psychol.* 2004;18(3):443-452.
11. Golombok S, Jadvá V, Lycett E, et al. Families created by gamete donation: follow-up at age 2. *Human Reprod.* 2005;20(1):286-293.
12. Golombok S, Murray C, Jadvá V, Lycett E, MacCallum F, Rust J. Non-genetic and non-gestational parenthood: consequences for parent-child relationships and the psychological well-being of mothers, fathers and children at age 3. *Hum Reprod.* 2006;21(7):1918-1924.
13. Kovacs GT, Mushin D, Kane H, Baker HW. A controlled study of the psycho-social development of children conceived following insemination with donor semen. *Hum Reprod.* 1993;8(5):788-790.
14. Bos, van Balen, 433.
15. Golombok S, Tasker F, Murray C. Children raised in fatherless families from infancy; family relationships and the socioemotional development of children of lesbian and single heterosexual mothers. *J Child Psychol Psychiat.* 1997;38(7):783-791.

16. MacCallum F, Golombok S. Children raised in fatherless families from infancy: a follow-up of children of lesbian and single heterosexual mothers at early adolescence. *J Child Psychol Psychiatr.* 2004;45(8):1407-1419.
17. Golombok S, Badger S. Children raised in mother-headed families from infancy: a follow-up of children of lesbian and single heterosexual mothers, at early adulthood. *Hum Reprod.* 2010;25(1):150-157.
18. Bos H, van Balen F. Planned gay father families in a kinship arrangement. Paper presented at: International Conference on LGBT Human Rights; 2009; Copenhagen, Denmark.
19. Frith L, Sawyer N, Kramer W. Forming a family with sperm donation: a survey of 244 non-biological parents. *Reprod Biomed Online.* 2012;24(7):709-718.
20. Jadvá V, Badger S, Morrissette M, Golombok S. “Mom by choice, single by life’s circumstance...” Findings from a large scale survey of the experiences of single mothers by choice. *Hum Fertil (Camb).* 2009;12(4):175-184.
21. Golombok S, Blake L, Casey P, Roman G, Jadvá V. Children born through reproductive donation: a longitudinal study of psychological adjustment. *J Child Psychol Psychiatr.* 2013;54(6):653-660.

Clinton Wang is a junior majoring in biomedical engineering at Yale University in New Haven, Connecticut. He is interested in many areas of health policy and medical ethics. In summer 2013, Clinton was an Ethics Group intern at the American Medical Association, where he conducted research on health promotion.

Related in VM

[Assisted Reproduction for Postmenopausal Women](#), January 2014

[Assisted Reproduction and *Primum Non Nocere*](#), September 2007

The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.

Copyright 2014 American Medical Association. All rights reserved.

Virtual Mentor

American Medical Association Journal of Ethics
January 2014, Volume 16, Number 1: 38-42.

STATE OF THE ART AND SCIENCE

Expanded Genetic Testing in Assisted Reproduction: Lessons Learned from Prenatal Testing

Susan Klugman, MD, and Siobhan M. Dolan, MD, MPH

The field of genetic testing is expanding to include new genetic technologies, including chromosomal microarray analysis (CMA) and whole-genome sequencing, and these technologies are increasingly being used on fetuses and embryos. Expanded prenatal genetic testing poses two main ethical challenges. When such testing is being done on fetuses, clinicians must counsel patients, who are deciding whether to continue pregnancies, in the absence of clear information about the significance of findings. When such testing is done on embryos for use in assisted reproduction, on what basis should embryos be chosen for implantation?

Chromosomal microarray analysis (CMA, also known as array-based comparative genomic hybridization) is a multiplex genomic test—one that tests a single sample of DNA for many conditions—that can detect microscopic deletions or duplications (called copy number variants or CNVs) on chromosomes. CMA permits the diagnosis of more than 100 conditions that can manifest in children as developmental delay/intellectual disabilities (DD/ID), autism spectrum disorders (ASD), or multiple congenital anomalies (MCA), as well as conditions that are relatively common but rarely diagnosed before birth, such as velocardiofacial syndrome and Williams syndrome. CMA has a 15 to 20 percent diagnostic yield among affected children across all studies [1], which, though low, far surpasses the 3 percent yield of traditional testing for chromosomal abnormalities via karyotype.

CMA has been clinically available in pediatrics since 2004. Between 2007 and 2010, statements by the American Academy of Pediatrics [2] and the American College of Medical Genetics [3] led to a practice change: standard karyotype analysis was replaced by chromosomal microarray analysis for children with developmental delays, autism spectrum disorders, or congenital anomalies not specific to a well-defined genetic syndrome. Since 2010, the American College of Medical Genetics has recommended it as a first-tier clinical diagnostic test in the evaluation of children and adults with unexplained DD/ID, ASD, and MCA [3, 4]. However, these same groups warn that CMA has its limitations and clinicians must realize that mosaicism and balanced translocations can be missed.

Prenatal Genetic Testing: Counseling in an Uncertain Situation

CMA technology can be used in prenatal diagnosis on samples obtained through chorionic villus sampling at 10-13 weeks of pregnancy or amniocentesis at 15-20 weeks of pregnancy. This has become increasingly common, especially in scenarios

in which CMA's clinical utility has been demonstrated, such as when the mother is 35 years of age or older, an increased risk has been noted on aneuploidy screening, or there is an abnormal anatomic finding in a prenatal ultrasound. A large multicenter study published in December 2012 showed that, for women who underwent invasive prenatal diagnosis and had a normal fetal karyotype, CMA revealed additional clinically relevant deletions or duplications (copy number variants or CNVs) in 6 percent of cases with an abnormal structural finding on ultrasound, 1.7 percent of cases with a 35-year-old or older mother, and 1.6 percent of cases with an elevated risk on aneuploidy screening [5]. Patients must understand that this testing on their fetus may reveal new genetic information about the parents, e.g., non-paternity or -consanguinity, which can have an impact on them and on their families and have ethical, legal, and insurance-related implications.

Another major possible challenge is that CMA can have positive or negative results or can reveal variants of uncertain significance (VOUS), variants not yet known to be associated with disease. VOUS are, thus, analogous to a small shadow on an x-ray that the radiologist does not feel is a mass but cannot be ignored. Variants of uncertain significance can be quite common in CMA, in part because large data sets that allow interpretation of findings are still being developed and often collect test results only from symptomatic children rather than recording prospective data on all pregnancies, both affected and healthy. Thus we do not know which variants are likely to lead to disease. Not all patients with a gene variant will exhibit signs or symptoms of a disorder, the signs and symptoms of people with a given disorder vary, and environmental and behavior factors can influence gene expression. All this makes it very difficult to predict the effect of a genetic change, to answer the question: is it a deleterious mutation or a benign variant?

This level of uncertainty raises ethical questions about how much information to reveal and when. Patients may need to make decisions about continuing a pregnancy based on information obtained in prenatal testing; this is clearly a highly emotionally and ethically charged situation. In a recent qualitative study of the impact of "abnormal" or ambiguous CMA results on prospective parents, Bernhardt et al. found that some women who agreed to CMA testing as "an offer too good to pass up" [6] and then obtained abnormal but uncertain results felt blindsided, and their results provoked frantic but futile searches for more definitive knowledge. For women who chose not to terminate their pregnancies after learning of the ambiguous findings, the experience of pregnancy was pervaded with severe anxiety. In cases where the variant identified in the fetus was also found in one of the parents, some parents reported that it called into question their own sense of normalcy. Some women wished they had not agreed to receive what one called "toxic knowledge" [7].

In response to these discoveries, Bernhardt et al. recommended careful counseling and extensive support; others suggest withholding information of uncertain clinical significance from patients even if they request it [6, 8, 9]. In our opinion, it would be inappropriate to withhold information that is reported on patients' test results. And

thus, pretest counseling is crucial in these situations so patients are prepared for all results.

At a minimum, providing CMA testing requires comprehensive pretest genetic counseling and posttest educational information about a large variety of possible conditions [10, 11]. But findings may indicate rare conditions about which barely any data or educational materials are available for parents, making thorough counseling difficult. It is also crucial to stress that normal CMA results do not mean absence of risk for pregnancy complications; if this point is not emphasized and such complications occur, patients can be shocked and ill-prepared.

Preimplantation Genetic Testing: Choosing Embryos

The clinical and counseling considerations and concerns raised by prenatal testing will come along to ART when whole-genome sequencing (WGS) is used to examine embryos before implantation. This may exacerbate the challenges that have been faced in fetal testing to date. In vitro fertilization has been in practice for several decades, and traditionally the embryos were selected for transfer by their appearance [12]. More recently, preimplantation genetic testing has been used to select the chromosomally normal embryos to transfer. Preimplantation genetic testing has proven valuable when choosing to identify embryos that do not carry mutations with well-known Mendelian inheritance, such as Huntington disease or Tay-Sachs disease. Preimplantation genetic testing for aneuploidy, however, has been controversial because it works as a screening test rather than as a diagnostic test, which it had initially been proposed to be; it is not always correct and does not necessarily raise the birth rate [13].

The good news is that advances in preimplantation genetic testing may make it possible to identify “better” embryos, those that will lead to implantation, a full-term pregnancy, perhaps a live birth [14, 15], or a pregnancy without certain complications such as preeclampsia. The ability to learn more about the embryo that could influence decisions about embryo quality and transfer [16] is intriguing. One can only surmise, however, that more intense genetic analysis of embryos is likely to show multiple variants of uncertain significance, and all the counseling needed for prenatal testing will need to be made available, and perhaps even expanded, for patients considering having embryos’ genomes sequenced. Will finding VOUS lead to discarding healthy embryos? Lastly, how will incidental findings be handled when performing whole-exome sequencing on an embryo?

In addition, there must be standards governing informed consent for these preimplantation tests. It is patients’ rights to know their test results and to make autonomous decisions accordingly; physicians cannot withhold test results from patients, even if they are ambiguous, and cannot choose embryos without consulting patients.

Conclusion

All in all, more intense genetic testing of embryos is in our future, as we move from expanded DNA testing of children to fetuses and finally to embryos. Clearly more research needs to be done to validate techniques so that we can provide the best options for our patients. The added information that will be provided by expanded genomic testing options is wonderful. It will likely help many couples identify problems and address them, thus leading to healthy families. But it will have side effects, including the need for parental specimens, the finding of variants of uncertain significance, and the need for more educational resources as well as genetic counselors and genetic services. A host of ethical, legal, and social issues will also be raised by expanded DNA testing on the embryo and these concerns must be the subject of thoughtful deliberation and societal debate.

References

1. Miller DT, Adam MP, Aradhya S, et al. Consensus statement: chromosomal microarray is a first-tier clinical diagnostic test for individuals with developmental disabilities or congenital anomalies. *Am J Hum Genet.* 2010;86(5):749-764.
2. Johnson CP, Myers SM, American Academy of Pediatrics Council on Children with Disabilities. Identification and evaluation of children with autism spectrum disorders. *Pediatrics.* 2007;120(5):1183-1215.
3. Manning M, Hudgins L, Professional Practice and Guidelines Committee. Array-based technology and recommendations for utilization in medical genetics practice for detection of chromosomal abnormalities. *Genet Med.* 2010;12(11):742-745.
4. Van den Veyver IB, Beaudet AL. Comparative genomic hybridization and prenatal diagnosis. *Curr Opin Obstet Gynecol.* 2006;18(2):185-191.
5. Wapner RJ, Martin CL, Levy B, et al. Chromosomal microarray versus karyotyping for prenatal diagnosis. *New Engl J Med.* 2012;367(23):2175-2184.
6. Bernhardt BA, Soucier D, Hanson K, Savage MS, Jackson L, Wapner RJ. Women's experiences receiving abnormal prenatal chromosomal microarray testing results. *Genet Med.* 2013;15(2):139-145.
7. Bernhardt, Soucier, Hanson, Savage, Jackson, Wapner, 142.
8. Berg JS, Khoury MJ, Evans JP. Deploying whole genome sequencing in clinical practice and public health: meeting the challenge one bin at a time. *Genet Med.* 2011;13(6):499-504.
9. McGillivray G, Rosenfeld JA, McKinlay Gardner RJ, Gillam LH. Genetic counselling and ethical issues with chromosome microarray analysis in prenatal testing. *Prenat Diagn.* 2012;32(4):389-395.
10. Reiff M, Ross K, Mulchandani S, et al. Physicians' perspectives on the uncertainties and implications of chromosomal microarray testing of children and families. *Clin Genet.* 2013;83(1):23-30.
11. Klugman S, Suskin B, Dar P, et al. Clinical utility of chromosomal microarray analysis in prenatal diagnosis: report of first 6 months in clinical

practice. *J Matern Fetal Neonatal Med.* October 23, 2013; epub ahead of print.

12. Montag M, Toth B, Strowitzki T. New approaches to embryo selection. *Reprod Biomed Online.* 2013;27(5):539-546.
13. Harper JC, Sengupta SB. Preimplantation genetic diagnosis: state of the art 2011. *Hum Genet.* 2012;131(2):175-186.
14. Mertzaniidou A, Wilton L, Cheng J, et al. Microarray analysis reveals abnormal chromosomal complements in over 70% of 14 normally developing human embryos. *Hum Reprod.* 2013;28(1):256-264.
15. Fragouli E, Wells D. Aneuploidy screening for embryo selection. *Semin Reprod Med.* 2012;30(4):289-301.
16. Preimplantation Genetic Diagnosis International Society. International conference on preimplantation genetic diagnosis. <http://www.pgdis2013.com/scientific-programme/conference-scientific-program>. Accessed October 1 2013.

Susan Klugman, MD, is an associate professor of clinical obstetrics and gynecology and women's health at the Albert Einstein College of Medicine and director of the Division of Reproductive Genetics at Montefiore Medical Center in New York City. At Yeshiva University, she is director of the fellowship for medical genetics and the medical director for the Program of Jewish Genetic Health. She started the Larchmont Women's Center and was its medical director before her genetics fellowship. She is board certified in both clinical genetics and obstetrics and gynecology.

Siobhan M. Dolan, MD, MPH, is a professor of clinical obstetrics and gynecology and women's health at the Albert Einstein College of Medicine and an attending physician in the Division of Reproductive Genetics at Montefiore Medical Center in New York City. Dr. Dolan maintains her clinical practice serving women and families in the Bronx. Her research interests focus on the integration of genetics into maternal-child health, specifically looking at ways to apply advances in genetics and genomics to prevent birth defects and preterm birth.

Related in VM

[Selecting the Traits of Children Prior to Birth](#), February 2012

The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.

Copyright 2014 American Medical Association. All rights reserved.

Virtual Mentor

American Medical Association Journal of Ethics
January 2014, Volume 16, Number 1: 43-48.

HEALTH LAW

Physician Duties in the Face of Deceitful Gamete Donors, Disobedient Surrogate Mothers, and Divorcing Parents

Judith Daar, JD

Family formation through assisted reproductive technologies (ART) accounts for 3 of every 100 children born in the United States today [1-3]. The demographic of ART-conceived children far exceeds the number of parent-child relationships formed through neonatal adoption, offering opportunities for parenthood that would have been elusive a generation ago. While the majority of ART usage involves couples undergoing in vitro fertilization using their own gametes—known as first-party assisted reproduction—a growing percentage of ART use involves third-party collaborators who assist in an individual's or couple's reproductive plan. These third party collaborators participate as sperm donors, egg donors, and gestational carriers; they are typically unrelated to the intended parent or parents and receive compensation for providing gametes or gestational services to the sponsoring prospective parent(s). The vast majority of third-party assisted reproduction scenarios proceed without complication or incident, but occasional mishaps do occur and are worthy of analysis [4].

In contrast to natural reproduction which enjoys the privacy and security of a closed two-party relationship, assisted conception is vulnerable to misconduct by the necessary presence of third parties in the reproductive equation. Ideally, all potential conduct attendant to a collaborative reproduction arrangement should be addressed by a written preconception agreement in which all parties participate voluntarily, transparently, and in good faith. In the event such an agreement is absent, deficient, or breached, intended parents, donors, surrogates, and physicians are best served by understanding their duties and the possible conflicts generated by each scenario. In a clinical practice that combines profound intimacy with arm's-length negotiated transactions, incidents of malfeasance can cause devastating emotional, psychological, physical, and financial harms. I explore these potential harms through three paradigmatic cases—the deceitful donor, the disobedient surrogate, and the divorcing intended parents.

Donor Misconduct: Adventures in Truth Telling

Gamete donors typically undergo extensive screening to determine their genetic, physical, psychological, and behavioral suitability to contribute eggs or sperm for another's reproductive plan. Nevertheless, donors can be less than forthcoming about at least two key aspects of their profile—their intentions to claim parental rights over any resulting children and their health histories. Active misrepresentation or passive omission of these essential facts may be revealed to a physician in the course of

donation. In egg donation, particularly, an infertility specialist may treat both the intended mother and her chosen donor and become aware of misrepresentation. What course of conduct is open to a doctor who learns of donor deceit?

As to the problem of undisclosed parental aspirations, intended parents who solicit gamete donors commonly presume the donors will neither retain nor assert any parental rights over a resulting child. American courts have processed more than a handful of cases in which donors initially declare a lack of intent to parent any resulting child, but harbor or later develop a desire to do so. Sperm and egg donors who were acquaintances of an intended mother at the time of donation have been awarded parental rights after stepping into a parenting role once the child is born [5-8]. What is the physician's role if a gamete donor discloses an intent to parent a resulting child after representations to the contrary?

Dilemmas in ART often pit two longstanding professional duties against each other—the duty to obtain informed consent and the duty to maintain patient confidentiality [9, 10]. Obtaining informed consent from a patient requires disclosure of any information that would be material to that person's decision to undergo or refuse treatment. Exceptions are limited to situations involving the patient's impaired decision-making capacity and do not apply in the case of donor misrepresentation [11]. Standing alone, the duty to obtain informed consent demands disclosure of a donor's "true intent" because such information is clearly material to a patient's decision to proceed with or continue the existing ART arrangement.

Knowing the limits and demands of disclosure is especially complicated when a physician treats both the donor and the intended mother, forming sacrosanct patient-physician relationships with both parties. A key feature of that relationship, the duty to maintain patient confidentiality, is essential to the patient's feeling free and safe to discuss matters of the utmost intimacy. Unconsented disclosure to any third party, especially another patient with a vital stake in the disclosing patient's care, must be carefully considered.

A first approach to managing the conflicting professional demands may be to consult preexisting written agreements between the parties for language about disclosure of material information. In some instances, parties waive their rights to physician confidentiality, enabling a treating or facilitating doctor to share important information with and about each signatory. Absent express waiver by the patient, disclosure may still be permissive. The duty to maintain patient confidentiality is not absolute. Disclosure of confidential patient information is permitted under certain circumstances, including an aim to avoid serious harm to a third party [10]. Assertion of parental rights by a gamete donor would, in all likelihood, inflict serious harm on the intended parents. Thus, unconsented disclosure can be justified. Ideally, the physician would convince the donor to discuss her thoughts and feelings about parenthood with the intended parents, but if she refuses the physician could proceed with the necessary disclosure.

These same conflicting duties of informed consent and confidentiality arise when a donor reveals previously undisclosed features of her health profile, such as a family history of heritable disease, untreated bouts of depression, prior substance abuse, or participation in a failed egg retrieval cycle. Some post-screening revelations may involve criteria that would have excluded the donor from eligibility under either federal or industry standards [12, 13]. Even if they are not grounds for excluding the donor, factors like those mentioned above would most likely have dissuaded the intended parent(s) from choosing the donor, and, thus, the information is highly material to the patient's assisted conception treatment. Further, while misrepresentations about a donor's parental aspirations are harmful to the intended parent(s), withholding or lying about health-related matters additionally threatens the well-being of a potential child.

A physician who becomes aware of previously undisclosed health-related information should discuss it with the donor. The donor may confirm the information and ask to withdraw from the arrangement. If the donor seeks to do so without alerting the intended parents to her nondisclosure, her request should be honored. The intended parent(s) can be informed that the prospective donor has been excluded from donating, but specific health-related findings need not be disclosed.

In other instances, a donor may wish to continue the treatment process, perhaps hopeful she remains a good candidate for donation. If the new information renders the donor ineligible under state, federal, or industry guidelines, she must be excluded from further participation. If she remains eligible for donation, with her express consent a physician can relay the newly discovered information to the intended parent(s) for their consideration. In all likelihood, discovery of new and potentially troublesome information at this late stage in the donation process will be difficult for all the parties involved. Physicians are encouraged to make themselves available for a candid and thorough group discussion.

Surrogate Parenting Arrangements Gone Awry

Surrogate parenting arrangements enable infertile women and same-sex male couples to become parents with the assistance of a gestational carrier who carries the child from implantation to delivery. In the main, these arrangements are memorialized in detailed agreements negotiated by the parties and their attorneys. In addition to provisions regarding compensation, surrogate parenting agreements contain language addressing the parties' expected behavior during the course of the pregnancy [14]. What is the physician's role in the face of a breach by the intended parents or the surrogate?

Professional societies strongly urge physicians to refrain from treating both the intended parents and the surrogate "because conflicts of interest may arise that would not allow the physician to serve all parties properly" [15]. Despite this recommendation, dual treatment may be preferred when an intended mother undergoes oocyte retrieval to contribute to the embryos transferred into the surrogate. A reproductive medicine specialist may continue to see both the intended

parents and the surrogate until her pregnancy is well established. What if, during this period of overlapping patient-physician relationships, the doctor learns of behaviors that violate the surrogacy agreement? Imagine the intended parents confide their marital discord and impending divorce in the face of a specific contract term requiring delivery of the child to an intact married couple [16]? Or consider a surrogate who confesses noncompliance with an “organic foods only” provision or enjoyment of contractually prohibited coffee and alcohol on a regular basis.

As a foundational matter, physicians involved in third-party reproduction should familiarize themselves with the written agreements their patients have signed [15]. If a contract calls for the sponsoring couple to be married at the time of the child’s birth or for the surrogate to eat a certain diet (including avoiding named substances), a physician can assume these behaviors are material to the parties’ decision making. In many instances, the parties’ preferences regarding the scope of disclosure required and permitted in the arrangement, including disclosure by physicians and other health care professionals, are embedded in the surrogacy contract. A careful drafter will appreciate and memorialize the need for parties to a surrogacy agreement to waive confidentiality to any material information discovered in the course of treatment. Express waivers of confidentiality represent an exception to a physician’s duty to maintain patient confidentiality. Under these circumstances, a physician can consider a two-part approach: (1) encourage the patient to disclose the breach to the other party, and (2) failing self-disclosure, the physician can discuss the breach with the affected party as material to their ongoing informed consent.

If the parties have not expressly waived confidentiality, practitioners must weigh the benefits and burdens of nonconsensual disclosure. Assisted reproduction scenarios are further complicated by the potential interests of offspring who may exist in vitro or in utero. Respect for patient autonomy includes the duty to provide information material to a patient’s decision making. Since breach of an agreement could provoke rescission of the contract, the potential balance of harms seems to weigh in favor of disclosure.

Conclusion

Assisting infertile patients become parents can be a richly rewarding area of practice, though its challenges often extend beyond the bedside. Physicians can best navigate any clinical and ethical challenges by familiarizing themselves with the terms of any written agreements, encouraging full self-disclosure by the parties, and respecting patient autonomy by adhering to the principles of informed consent.

References

1. Centers for Disease Control and Prevention Assisted reproductive technology: 2010 national summary report. http://www.cdc.gov/art/ART2010/PDFs/ART_2010_National_Summary_Report.pdf. Accessed November 20, 2013. This reports the birth of 61,564 IVF-conceived infants in 2010.

2. Institute for Science, Law & Technology Working Group (ISLAT). Art into science: regulation of fertility techniques. *Science*. 1998;281(5377):651-652. This reports 60,000 births of children conceived through artificial insemination by donor (AID) annually.
3. Centers for Disease Control and Prevention. Births: final data for 2010. *Natl Vital Stat Rep*. Aug. 28, 2012; 61(1):1. http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_01.pdf. Accessed November 19, 2013. This reports 3,999,386 live births in the US in 2010. Thus, children conceived through ART (combined IVF and AID) in the US in 2010 comprised 3 percent of all live births.
4. Hansen M. As surrogacy becomes more popular, legal problems proliferate. *ABA J*. 2011;97:52-57. http://www.abajournal.com/magazine/article/as_surrogacy_becomes_more_popular_legal_problems_proliferate/. Accessed November 20, 2013.
5. *Thomas S. v Robin Y.*, 209 AD 2d 298, 618 NYS2d 356 (1995).
6. *Jhordan C. v Mary K.*, 179 Cal App 3d 386, 224 Cal Rptr 530 (1986).
7. *K.M. v E.G.*, 37 Cal 4th 130, 117 P3d 673, 33 Cal Rptr 3d 61 (2005).
8. *T.M.H. v D.M.T.*, 79 So 3d 787 (FL 2011).
9. American Medical Association. Opinion 8.08 Informed consent. *Code of Medical Ethics*. Chicago, IL: American Medical Association; 2006. <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion808.page>. Accessed November 20, 2013.
10. American Medical Association. Opinion 5.05 Confidentiality. *Code of Medical Ethics*. Chicago, IL: American Medical Association; 2006. <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion505.page>. Accessed November 20, 2013.
11. American Medical Association. Opinion 8.082 Withholding information from patients. *Code of Medical Ethics*. Chicago, IL: American Medical Association; 2006. <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8082.page>. Accessed November 20, 2013.
12. US Food and Drug Administration Center for Biologics Evaluation and Research. Guidelines for industry: eligibility determination for donors of human cells, tissue and cellular and tissue-based products (HCT/Ps) [2007]. <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm091345.pdf>. Accessed November 19, 2013.
13. Practice Committee of the American Society for Reproductive Medicine; Practice Committee of Society for Assisted Reproductive Technology. Recommendations for gamete and embryo donation: a committee opinion. *Fertil Steril*. 2013;99(1):47-62.
14. Fruchtman C. Considerations in surrogacy contracts. *Whittier L Rev*. 1999;21:429-433.
15. American College of Obstetricians and Gynecologists Committee on Ethics. ACOG committee opinion no. 397: surrogate motherhood.

http://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Ethics/Surrogate_Motherhood. Accessed November 19, 2013.
16. *In re Marriage of Moschetta*, 25 Cal App 4th 1218 (1994).

Judith Daar, JD, is a professor of law at Whittier Law School and a clinical professor of medicine in the School of Medicine at the University of California, Irvine. She is a member of the American Society for Reproductive Medicine Ethics Committee and past president of the American Society of Law, Medicine and Ethics. Her casebook, *Reproductive Technologies and the Law*, has been used in classrooms across the country.

Related in VM

[Physician Responsibility When a Surrogate Mother Breaks Her Contract](#), January 2014

[Health and Development of Children Conceived through Assisted Reproduction](#), January 2014

The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.

Copyright 2014 American Medical Association. All rights reserved.

Virtual Mentor

American Medical Association Journal of Ethics
January 2014, Volume 16, Number 1: 49-56.

HEALTH LAW

Fully Informed Consent for Prospective Egg Donors

Naomi Cahn, JD, and Jennifer Collins, JD

Jessica saw the ads on her college campus: egg donor wanted, high SAT scores, willing to pay, contact Egg Donors R Us. She was a financially struggling college junior, and the idea of helping people have children appealed to her. She called Egg Donors R Us and, after the receptionist asked her a few questions, she was invited to come to the clinic and fill out a questionnaire. It asked, for example, if she had dimples and freckles but not if she understood the medical procedures or risks involved in egg donation. She was given a provisional acceptance, had an interview with a nurse and a psychological consultant, and then had blood drawn for final eligibility checks.

A few months later, she was matched with a recipient and finally given the clinic's informed consent form. She barely looked at it before signing; she was excited to begin the process that would help another woman as well as pay her tuition bills.

So just what did Jessica sign? What did it tell her? What legal requirements surround the informed consent form for donating eggs and sperm? Although approximately 12 percent of all assisted reproductive cycles in the United States (more than 18,000 cycles each year) involve donor eggs [1], and countless pregnancies are achieved every year using donor sperm, the donation process is only lightly regulated, particularly in the realm of informed consent.

Regulations

The federal regulations that do exist fall into two categories: safety testing and truth in advertising. Neither deals directly with informed consent. With regard to safety testing, donor gametes—sperm, eggs, and embryos—are regulated by the FDA under the category of human cells, tissues, and cellular and tissue-based products (HCT/Ps) [2, 3]. The applicable regulations focus on donor testing and record keeping and require that all entities handling sperm, eggs, or embryos register with the FDA [4, 5]. In addition, the FDA requires screening for each donor that includes a physical examination and a medical history interview [6]. With very limited exceptions, donors are also subject to testing aimed primarily at preventing communicable diseases [7]. Following the testing, semen must be frozen and quarantined, to be released six months later when certified as “disease-free.” States may impose their own licensing requirements above and beyond the federal regulations [8].

A second set of federal requirements, based on the 1992 Fertility Clinic Success Rate and Certification Act, focuses on truth in advertising and relates primarily to

reporting requirements by fertility centers engaging in assisted reproductive technology (defined as the manipulation of both eggs and sperm) to ensure that clinics are not claiming inaccurate pregnancy rates [9]. These truth-in-advertising laws do not regulate entities that only handle sperm.

Because no federal laws regulate the informed consent process by, for example, specifying what information donors must be given before they provide gametes, the conscientious fertility center must look elsewhere.

One possible source is the American Society for Reproductive Medicine (ASRM), the self-regulatory association for assisted reproductive technology (ART) professionals, which has developed recommendations applicable to sperm, egg, and embryo donations. Unlike the FDA's, which apply only to donors, the ASRM's guidelines address both donors and recipients [10]. The ASRM, of course, has no enforcement authority apart from excluding noncomplying entities from membership. Accordingly, it "strongly recommends" rather than mandates.

Psychological evaluation and counseling are strongly recommended for donors, and genetic evaluation "should" be performed [11]. If a psychological assessment is done, then the guidelines recommend that it "ensure that the donor has been informed about all relevant aspects of the medical treatment" [12]. With respect to the possibility of identity disclosure, the guidelines note that the assessment should determine whether the donor has been "well informed about the extent to which information about [him or her may] be disclosed and about any plans that may exist relating to future contact" [13]. In short, the guidelines are detailed about the type of testing to be performed, but provide only summary recommendations concerning the scope and details of psychological counseling and evaluation that are recommended.

Finally, a few states have laws specifically focused on the egg-donation consent process [14]. Since 2010, egg donors in Arizona must be provided with specific information about the hormones they will be taking, the surgical procedures, and the risks [15]. California also has specific requirements concerning most steps involved in egg donation, requiring all entities that post advertisements offering "financial payment or compensation of any kind" for oocyte donation to certify that they have complied with ASRM requirements or include a notice stating:

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 [16].

New York has imposed requirements that the donor receive information about the “risks of any drugs, surgical procedures and/or anesthesia administered,” as well as the potential uses of the gametes [17].

Analysis

In this haphazard array of guidelines and state laws, the value of informed consent may be easy to overlook, but it is vitally important for several key reasons. First, state health care and tort law (particularly in the form of medical malpractice law) require informed consent to ensure that patients are involved in their own medical decision making, and physicians face tort liability for a failure to obtain informed consent. While there are problems with informed consent procedures in the United States—for example, the focus is on the physician providing information, rather than ensuring patient understanding [18]—the general principle is to promote patient autonomy. The focus of informed consent in ART has so far been on egg donors, but sperm donors also need adequate information to consent to the procedures.

Second, certainly for egg donors, donation involves potential risks. In one of the few studies of egg donors, the authors found that only a third knew about the possibility of ovarian hyperstimulation, only one-fifth knew about the possibility of infertility and the risk associated with the egg collection procedure, and only one in eight knew about the risks from the anesthesia used during egg recovery [19]. When it came to psychological aspects of the donation process, less than a third anticipated that they might feel a sense of loss or any type of emotional connection to their donated eggs or the resulting children, and only five percent were aware of the risk that a child might try to find them [19]. In addition, there is little research on the long-term impact of egg donation, including psychological aspects, and informed consent to unknown risks is particularly problematic.

Finally, gamete donation differs from most other medical procedures in three critical ways:

The end result is the creation of a child. Both egg and sperm donors may report complex emotions about their feelings towards resulting children [20, 21], and, notwithstanding promises of anonymity, donors may become interested in searching for offspring and offspring may search for their donors [22]. But the federal regulations say nothing about identity disclosure, and, as discussed earlier, even the ASRM guidelines only briefly mention disclosure, given that their primary foci are safety and recruitment, not the children who are born from donor gametes.

Egg donation is a medical procedure that involves significant medical risk yet provides no medical benefit to the donor. Indeed, the procedure is being done for someone else’s benefit. The most analogous situation is that of a living organ donor (although organ donation is not compensated). The Organ Procurement and Transplantation Network takes this risk so seriously that it requires provision of an independent donor advocate to ensure donors understand, among other issues, that

they “will undertake risk and will receive no medical benefit from the operative procedure of donation” [23].

Decisions regarding egg donation can be impacted by outside sources. Just as the organ transplant donor’s decision may be influenced by pressure from family members, prospective egg donors can be influenced by external factors, particularly the potentially distorting factor of financial payment. The importance of financial compensation in egg donors’ decision-making processes is plainly demonstrated by the fact that countries that have banned the practice of compensation for egg donors have faced significant egg shortages [24]. Yet the ASRM guidelines barely mention this issue. They only urge the minimization of the amount of payment so donors are not “unduly induce[d]” and evaluation for coercion during the psychological assessment, but do not suggest including a discussion of this issue in the informed consent process so donors can consider whether their judgment is in fact being impacted by the promise of financial reward.

Recommendations

So what is a reasonable fertility center to do when it comes to donors? (Disclosure to recipients is important but is outside the scope of this article.) At the least, centers should mandate counseling and, potentially, even require the use of independent donor advocates during an informed consent process comparable to the one used in the context of organ donation. The informed consent forms should ensure not only that information is conveyed but also that the donor understands and is making the decision voluntarily [25]. For example, an intriguing new tool provides feedback on whether prospective donors comprehend the information they have received [25]. To develop that tool, researchers adapted a validated questionnaire used for cancer patients enrolling in clinical trials to assess whether egg donors had both a subjective and objective appreciation of the donation process, that is, “how well informed the donor feels about” the egg donation process and the “facts and concepts relevant to oocyte donation” [26]. The tool proved both reliable and readable—a common challenge for many medical documents—in pilot testing at the UCSF Center for Reproductive Health [25], and it would be useful in evaluating existing consent forms. In addition, the informed consent process should start at the time of initial screening and agreement to participate rather than later in the process, when a donor may already feel psychologically invested in seeing the donation process through to completion.

At a minimum, counseling should cover the following points, all of which should also be addressed in writing in the informed consent documentation:

1. *Detailed medical risks.* While the ASRM guidelines do recommend disclosure of the risks involved, they do not specify what the disclosure must include [27]. Although there are essentially no risks for sperm donors, the medical risks for egg donors are significant and need to be adequately addressed. The information provided should go beyond the basic acknowledgement that there is “a small risk (1 in 200 women) of developing ovarian hyper-stimulation syndrome (OHSS)” and include details about the

symptoms of the syndrome and under what circumstances a woman should call the clinic. In addition, donors must be told that there has been very little research about the long-term impact of egg donation and at least some physicians believe infertility and death are possible risks [28, 29].

2. *Information about whether donor eggs may be used for research purposes.* A recent study concluded that only a small percentage of clinics inform potential donors that their eggs may be used for research, including stem cell research, and recommended that, in light of the moral or religious objections some donors may have, this information be disclosed in plain language in informed consent documents [30]. The ASRM urges that informed consent be obtained from donors if egg sharing is “contemplated” [31].
3. *A warning about the risks of multiple donations and donating at multiple clinics.* There is currently no mandatory nationwide egg donor registry in the United States and no coordination between different clinics. Thus, it is quite possible for a woman to donate eggs at more than one clinic. This poses risks in two ways. First, it is believed that the medical risks increase with the number of cycles [32]. Second, donating at more than one clinic increases the possibility of creating unknown half-siblings [33].
4. *Confidentiality issues.* The ASRM guidelines currently state only that donors “should be assured that their confidentiality will be protected insofar as federal and local statutes permit” [34]. This essentially provides the donors with no information at all. Donors should be informed that: (a) current regulations are subject to revision; (b) children resulting from their donation may one day contact them; and (c) donors have been identified even when clinics and donors have attempted to maintain confidentiality through registries. Donors should also be informed whether or not they have control over potential recipients.
5. *Compensation.* A frank discussion of the possibility that the promise of significant financial payment may be influencing the donor’s assessment of risk, and disclosure of who is paying the fees for counseling and legal services—if it is the clinic, for example, that fact needs to be disclosed to donors. This discussion could occur while addressing the donor’s motivations. Money will certainly figure as one reason for donating; the important issue is assuring that there is no coercion.

Although fertility centers should take these steps voluntarily, legal regulation must provide the enforcement necessary to ensure uniform implementation. Self-regulation works much of the time, but not always [35]. Studies increasingly show that, at least with respect to egg donation, even fertility centers that are located in California, with its legal requirements for egg-donor advertisements, and that are members of the Society for Assisted Reproductive Technologies are not in full compliance when it comes to advertising and information disclosure [36, 37]. While professional standards are critical to promoting good medical care, outside monitoring will protect gamete donors, recipients, and children.

References

1. Centers for Disease Control and Prevention. Section 4: ART cycles using donor eggs. In: *Assisted Reproductive Technology (ART) 2010 National Summary Report*. <http://www.cdc.gov/art/ART2010/section4.htm>. Accessed September 8, 2013.
2. US Food and Drug Administration. How do I screen a donor? 21 CFR sec 1271.75 (2006). <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1271.75>. Accessed November 22, 2013.
3. US Food and Drug Administration. What donor testing is required for different types of cells and tissues? 21 CFR sec 1271.85(a)-(c) (2005). <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1271.85>. Accessed November 22, 2013. The regulations require anonymously donated gametes to be tested for the following diseases: human immunodeficiency virus, type 1; human immunodeficiency virus, type 2; hepatitis B virus; hepatitis C virus; treponema pallidum; human T-lymphotropic virus, type I; human T-lymphotropic virus, type II; cytomegalovirus; chlamydia trachomatis; and neisseria gonorrhoea.
4. US Food and Drug Administration. When do I register, submit an HCT/P list, and submit updates? 21 CFR sec 1271.21 (2001). <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1271.21>. Accessed November 22, 2013.
5. US Food and Drug Administration. Tissue establishment registration. <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/TissueEstablishmentRegistration/default.htm>. Accessed September 8, 2013. The two-page form is available here: <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM082428.pdf>. Accessed September 8, 2013.
6. US Food and Drug Administration. What you should know—reproductive tissue donation. <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/TissueSafety/ucm232876.htm>. Accessed September 8, 2013.
7. Knaplund KS. Synthetic cells, synthetic life, and inheritance. *Valparaiso Law Rev.* 2011;45(4):1371-1386.
8. Pi VL. Regulating sperm donation: Why requiring exposed donation is not the answer. *Duke J Gender Law Policy.* 2009;16(2):379-401.
9. Centers for Disease Control and Prevention. Assisted reproductive technology (ART): commonly asked questions about the US ART clinic reporting system. <http://www.cdc.gov/art/ART2010/faq.htm#2>. Accessed September 8, 2013.
10. Practice Committee of the American Society for Reproductive Medicine; Practice Committee of the Society for Assisted Reproductive Technology (ASRM/SART). Recommendations for gamete and embryo donation: a committee opinion. *Fertil Steril.* 2013;99(1):47-62.e1.
11. ASRM/SART, 49, 50, 54, 55, 62.e1.
12. ASRM/SART, 60.

13. ASRM/SART, 59.
14. Cone KL. Family law—egg donation and stem cell research—eggs for sale: The scrambled state of legislation in the human egg market. *University of Arkansas at Little Rock Law Rev.* 2012;35(1):189-216.
15. Informed consent for egg donation; requirements; unprofessional conduct, Ariz Rev Stat Ann sec 36-1702 (West 2010).
16. Oocyte donation; advertisement; screening process; procedures, Cal Health and Safety Code sec 125325 (West 2010).
17. Informed consent, NY Comp Codes R & Regs title 10, sec 52-8.8(a) (2000).
18. Suter SM. The politics of information: informed consent in abortion and end-of-life decision making. *Am J Law Med.* 2013;39(1):7-61.
19. Kenney NJ, McGowan ML. Looking back: egg donors' retrospective evaluations of their motivations, expectations, and experiences during their first donation cycle. *Fertil Steril.* 2010;93(2):455-466.
20. Almeling R. *Sex Cells: The Medical Market for Eggs and Sperm.* Berkeley: University of California Press; 2011.
21. Belkin L. An egg donor's tale. *Motherlode. New York Times.* January 10, 2011. http://parenting.blogs.nytimes.com/2011/01/10/an-egg-donors-tale/?_r=1. Accessed November 25, 2013.
22. Kramer W, Cahn N. *Finding Our Families: A First-of-Its-Kind Book for Donor-Conceived People and Their Families.* New York, NY: Avery Trade; 2013.
23. The Organ Procurement and Transplantation Network. Guidance for the informed consent of living donors. http://optn.transplant.hrsa.gov/ContentDocuments/Guidance_InformedConsentLiving_Donors.pdf. Accessed September 8, 2013.
24. Krawiec KD. Sunny samaritans and egomaniacs: price-fixing in the gamete market. *Law Contemp Probl.* 2009;72(3):59-90.
25. Skillern A, Cedars M, Huddleston H. Egg Donor Informed Consent Tool (EDICT): development and validation of a new informed consent tool for oocyte donors. *Fertil Steril.* 2013;99(6):1733-1738.
26. Skillern, Cedars, Huddleston, 1734.
27. ASRM/SART, 58.
28. Schneider J. Fatal colon cancer in a young egg donor: a physician mother's call for follow-up and research on the long-term risks of ovarian stimulation. *Fertil Steril.* 2008;90(5):2016.e1-e5.
29. Kramer W, Schneider J, Schultz N. US oocyte donors: a retrospective study of medical and psychosocial issues. *Hum Reprod.* 2009;24(12):3144-3149.
30. Schaefer GO, Sinaii N, Grady C. Informing egg donors of the potential for embryonic research: a survey of consent forms from US in vitro fertilization clinics. *Fertil Steril.* 2012;97(2):427-433.
31. ASRM/SART, 55.
32. Practice Committee of the American Society for Reproductive Medicine. Repetitive oocyte donation. *Fertil Steril.* 2008;90(5 Suppl):S194-S195.

33. Campo-Englestein L. Why we need oversight for egg donation. *Bioethics Today*. June 17, 2013. <http://www.amc.edu/bioethicsblog/post.cfm/why-we-need-oversight-for-egg-donation>. Accessed November 22, 2013.
34. ASRM/SART, 53, 58.
35. Levine AD. Self-regulation, compensation, and the ethical recruitment of oocyte donors. *Hastings Cent Rep*. 2010;40(2):25-36.
36. Alberta HB, Berry RM, Levine AD. Risk disclosure and the recruitment of oocyte donors: are advertisers telling the full story? [draft].
37. Alberta HB, Berry RM, Levine AD. Compliance with donor age recommendations in oocyte donor recruitment advertisements in the USA. *Reprod Biomed Online*. 2013;26(4):400-405.

Naomi Cahn, JD, is the Harold H. Greene Professor of Law at George Washington University in Washington, DC, and the co-author of *Finding Our Families: A First-of-its-Kind Book for Donor-Conceived People and their Families* (2013).

Jennifer Collins, JD, is the vice provost at Wake Forest University and a professor at Wake Forest Law School in Winston-Salem, North Carolina. She is the co-author of *Privilege or Punish: Criminal Justice and the Challenge of Family Ties* (2009).

Acknowledgments

Our thanks to June Carbone, Jodi LeBolt, Kimberly Krawiec, Ana Iltis, Jody Madeira, and Aaron Levine for inspiration and comments.

Related in VM

[Egg-Donor Price Fixing and *Kamakahi v. American Society for Reproductive Medicine*](#), January 2014

[AMA Code of Medical Ethics' Opinions on Assisted Reproductive Technology](#), January 2014

Disclaimer

The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental.

The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.

Copyright 2014 American Medical Association. All rights reserved.

Virtual Mentor

American Medical Association Journal of Ethics
January 2014, Volume 16, Number 1: 57-62.

POLICY FORUM

Egg-Donor Price Fixing and *Kamakahi v. American Society for Reproductive Medicine*

Kimberly D. Krawiec, JD

In April 2011, Lindsay Kamakahi caused an international stir by suing the American Society for Reproductive Medicine (ASRM), the Society for Assisted Reproductive Technology (SART), all SART-member fertility clinics, and all egg agencies that agreed to abide by the ASRM-SART egg donor compensation guidelines on behalf of herself and other oocyte donors [1]. The suit challenged the ASRM-SART oocyte-donor compensation guidelines, which limit payments to egg donors to \$5,000 (\$10,000 under special circumstances), as an illegal price-fixing agreement in violation of United States antitrust laws. These laws prohibit business practices that unreasonably restrict competition and result in higher consumer prices for products and services. In March 2013, the court denied the defendants' motion to dismiss the case, thus paving the way for the litigation to proceed [2].

Kamakahi's suit, despite the hoopla accompanying it, is in many ways unexceptional, alleging a fairly straightforward violation of the Sherman Act's prohibition against contracts, conspiracies, and combinations in restraint of trade [3]. But oocytes are hardly the common stuff of Sherman Act claims, and the application of federal antitrust law in such a new and unusual setting was bound to draw substantial attention [4].

The ensuing debate revealed many misconceptions about oocyte donation, the allegations in the case, and antitrust law's application to the ASRM-SART oocyte donor compensation guidelines, some of which I aim to dispel in this article. For example, ASRM and others have defended the guidelines as a means to ensure low-cost fertility services for their patients, a contention that, as I will later explain, is flatly at odds with basic economic theory and evidence. Others, including ASRM representatives, have derided the suit as frivolous, an allegation that should be put to rest by the court's recent denial of the defendants' motion to dismiss [5]. Although the case is still in the early stages and the outcome remains to be seen, the complaint is far from frivolous.

The ASRM Guidelines

ASRM and SART have taken the position since at least 1994 that "reasonable" compensation to gamete donors is ethically permissible. It was not until 2000, however, in the wake of increasing public attention to rising rates of egg-donor compensation, that ASRM specifically defined "reasonable" and began formal efforts to cap egg-donor compensation [6].

A 2000 report of the ASRM Ethics Committee on financial incentives for egg donors stated that “payments to women providing oocytes should be fair and not so substantial that they become undue inducements that will lead donors to discount risks” [7] and analogized the egg-donation process to the sperm-donation process. A prior study had concluded that sperm donors earned an hourly average of \$60 to \$75 in 2000 and estimated that egg donors spend 56 hours in a medical setting per donation cycle [8]. If egg donors were paid the same hourly rate as sperm donors, the ASRM report concluded, then a payment amount of \$3,360 to \$4,200 per egg-donation cycle would be reasonable.

According to ASRM, however, because egg donation involves a time commitment, risk, and discomfort not associated with sperm donation, egg donors deserve higher amounts. The report concluded that “although there is no consensus on the precise payment that oocyte donors should receive, at this time sums of \$5,000 or more require justification and sums above \$10,000 go beyond what is appropriate” [7]. In 2007, ASRM issued new guidelines that restated these amounts and rationales [9]. The amounts have not been increased since ASRM adopted them more than 10 years ago.

The Sherman Act Challenge

The Kamakahi complaint alleges that the ASRM-SART guidelines, as a naked price-fixing agreement, are a *per se* violation of the Sherman Act, meaning that the guidelines are so injurious to the public that they should be conclusively presumed illegal without inquiry into whether competition is actually reduced or consumers are actually harmed. Agreements among competitors to fix prices have long been considered *per se* illegal under section 1 of the Sherman Act, due to their perceived negative effects on competition [10]. This is true of both agreements to fix output prices at some maximum (sellers’ cartel agreements) and agreements to fix input prices at some minimum (buyers’ cartel agreements, such as the ASRM-SART guidelines). Classifying an agreement as a *per se* violation dispenses with the need to inquire into market structure, the market power of the violators, or the anticompetitive effects of the behavior. Under a *per se* analysis, therefore, the ASRM guidelines would be conclusively presumed illegal [10]. The court’s denial of ASRM’s motion to dismiss Kamakahi’s *per se* claim, therefore, is a substantial preliminary victory for the plaintiffs.

Kamakahi also contends that the guidelines violate the Sherman Act under a rule-of-reason analysis, which Courts sometimes apply to alleged anticompetitive behavior by nonprofit or professional associations when the same conduct would be considered *per se* illegal if carried out by business organizations. Such judicial deference is not explicitly a product of the organizational form or nonprofit status of the defendants, but rather of a perception that, in many such cases, the anticompetitive effects of the agreement or the intentions of the alleged violators are not immediately discernible [11, 12]. However, the negative economic impacts of the ASRM-SART guidelines are readily apparent, and the claimed procompetitive

benefits are highly contestable. As a result, the ASRM guidelines are problematic even under a rule-of-reason analysis.

Effects and Purposes of the ASRM Guidelines

ASRM defends the guidelines as a means of keeping the price of fertility services low, thus benefiting fertility treatment patients [13]. But the guidelines plainly produce the same risks of anticompetitive effects present in any other collusive buyers' agreement: product scarcity, which deprives fertility treatment patients of the full range and number of oocytes that would be available to them in a free market. This scarcity drives up the price consumers are willing to pay for the bundle of goods and services that will result in the creation of an embryo for implantation. Because the price of a necessary input—the oocyte—has been capped, however, the excess that consumers are willing to pay (termed “rents” by economists) can be captured by the providers of fertility services [14]. Consumers are thus typically harmed, not helped, by successful price-fixing agreements, including the ASRM-SART guidelines, to the extent the agreements are effective.

ASRM asserts procompetitive justifications in defense of the guidelines, contending, for example, that they protect the health and safety of both egg donors and recipients of assisted reproduction services, by encouraging donors to honestly disclose medical and social histories—a goal that would be undermined by high payments. In addition, the defense argues that egg-donor compensation rates dictated by the marketplace, rather than by the guidelines, risk the exploitation and undue inducement of egg donors and may commodify human life and particular genetic traits. These alleged effects of the guidelines are procompetitive because enhancing the safety and social acceptability of the egg donation process may encourage women to donate eggs and help promote the view among those affected by infertility that the use of donated oocytes is a safe and responsible treatment, thus improving the market [13].

Assuming that safety, coercion, and commodification concerns could, in the absence of the guidelines, undermine the market for fertility services and assuming further that it is possible to structure financial incentives to egg donors in a manner that alleviates those concerns while compensating oocyte donors for the time, effort, and health risks associated with the procedure (as opposed to banning payments to oocyte donors altogether), there is no evidence that the ASRM-SART guidelines strike that balance. In fact, there is no indication that ASRM even considered such factors when setting standards for egg donor compensation. As previously discussed, ASRM used sperm donation as a benchmark and then stated that the additional time, risk, and discomfort experienced by egg donors justified an additional payment—up to \$5,000 and no more—without explaining where that amount came from, why it might represent a reasonable compensation for the additional burdens that the committee agreed egg donors faced, or how this limit addressed the safety, coercion, and commodification risks that the committee contended the free market poses.

Moreover, the ability of any payment to coerce or induce action depends on the recipient's financial need. Accordingly, setting egg-donor compensation caps without reference to the potential donor's economic status does not effectively address financial coercion and undue inducement concerns. Ironically, the most likely effect of the guidelines is to drive from the market those donors with the highest opportunity costs, who tend to be better educated and of a higher socioeconomic status. These donors are arguably in a better position to evaluate the risks of egg donation against the monetary benefits, rendering them less susceptible to any "coercive" effects of monetary compensation, because they are more likely to have other income opportunities from which to choose.

In addition, there may be less draconian safeguards that could address many of these concerns more effectively and without the accompanying anticompetitive effects. For example, mandating egg-donor advocates, egg-donor screening, and other measures might promote the informed and voluntary nature of each donation and eliminate donors who appear financially needy or who have not carefully weighed the risks of donation. Similarly, the guidelines' existing prohibitions on compensation linked to particular donor traits, such as race, ethnicity, or intelligence measures, might guard against some eugenics and commodification effects, though recent research suggests this guidance is widely ignored [15, 16].

Finally, some commenters have made a particularly odd argument—that the guidelines are appropriate and not illegal because they are unenforced and ineffective [17, 18]. This contention raises the question: if the compensation guidelines are not successfully controlling oocyte donor compensation, then why do they exist? What possible purpose might be served by ineffective and unenforced egg-donor compensation caps? The most likely possibility is a desire to avoid industry controversy, including controversy related to oocyte-donor compensation. Negative public attitudes toward fertility treatments threaten to prompt into action state and federal lawmakers who, to date, have been largely willing to rely on industry self-regulation of fertility services. It is thus possible that industry attempts to control egg-donor compensation are prompted by a desire to forestall government intervention, either by attempting to address perceived problems (albeit without success) or by providing the appearance of addressing such problems.

ASRM thus faces a dilemma. To acknowledge that the guidelines are ineffective is to concede that they fail to further the alleged safety, anticoercion, and anticommodification goals that form the ASRM defense and to concede that industry self-regulation has failed. To defend the effectiveness of the guidelines is to concede that they reduce egg-donor compensation below the levels that would operate in a market free of such restraints, thus assisting the plaintiffs' case.

Conclusion

Kamakahi v. ASRM is still in the early stages of litigation, and both the plaintiffs and defendants have hurdles to overcome before a decision is reached on the merits of the case. For example, the court will need to evaluate the procompetitive arguments

raised by the defense and, should the court decide to proceed under a rule-of-reason analysis, the plaintiffs will need to prove elements such as the market power of the defendants and the anticompetitive effects of the guidelines that would be presumed under a *per se* analysis. But the suit is an important one that could signal a change in public attitudes about the propriety of mixing money with motherhood. It should—and will—be closely watched.

References

1. *Lindsay Kamakahi v American Society for Reproductive Medicine*, class action complaint, case no. 3:11-CV-1781 (N D Cal, filed April 12, 2011).
2. *Lindsay Kamakahi v American Society for Reproductive Medicine*, order denying motion to dismiss, case no. 3:11-CV-1781. (N D Cal, decided March 29, 2013).
3. Trusts, etc., in restraint of trade illegal; penalty. 15 USC sec 1 (2006).
4. The market in human eggs: underpaid ovaries. *Economist*. April 20, 2011. <http://www.economist.com/node/18586864>. Accessed November 23, 2013.
5. Fertility Authority. Lawsuit alleges price fixing on egg donation. <http://www.fertilityauthority.com/articles/lawsuit-alleges-price-fixing-egg-donation>. Accessed November 6, 2013. Article quotes ASRM Director of Public Affairs Sean Tipton as saying, “This lawsuit is frivolous, and we fully expect the court will treat it as such.”
6. Ethics Committee of the American Society for Reproductive Medicine. Financial incentives in recruitment of oocyte donors. *Fertil Steril*. 2000;74(2):216.
7. Ethics Committee of ASRM, 219.
8. Seibel MM, Kiessling A. Compensating egg donors: equal pay for equal time? *N Engl J Med*. 1993;328(10):737.
9. Ethics Committee of the American Society for Reproductive Medicine. Financial compensation of oocyte donors. *Fertil Steril*. 2007;88(2):305, 308.
10. *National Society of Professional Engineers v United States*, 435 US 679, 692 (1978).
11. *Arizona v Maricopa County Medical Society*, 457 US 332, 342-57 (1982).
12. *Goldfarb v Va. State Bar*, 423 US 886 (1975).
13. *Lindsay Kamakahi v American Society for Reproductive Medicine*, US Dist Ct, N Dist Cal. Defendant’s motion to dismiss plaintiff’s first amended class action complaint. Case no. 3:11-CV-1781:16 (filed July 15, 2011).
14. Krawiec KD. Sunny samaritans and egomaniacs: price-fixing in the gamete market. *Law Contemp Probl*. 2009;72(3):59-90.
15. Tabarrok A. The oocyte cartel. *Marginal Revolution*. June 17, 2013. <http://marginalrevolution.com/marginalrevolution/2013/06/the-oocyte-cartel.html>. Accessed November 25, 2013.
16. Levine AD. Self-regulation, compensation, and the ethical recruitment of oocyte donors. *Hastings Cent Rep*. 2010;40(2):25-36.
17. Shanks P. Trust-busting in the baby business? *Biopolitical Times*. May 5, 2011. <http://www.biopoliticaltimes.org/article.php/United%20Kingdom:%20Human-Animal%20Hybrid%20EmbryosApr%202008><http://www.>

- geneticsandsociety.org/article.php?id=5697. Accessed November 23, 2013.
18. Vorzimer A. A law professor comments on the egg donor class action lawsuit. *Spin Doctor*. April 19, 2011.
<http://www.eggdonor.com/blog/2011/04/19/law-professor-comments-egg-donor-class-action-lawsuit/>. Accessed November 23, 2013.

Kimberly D. Krawiec, JD, is the Kathrine Robinson Everett Professor of Law and a senior fellow at the Kenan Institute for Ethics at Duke University in Durham, North Carolina.

Related in VM

[Fully Informed Consent for Prospective Egg Donors](#), January 2014

[AMA Code of Medical Ethics' Opinions on Assisted Reproductive Technology](#), January 2014

The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.

Copyright 2014 American Medical Association. All rights reserved.

Virtual Mentor

American Medical Association Journal of Ethics
January 2014, Volume 16, Number 1: 63-69.

MEDICINE AND SOCIETY

Who Pays? Mandated Insurance Coverage for Assisted Reproductive Technology

Katie Falloon and Philip M. Rosoff, MD, MA

Bearing and raising children has been considered central to family life for as long as humans have been humans [1]. While adoption had been primarily a mechanism to secure a home for a child, it also offered a way for adults to establish a family. For couples unable to bear their own children, the stigma of barrenness could sometimes be relieved by adoption. Until relatively recently, this was accomplished by bringing orphans into the homes of relatives [2]. Indeed, the practice of adoption has ancient roots—among the 282 laws in the Code of the Hammurabi, one of the oldest legal documents in the world, are provisions regarding adoptions [3]. Though the modern conception of adoption, in which the best interests of the child are considered paramount, was much slower to develop (the first modern adoption laws weren't passed until 1851, in Massachusetts) [4], for about as long as people have been able to write, we've considered adoption something worth doing and writing about [2, 5].

In 1978, however, with the birth of the first test tube baby [6], another option for the childless emerged—with the help of in vitro fertilization (IVF), infertile couples could have a child genetically related to them—and the field of assisted reproductive technology (ART) was thus created [7]. During the last 35 years more than 5 million babies have been born through ART [7].

As with most technologically sophisticated medical interventions, ART isn't cheap. While there are many examples of treatments that are more costly—depending on the novelty of the chemotherapy drug, a cancer patient can rack up bills in the hundreds of thousands—the average cost per cycle for IVF, around \$12,500 [8], is far from insignificant. The total costs for actually achieving a live birth are even higher—estimates range from around \$66,000 to \$114,000—because the implantation success rate per cycle can range from 4 to 36 percent depending on the woman's age and other factors [9-11]. Currently, only about a third of states have mandated insurance coverage of infertility treatment, but the vast majority of health insurance plans in other states do not offer coverage; hence, most people pay out of pocket [12]. Furthermore, Medicaid does not pay for ART anywhere in the US [13].

Arguments in Favor of Mandated Insurance Coverage for ART

There are many reasons why mandated insurance coverage is appealing and why it would be desirable for this technology to be available to all those who want it. Infertility affects approximately 10 percent of couples at any given time worldwide, and the high cost of ART is a major barrier to its use [8]. National survey data

indicate that insurance coverage and finances are the main factors in whether or not a woman seeks medical help to become pregnant [14, 15]. There is an 11 percent chance that low-income women will pursue ART, while high-income women are almost twice as likely to do so [15]. It is therefore not surprising that those who have access to ART are wealthier and have had more education than the average person [14, 16].

Though unsurprising, this fact is morally problematic. If genetic reproduction is broadly believed to be of truly fundamental importance, then access to IVF in a just society would depend on need, not on morally irrelevant characteristics like wealth or education status [17, 18]. The service would be available to everyone who could medically benefit from it, rather than only to those who could pay for it. The idea behind the insurance mandate is thus a logical one—lower costs for ART services so that use of the technology would be based less on financial status. Use of ART is higher in states where insurance coverage for it is mandatory, suggesting that mandates are having the desired effect [15, 19].

A number of scholars have also argued that mandating insurance coverage reduces the risks associated with ART and, in the long run, cuts costs that arise from the incentive infertility clinics have to increase the live-birth rate by implanting large numbers of embryos per IVF cycle [8, 15, 20]. Successful implantation of multiple embryos means the woman requires more monitoring during pregnancy and is more likely to have a preterm delivery, while the infants are at increased risk for complications ranging from cerebral palsy to neurological problems [21]. It is estimated that these complications may cost up to \$26.2 billion per year [17, 20]. In 2006, the American Society for Reproductive Medicine (ASRM) enacted guidelines encouraging single-embryo transfer for those with a favorable prognosis and transferring no more than two embryos in women younger than 35 years old and no more than three in those 35-37 years old, yet the rates of multiple births continue to climb [21, 22]. The number of triplets or higher-order multiples has risen more than 400 percent since 1980, mostly because of increasing use of fertility treatments [22]. Since insurance mandates lower out-of-pocket expenses, they diminish this incentive to “make the most” of each cycle, and in states with insurance mandates fewer embryos are transferred each cycle [20]. Without cost significantly influencing their decisions, couples can focus on what is healthiest rather than what is most affordable, and doctors face less pressure from their patients to stray from ASRM guidelines, with a resulting decrease in multiple births [15, 21, 23].

Some bioethicists have convincingly argued that infertility is a medical condition that deserves remedy. For example, Josephine Johnston and Michael Gusmano of the Hastings Center argue that, while infertility may not kill a patient, neither do countless other medical conditions that nevertheless receive insurance coverage [21]. They further argue that fertility treatments are not “lifestyle medicine” akin to elective cosmetic surgery, as they are sometimes characterized, but rather a medical treatment because they relieve the suffering imposed by infertility [21]. But the suffering experienced by the infertile must be greater and qualitatively different from

that imposed by simply not being in the pregnant state and giving birth; there must be some features about raising a genetically related child that distinguish it in an elemental way from other means of creating a family.

Infertility certainly does impact quality of life—one study found that 50 percent of women and 15 percent of men rated infertility as “the most upsetting events of their lives” [21]; another found that infertile women had psychological symptom scores similar to those of people suffering from diseases like cancer [24]; and yet another found that infertile men experienced anxiety and depression [25]. In 2008, the World Health Organization joined the ASRM in classifying infertility as a disease [11]. And, in *Bragdon v. Abbot*, the US Supreme Court ruled that the inability to reproduce was a disability and thus afforded the protections of the Americans with Disabilities Act [11, 26].

Would Mandated Insurance Coverage Achieve These Goals?

Though the arguments that infertility is a disease have merit, for a variety of troubling reasons we believe they have failed to prove that insurance coverage should be mandated to address this issue. Analysis of access to and utilization of ART in states with insurance mandates reveals major social and ethnic disparities, and, while mandating coverage in select states did make ART more broadly available to those with health insurance, it did not make the distribution of ART more equitable. For instance, in Massachusetts, one state that enacted an insurance mandate, the majority of people accessing services are still Caucasian, highly educated, and relatively well-off [17, 27]. Even with insurance mandates, then, ART services remain effectively unavailable to the poor and uninsured, a population that has the same or greater incidence and prevalence of infertility than their more financially advantaged peers [28].

In addition, health insurance is expensive, and with the cost of medical care steadily rising, it is important to consider carefully where funds should go and whether coverage of ART should be given priority over other needed treatments. The newly enacted Affordable Care Act (ACA) makes no explicit recommendations about whether or not infertility treatments should be covered, and states that already mandate coverage for ART services may choose to include them as an essential health benefit [29]. While some believe that coverage for ART undermines the idea of affordable basic care at the heart of the ACA, others argue that including infertility as an essential health benefit will be cost effective [29].

But arguments about cost effectiveness remain unconvincing, given the complexities of both the technology and the outcomes being measured (pregnancy as distinct from live birth and a baby who makes it home from the hospital) [17]. The decrease in multiple births in states with mandated coverage for ART may reduce long-term costs, but it has been suggested that the reduction might be due to the fact that people with poorer prognoses undergo treatment in those states, lowering the number of babies born whether or not rates of embryo transfer are affected [20, 30]. Moreover, stricter regulation of ART protocols and more stringent enforcement of ASRM

guidelines could prove just as effective at limiting the number of embryos implanted as mandating insurance coverage.

Is ART Legitimately Preferable to Adoption?

To make a convincing case for government-mandated coverage, one would have to argue that medicine (through ART) offers a means to parenthood that is superior to the nonmedical means (through adoption).

Clearly, some infertile couples feel that ART is preferable—if they didn't, there wouldn't be such demand for the service—and it is worth exploring why. Yet three of the reasons given by the infertile couples surveyed by van Balen and colleagues about their preference for ART over adoption—not wanting children with behavioral problems, reluctance to fill out the paperwork adoption requires, and the fear that they will be unable to adopt successfully [31]—are misguided. Genetically related children may have behavioral problems too, and, while adoption may require paperwork, medical treatment of infertility involves a great investment of time and emotional energy, which can be just as taxing as filling out forms, if not more so. Moreover, adoption boasts a “success” rate much higher than the approximately 4 to 40 percent chance (depending on age) that a cycle of IVF will result in a live birth [10]. Rather than making ART superior, the low success rate and substantial fiscal, emotional, and physical investment required make ART in many ways inferior to adoption.

Among the other reasons for preferring ART offered by couples in van Balen's and colleagues' survey were the desire for genetically related children and concerns about cultural differences [31]. We do not consider these to be convincing ethical claims for the superiority of ART. If the goal is allowing infertile couples to become parents, and that is the standard on which we judge both services, then the fact that some people value genetic and cultural relatedness does not conclusively make ART a better means for becoming parents or obligate society to make it possible for them to have genetically related children by mandating insurance coverage for ART.

Moreover, if we choose to consider which option is better for society as a whole (rather than for a given infertile couple) we could reasonably argue that adoption is the better choice. There are large numbers of children without homes, children whose adoption would, in most cases, improve their lives [11]. In addition to being more accessible and affordable than ART, adoption brings with it the social good of giving a child who is without parents a chance to grow up in a loving home and reduces governmental expenditures for that child's support [8].

The State's Role

It is unfortunate that some couples are able to carry and give birth to genetically related children while others are unable to do so and must live with the accompanying heartbreak. It is also unfair that some couples can afford to pay to have genetically related children while others cannot. Norman Daniels has argued that the state should allow people to pursue “the array of life plans reasonable

persons are likely to develop for themselves” [32], which includes having biological children. But though the world in which we live is devastatingly imperfect and many suffer from bad luck in the “natural lottery” [32], it is hard to find moral justification for a state responsibility to promote access to having biologically related children in particular. While Article 16 of the UN Declaration of Human Rights states that “men and women of full age, without any limitation due to race, nationality, or religion, have the right to marry and have a family” [33], it does not obligate the state to help people achieve these goals beyond merely refraining from preventing them. Nor does the Declaration of Human Rights mention a right to genetically related children with cultural backgrounds similar to those of their parents. In our view, a reasonably just state should offer coverage for medical treatments for which alternatives do not exist, and ART does not meet that criterion—adoption remains an extremely good alternative.

Conclusion

Ultimately, the loss and hardship of infertility are undeniable, and the desire to help people suffering from that loss is a worthwhile one. Parenthood is, and should be, available to all, but a certain route to parenthood is not. Mandated insurance coverage for ART shouldn't be either.

References

1. Narvaez D. The emotional foundations of high moral intelligence. *New Dir Child Adolesc Dev.* 2010;2010(129):77-94.
2. Zamostny KP, O'Brien KM, Baden A L, Wiley MO. (2003). The practice of adoption history, trends, and social context. *Couns Psychol.* 2003;31:651-678.
3. Horne C, Johns C, King LW. Ancient history sourcebook: Code of Hammurabi c. 1780 BCE. Fordham University. <http://www.fordham.edu/halsall/ancient/hamcode.asp>. Accessed September 25, 2013.
4. Massachusetts Trial Court Law Libraries. Massachusetts law about adoption. <http://www.lawlib.state.ma.us/subject/about/adoption.html>. Accessed October 19 2013.
5. Hawes JM. Creating new families: this history of adoption in the United States. *Rev Am Hist.* 2004;32(1):90-96.
6. The world's first test tube baby. *American Experience.* PBS. <http://www.pbs.org/wgbh/americanexperience/features/general-article/babies-worlds-first/>. Accessed November 10, 2013.
7. Five million babies born with help of assisted reproductive technologies [press release]. Washington, DC: American Society of Reproductive Medicine Office of Public Affairs; October 14, 2013. http://www.asrm.org/Five_Million_Babies_Born_with_Help_of_Assisted_Reproductive_Technologies/. Accessed October 15, 2013.
8. Chambers G, Hoang V, Zhu R, Illingworth P. A reduction in public funding for fertility treatment--an econometric analysis of access to treatment and savings to government. *BMC Health Serv Res.* 2012;12(1):142.

- <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3464128/pdf/1472-6963-12-142.pdf> Accessed December 1, 2013.
9. Neumann PJ, Gharib SD, Weinstein MC. The cost of a successful delivery with in vitro fertilization. *New Engl J Med.* 1994;331(4):239-243.
 10. Society for Assisted Reproductive Technologies. Clinic summary report 2011.
https://www.sartcorsonline.com/rptCSR_PublicMultYear.aspx?ClinicPKID=0. Accessed October 18, 2013.
 11. Cohen IG, Chen DL. Trading-off reproductive technology and adoption: does subsidizing IVF decrease adoption rates and should it matter? *Minn Law Rev.* 2010;(95):485.
 12. Jain T, Harlow BL, Hornstein MD. Insurance coverage and outcomes of in vitro fertilization. *N Engl J Med.* 2002;347(9):661-666.
 13. National Council on Disability. Chapter 11: Assisted reproductive technologies. *Rocking the Cradle: Ensuring the Rights of Parents with Disabilities and Their Children.*
<http://www.ncd.gov/publications/2012/Sep272012/Ch11>. Accessed October 11, 2013.
 14. Farley Ordozensky Staniec J, Webb NJ. Utilization of infertility services: how much does money matter? *Health Serv Res.* 2007;42(3 part 1):971-989.
 15. Connolly M, Ledger W, Postma M. Economics of assisted reproduction: access to fertility treatments and valuing live births in economic terms. *Hum Fertil.* 2010;13(1):13-18.
 16. Stephen EH, Chandra A. Use of infertility services in the United States: 1995. *Fam Plann Perspect.* 2000;32(3):132-137.
 17. Mladovsky P, Sorenson C. Public financing of IVF: a review of policy rationales. *Health Care Anal.* 2010;18(2):113-128.
 18. Culyer AJ. Equity—some theory and its policy implications. *J Med Ethics.* 2001;27(4):275-283.
 19. Hammoud AO, Gibson M, Stanford J, White G, Carrell DT, Peterson M. In vitro fertilization availability and utilization in the United States: a study of demographic, social, and economic factors. *Fertil Steril.* 2009;91(5):1630-1635.
 20. Martin JR, Bromer JG, Sakkas D, Patrizio P. Insurance coverage and in vitro fertilization outcomes: a U.S. perspective. *Fertil Steril.* 2011;95(3):964-969.
 21. Johnston J, Gusmano MK. Why we should all pay for fertility treatment: an argument from ethics and policy. *Hastings Cent Rep.* 2013;43(2):18-21.
 22. Practice Committee of American Society for Reproductive Medicine; Practice Committee of Society for Assisted Reproductive Technology. Criteria for number of embryos to transfer: a committee opinion. *Fertil Steril.* 2013;99(1):44-46. Accessed November 19, 2013.
 23. Sunde A. Europe's declining population and the contribution of ART. *Pharm Policy Law.* 2007;9:79-89.
 24. Domar AD, Zuttermeister PC, Friedman R. The psychological impact of infertility: a comparison with patients with other medical conditions. *J Psychosom Obstet Gynaecol.* 1993;14 Suppl:45-52.

25. Freeman EW, Boxer AS, Rickels K, Tureck R, Mastroianni L Jr. Psychological evaluation and support in a program of in vitro fertilization and embryo transfer. *Fertil Steril*. 1985;43(1):48-53.
26. *Bragdon v Abbott*, 524 US 624, 629; 118 S Ct 2196 (1998).
27. Jain T, Hornstein MD. Disparities in access to infertility services in a state with mandated insurance coverage. *Fertil Steril*. 2005;84(1):221-223.
28. Chandra A, Copen C, Stephen E. Infertility and impaired fecundity in the United States, 1982-2010: data from the National Survey of Family Growth. *National Health Stat Rep*. 2013;67:1-19.
29. Omurtag K, Adamson GD. The Affordable Care Act's impact on fertility care. *Fertil Steril*. 2013;99(3):652-655.
30. Henne MB, Bundorf MK. Insurance mandates and trends in infertility treatments. *Fertil Steril*. 2008;89(1):66-73.
31. van Balen F, Verdurmen J, Ketting E. Choices and motivations of infertile couples. *Patient Educ Couns*. 1997;31(1):19-27.
32. Daniels N. *Just Health: Meeting Health Needs Fairly*. New York, NY: Cambridge University Press; 2008.
33. United Nations. Universal Declaration of Human Rights. <http://www.un.org/en/documents/udhr/index.shtml#a16d>. Accessed October 10, 2013.

Katie Falloon is a second-year medical student at Duke University School of Medicine in Durham, North Carolina. She graduated magna cum laude from Yale University with a degree in English.

Philip M. Rosoff, MD, MA, is a professor of pediatrics (oncology) and medicine at the Duke University School of Medicine and Duke University Medical Center in Durham, North Carolina. He is also chair of the center's ethics committee and a member of the Trent Center for Bioethics, Humanities and History of Medicine. His research interests and scholarly work are in the area of medical resource allocation, especially rationing. His book *Rationing Is Not a Four-Letter Word: Setting Limits on Healthcare* will be published in spring 2014 by MIT Press.

Related in VM

[AMA Code of Medical Ethics' Opinions on Assisted Reproductive Technology](#), January 2014

The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.

Copyright 2014 American Medical Association. All rights reserved.

Virtual Mentor

American Medical Association Journal of Ethics
January 2014, Volume 16, Number 1: 70-85.

Suggested Readings and Resources

Alberta HB, Berry RM, Levine AD. Compliance with donor age recommendations in oocyte donor recruitment advertisements in the USA. *Reprod Biomed Online*. 2013;26(4):400-405.

Alberta HB, Berry RM, Levine AD. Risk disclosure and the recruitment of oocyte donors: are advertisers telling the full story? [draft].

Almeling R. *Sex Cells: The Medical Market for Eggs and Sperm*. Berkeley: University of California Press; 2011.

American College of Obstetricians and Gynecologists Committee on Ethics. ACOG committee opinion no. 397: surrogate motherhood. http://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Ethics/Surrogate_Motherhood. Accessed November 19, 2013.

American Medical Association. Opinion 5.05 Confidentiality. *Code of Medical Ethics*. Chicago, IL: American Medical Association; 2006. <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion505.page>. Accessed November 20, 2013.

American Medical Association. Opinion 8.08 Informed consent. *Code of Medical Ethics*. Chicago, IL: American Medical Association; 2006. <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion808.page>. Accessed November 20, 2013.

American Medical Association. Opinion 8.082 Withholding information from patients. *Code of Medical Ethics*. Chicago, IL: American Medical Association; 2006. <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8082.page>. Accessed November 20, 2013.

American Society for Reproductive Medicine. State infertility insurance laws. <http://www.asrm.org/detail.aspx?id=2850>. Accessed November 18, 2013.

Arizona v Maricopa County Medical Society, 457 US 332, 342-57 (1982).

Attain IVF. What do the Attain IVF programs include? <http://attainivf.attainfertility.com/attain-ivf-includes>. Accessed November 18, 2013.

Baran A, Pannor R. *Lethal Secrets*. New York, NY: Amistad; 1993.

Belkin L. An egg donor's tale. *Motherlode*. *New York Times*. January 10, 2011. http://parenting.blogs.nytimes.com/2011/01/10/an-egg-donors-tale/?_r=1. Accessed November 25, 2013.

Berg JS, Khoury MJ, Evans JP. Deploying whole genome sequencing in clinical practice and public health: meeting the challenge one bin at a time. *Genet Med*. 2011;13(6):499-504.

Bernhardt BA, Soucier D, Hanson K, Savage MS, Jackson L, Wapner RJ. Women's experiences receiving abnormal prenatal chromosomal microarray testing results. *Genet Med*. 2013;15(2):139-145.

Blyth E. Guidelines for infertility counselling in different countries: is there an emerging trend? *Hum Reprod*. 2012;27(7):2046-2057.

Boivin J, Appleton TC, Baetens P, et al. Guidelines for counselling in infertility: outline version. *Hum Reprod*. 2001;16(6):1301-1304.

Bos H, van Balen F. Children of the new reproductive technologies: social and genetic parenthood. *Patient Educ Couns*. 2010;81(3):429-435.

Bos H, van Balen F. Planned gay father families in a kinship arrangement. Paper presented at: International Conference on LGBT Human Rights; 2009; Copenhagen, Denmark.

Bragdon v Abbott, 524 US 624, 629; 118 S Ct 2196 (1998).

Brewaeys A, Ponjaert I, van Hall EV, Golombok S. Donor insemination: child development and family functioning in lesbian mother families. *Hum Reprod*. 1997;12(6):1349-1359.

Brinsden PR. Gestational surrogacy. *Hum Reprod Update*. 2003;9(5):483-491.

Campo-Englestein L. Why we need oversight for egg donation. *Bioethics Today*. June 17, 2013. <http://www.amc.edu/bioethicsblog/post.cfm/why-we-need-oversight-for-egg-donation>. Accessed November 22, 2013.

Centers for Medicare and Medicaid Services. Glossary. Essential health benefits. <https://www.healthcare.gov/glossary/essential-health-benefits/>. Accessed November 18, 2013.

Centers for Medicare and Medicaid Services Center for Consumer Information and Insurance Oversight (CCIIO). Connecticut EHB benchmark plan. <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/connecticut-ehb-benchmark-plan.pdf>. Accessed November 19, 2013.

CCIIO. Additional Information on proposed state essential benefits benchmark plans. <http://www.cms.gov/cciiio/resources/data-resources/ehb.html>.

CCIIO. Hawaii EHB benchmark plan. <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/hawaii-ehb-benchmark-plan.pdf>. Accessed November 19, 2013.

CCIIO. Illinois EHB benchmark plan. <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/illinois-ehb-benchmark-plan.pdf>. Accessed November 19, 2013.

CCIIO. Massachusetts EHB benchmark plan. <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/massachusetts-ehb-benchmark-plan.pdf>. Accessed November 19, 2013.

CCIIO. Michigan EHB benchmark plan. <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/michigan-ehb-benchmark-plan.pdf>. Accessed November 19, 2013.

CCIIO. Nevada EHB benchmark plan. <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/nevada-ehb-benchmark-plan.pdf>. Accessed November 19, 2013.

CCIIO. Rhode Island EHB benchmark plan. <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/rhode-island-ehb-benchmark-plan.pdf>. Accessed November 19, 2013.

CCIIO. Texas EHB benchmark plan. <http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/texas-ehb-benchmark-plan.pdf>.

Center for Reproductive Medicine of New Mexico website. <http://infertility-ivf.com/>. Accessed November 21, 2013.

Centers for Disease Control and Prevention Assisted reproductive technology: 2010 national summary report. http://www.cdc.gov/art/ART2010/PDFs/ART_2010_National_Summary_Report.pdf. Accessed November 20, 2013.

Centers for Disease Control and Prevention. Assisted reproductive technology (ART): commonly asked questions about the US ART clinic reporting system. <http://www.cdc.gov/art/ART2010/faq.htm#2>. Accessed September 8, 2013.

Centers for Disease Control and Prevention. Section 4: ART cycles using donor eggs. In: *Assisted Reproductive Technology (ART) 2010 National Summary Report*. <http://www.cdc.gov/art/ART2010/section4.htm>. Accessed September 8, 2013.

Centers for Disease Control and Prevention. Births: final data for 2010. *Natl Vital Stat Rep.* Aug. 28, 2012; 61(1):1.
http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_01.pdf. Accessed November 19, 2013. This reports 3,999,386 live births in the US in 2010. Thus, children conceived through ART (combined IVF and AID) in the US in 2010 comprised 3 percent of all live births.

Chambers G, Hoang V, Zhu R, Illingworth P. A reduction in public funding for fertility treatment--an econometric analysis of access to treatment and savings to government. *BMC Health Serv Res.* 2012;12(1):142.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3464128/pdf/1472-6963-12-142.pdf>
Accessed December 1, 2013.

Chandra A, Copen C, Stephen E. Infertility and impaired fecundity in the United States, 1982-2010: data from the National Survey of Family Growth. *National Health Stat Rep.* 2013;67:1-19.

Cico K. Ten best fertility centers. *Parents.* <http://www.parents.com/getting-pregnant/infertility/treatments/best-fertility-centers/>. Accessed November 18, 2013.

Clamar A. Psychological implication of the anonymous pregnancy. In: Offerman-Zuckerberg J, ed. *Gender in Transition: A New Frontier*. New York, NY: Plenum; 1989.

Cohen IG, Chen DL. Trading-off reproductive technology and adoption: does subsidizing IVF decrease adoption rates and should it matter? *Minn Law Rev.* 2010;(95):485.

Colorado Center for Reproductive Medicine. Basic infertility services.
<http://www.colocrm.com/Services/BasicInfertilityServices.aspx>. Accessed November 21, 2013.

Cone KL. Family law—egg donation and stem cell research—eggs for sale: The scrambled state of legislation in the human egg market. *University of Arkansas at Little Rock Law Rev.* 2012;35(1):189-216.

Connolly M, Ledger W, Postma M. Economics of assisted reproduction: access to fertility treatments and valuing live births in economic terms. *Hum Fertil.* 2010;13(1):13-18.

Culyer AJ. Equity—some theory and its policy implications. *J Med Ethics.* 2001;27(4):275-283.

Daniels N. *Just Health: Meeting Health Needs Fairly*. New York, NY: Cambridge University Press; 2008.

Detsky AS, Naglie G, Krahn MD, Naimark D, Redelmeier DA. Primer on medical decision analysis: part 1--getting started. *Med Decis Making*. 1997;17(2):123-125.

Detsky AS, Naglie G, Krahn MD, Redelmeier DA, Naimark D. Primer on medical decision analysis: part 2--building a tree. *Med Decis Making*. 1997;17(2):126-135.

Domar AD, Zuttermeister PC, Friedman R. The psychological impact of infertility: a comparison with patients with other medical conditions. *J Psychosom Obstet Gynaecol*. 1993;14 Suppl:45-52.

Ethics Committee of American Society for Reproductive Medicine. Fertility treatment when the prognosis is very poor or futile: a committee opinion. *Fertil Steril*. 2012;98:e6-e9.

Ethics Committee of the American Society for Reproductive Medicine. Oocyte or embryo donation to women of advanced age: a committee opinion. *Fertil Steril*. 2013;100(2):337-340.

Ethics Committee of the American Society for Reproductive Medicine. Risk sharing or refund programs in assisted reproduction: a committee opinion. *Fertil Steril*. 2013;100(2):334-336. Accessed November 19, 2013.

Ethics Committee of the American Society for Reproductive Medicine. Financial incentives in recruitment of oocyte donors. *Fertil Steril*. 2000;74(2):216.

Ethics Committee of the American Society for Reproductive Medicine. Financial compensation of oocyte donors. *Fertil Steril*. 2007;88(2):305, 308.

Farley Ordozensky Staniec J, Webb NJ. Utilization of infertility services: how much does money matter? *Health Serv Res*. 2007;42(3 part 1):971-989.

Fertility Authority. Lawsuit alleges price fixing on egg donation. <http://www.fertilityauthority.com/articles/lawsuit-alleges-price-fixing-egg-donation>. Accessed November 6, 2013.

Five million babies born with help of assisted reproductive technologies [press release]. Washington, DC: American Society of Reproductive Medicine Office of Public Affairs; October 14, 2013. http://www.asrm.org/Five_Million_Babies_Born_with_Help_of_Assisted_Reproductive_Technologies/. Accessed October 15, 2013.

Florida Institute for Reproductive Medicine. IVF guarantee program. <http://www.fertilityjacksonville.com/costs/cost-information/ivf-guarantee-program/>. Accessed November 18, 2013.

Fragouli E, Wells D. Aneuploidy screening for embryo selection. *Semin Reprod Med.* 2012;30(4):289-301.

Freeman EW, Boxer AS, Rickels K, Tureck R, Mastroianni L Jr. Psychological evaluation and support in a program of in vitro fertilization and embryo transfer. *Fertil Steril.* 1985;43(1):48-53.

Frith L, Sawyer N, Kramer W. Forming a family with sperm donation: a survey of 244 non-biological parents. *Reprod Biomed Online.* 2012;24(7):709-718.

Fruchtman C. Considerations in surrogacy contracts. *Whittier L Rev.* 1999;21:429-433.

Goldfarb v Va. State Bar, 423 US 886 (1975).

Golombok S, Badger S. Children raised in mother-headed families from infancy: a follow-up of children of lesbian and single heterosexual mothers, at early adulthood. *Hum Reprod.* 2010;25(1):150-157.

Golombok S, Blake L, Casey P, Roman G, Jadvá V. Children born through reproductive donation: a longitudinal study of psychological adjustment. *J Child Psychol Psychiatr.* 2013;54(6):653-660.

Golombok S, Brewaeys A, Cook R, et al. The European study of assisted reproduction families: family functioning and child development. *Hum Reprod.* 1996;11(10):2324-2331.

Golombok S, Brewaeys A, Giavazzi MT, et al. The European study of assisted reproduction families: the transition to adolescence. *Hum Reprod.* 2002;17(3):830-840.

Golombok S, Cook R, Bish A, Murray C. Families created by the new reproductive technologies: quality of parenting and social and emotional development of the children. *Child Dev.* 1995;66(2):285-298.

Golombok S, Jadvá V, Lycett E, et al. Families created by gamete donation: follow-up at age 2. *Human Reprod.* 2005;20(1):286-293.

Golombok S, Lycett E, MacCallum F, et al. Parenting infants conceived by gamete donation. *J Fam Psychol.* 2004;18(3):443-452.

Golombok S, MacCallum F, Goodman E, Rutter M. Families with children conceived by donor insemination: a follow-up at age twelve. *Child Dev.* 2002;73(3):952-968.

Golombok S, Murray C, Jadvá V, Lycett E, MacCallum F, Rust J. Non-genetic and non-gestational parenthood: consequences for parent-child relationships and the psychological well-being of mothers, fathers and children at age 3. *Hum Reprod.* 2006;21(7):1918-1924.

Golombok S, Tasker F, Murray C. Children raised in fatherless families from infancy; family relationships and the socioemotional development of children of lesbian and single heterosexual mothers. *J Child Psychol Psychiat* 1997;38(7):783-791.

Gugucheva M. *Council for Responsible Genetics Special Report: Surrogacy in America.*
<http://www.councilforresponsiblegenetics.org/pagedocuments/kaevej0a1m.pdf> .
Accessed September 1, 2013.

Hammoud AO, Gibson M, Stanford J, White G, Carrell DT, Peterson M. In vitro fertilization availability and utilization in the United States: a study of demographic, social, and economic factors. *Fertil Steril.* 2009;91(5):1630-1635.

Handyside AH, Kontogianni EH, Hardy K, Winston RM. Pregnancies from biopsied human preimplantation embryos sexed by Y-specific DNA amplification. *Nature.* 1990;344(6268):768-770.

Hansen M. As surrogacy becomes more popular, legal problems proliferate. *ABA J.* 2011;97:52-57.
http://www.abajournal.com/magazine/article/as_surrogacy_becomes_more_popular_legal_problems_proliferate/. Accessed November 20, 2013.

Hansen M, Kurinczuk JJ, de Klerk N, Burton P, Bower C. Assisted reproductive technology and major birth defects in Western Australia. *Obstet Gynecol.* 2012;120(4):852-863.

Harper JC, Sengupta SB. Preimplantation genetic diagnosis: state of the art 2011. *Hum Genet.* 2012;131(2):175-186.

Hawes JM. Creating new families: this history of adoption in the United States. *Rev Am Hist.* 2004;32(1):90-96.

Henne MB, Bundorf MK. Insurance mandates and trends in infertility treatments. *Fertil Steril.* 2008;89(1):66-73.

Horne C, Johns C, King LW. Ancient history sourcebook: Code of Hammurabi c. 1780 BCE. Fordham University.
<http://www.fordham.edu/halsall/ancient/hamcode.asp>. Accessed September 25, 2013.

Hornslet M, Danielsen S. *Adoptionsloven*. Copenhagen, Denmark: Juristforbundet Forlag; 1974.

Humphriss R, Hall A, May M, Zuccolo L, Macleod J. Prenatal alcohol exposure and childhood balance ability: findings from a UK birth cohort study. *BMJ Open*. 2013;3(6). Epub June 17, 2013.

In re Marriage of Moschetta, 25 Cal App 4th 1218 (1994).

Indian woman gives birth at age of 70. *Telegraph*.
<http://www.telegraph.co.uk/news/worldnews/asia/india/3683289/Indian-woman-gives-birth-at-age-of-70.html>. Accessed November 25, 2013.

Infertility Center of St. Louis website. <http://www.infertile.com/>. Accessed November 21, 2013.

Informed consent for egg donation; requirements; unprofessional conduct, Ariz Rev Stat Ann sec 36-1702 (West 2010).

Informed consent, NY Comp Codes R & Regs title 10, sec 52-8.8(a) (2000).

Institute for Science, Law & Technology Working Group (ISLAT). Art into science: regulation of fertility techniques. *Science*. 1998;281(5377):651-652.

Jadva V, Badger S, Morrissette M, Golombok S. "Mom by choice, single by life's circumstance..." Findings from a large scale survey of the experiences of single mothers by choice. *Hum Fertil (Camb)*. 2009;12(4):175-184.

Jain T, Harlow BL, Hornstein MD. Insurance coverage and outcomes of in vitro fertilization. *N Engl J Med*. 2002;347(9):661-666.

Jain T, Hornstein MD. Disparities in access to infertility services in a state with mandated insurance coverage. *Fertil Steril*. 2005;84(1):221-223.

Jhordan C. v Mary K., 179 Cal App 3d 386, 224 Cal Rptr 530 (1986).

Johnson CP, Myers SM, American Academy of Pediatrics Council on Children with Disabilities. Identification and evaluation of children with autism spectrum disorders. *Pediatrics*. 2007;120(5):1183-1215.

Johnston J, Gusmano MK. Why we should all pay for fertility treatment: an argument from ethics and policy. *Hastings Cent Rep*. 2013;43(2):18-21.

K.M. v E.G., 37 Cal 4th 130, 117 P3d 673, 33 Cal Rptr 3d 61 (2005).

Kahraman S, Beyazyurek C, Ekmekci CG. Seven years of experience of preimplantation HLA typing: a clinical overview of 327 cycles. *Reprod Biomed Online*. 2011;23(3):363-371.

Kallen B, Finnstrom O, Lindam A, Nilsson E, Nygren KG, Olausson PO. Cancer risk in children and young adults conceived by in vitro fertilization. *Pediatrics*. 2010;126(2):270-276.

Kenney NJ, McGowan ML. Looking back: egg donors' retrospective evaluations of their motivations, expectations, and experiences during their first donation cycle. *Fertil Steril*. 2010;93(2):455-466.

Kesmodel US, Eriksen HL, Underbjerg M, et al. The effect of alcohol binge drinking in early pregnancy on general intelligence in children. *BJOG*. 2012;119(10):1222-1231.

Klugman S, Suskin B, Dar P, et al. Clinical utility of chromosomal microarray analysis in prenatal diagnosis: report of first 6 months in clinical practice. *J Matern Fetal Neonatal Med*. October 23, 2013; epub ahead of print.

Knaplund KS. Synthetic cells, synthetic life, and inheritance. *Valparaiso Law Rev*. 2011;45(4):1371-1386.

Kovacs GT, Mushin D, Kane H, Baker HW. A controlled study of the psycho-social development of children conceived following insemination with donor semen. *Hum Reprod*. 1993;8(5):788-790.

Krahn MD, Naglie G, Naimark D, Redelmeier DA, Detsky AS. Primer on medical decision analysis: part 4--analyzing the model and interpreting the results. *Med Decis Making*. 1997;17(2):142-151.

Kramer W, Cahn N. *Finding Our Families: A First-of-Its-Kind Book for Donor-Conceived People and Their Families*. New York, NY: Avery Trade; 2013.

Kramer W, Schneider J, Schultz N. US oocyte donors: a retrospective study of medical and psychosocial issues. *Hum Reprod*. 2009;24(12):3144-3149.

Krawiec KD. Sunny samaritans and egomaniacs: price-fixing in the gamete market. *Law Contemp Probl*. 2009;72(3):59-90.

Larcher V. The health of children conceived by assisted reproduction technologies. *Arch Dis Child*. 2007;92(8):668-669.

Levens ED, Richter KS, Levy MJ. Money-back guarantees. *Semin Reprod Med*. 2013;31(03):198-203.

Levin A. World's first test tube baby pregnant again—Louise Brown, 35, reveals her joy at expecting a second child six years after giving birth to a son. *Daily Mail*. July 20, 2013. <http://www.dailymail.co.uk/news/article-2371716/Worlds-test-tube-baby-Louise-Brown-pregnant-second-child.html>. Accessed November 10, 2013.

Levine AD. Self-regulation, compensation, and the ethical recruitment of oocyte donors. *Hastings Cent Rep*. 2010;40(2):25-36.

Lindsay Kamakahi v American Society for Reproductive Medicine, class action complaint, case no. 3:11-CV-1781 (N D Cal, filed April 12, 2011).

Lindsay Kamakahi v American Society for Reproductive Medicine, US Dist Ct, N Dist Cal. Defendant's motion to dismiss plaintiff's first amended class action complaint. Case no. 3:11-CV-1781:16 (filed July 15, 2011).

Lindsay Kamakahi v American Society for Reproductive Medicine, order denying motion to dismiss, case no. 3:11-CV-1781. (N D Cal, decided March 29, 2013).

Ludwig AK, Sutcliffe AG, Diedrich K, Ludwig M. Post-neonatal health and development of children born after assisted reproduction: a systematic review of controlled studies. *Eur J Obstet Gynecol Reprod Biol*. 2006;127(1):3-25.

MacCallum F, Golombok S. Children raised in fatherless families from infancy: a follow-up of children of lesbian and single heterosexual mothers at early adolescence. *J Child Psychol Psychiatr*. 2004;45(8):1407-1419.

Mains L, Zimmerman M, Blaine J, et al. Achievement test performance in children conceived by IVF. *Hum Reprod*. 2010;25(10):2605-2611.

Malizia BA, Hacker MR, Penzias AS: Cumulative live-birth rates after in vitro fertilization. *N Engl J Med*. 2009;360(3):236-243.

Manning M, Hudgins L, Professional Practice and Guidelines Committee. Array-based technology and recommendations for utilization in medical genetics practice for detection of chromosomal abnormalities. *Genet Med*. 2010;12(11):742-745.

Martin JR, Bromer JG, Sakkas D, Patrizio P. Insurance coverage and in vitro fertilization outcomes: a U.S. perspective. *Fertil Steril*. 2011;95(3):964-969.

Massachusetts Trial Court Law Libraries. Massachusetts law about adoption. <http://www.lawlib.state.ma.us/subject/about/adoption.html>. Accessed October 19 2013.

McGillivray G, Rosenfeld JA, McKinlay Gardner RJ, Gillam LH. Genetic counselling and ethical issues with chromosome microarray analysis in prenatal testing. *Prenat Diagn*. 2012;32(4):389-395.

- Melhem NM, Walker M, Moritz G, Brent DA. Antecedents and sequelae of sudden parental death in offspring and surviving caregivers. *Arch Pediatr Adolesc Med*. 2008;162(5):403-410.
- Mertzanidou A, Wilton L, Cheng J, et al. Microarray analysis reveals abnormal chromosomal complements in over 70% of 14 normally developing human embryos. *Hum Reprod*. 2013;28(1):256-264.
- Miller DT, Adam MP, Aradhya S, et al. Consensus statement: chromosomal microarray is a first-tier clinical diagnostic test for individuals with developmental disabilities or congenital anomalies. *Am J Hum Genet*. 2010;86(5):749-764.
- Mladovsky P, Sorenson C. Public financing of IVF: a review of policy rationales. *Health Care Anal*. 2010;18(2):113-128.
- Montag M, Toth B, Strowitzki T. New approaches to embryo selection. *Reprod Biomed Online*. 2013;27(5):539-546.
- Naglie G, Krahn MD, Naimark D, Redelmeier DA, Detsky AS. Primer on medical decision analysis: part 3--estimating probabilities and utilities. *Med Decis Making* 1997;17(2):136-141.
- Narvaez D. The emotional foundations of high moral intelligence. *New Dir Child Adolesc Dev*. 2010;2010(129):77-94.
- National Conference of State Legislatures. State health insurance mandates and the ACA essential benefits provisions. <http://www.ncsl.org/issues-research/health/state-ins-mandates-and-aca-essential-benefits.aspx>. Accessed November 21, 2013.
- National Council on Disability. Chapter 11: Assisted reproductive technologies. *Rocking the Cradle: Ensuring the Rights of Parents with Disabilities and Their Children*. <http://www.ncd.gov/publications/2012/Sep272012/Ch11>. Accessed October 11, 2013.
- National Society of Professional Engineers v United States*, 435 US 679, 692 (1978).
- Neumann PJ, Gharib SD, Weinstein MC. The cost of a successful delivery with in vitro fertilization. *New Engl J Med*. 1994;331(4):239-243.
- Nevada Center for Reproductive Medicine website. <http://www.nevadafertility.com/nevada/>. Accessed November 21, 2013.
- NYU Langone Fertility Center. Treatment for all stages of infertility. <http://www.nyufertilitycenter.org/>. Accessed November 21, 2013.

Oldest woman to give birth dies, leaving twins. *USA Today*. July 15, 2009. http://usatoday30.usatoday.com/news/world/2009-07-15-spain-oldest-woman-birth_N.htm. Accessed November 25, 2013.

Omurtag K, Adamson GD. The Affordable Care Act's impact on fertility care. *Fertil Steril*. 2013;99(3):652-655.

Oocyte donation; advertisement; screening process; procedures, Cal Health and Safety Code sec 125325 (West 2010).

Oregon Health Sciences University. Fertility services at OHSU. <http://www.ohsu.edu/xd/health/services/women/services/fertility/>. Accessed November 21, 2013.

Paoloni-Giacobino A. Implications of reproductive technologies for birth and developmental outcomes: imprinting defects and beyond. *Expert Rev Mol Med*. 2006;8(12):1-14.

Patra J, Bakker R, Irving H, Jaddoe VW, Malini S, Rehm J. Dose-response relationship between alcohol consumption before and during pregnancy and the risks of low birthweight, preterm birth and small for gestational age (SGA)-a systematic review and meta-analyses. *BJOG*. 2011;118(12):1411-1421.

Pi VL. Regulating sperm donation: Why requiring exposed donation is not the answer. *Duke J Gender Law Policy*. 2009;16(2):379-401.

Politi MC, Lewis CL, Frosch DL. Supporting shared decisions when clinical evidence is low. *Med Care Res Rev*. 2013;70(1 Suppl):113S-128S.

Practice Committee of American Society for Reproductive Medicine. Diagnostic evaluation of the infertile female: a committee opinion. *Fertil Steril*. 2012;98(2):302-307. Accessed November 19, 2013.

Practice Committee of the American Society for Reproductive Medicine. Repetitive oocyte donation. *Fertil Steril*. 2008;90(5 Suppl):S194-S195.

Practice Committee of American Society for Reproductive Medicine; Practice Committee of Society for Assisted Reproductive Technology. Criteria for number of embryos to transfer: a committee opinion. *Fertil Steril*. 2013;99(1):44-46. Accessed November 19, 2013.

Practice Committee of the American Society for Reproductive Medicine; Practice Committee of the Society for Assisted Reproductive Technology. Recommendations for gamete and embryo donation: a committee opinion. *Fertil Steril*. 2013;99(1):47-62.e1.

Preimplantation Genetic Diagnosis International Society. International conference on preimplantation genetic diagnosis. <http://www.pgdis2013.com/scientific-programme/conference-scientific-program>. Accessed October 1 2013.

Reiff M, Ross K, Mulchandani S, et al. Physicians' perspectives on the uncertainties and implications of chromosomal microarray testing of children and families. *Clin Genet*. 2013;83(1):23-30.

Rosato JL. The children of ART (assisted reproductive technology): should the law protect them from harm? *Utah L Rev*. 2004:57-110.

Salihu HM, Shumpert MN, Slay M, Kirby RS, Alexander GR. Childbearing beyond maternal age 50 and fetal outcomes in the United States. *Obstet Gynecol*. 2003;102(5 pt 1):1006-1014.

Schaefer GO, Sinaii N, Grady C. Informing egg donors of the potential for embryonic research: a survey of consent forms from US in vitro fertilization clinics. *Fertil Steril*. 2012;97(2):427-433.

Schieve LA, Meikle SF, Ferre C, Peterson HB, Jeng G, Wilcox LS. Low and very low birth weight in infants conceived with use of assisted reproductive technology. *NEJM*. 2002;346(10):731-737.

Schneider J. Fatal colon cancer in a young egg donor: a physician mother's call for follow-up and research on the long-term risks of ovarian stimulation. *Fertil Steril*. 2008;90(5):2016.e1-e5.

Seibel MM, Kiessling A. Compensating egg donors: equal pay for equal time? *N Engl J Med*. 1993;328(10):737.

Shanks P. Trust-busting in the baby business? *Biopolitical Times*. May 5, 2011. <http://www.biopoliticaltimes.org/article.php/United%20Kingdom:%20Human-Animal%20Hybrid%20EmbryosApr%202008><http://www.geneticsandsociety.org/article.php?id=5697>. Accessed November 23, 2013.

Skillern A, Cedars M, Huddleston H. Egg Donor Informed Consent Tool (EDICT): development and validation of a new informed consent tool for oocyte donors. *Fertil Steril*. 2013;99(6):1733-1738.

Skogerbo A, Kesmodel U, Denny C, et al. The effects of low to moderate alcohol consumption and binge drinking in early pregnancy on behaviour in 5-year-old children: a prospective cohort study on 1628 children. *BJOG*. 2013;120(9):1042-1050.

Skogerbo A, Kesmodel US, Wimberley T, et al. The effects of low to moderate alcohol consumption and binge drinking in early pregnancy on executive function in 5-year-old children. *BJOG*. 2012;119(10):1201-1210.

Society for Assisted Reproductive Technologies. Clinic summary report 2011. https://www.sartcorsonline.com/rptCSR_PublicMultYear.aspx?ClinicPKID=0. Accessed October 18, 2013.

Society for Assisted Reproductive Technology. SART national summary: IVF success rates: find a clinic. http://www.sart.org/find_frm.html. Accessed November 20, 2013.

Sokol RJ, Delaney-Black V, Nordstrom B. Fetal alcohol spectrum disorder. *JAMA*. 2003;290(22):2996-2999.

Solnit AJ, Schowalter JE, Nordhaus BF. Best interests of the child in the family and community. Social, legal, and medical implications for pediatricians. *Pediatr Clin North Am*. 1995;42(1):181-191.

Solnit AJ. The bioethics of children's rights. *Isr J Psychiatry Relat Sci*. 2004;41(1):4-16.

Southern California Reproductive Center website. <http://www.scrxivf.com/>. Accessed November 21, 2013.

Stephen EH, Chandra A. Use of infertility services in the United States: 1995. *Fam Plann Perspect*. 2000;32(3):132-137.

Stromberg B, Dahlquist G, Ericson A, Finnstrom O, Koster M, Stjernqvist K. Neurological sequelae in children born after in-vitro fertilisation: a population-based study. *Lancet*. 2002;359(9305):461-465.

Sunde A. Europe's declining population and the contribution of ART. *Pharm Policy Law*. 2007;9:79-89.

Suter SM. The politics of information: informed consent in abortion and end-of-life decision making. *Am J Law Med*. 2013;39(1):7-61.

T.M.H. v D.M.T., 79 So 3d 787 (FL 2011).

Tabarrok A. The oocyte cartel. *Marginal Revolution*. June 17, 2013. <http://marginalrevolution.com/marginalrevolution/2013/06/the-oocyte-cartel.html>. Accessed November 25, 2013.

Texas Health Presbyterian website. <http://texasivf.com/>. Accessed November 21, 2013.

The market in human eggs: underpaid ovaries. *Economist*. April 20, 2011. <http://www.economist.com/node/18586864>. Accessed November 23, 2013.

The Organ Procurement and Transplantation Network. Guidance for the informed consent of living donors. http://optn.transplant.hrsa.gov/ContentDocuments/Guidance_InformedConsentLiving_Donors.pdf. Accessed September 8, 2013.

The Ronald Perelman and Claudia Cohen Center for Reproductive Medicine at Weill Cornell Medical College. Cutting-edge treatments. <http://www.ivf.org/>. Accessed November 21, 2013.

The world's first test tube baby. *American Experience*. PBS. <http://www.pbs.org/wgbh/americanexperience/features/general-article/babies-worlds-first/>. Accessed November 10, 2013.

Thomas S. v Robin Y., 209 AD 2d 298, 618 NYS2d 356 (1995).

Trusts, etc., in restraint of trade illegal; penalty. 15 USC sec 1 (2006). 15 USC sec 1 (2006).

Underbjerg M, Kesmodel US, Landro NI, et al. The effects of low to moderate alcohol consumption and binge drinking in early pregnancy on selective and sustained attention in 5-year-old children. *BJOG*. 2012;119(10):1211-1221.

United Nations. Universal Declaration of Human Rights. <http://www.un.org/en/documents/udhr/index.shtml#a16d>. Accessed October 10, 2013.

US Food and Drug Administration. Tissue establishment registration. <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/TissueEstablishmentRegistration/default.htm>. Accessed September 8, 2013.

US Food and Drug Administration. How do I screen a donor? 21 CFR sec 1271.75 (2006). <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1271.75>. Accessed November 22, 2013.

US Food and Drug Administration. What donor testing is required for different types of cells and tissues? 21 CFR sec 1271.85(a)-(c) (2005). <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1271.85>. Accessed November 22, 2013.

US Food and Drug Administration. What you should know—reproductive tissue donation. <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/>

TissueSafety/ucm232876.htm. Accessed September 8, 2013.

US Food and Drug Administration. When do I register, submit an HCT/P list, and submit updates? 21 CFR sec 1271.21 (2001). <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1271.21>. Accessed November 22, 2013.

US Food and Drug Administration Center for Biologics Evaluation and Research. Guidelines for industry: eligibility determination for donors of human cells, tissue and cellular and tissue-based products (HCT/Ps) [2007]. <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm091345.pdf>. Accessed November 19, 2013.

Utian WH, Sheean L, Goldfarb JM, Kiwi R. Successful pregnancy after in vitro fertilization and embryo transfer from an infertile woman to a surrogate. *N Engl J Med*. 1985;313(21):1351-1352.

van Balen F, Verdurmen J, Ketting E. Choices and motivations of infertile couples. *Patient Educ Couns*. 1997;31(1):19-27.

Van den Veyver IB, Beaudet AL. Comparative genomic hybridization and prenatal diagnosis. *Curr Opin Obstet Gynecol*. 2006;18(2):185-191.

Verlinsky Y, Rechitsky S, Schoolcraft W, Strom C, Kuliev A. Preimplantation diagnosis for Fanconi anemia combined with HLA matching. *JAMA*. 2001;285(24):3130-3133.

Verpoest W. PGD and HLA matching: not a quick fix. *Reprod Biomed Online*. 2011;23(3):271-273.

Vorzimer A. A law professor comments on the egg donor class action lawsuit. *Spin Doctor*. April 19, 2011. <http://www.eggdonor.com/blog/2011/04/19/law-professor-comments-egg-donor-class-action-lawsuit/>. Accessed November 23, 2013.

Wapner RJ, Martin CL, Levy B, et al. Chromosomal microarray versus karyotyping for prenatal diagnosis. *New Engl J Med*. 2012;367(23):2175-2184.

Wu AK, Elliott P, Katz PP, Smith JF. Time costs of fertility care: the hidden hardship of building a family. *Fertil Steril*. 2013;99(7):2025-2030.

Zamostny KP, O'Brien KM, Baden A L, Wiley MO. (2003). The practice of adoption history, trends, and social context. *Couns Psychol*. 2003;31:651-678.

Ziporyn T. Medical decision making: analyzing options in the face of uncertainty. *JAMA*. 1983;249(16):2133-2135, 2138-2141.

Copyright 2014 American Medical Association. All rights reserved.

Virtual Mentor

American Medical Association Journal of Ethics
January 2014, Volume 16, Number 1: 86-88.

About the Contributors

Theme Issue Editor

Katie Falloon is a second-year medical student at Duke University School of Medicine in Durham, North Carolina. She graduated magna cum laude from Yale University with a degree in English.

Contributors

Naomi Cahn, JD, is the Harold H. Greene Professor of Law at George Washington University in Washington, DC, and the co-author of *Finding Our Families: A First-of-its-Kind Book for Donor-Conceived People and their Families* (2013).

Natalie A. Clark, MD, is a third-year obstetrics and gynecology resident at the University of Michigan in Ann Arbor who is applying to fellowships in reproductive endocrinology and infertility.

Jennifer Collins, JD, is the vice provost at Wake Forest University and a professor at Wake Forest Law School in Winston-Salem, North Carolina. She is the co-author of *Privilege or Punish: Criminal Justice and the Challenge of Family Ties* (2009).

Judith Daar, JD, is a professor of law at Whittier Law School and a clinical professor of medicine in the School of Medicine at the University of California, Irvine. She is a member of the American Society for Reproductive Medicine Ethics Committee and past president of the American Society of Law, Medicine and Ethics. Her casebook, *Reproductive Technologies and the Law*, has been used in classrooms across the country.

Alan H. DeCherney, MD, is head of the Program in Reproductive and Adult Endocrinology at the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health in Bethesda, Maryland. His medical degree is from Temple University School of Medicine, his internship in medicine was at the University of Pittsburgh, and his residency in obstetrics and gynecology, at the University of Pennsylvania. His interests include both basic and clinical endocrinology in the areas of endometriosis, infertility and assisted reproductive techniques, leiomyoma, polycystic ovarian syndrome, ectopic pregnancy, implantation and oocyte physiology, and health policy in reproduction.

Siobhan M. Dolan, MD, MPH, is a professor of clinical obstetrics and gynecology and women's health at the Albert Einstein College of Medicine and an attending physician in the Division of Reproductive Genetics at Montefiore Medical Center in New York City. Dr. Dolan maintains her clinical practice serving women and

families in the Bronx. Her research interests focus on the integration of genetics into maternal-child health, specifically looking at ways to apply advances in genetics and genomics to prevent birth defects and preterm birth.

Senait Fisseha, MD, JD, is an associate professor of obstetrics and gynecology and chief of the Division of Reproductive Endocrinology and Infertility at the University of Michigan in Ann Arbor.

Leslie P. Francis, PhD, JD, is Distinguished Alfred C. Emery Professor of Law and Distinguished Professor of Philosophy at the University of Utah in Salt Lake City. She is a member of the ethics committee of the American Society of Reproductive Medicine and is editing the *Handbook on Reproductive Ethics* for Oxford University Press.

Emily S. Jungheim, MD, MSCI, is a scholar in the Women's Reproductive Health Research program and an assistant professor of reproductive endocrinology and infertility at the Washington University School of Medicine in Saint Louis. Dr. Jungheim completed her residency training in obstetrics and gynecology at Duke University, followed by a fellowship in reproductive endocrinology and infertility at Washington University in Saint Louis, where she also completed a master's of science in clinical investigation. Her research focuses on lifestyle and reproductive health.

Susan Klugman, MD, is an associate professor of clinical obstetrics and gynecology and women's health at the Albert Einstein College of Medicine and director of the Division of Reproductive Genetics at Montefiore Medical Center in New York City. At Yeshiva University, she is director of the fellowship for medical genetics and the medical director for the Program of Jewish Genetic Health. She started the Larchmont Women's Center and was its medical director before her genetics fellowship. She is board certified in both clinical genetics and obstetrics and gynecology.

Kimberly D. Krawiec, JD, is the Kathrine Robinson Everett Professor of Law and a senior fellow at the Kenan Institute for Ethics at Duke University in Durham, North Carolina.

Saima Rafique, MBBS, DGO, is a clinical researcher at the Program in Reproductive and Adult Endocrinology at the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health in Bethesda, Maryland. She completed her medical study and residency in obstetrics and gynecology at Jawaharlal Nehru Medical College in Aligarh, India. Her research interests include women's health, infertility (including primary ovarian insufficiency) and assisted reproductive techniques, and community-based participatory research.

Philip M. Rosoff, MD, MA, is a professor of pediatrics (oncology) and medicine at

the Duke University School of Medicine and Duke University Medical Center in Durham, North Carolina. He is also chair of the center's ethics committee and a member of the Trent Center for Bioethics, Humanities and History of Medicine. His research interests and scholarly work are in the area of medical resource allocation, especially rationing. His book *Rationing Is Not a Four-Letter Word: Setting Limits on Healthcare* will be published in spring 2014 by MIT Press.

Clinton Wang is a junior majoring in biomedical engineering at Yale University in New Haven, Connecticut. He is interested in many areas of health policy and medical ethics. In summer 2013, Clinton was an Ethics Group intern at the American Medical Association, where he conducted research on health promotion.

Copyright 2014 American Medical Association. All rights reserved.