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Ethics and Reproductive Care

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FROM THE EDITOR
Advancing Innovation in Reproductive Care

Obstetrics and gynecology involves the provision of medical and surgical care to women over their lifespan, a breadth of caregiving that sets the field apart. Perhaps more striking, though, is the sociopolitical attention women's health has garnered in the United States. Recent legislative efforts have empowered politicians, employers, health professionals, insurers, and even the parents of adolescents to restrict women's reproductive choices, both domestically and even internationally through prohibitions on uses for federal funds. This phenomenon has more than short-term health consequences. Our society's intense concern with reproductive care has also hampered our ability to innovate and improve outcomes in the long term. Such efforts include "fetal personhood" legislation that threatens the legality of treatment for infertility or ectopic pregnancy, restrictions on research involving pregnant women or embryonic stem cells, and limited insurance coverage for the most efficacious forms of contraception.

Emotions can run high around childbearing, parenthood, and babies. Society, it seems, wants a voice in what happens to all "its" children, from conception forward. This voice, however, is not a unified one, but a raucous discourse of disparate views often based on fundamentally differing values and beliefs. So for leaders in biomedicine, maintaining an objective and dispassionate stance is a challenging but critical requirement for providing and improving reproductive medicine. This theme issue of *Virtual Mentor* addresses areas of innovation in the field of women's health and highlights some of the ethical pitfalls we encounter in the attempt to advance reproductive care.

This month's three ethics case commentaries address the challenges of keeping up with new guidelines and technologies. Frank A. Chervenak and Laurence B. McCullough discuss a patient's request for an elective labor induction before 39 weeks. Marc M. Beuttler, Kara N. Goldman, and Jamie A. Grifo argue for providing ovarian reserve testing to promote informed decision making for women interested in future fertility, regardless of the anxiety that accompanies such discussions. And Harry J. Lieman and Andzrej K. Breborowicz discuss the ethical considerations related to sex selection in pregnancies conceived through in vitro fertilization (IVF).

In the state of the art and science section are discussions of two more technological advancements: Monique A. Spillman and Robert M. Sade address the rapid propagation of robotic gynecologic surgery and the ethical questions it has engendered. Stephanie J. Miller and Joseph B. Davis discuss whether, in the absence of meaningful standards for experience or certification, the disclosure of a fertility

clinic's experience with egg freezing—a procedure considered experimental until recently—will be useful for patient decision making.

Two articles discuss matters of justice. Caroline Bass and Joseph Gregorio elucidate how a lack of appropriate regulation has led to subpar treatment of egg donors. Carolyn Payne and Nicole Fanarjian review a study that sought to identify the causes of racial disparities in the use of the long-acting reversible contraception.

The remaining pieces address society's preoccupation with pregnancy and the fetus. Kavita Shah Arora and Christina Salazar examine the logical and ethical flaws in laws that restrict abortions based on the assertion that a 20-week fetus can feel pain. Ruth Macklin gives a more general overview of legislative, judicial, and physician-led restrictions on abortion in the US, maintaining her contention that the pregnant woman alone should "have the final say" in the future of her fetus. Two articles question common obstetric practices. Stephen T. Chasen challenges the wisdom of aggressive interventions to prolong pregnancy in patients with advanced cervical dilation prior to viability of the fetus. Lauri J. Romanzi weighs in on the debate, raging in both medical literature and the lay "mommy wars," on the medicalization of childbirth. Finally, in this month's podcast, Sarah S. Richardson elaborates her research in maternal effects—the influences of a pregnant woman's behavior, exposures, and physiology on her offspring's future health and development. This set of pieces highlights the moral ramifications of the widespread entanglement of society and trends in reproductive care.

As we continue to attempt to push reproductive medicine ever forward, we must continue to balance the quest for scientific advancement with the responsibility to maintain thoughtfulness and irreproachable ethics in the provision of women's health care.

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ETHICS CASE

Informing Patients about Declining Fertility

Commentary by Marc M. Beuttler, MA, Kara N. Goldman, MD, and Jamie A. Grifo, MD, PhD

Niki, a 37-year-old single woman, has been seeing her gynecologist, Dr. Goldstein, for the past 15 years. A busy attorney trying to make partner at a high-powered firm, Niki has focused on her career during that time. She wants to marry and have a family, but is surrounded by women who have waited until their late 30s and early 40s to have children and envisions doing the same. From what Niki sees around her, this timeframe has become the norm for professional women. When she calls to schedule her annual visit, the receptionist tells her that Dr. Goldstein is on an extended leave, but that one of her partners, Dr. Chang, can see Niki instead.

Everything proceeds as usual during the visit. When Dr. Chang asks whether Niki plans on having children, she says that she plans on having at least one child. Dr. Chang explains briefly that a woman's fertility naturally begins declining in the mid-30s, and she offers Niki a serum anti-Mullerian hormone (AMH) test to evaluate her ovarian reserve [1]. She suggests that Niki might find this information useful in deciding how to balance her career and reproductive future. As a lifelong planner, Niki agrees to the test and thanks Dr. Chang for telling her about it. As she is leaving, Dr. Chang tells her that Dr. Goldstein is reviewing her patients' test results remotely and will be the one to call her with them.

A week later, Dr. Chang is just coming out of another patient visit when her assistant tells her that Dr. Goldstein is on the phone, waiting to speak to her about "a very urgent issue." When she picks up the call, Dr. Goldstein says in a very agitated manner, "Why would you check AMH levels on Niki? They came back nearly undetectable. What am I supposed to tell her? She doesn't even have a partner! She's going to freak out, and all of this could have been prevented!"

Dr. Chang replies that she provides fertility counseling and AMH testing to all her patients because she believes patients deserve access to this information. Dr. Goldstein counters that this approach creates unnecessary fear among career women who should not face additional pressure from their physicians to think about children when they can use reproductive technologies to achieve pregnancy on their own timeline.

Commentary

Niki sees female colleagues having children into their late 30s and early 40s, and today the media often highlights celebrities conceiving into their mid-40s. The

message to women is deceiving; a woman is unlikely to conceive in her 40s without assisted reproductive technologies (ART) and possibly even donor oocytes [2]. Surveyed women often overestimate the likelihood of spontaneous pregnancy at all ages [3]. Operating on the knowledge that fertility declines gradually but significantly beginning at age 32, and more rapidly after age 37 [2], Dr. Chang educates Niki on declining fertility and recommends anti-Mullerian hormone (AMH) testing.

Trends clearly reflect that women are delaying childbearing: over the last three decades there has been a 150 percent increase in the number of women in industrialized countries giving birth between the ages of 35 and 39 and a significant increase in the number of women aged 40-44 who do so [4]. Increased access to ART affords women the opportunity to attempt to defer reproduction, but it doesn't guarantee biological parenthood. The percent of autologous in vitro fertilization (IVF) cycles resulting in live birth is approximately 22.1 in women ages 38-40, 12.4 in women ages 41-42, and only 5 in women ages 43-44 [2].

At the same time, the miscarriage rate increases to approximately 20 percent in women ages 38-40 and 30 percent in women ages 40-42 [5], and the number of chromosomally normal embryos in a patient's cohort diminishes significantly with age [6]. IVF with preimplantation genetic screening (PGS) followed by embryo transfer can overcome the diminishing effect of maternal age on implantation after IVF [7, 8]; however, this requires that a patient undergo IVF with PGS and assumes that a woman will have a normal embryo available for transfer, which is true for less than half of women over 40 years of age [6]. Therefore, the most reliable way to ensure that a woman not only conceives but also has a safe pregnancy and healthy baby is for her to conceive at a younger age, or at least with younger oocytes.

Informed Decision Making

Reproductive physicians have a responsibility to educate and to counsel those patients who express an interest in becoming pregnant, and, while testing AMH levels may not fall within a typical gynecology visit, Niki's age and interest in having children make testing her ovarian reserve relevant. However, it is not enough to merely recommend testing; the rationale behind and accuracy of such tests should be explained to the patient and the physician should use this opportunity to help the patient reflect on what she will do if she receives surprising results. These difficult conversations encourage the patient to take ownership of decisions related to testing and her future.

If Niki's aim is to achieve a biological pregnancy, and especially if she wishes to have more than one biological child, it is in her best interest to have access to this knowledge and the tools with which to make an informed decision. In addition to testing AMH levels, Dr. Chang could also have suggested other methods of ovarian reserve testing, including early-follicular-phase follicle stimulating hormone (FSH) and antral follicle count [1]. While these tests have limitations, taken together they may help the patient and physician to interpret results. Conflicting information

would highlight the fact that such tests do not predict the future and may sometimes overstate certain data. Relying on one abnormal lab result might force Niki to make drastic decisions regarding her reproductive future. Providing her with supplementary information could help to eliminate or qualify potential risks and paint a fuller picture from which to decide what procedures best fit Niki's life goals.

With knowledge of a declining ovarian reserve, Niki might consider attempting to conceive in the immediate future using anonymous or directed donor sperm, or she might choose cryopreservation of her oocytes for later use [9]. Oocyte cryopreservation is widely offered as a means to preserve fertility for women at risk of fertility loss because of cancer treatment or another illness. Women are also beginning to pursue oocyte cryopreservation electively as a means to defer reproduction for personal or professional reasons [9, 10]. The technology has evolved to the point that live birth rates using cryopreserved oocytes are similar to live birth rates using fresh oocytes [11]. If Niki is unable to pursue pregnancy at this point in her life, cryopreserved oocytes could offer hope for biological parenthood in the future when her only other alternative might be donor gametes [12]. Surveyed women who pursued oocyte cryopreservation for deferred reproduction described the process as "empowering" and reported feeling that they had improved their reproductive futures [13]. Whatever Niki decides, her ability to make an informed decision is impossible without professional knowledge on declining fertility.

Autonomy and Paternalism

By providing information, Dr. Chang seeks to respect Niki's reproductive autonomy; that is, her right to determine her own actions regarding family planning [14]. Respect for autonomy extends from the idea that no one is in a better position to know how a patient's life should go than the patient herself [14]. Thus Niki is the best one to determine what to do with Dr. Chang's professional knowledge in the context of her life goals. Autonomous choices should be informed by professional knowledge and relevant information without a physician's preconceived opinions or value judgments. Deciding what is relevant is not always easy; one does not want to unduly influence or burden a patient with knowledge of inconsequential theoretical risks. Ultimately, the physician must use medical expertise and judgment in providing a patient with the information that is relevant to his or her goals [14].

Here, Dr. Chang has decided that information about Niki's current and future state of fertility may serve her interest in having a child or children. Dr. Chang offers this information in support of Niki's values and goals. If Niki wishes to have biological children, information regarding her ovarian reserve could help her achieve the family architecture she desires and could impact her immediate life as well as her overarching life goals and values. Though it is not a physician's duty to presume what is in a patient's best interests, if a physician recommends testing to determine a given risk, it is his or her responsibility to initiate conversations on how to use and evaluate test results and to be sure that a patient understands testing options. Failure to educate patients could affect decision making and diminish autonomy.

While Dr. Goldstein is perhaps correct that knowledge of AMH levels will force Niki to weigh her options and to consider both her career and family goals, it is overly paternalistic for Dr. Goldstein to use deception, nondisclosure, or manipulation to bypass Niki's preferences and to guide or force her actions, even with the justification that doing so is in her best interests [14]. Sometimes we feel that paternalism is justified, e.g., in the case of seatbelt laws or compulsory education. But in the case of the patient-physician relationship, it is better to err on the side of respect for patient autonomy and empower patients in a nondirective way. With this in mind, physicians should offer what they believe is the best standard of care. If they believe that standard of care involves offering a particular test, in this case AMH, then the physician should clearly inform the patient about its existence, its use, and its accuracy. The physician is a consultant who helps facilitate the patient's own reasoned and reflective decisions about reproduction and health in the context of individual life goals and expressed preferences. Maintaining this role is an important means of respecting autonomy and eschewing paternalism.

Dr. Goldstein's anger at Dr. Chang may actually reflect regret that she herself did not consider Niki's ovarian reserve. Surely the patient's interest in having children has come up at least once during the 15 years that Dr. Goldstein was Niki's physician. Whatever the reason, the conflict between the two physicians' standards of care and opinions of what constitutes responsible practice highlights the ongoing tensions between paternalism and autonomy in medicine. While Dr. Goldstein is wrong to withhold testing that could provide Niki with valuable information, Dr. Chang's testing of Niki's AMH levels without discussing possible risk could have resulted in a subtler harm. The patient should be informed of the availability of testing and its limitations and ultimately be empowered to make a decision about whether or not to pursue it.

Medical practices vary, and while a physician seeing someone else's patient has a responsibility to keep the primary physician informed, he or she also has a duty to deliver what he or she believes is the best standard of care. In this regard, Dr. Chang acted correctly: she provided what she believed was the best standard of care; she sought to respect Niki's autonomy by providing her with relevant professional knowledge; and she sent notes and results to Dr. Goldstein, the primary physician.

Dr. Goldstein's worries are valid, but this does not permit her to withhold relevant information about Niki's ovarian reserve. Rather, she should sensitively inform Niki about her ovarian reserve, what this means, and what her options are. Discussing the risk of diminishing fertility is difficult, but fully informing a patient of her options so that she can make the best decision for herself within the context of her own life is what respect for persons requires.

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ETHICS CASE

The Professional Responsibility Model and Patient Requests for Nonindicated Early Delivery

Commentary by Frank A. Chervenak, MD, and Laurence B. McCullough, PhD

Jane, at 37 weeks and 3 days gestation in her second pregnancy, is meeting with her obstetrician, Dr. Stevens, for a routine prenatal visit. As the visit is wrapping up, Jane mentions that, due to her work schedule, a week from now would be the best time for her to deliver, and she requests a labor induction during that week. Seeing the curiosity on Dr. Stevens' face, she says plaintively, "The baby is already full-term, right? Waiting longer is only going to make it harder for me to keep up with my job!"

Dr. Stevens agrees. "Yup, 37 weeks and beyond is considered full-term. You had an uncomplicated vaginal delivery last time, let's do it. We'll call once we get you on the schedule." At the end of office hours, he sits down to submit the scheduling request, but when he logs into his email, he sees a reminder email from the head of the quality improvement (QI) committee of the OB/GYN department at his hospital. The message reiterates the hospital's adoption of a policy that will bring the department in line with the recommendation by the American College of Obstetricians and Gynecologists (ACOG) against elective deliveries prior to 39 weeks.

Dr. Stevens realizes that scheduling this induction may become an uphill battle. In his low-risk practice at a community hospital, he has been offering labor induction for low-risk patients for nearly 30 years, and, when the QI committee first approached him about this initiative, he went so far as to complete a retrospective audit confirming that his outcomes have been comparable to those of other obstetricians working at that hospital. He feels strongly that the mother's request should be honored, and wonders what will be the best way to achieve this.

Commentary

The professional responsibility model of obstetric ethics is based on the ethical concept of medicine as a profession. Introduced in the late eighteenth century by the Scottish physician-ethicist John Gregory (1724-1773) and the English physician-ethicist Thomas Percival (1740-1804), this concept has three components. The physician should commit (a) to becoming scientifically and clinically competent, (b) to using his or her clinical knowledge and skills primarily for the clinical benefit of patients, systematically keeping self-interest secondary, and (c) to preserving medicine as a public trust and not a self-interested merchant guild, which it had been for centuries [1].

The first two commitments are directly relevant to the case. Physicians fulfill the first commitment, to scientific and clinical competence, by making medical decisions on the basis is of deliberative clinical judgment. Physicians fulfill the second commitment by focusing on high-quality patient care.

Deliberative clinical judgment aims to responsibly reduce uncontrolled variation in clinical judgment and practice based on it, thereby improving the quality of both. It should be based on the best available evidence and rigorous assessment of one's clinical judgment and practices to bring them into accord with the best available evidence. Deliberative clinical judgment should also be transparent—the bases for decisions made explicit rather than implicit—to prevent unacceptable shortcuts in clinical reasoning. Evidence-based, rigorous, and transparent deliberative clinical judgment, by its scientific and clinical excellence, creates accountability among clinical colleagues and trainees. Evidence-based clinical guidelines that are kept current with changing evidence support and guide deliberative clinical judgment and practice. Using such guidelines requires disciplined, not simple-minded, clinical reasoning.

Evidence-based clinical guidelines are essential for maintenance and improvement of the quality of patient care. Deliberative clinical judgment rules out elective induction before 39 weeks because it can result in iatrogenic neonatal prematurity, as well as an increased risk of an unnecessary cesarean delivery. Dr. Stevens therefore made a clinical error when he agreed to the patient's request for induction prior to 39 weeks. His first professional responsibility to the patient is to recognize that his own experience with induction before 39 weeks is not an adequate basis for deliberative clinical judgments about the benefits and risks of early induction, because of factors such as selection bias and the relatively small sample size. He therefore should follow the ACOG guideline and hospital policy based on that guideline.

To fulfill the second commitment of this ethical concept—applying his clinical knowledge and skills primarily for the clinical benefit of patients—requires that he correct the error of accepting the patient's request. He should do so by explaining to her that deliberative clinical judgment no longer supports induction before 39 weeks and that he will therefore follow the ACOG guideline and hospital policy.

The third commitment of the ethical concept of medicine as a profession—maintaining public trust in medicine—should be discharged by Dr. Stevens in the informed consent process. The professional responsibility model of obstetric ethics obligates the obstetrician to empower the pregnant woman to make decisions about her care. The obstetrician does so, first, by identifying all medically reasonable alternatives and presenting them to the pregnant woman. In obstetric practice, a medically reasonable alternative is one that is technically possible and, in deliberative clinical judgment, expected to benefit the pregnant, fetal, and neonatal patients clinically. A request for clinical management by a patient does not establish that form of clinical management as medically reasonable. Induction before 39

weeks, for the reasons explained above, is not medically reasonable and therefore should not be offered. If a pregnant woman requests this or any other form of clinical management that is not medically reasonable, the obstetrician should explain why he or she did not offer the requested management as a "reasonable alternative." This explanation constitutes the information without which the woman cannot make a truly informed decision—be it consent or refusal. Most patients lack the requisite expertise to interpret relevant evidence and make the best clinical judgment on their own. Supplying such information, followed by the physician's recommendation, empowers and therefore does not violate respect for the pregnant woman's autonomy.

The patient's request is understood in ethical reasoning to be a positive right: a claim on the resources, time, and effort of others to protect and promote her interests as she understands them. In ethical theory, positive rights are not absolute but come with limits; the only ethical question is what those limits are [2]. Deliberative clinical judgments about medical reasonableness justifiably limit a patient's positive right to treatment when the treatment requested is not medically reasonable.

In summary, it is not uncommon for pregnant patients to make requests that are not supported in deliberative clinical judgment and are therefore not medically reasonable. It is a clinical mistake to acquiesce to such requests. Dr. Stevens has made such a mistake, and he should correct this mistake by fulfilling the three professional responsibilities described above.

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ETHICS CASE
Sex Selection for Family Balancing
Commentary by Harry J. Lieman, MD, and Andrzej K. Breborowicz, MD, PhD

Dr. Shah is the medical director of a busy fertility practice. In the middle of office hours, she sees a couple scheduled for an in vitro fertilization (IVF) consultation. The Warrens are longstanding patients who have already had three boys via IVF. They had trouble conceiving naturally due to Mrs. Warren's blocked Fallopian tubes, presumably related to extensive scarring due to complications from a childhood appendectomy. Dr. Shah is surprised to see this couple again because, at the time of the last pregnancy, they had mentioned that finances would preclude them from having a fourth child. Now they tell her that, having reconsidered all the options since their youngest son was born, they have concluded that, despite the financial struggles IVF entails, they would like to have a daughter. If they can select only female embryos for transfer, they tell her, they would go through it again.

Dr. Shah is unsure what to think of this request. Having another child will require IVF, but she cautions them that there is extra cost and risk associated with the embryo manipulation required to determine sex. Additionally, there is always the possibility that all the embryos in the cycle will be male. The couple states that, in that case, they would not have any of the male embryos transferred, since they do not want another son. They say that they are willing to undertake the cost and invasive procedures even with the knowledge that they might not get any healthy female embryos. Dr. Shah tells them that she will have to discuss this request with the rest of the practice, including the embryologists, to see if all parties involved are comfortable with proceeding.

Commentary
The field of reproductive endocrinology and infertility (REI), particularly the procedure of in vitro fertilization (IVF), has always been controversial. Whether it was the initial report of fertilization of an oocyte outside of the human body [1], the first successful human IVF cycle and the birth of Louise Brown [2], or the original description of preimplantation genetic diagnosis (PGD) in couples with a known family history of X-linked diseases [3], these cutting-edge technologies have often raised challenging ethical, moral, and religious questions for medicine and for society.

There have been vast improvements in IVF laboratory techniques and genetic testing. With the expanded indications for PGD and the promotion of preimplantation genetic screening (PGS) to identify aneuploid embryos during IVF cycles, the physicians caring for patients undergoing IVF will be presented with this

ethical dilemma of sex selection on a more frequent and regular basis. This should not be surprising to the medical world or society. Once these techniques have gained accuracy and the IVF process has gained acceptance as a way to conceive, the question asked by many will be, "Why not take advantage of the available technology?" Do physicians or professional societies have the right to limit the use of these available techniques? For elective use, as in the scenario highlighted above, many would say yes, they do. Some European countries prohibit the use of PGD for elective sex selection [4, 5]; the US does not regulate PGD nor limit its use to specific indications.

The subject of sex selection generates mixed views, given its medical, ethical, and, potentially, societal implications. These issues revolve around patient autonomy and reproductive liberty, the unknown risks of the procedures to the offspring, the possible fomenting of societal gender bias, and potential limitations on access to medical care. The slippery slope concern is also raised as an argument against elective sex selection: once the threshold of applying the technology for one nonessential indication is crossed, there is reason to believe we will not stop at sex and will seek to select other non-health-related traits in embryos.

Techniques

Currently, there are three available methods for sex selection. The first option is prefertilization sperm sorting using flow cytometry, which can provide a semen sample enriched with sperm that bear the desired sex chromosome. Its accuracy is in the 84-92 percent range, and it is not yet available in the US [6, 7]. At the opposite end of the spectrum, the most extreme form of sex selection occurs after conception in the form of elective termination of pregnancy if prenatal testing shows the sex of the fetus is the opposite of that desired. In certain regions of the world, such as India, such procedures are commonly performed, despite being illegal [8, 9].

A midpoint option is the one presented in the case above, and for some it is the ethically preferable choice because it avoids prenatal determination and possible elective termination [10]. This is preimplantation genetic diagnosis and screening (PGD/S) of embryos. According to Baruch et al, using data given voluntarily by centers providing PGD to their patients in 2005, approximately 9 percent of reported IVF/PGD cycles performed in the US in 2005 were done for nonmedical sex selection [11]. In PGD/PGS, the embryos created through IVF undergo biopsy at the cleavage cell stage (on day 3 of existence) or a trophectoderm biopsy of the blastocyst (day 5 of existence). The blastomere cell (or cells) or the trophectoderm cells are sent for genetic testing and only the embryos of the desired sex are transferred. The remaining embryos of the other sex can be discarded or cryopreserved for future use.

Risks

If the Warrens want to have another child at all, Mrs. Warren will be going through IVF. If they pursued sex selection, they would only need to add the biopsy of the embryos, genetic testing, and selection. These procedures generate additional costs

but do not in themselves expose the patient to any additional risks. There is some evidence that the manipulation of the embryos can be detrimental to their implantation potential [12], and, overall, there is limited data on the impact of biopsies on the risk to the offspring [13, 14]. The Warrens will obviously need to be fully informed of all known risks and implications.

Reasons and Justifications

The Warrens are interested in having a female child for "family balancing." If this couple had been asking for sex selection with their first attempt at IVF, it would have raised concerns about gender bias and possible societal sex-ratio imbalances. In that setting perhaps the physician caring for the couple would be less inclined to perform the PGD. When couples who are undergoing IVF for medical reasons already have a child or children of one sex and then pursue PGD to identify embryos for transfer of the other sex it raises less concern about contributing to an imbalance of the sexes in the general population.

The more difficult scenarios are sex selection requests from otherwise healthy or subfertile couples without medical indications for IVF. The treatment is driven only by a desire to have a child of a certain sex. Even with IVF risks relatively low for women undergoing the process, the use of a limited health care resource without normal clinical justifications may be cause for concern. Because these elective and nonindicated procedures will not be covered by any insurance, only patients of a certain socioeconomic class would be able to afford them, which might not be equitable. As of this writing, our ethics committee has not permitted patients to undergo IVF for sex selection when IVF is not otherwise indicated.

Ethical Guidance

The American Society for Reproductive Medicine (ASRM) Ethics Committee condones the use of PGD for serious adult-onset conditions for which there are no treatments [15]. Similarly, its most recent committee opinion on "sex selection and preimplantation genetic diagnosis" suggests that it is ethically acceptable to use PGD and sex selection for *medical* reasons. However, the committee has not come to a consensus on elective sex selection [16, 17]. The use of PGD for elective sex selection, even by couples already undergoing medically indicated IVF, is not encouraged, and certainly initiating IVF and PGD solely for sex selection in fertile patients is discouraged.

The European Society of Human Reproduction and Embryology (ESHRE) Task Force on Ethics and Law suggests that

> a cautious approach would be to allow preconception sex selection for family balancing in a setting designed to gain further data about all relevant aspects. The family-balancing requirement could be set at having at least one or at least more than one child of the non-requested sex in the household. Under the same family-balancing condition, professionals should then also be allowed to fulfil requests

> for additional sex selection after PGD or PGS, in cases where there are embryos of both sexes and in which the choice between those embryos is not fully determined by medical criteria [18].

Often REI practices that are affiliated with academic institutions have the opportunity to present ethically challenging cases to an ethics committee. As elective sex selection has yet to be considered an accepted practice by the ASRM, it has become standard at Albert Einstein College of Medicine's Montefiore Medical Center that all couples requesting sex selection for social, nonmedical reasons have their cases presented to the committee at the medical school. Each case is considered on its own merit. The committee weighs the justifications for the procedure against the potential risk to the couple and the future offspring and the potential impact on society. For treatment to ensue, the committee must arrive at a consensus based on the available facts. The patients making these requests are made aware of this and their treatments are delayed until the committee reviews their cases.

Conclusion

More data on PGD use will help clarify what oversight is needed. Currently, though the ESHRE PGD consortium has already reported on ten years of data [19] and continues to collect, there is only limited data from the US [11]. Within the last two years, the Society for Assisted Reproductive Technologies (SART) has been collecting data prospectively for all PGD cases conducted at SART-affiliated programs in the US. This will permit an adequate assessment of the prevalence and the indications for PGD/S for sex selection. This data will allow professional societies to understand whether current PGD/S use is ethically sound and socially appropriate; if so, they will be able to reassure concerned members of the public, and, if not, they will be able to formulate guidelines and limitations to ensure responsible use.

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

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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.

Related in VM
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Shared Decision Making about IVF for Savior Siblings, January 2014

Virtual Mentor
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IN THE LITERATURE

Seeking Causes for Race-Related Disparities in Contraceptive Use

Carolyn Payne and Nicole Fanarjian, MD, MSCR

Rocca CH, Harper CC. Do racial and ethnic differences in contraceptive attitudes and knowledge explain disparities in method use? *Perspect Sex Reprod Health*. 2012;44(3):150-158.

About 6.5 million pregnancies occur annually in the United States. Of these, roughly half are unplanned, a percentage that has remained relatively steady for decades [1]. This is, as the American College of Obstetricians and Gynecologists (ACOG) has noted, a public health crisis [2]. Studies have suggested that unplanned pregnancy is associated with poorer maternal and infant health outcomes [3]. In addition, while unplanned does not necessarily equate to unwanted, we do know that approximately half of unplanned pregnancies end in abortion [1]. Unintended pregnancies also place a significant financial burden on the public sector: estimates regarding the birthing costs alone for unplanned pregnancy supported by public funding totaled over 11 billion dollars in 2006 [4].

Planning for pregnancy is important to optimize not only clinical outcomes, but also the context and the circumstances surrounding the pregnancy. Since the typical American couple wants to have two children, and most women are fertile for three or four decades, most women, even those who intend to have children, will spend around 30 years trying to avoid pregnancy [5]. A person's choice of contraceptive method and rates of continuation are directly related to the risk of becoming pregnant. It is not surprising that higher rates of unintended pregnancies occur among those using less effective forms of contraception or no contraception at all [6]. Physicians, therefore, have a responsibility not only to help women plan pregnancies but also to aid in the prevention of unplanned pregnancies.

Which Contraceptives Are Best?

Collectively, contraceptive-dispensing implants and intrauterine devices (IUDs) are referred to as long-acting reversible contraceptives (LARCs). LARCs offer several advantages over all other methods of contraception. Because they are placed (either in the uterus or under the skin) by a health care professional, their effectiveness does not rely on the user. LARCs have the lowest failure rates of available reversible contraceptive methods, are effective from three to ten years, and provide a quick return to fertility when discontinued [7]. Implants and IUDs are not new technologies, but current iterations have improved their side-effect profiles and made them more desirable.

The American College of Obstetrics and Gynecology recommends that physicians consider LARCs the first-line contraceptive method for most women [2]. LARCs are not right for every woman, but there are very few contraindications.

Contraceptive Use in the United States

Women are highly motivated to use contraceptives, and the great majority of women do. More than ninety-nine percent of women who have ever had sex have used a method of contraception at some point [8]. Unfortunately, despite a growing body of evidence that LARCs are safe and highly effective (with a failure rate of less than 1 percent) and can be used by almost any woman, adoption of LARCs remains low. The majority of US women using a reversible contraceptive method are using oral contraceptive pills or condoms, which have 9 percent and 18 percent typical failure rates, respectively [9, 10]. In 2009 only 8.5 percent of US women at risk of becoming pregnant reported using LARCs. The trend, however, is promising: six years earlier, only 2.4 percent of US women were using LARCs [11], and the Affordable Care Act's reduction of financial barriers to using LARCs may contribute to a significant increase in their use.

Does Race Influence Choice of Contraception Method?

Race-related disparities exist in the choice of birth control methods, with women of color generally using less effective methods. Black women are more likely than white women to report using a contraceptive method associated with lower efficacy (e.g., withdrawal, condoms) or no contraception at all [6]. They are, therefore, three times as likely as white women to experience an unintended pregnancy. Hispanic women, too, are less likely to use highly effective forms of contraception (LARCs and hormonal methods) and twice as likely to experience unintended pregnancy as are white women [12].

We do not fully understand whether or how race influences contraceptive choice and subsequently contributes to disparities in unintended pregnancy rates. If we were able to identify the factors that inform women's choices about contraception, efforts aimed at addressing those factors might significantly reduce disparities in the use of the most effective forms of contraception and thus reduce the rates of unintended pregnancy.

In 2012, researchers from the Bixby Center for Global Reproductive Health sought to investigate a possible relationship between race and contraception-related choices and summarized their work in "Do Racial and Ethnic Differences in Contraceptive Attitudes and Knowledge Explain Disparities in Method Use?" [13]. Using data collected in the 2009 National Survey of Reproductive and Contraceptive Knowledge, the authors found significant racial differences in attitudes about contraception, pregnancy, and control over one's fate (fatalism).

They found that blacks and Hispanics were more likely than whites to believe that the government encourages contraceptive use to limit minority populations and that Hispanics were more likely to report positive feelings about an unplanned pregnancy

than blacks or whites. Their study did not, however, find an association between these attitudes and contraceptive choice.

The only attitude they found that consistently influenced contraceptive choice was skepticism that the government ensures contraceptive safety. This belief was associated with decreased use of highly effective forms of contraceptive methods, but it was equally prevalent among the members of all racial groups studied. Ultimately, the findings did not suggest that racial differences in attitudes about contraception, pregnancy, and fatalism were responsible for current disparities in contraceptive use. The authors suggest there may be other race-correlated factors influencing choice of contraception that were not covered by this study.

Their study did find that, in general, less knowledge about contraceptives is associated with decreased use of the more highly effective forms. Levels of such knowledge were lower among Hispanics than among blacks and whites, and Hispanics were more likely to report a feeling of low control over the timing of their pregnancies. This suggests that improving knowledge about contraception, especially among Hispanics, could reduce some disparities in method choice.

Other Possible Factors

The authors of the study conclude that disseminating information about contraceptive methods could result in a reduction of disparities in use. Indeed, the Contraceptive Choice Project demonstrated that when patients were counseled about all forms of birth control and barriers to choice (including financial) were removed, 75 percent of patients chose the most effective forms of contraception: implants and intrauterine devices (IUDs) [14]. This suggests that, in addition to knowledge about contraception options, financial considerations impact women's choices, and financial constraints may be inequitably distributed across racial groups. Information about the distribution of financial constraints among members of various racial groups could more fully and accurately elucidate the relationship between race and contraception use.

Conclusion

As physicians, we have a responsibility to improve maternal health by helping women plan their pregnancies. Highly effective methods of contraception exist, yet the majority of women at risk for unintended pregnancy are not using these methods. Women of color are even less likely to be using these methods. It is therefore especially important when discussing contraception with women of color to provide evidence-based, comprehensive counseling and address barriers to uptake and continuation of contraception use.

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STATE OF THE ART AND SCIENCE

Disclosure of Experience with Oocyte Cryopreservation

Stephanie J. Miller, MD, and Joseph B. Davis, DO

Oocyte cryopreservation or "freezing" has recently become available for patients with concerns about future fertility. Fertility can be preserved through oocyte cryopreservation before gonadotoxic chemotherapy, oophorectomy in young patients with BRCA mutations, or impending ovarian failure in young patients with Turner syndrome [1]. In addition, oocyte freezing has become more common as a means to "bank eggs" from oocyte donors to reduce cost and increase availability of donor eggs to women with diminished ovarian reserve [2]. Some women who wish to delay childbearing for personal or professional reasons are electively freezing their own eggs to retain their fertility potential.

The technology was, until recently, considered experimental, and its availability was limited to academic medical centers. Over the past 10 years, reassuring data about its safety has emerged, prompting the American Society for Reproductive Medicine (ASRM) and Society for Assisted Reproductive Technology (SART) to remove the "experimental" label [1]. As more institutions have begun to offer egg freezing, the success rates have varied widely with different techniques and levels of experience [3]. The question can now be raised: "Should institutions that offer oocyte cryopreservation be required to inform patients of their levels of experience with this new technology?" This article will make the ethical case that they should not be required to do so.

The implementation of new medical advancements is always plagued by tensions between the needs for completely informed patient consent and for the gaining of experience through using the new technology on patients. To respect patient autonomy, physicians are obligated to provide them with enough accurate information for them to make decisions. As is commonly seen with surgical technology developments such as laparoscopy and now robot-assisted surgery, physicians find themselves debating how much to tell a patient about their experience with a particular procedure [4]. Ultimately, the question is whether hearing certain information about an institution's experience with oocyte cryopreservation would help patients to make informed medical decisions.

What Information Would Patients Receive?

An institution's "experience" with oocyte cryopreservation can encompass many different elements, such as: the number of oocyte collection and freezing cycles performed, the number of surviving thawed oocytes from those cycles, the number of pregnancies resulting from implantation of thawed oocytes, the embryologists' levels

of oocyte cryopreservation training, and lab certifications for egg freezing. Currently there is no standardized, nationally recognized training program or certification in oocyte cryopreservation beyond the training required to perform IVF, so it is unclear how to measure experience. Even if it was determined that success rate should be used as a proxy for experience, a practice could have performed a large number of oocyte cryopreservation cycles but have no outcome data to report until their patients return to use their frozen oocytes.

Would That Information Be Accurate and Helpful In Decision Making?

Out-of-date information. A new employee's "success rates" would not be reflected in the clinic's data until that person had been with the practice for an extended period of time. Moreover, many clinic clients delay using their frozen oocytes for several years, by which time the experience of the center would have increased, calling into question the relevance of the information disclosed.

Lack of evidence. There is no data to support which measures of experience result in improved outcomes for patients and, therefore, which measures are relevant for decision making. Until standardization is in place for training, certification, and data reporting, disclosure of "experience" would not give patients particularly useful information for decision making.

Furthermore, an institution's level of experience does not affect the risk to the maternal patient or the embryos. Clinics offering oocyte freezing are primarily well-established IVF centers. The procedural risks to women undergoing oocyte collection are the same as those associated with oocyte retrieval for the purposes of IVF, hence the center's specific experience with egg freezing has no impact on maternal risks. Additionally, long-term data from academic centers that experimented with this technology have shown no increased risk of malformations in embryos generated from frozen oocytes [5]. If the level of experience involved altered the risk profile, this would be important information for decision making, but it does not.

It is our opinion that there is no ethical mandate to disclose experience with egg freezing until measures of experience and validated training standards can be correlated with improved outcomes for patients. Until then, information about experience will not be useful in decision making.

Gaining "Experience," However That Term Is Defined

If centers are required to disclose experience with oocyte cryopreservation, by any of the measures mentioned above, should newer centers offer patients incentives to undergo egg freezing while they are developing their programs? This question arises from the tension (mentioned at the outset of the article) between patients' right to be fully informed and the clinic's or center's need to develop its history of successful procedures. Offering incentives could imply that the quality of service is substandard, which could have the opposite of the intended effect, causing patients to go to more established centers. If pregnancy from previously frozen oocytes were to

be the standard for measuring "experience," new centers might only accept patients with a high probability of successful pregnancy, exacerbating the problem of unequal access to medical services for patients with complex medical and fertility problems. Finally, if newer clinics and those not associated with academic health centers disclosed less experience—as measured by whatever standard is ultimately settled upon—it would become more difficult for them to gain the needed experience. This would mean that many patients seeking fertility services would have to travel long distances for care. Many examples of this outcome exist in, for example, expert cancer or organ transplantation care, but it creates unequal access to care for those outside of large urban centers.

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STATE OF THE ART AND SCIENCE

I, Robotic Surgeon

Monique A. Spillman, MD, PhD, and Robert M. Sade, MD

When Isaac Asimov penned his famous novel, *I, Robot* [1], he presented the world with three Laws of Robotics. His laws were intended for human interactions with fictional *autonomous* robots. We can apply the laws to our understanding of the current surgeon interface with robotic surgical systems if we acknowledge that the autonomy resides in the surgeon. The new technology gets the attention, but robotic surgery still remains a human endeavor of medical practice and should be subject to the same principles of medical education and ethics as any other method of surgery. In this paper, we will apply the concepts of the Three Laws to explore ethical questions surrounding the education of resident physicians in robotic surgery, appropriate responses of trainees to robot system failures, and the financial conflicts of interest facing residents who become robotic surgeons.

First Law: A Robot Must Not Harm a Patient

The First Law of Robotics states that "A robot may not injure a human being or, through inaction, allow a human being to come to harm." Applying this law with the surgeon as seat of the robot's autonomous will accords with the ethical principle of nonmaleficence that requires that physicians' actions not intentionally cause harm. The two questions for the training of new surgeons, then, are can training in robotic surgery hurt patients and can lack of training in robotic surgery, "through inaction, allow a human being to come to harm" [1]? The argument has been made that training in robotic hysterectomy is hampering the development of residents' skills in traditional techniques [2] and may therefore be contributing to producing newly minted surgeons who are underprepared for practice. In this sense, the training could be said to harm patients.

What about nonuse of robotic surgery allowing "a human to come to harm"? If one views the robot as simply another tool in the surgeon's armamentarium, one that is neither better nor worse than the tools of traditional laparoscopy or laparotomy, then omitting robotic training from graduate medical education is ethically neutral. If one views robotic surgery as a major advance that allows more patients to have complex minimally invasive surgeries with shorter recovery times, however, then omission of robotic surgical training would in fact, be harmful to the population of patients that the trainee would serve in the future.

An important caveat in attempting to answer both questions is the metaethical principle that good ethics begins with good facts. The facts that could help answer the ethical questions related to dedicated training time for robotic versus

laparoscopic and open techniques of hysterectomy are not available, so these questions remain open.

Second Law: Robot Malfunctions Must Be Reported

Asimov's Second Law of Robotics is: "A robot must obey the orders given to it by human beings, except where such orders would conflict with the First Law" [1]. The Engineering and Physical Sciences Research Council translates this succinctly as, "Robots are products. They should be designed using processes which assure their safety and security" [3].

Surgical tools have become increasingly more complex and prone to failure. This is certainly the case with complex robotic surgery systems, which contain multiple components. Communication among the patient docking arms, camera, and surgeon console are critical for the success of the operation, as well as patient safety, and failure of the system at any of these critical nodes could cause harm to the patient. The responsibility for preventing that harm resides with the surgeon who is using the robot. He or she must report a malfunction of the robotic equipment to the manufacturer, hospital risk management, and, for serious adverse events, the Food and Drug Administration (FDA). Failure to do so is a lapse of the surgeon's ethical duty [4]. This duty is particularly important in light of the FDA's recent warning letter to Intuitive Surgical, Inc., manufacturers of a robotic system, criticizing the company for delaying reports of technical issues that could have resulted in patient harm [5].

Third Law: Promotion of Robots Leads to Conflicts of Interest

The Third Law of Robotics is: "A robot must protect its own existence" as long as doing so does not interfere with the first two laws. Robotic surgery has become big business for both the manufacturers and the hospitals that have invested in the multimillion-dollar equipment [6]. The third law implies that the autonomous robot—in our case, the autonomous robot-using surgeon—protect the existence and promote the use of robotic surgery. Trainees in robotic surgery, however, must be aware of the intense financial pressures to use the technology, and they must be cognizant of a critically important distinction: the primary ethical obligation of a physician is to the patient, while the primary fiduciary duty of the company is to its stockholders. This difference presents a significant danger—co-optation by hospital administrators or industry representatives that may result in treatment choices that do not primarily benefit the patient. Surgeons might be co-opted in a couple of ways.

Advertising. Hospitals may invest heavily in advertising of robotic surgery and anticipate that their surgeons will participate in the advertising. For gynecologic surgery, advertising images (64.1 percent) and text (24 percent) are often provided directly by the manufacturer of the system [7]. Newly minted surgeons should be aware of how their credentials are used in advertising and ensure that any such advertising is accurate. Some surgical specialty organizations hold surgeons responsible for the truth and accuracy of all advertising related to their programs, regardless of whether they were consulted before publication of the advertising

material. For example, the American College of Obstetricians and Gynecologists Committee on Ethics states, "In considering appropriate marketing practices, physicians should evaluate not only their own actions but also those undertaken on their behalf by hospitals or other health care centers that may be marketing their services" [8]. Claims of superiority of the robotic procedure, one surgeon, or one surgical center over another must be backed up by objective data. In the absence of such data, claims of superiority may not only fail the sniff test, but may be considered untruthful, misleading, or deceptive [9] and thereby unethical and possibly illegal. An important and highly relevant problem is that few high-quality data (such as randomized controlled trials) have compared robotic surgery with other methods, so the range of accurate marketing claims is limited [6].

Costs. Hospitals that have made large capital investments in robotic systems are pushing surgeons to have the robots in use daily to increase the return on the hospitals' investment, as recommended in the memorandum to hospital executives from Intuitive Surgical [10]. The cost of robotic procedures is considerably higher than that of comparable procedures performed by laparoscopy (although the cost differential decreases somewhat with an increasing volume of robotically performed surgeries) [6, 11]. Switching surgeries to the robotic platform is certainly a "high-cost" conversion, and, again, reliable and consistent data that robotic hysterectomy presents higher quality or better outcomes are lacking [12]. In the current health care reform environment, cost and quality are garnering more attention than ever before. By shifting resident teaching time from standard laparoscopy to robotic surgery, we may be producing "high-cost" surgeons who will be penalized by insurers, whether or not the cost is justified by better outcomes.

Conclusion

So is robotic surgery training in residency a good thing or a bad thing? Only time, experience, and reliable data will tell. The market forces driving this technology today may be completely different in 10 years. However, the timeless ethical and educational principles in surgical training will outlast the popular technology of today as well as the next surgical fad. As always, the paramount consideration must be the safety of the patient, rather than the exact tools utilized for the surgery.

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Disclosure

Dr. Spillman has participated in the Intuitive Surgical, Inc. initial robotic surgery training course online and in person, and does perform robotic surgery in her practice

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POLICY FORUM
Fetal Pain Legislation
Kavita Shah Arora, MD, MBE, and Christina Salazar, MD

The 1992 Supreme Court ruling in *Planned Parenthood of Southeastern Pennsylvania v. Casey* codified that, given the state's compelling interest in a fetus after viability, opposing claims to rights must be balanced [1]. That is, a pregnant woman's autonomous decision to terminate a pregnancy after viability must be balanced with the state's interest in the ongoing gestation and ultimate delivery of the fetus. The codification of this balancing act has opened the door to a variety of state-based initiatives that seek to impose restrictions on access to and provision of terminations of pregnancy. One such set of initiatives are the fetal pain bills that began to be introduced at both the state and federal levels in 2010 [2]. Nebraska became the first state to pass a law based on model legislation drafted by the National Right to Life Committee banning abortion after 20 weeks, asserting that fetuses can experience pain after this gestational point. Eight states have since joined Nebraska in restricting abortions on the basis of fetal pain—Alabama, Arkansas, Indiana, Kansas, Louisiana, North Dakota, Oklahoma, and Texas. A total of twelve states, including some listed above, mandate that patients be given written literature during abortion counseling services that discusses the possible ability of a fetus to feel pain [2].

Very few (less than 1.2 percent) of termination procedures are performed after 21 weeks in the United States [3], so the legislation pertains to a small minority of termination procedures. However, given that the dating of a pregnancy (from the last menstrual period or moment of conception) is not defined in many of the state laws, it is potentially unclear at what gestational age scripted counseling and termination bans take effect.

Logical Problems
These laws are logically flawed. If we as a society believed we should not be doing procedures that may cause pain (the argument used by proponents of fetal pain legislation), *all* invasive procedures and surgeries would be banned [4]. It would appear, rather, that the widely recognized ethical obligation is to *limit* pain to the best of our abilities, not to ban anything that may be painful.

If the goal is (as it is in most invasive medical interventions) to prevent or limit possible pain, rather than to prevent terminations, a more robust and defendable position would be to require fetal analgesia during terminations after the gestational age at which scientific evidence suggests the fetus has developed the ability to feel pain. That, rather than banning terminations, would represent an attempt to prevent

fetal pain. Even that position, however, is suspect. If these laws are justified by concern about fetal pain, that concern should extend to situations other than terminations: proponents of fetal pain laws should also be advocating for, for example, mandated general anesthesia during fetal surgery and vaginal deliveries. That they are not indicates that concern about fetal pain may not, in fact, be the priority underlying these bills.

Ethical Problems

These laws are unethical on two counts: they undermine the scientific accuracy of the information physicians give patients that is crucial to high-quality patient care and they trample the respect for patient autonomy central to medical ethics.

One would hope that there would be substantial rigorous medical evidence to justify the passage of this kind of fact-dependent legislation, but this has not been the case. These laws are based on scientifically ungrounded ideas: they conflate nociception, the triggering of autonomic responses to harmful stimuli, with pain. While the neural pathways that send nociceptive signals have completed development by 23 weeks, a comprehensive, nonpartisan, multidisciplinary review of almost 2,000 fetal pain studies concluded that "the capacity for functional pain perception in preterm neonates probably does not exist before 29 or 30 weeks" [5]. Until the conscious ability to process nociceptive signals develops, it is definitionally and physically impossible to register pain [6]. Allowing a nonmedical third party (e.g., the government) to dictate that counseling and treatment be based on sources other than evidence, clinical judgment, and the patient's wishes undermines the scientific accuracy and patient-centeredness of the counseling process.

Secondly, these laws run afoul of medical ethics by mandating the privileging of nonmaleficence towards the fetus over maternal autonomy. The implication is that the capacity for fetal pain changes its moral status sufficiently to trump the rights to bodily integrity and privacy of the woman carrying it. This is in direct opposition to *Roe v. Wade* [7] and the widespread perception that, in medical ethics, respect for autonomy is "first among equals" [8].

Conclusion

The scientific, legal, and philosophical communities have grappled with the large body of available neurobiological and clinical evidence available in order to establish a scientific understanding of fetal pain [6]. *Gonzalez v. Carhart* set a precedent requiring the nearly impossible standard of "medical certainty" to overturn state gestational-age-based restrictions on abortion [9]. Given this hurdle, it is unlikely that these laws will be overturned on the basis of science alone, despite the preponderance of evidence stating that a 20-week fetus is unable to feel pain [10].

It is crucial that the balancing of maternal autonomy with nonmaleficence toward the fetus be based on the highest quality of evidence and contravene neither accepted principles of medical ethics nor federal law. As currently written, fetal pain

legislation attempts to subvert the careful balance required by *Casey* at the expense of ethical practice and women's health.

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POLICY FORUM
Conflicts of Interest for Physicians Treating Egg Donors
Caroline Bass and Joseph Gregorio

While egg donation may seem like a feasible source of income for young, financially needy women, donor care can be ethically compromised by the conflicts of interest and incentives inherent in the current donor-egg in vitro fertilization (IVF) process These features of the donor-physician relationship mean that not all donors undergo an adequate informed consent process or consistently receive quality care or enjoy a trusting patient-physician relationship.

Structural Problems
In most cases the same physician treats both the donor and the recipient, forcing physicians to balance recipients' intense desire for a child with donor safety [1]—an inherent conflict of interest. Hence, it is unclear that egg donation is compatible with the existing paradigm of the patient-physician relationship because the donor is, in some respects, a "third party" [2]. Because ARTs are expensive, time-consuming, and emotionally taxing for intended parents [3], physicians may intentionally or inadvertently overlook the medical needs and preferences of the donor in an attempt to maximize the chances of a successful pregnancy [4]. This conflict of interest may manifest as a standoffish relationship with the donor or subpar medical care [5]. Physicians with conflicting responsibilities to recipients and donors may also withhold relevant information from the donor or encourage apprehensive donors to finish the cycle by appealing to the recipient's desire for a child [6].

The current reporting regime in the US may provide physicians with an added incentive to favor recipients over donors. Because fertility treatments can be extremely lucrative for fertility clinics, advertised rates on fertility outcomes and birth rates provide clinics with a financial incentive to maximize fertility rates [7]. Physicians are not required to report or even record the clinical activities that affect donors such as the type and amount of drugs used for stimulating egg production, the number of eggs retrieved, or complications [8]. Furthermore, because physicians are not required to follow up with donors after the eggs are removed, they have no external incentive to find out if any posttreatment complications occur nor any obligation to help the donor with known complications during or after the treatment cycle [9].

There are few laws in the US that govern the donor-physician relationship. The federal laws that concern egg donations for IVF merely require clinics to report their fertility success rates to the Centers for Disease Control [10], to register with the Food and Drug Administration, and to screen donors for communicable diseases

[11]. Although these regulations help protect recipients from communicable diseases and deceptive fertility success claims [2], they do little to protect donors [12]. There are no mandatory regulations that control the informed consent process and other aspects of the physician-donor relationship or that require clinics to record or report aspects of donor treatments performed or medical complications that result from them [2]. Arizona passed a law that unequivocally states that a patient-physician relationship exists between the donor and the physician [13]. It might be beneficial for other states to follow suit.

The lack of any formal regulatory structure at the federal level and patchwork of state laws regarding egg donation for IVF illuminates the reality that there are greater legal protections for embryos and unborn children in the United States than there are for vulnerable egg donors during the ART process [2].

Problems in the Donor-Physician Relationship

Informed consent in egg donation often falls short of best ethical practices for disclosure [14]. Though nearly two-thirds of egg donors reported being satisfied with the information they received during the donation process, more than 36 percent of donors would have liked more information about the risks of donation [15]. Additional studies of past donors are cause for concern. One follow up study of former egg donors found that 20 percent were not aware of any medical risks at the time of their donation [13]. Two-thirds were unaware of the risk of ovarian hyperstimulation (while 12.5 percent experienced it) [13]; less than 10 percent were aware that the procedure could cause pain and cramping (while 45 percent experienced those sensations [13]; and no respondents reporting being aware of the possibility of ovarian cysts (whereas 2.5 percent of them experienced them) [13]. As a whole, current disclosure practices are inadequate, most likely because clinics are free to devise the particularities of their own informed consent processes [12].

Some donors report that physicians and clinic staff treated them like second-class patients and that their care was cold, discontinuous, and abruptly terminated after egg retrieval [5]. One young donor describes how the high stakes of ARTs enticed her physician to prioritize the recipient's desire for a child above her safety: "Once the eggs were fertilized and transferred, I met my intended mother. This woman told me that I had a right to know that I was going through premature ovarian failure…. All of my eggs ended up dying so she wasn't able to get pregnant…. When I asked why I hadn't heard this from the doctors, she said they wanted to wait until the end because 'they didn't want to have any negative energy' during the cycle. It blew my mind" [16].

Previously Proposed Interventions

Legislative interventions. Only a few states have taken steps to safeguard egg donors [17], even though states are best suited to regulate and enforce these types of laws because of their control over the licensure and certification of physicians and facilities. California requires clinics that recruit donors via ads that offer compensation to either certify that they have complied with ASRM requirements or

to include a notice explaining that donation involves certain screening and medical procedures that carry some risks [18]. California also requires that clinics provide a more detailed explanation of the procedure and risks before creating a contract or beginning treatment [18]. New York has specific requirements regarding what must be covered under informed consent [19], and Arizona requires disclosures regarding the procedure and risks involved [20].

Whether or not these laws adequately protect donors from the dangers of egg procurement, it is promising that some states have taken measures to protect this vulnerable and unprotected population of patients. Other states that allow egg donation should enact some type of legislation to protect donors. Although varying laws between states may create the potential for interstate reproductive tourism, the "laboratory of the states" can experiment with legislation to determine what regulations are optimal.

Professional interventions. Professional organizations like the American Society for Reproductive Medicine (ASRM) issue guidelines for fertility clinics and physicians [12]. As concern about the lack of informed consent in egg donation mounts, ASRM and others have taken notice. In January 2014, ASRM released new guidelines for donor informed consent, suggesting that the informed consent process should begin earlier in the donation process and include "explanatory figures and diagrams detailing the medical procedure; descriptions of and statistics for multiple risks; opportunities to grant or withhold consent to use of donated tissues in subsequent research, and information about compensation" [21]. However, these guidelines are merely "strong recommendations" because the ASRM has no enforcement authority beyond excluding noncompliant physicians and facilities from membership [22].

Mechanical improvements to informed consent. Researchers Amanda Skillern, Marcelle Cedars , and Heather Huddleston are touting their Egg Donor Informed Consent Tool (EDICT) as the solution to the current inadequate practices [23]. The EDICT measures donors' own subjective assessment of their understanding of the donation process and their objective comprehension of the risks [23]. A recent study reported that donors who received an hour long audiovisual presentation on donation drastically improved on both the subjective and objective measurements of informed consent [23]. Researchers believe this "provides evidence for the first time that prospective oocyte donors are capable of giving true informed consent, which requires capacity and the ability to understand disclosed information and its reasonably foreseeable consequences" [23].

The EDICT's efficacy or utility in evaluating informed consent processes notwithstanding, attaining truly informed consent requires something beyond a mere clinical presentation of facts, risks, and benefits; disclosure is a trust-building exercise between physician and patient [24]. The donor-physician relationship cannot foster true informed consent when physicians must juggle competing responsibilities and conflicts of interests. Whether this pressure is intentional or

inadvertent, donors are more likely to face manipulation when physicians treat both donor and intended parents [25].

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MEDICINE AND SOCIETY

Judicial, Legislative, and Professional Attempts to Restrict Pregnant Women's Autonomy

Ruth Macklin, PhD

The way a question is framed is important for understanding what lies behind the question. I was asked to write an essay answering the question, "Who should have a say in protecting the unborn?" This includes a number of presuppositions. The first relates to the term "unborn" to refer to the fetus. The implication is that there are two different types of persons: those who are born and those who are not yet born. The presupposition is that those who are not yet born will eventually undergo a change in temporal and geographic status and will, in time, be born. Some in the pro-life movement even prefer the term "pre-born." Here is an example of such thinking around this concept:

> I was struck by the term that many pro-life advocates continue to use when speaking about a child in the womb: *unborn.* Of all the prefixes that we could use in referring to the precious life in the womb, I have yet to determine why the term *unborn* was chosen…[W]ith the knowledge and understanding that life begins at fertilization, and that we are living human beings in the womb, why don't we *all* use the reference *preborn* [1]?

But a fetus may ultimately not be born, either because natural causes or the pregnant woman's choice results in its demise before birth. The terms we use to describe life in the womb should not include a presupposition that birth is the intended or inevitable outcome.

A second presupposition in the title relates to the term "protecting." It conjures up an image of a defenseless being threatened with an attack of some sort. It is true that vulnerable persons stand in need of protection from harm, whether at the hands of other human beings or from natural disasters such as hurricanes and earthquakes. From what do fetuses need protecting? The presupposition is that the pregnant woman herself may be visiting harm on the fetus, possibly by ingesting drugs or alcohol, by refusing a medical intervention aimed at the fetus, or by seeking to terminate its life by means of abortion. Does this mean that someone other than pregnant women should "have a say" in decisions about fetuses' interests?

The third presupposition lies in the form of the question. To ask "Who should have a say in protecting the fetus?" presumes that someone other than the pregnant woman may have a say. Should it be the pregnant woman's obstetrician? Should it be the

state? Should it be pro-life demonstrators seeking to close down a clinic that provides abortions? And what does it mean to "have a say?"

My contention is that a pregnant woman is the only one who should ultimately "have a say" in what happens to the fetus. Physicians may have a say, of course, in making recommendations to women for maintaining a healthy pregnancy. They may have "a say" but not the last word. The last word, up until the time a baby is born, belongs to the pregnant woman. The ethical principle from which this claim derives is respect for autonomy. That principle requires that patients with decisional capacity have the right to determine what medical treatments may be administered to them. This right has been enshrined in the United Nations human rights convention (the Convention on the Elimination of All Forms of Discrimination Against Women) that spells out a variety of circumstances ensuring equality of women and men. In particular, Article 16 says that states should ensure that women have "the same rights [as men] to decide freely and responsibly on the number and spacing of their children and to have access to the information, education and means to enable them to exercise these rights" [2]. One plausible interpretation of this article is that women have the right to determine when and whether to initiate a pregnancy, when and whether to terminate a pregnancy, and the manner in which childbirth will be carried out.

But many do not hold this view, in which women's right to autonomous decision making takes primacy in matters of pregnancy. The remainder of this essay will explore past and current actions by the state and physicians that attempt to restrict pregnant women for the sake of the fetus, thereby violating their right to autonomous decision making.

Actions by the State Regarding Abortion in the US

As long as *Roe v. Wade* is not overturned, women have a constitutional right to abortion in the United States. The Supreme Court opined that the state has an interest in "potential life"—meaning the life of the fetus—but that that interest does not become "compelling" (which is to say it would not justify the government's impinging on the individual's constitutional right to be free of law) until the time of viability [3]. But the state has sought to "protect" the fetus by legislating a variety of measures that make it difficult for women to obtain safe, legal abortions, some of which limit what pregnant women may do and some of which restrict physicians in one way or another [4].

There are a variety of types of state and federal laws regarding abortion currently in effect: requirements of physicians and clinics that provide abortions; limits on the gestational circumstances under which abortions may be performed; requirements of the clinician-patient encounter, such as state-mandated counseling and post-counseling waiting periods; limits on public funding and private insurance coverage of abortions; laws that protect clinicians' and institutions' refusals to perform abortions; and laws requiring parental involvement when minors seek abortions (see table 1).

It is abundantly clear that most states in the US "have a say" in the circumstances in which women may seek an abortion.

State Laws and Criminal Prosecutions of Pregnant Women

For well over a decade, prosecutors in some states have charged pregnant women with actions that constitute a crime, most often when women are discovered to be using illegal drugs or alcohol during their pregnancies. According to the National Advocates for Pregnant Women, at least 126 women in South Carolina have been arrested during their pregnancies, mostly for using drugs or alcohol that could harm the fetus. In 1997 [13] the Supreme Court of South Carolina "by judicial fiat...declared that viable fetuses are legal persons and that pregnant women who use illegal drugs or engage in any other behavior that jeopardizes the fetus can be prosecuted as a child abusers or murderers" [14].

One tactic used by prosecutors has been to invoke existing laws that punish "delivering drugs to a minor" and assert that a pregnant woman using illegal substances delivers the drugs to the fetus through the umbilical cord [15-17]. In some cases, women undergoing prenatal care have been secretly tested for cocaine use [18]. In other cases, physicians have reported women whom they knew to be using drugs to state authorities [19].

It is clear from these and other examples that states have at least sought to "have a say" in protecting the fetus. But, following initial attempts at prosecution, judges have rejected almost all cases brought to court under existing criminal law statutes. The judicial reasoning has been that granting rights to the fetus threatens women's rights and the best interest of children [20]. No one believes that it is a good thing for women who are pregnant to use substances that have the potential to harm the fetus. The question is whether criminal prosecution is an ethically acceptable course of action in this situation.

Actions by Physicians

In addition to reporting drug-using pregnant women to the authorities, physicians have engaged in more direct attempts to coerce pregnant women for the sake of the fetus. Perhaps the most egregious are forced caesarean sections, in which a judge's approval overrides the woman's refusal. Some contend that the prospect of third-trimester fetal death or a lifetime physical or mental disability for the resulting child can justify overriding the woman's autonomy [21].

Physicians have also sought court orders to override a pregnant patient's wish when Jehovah's Witnesses refuse blood transfusions, but courts have ruled both ways in this situation, with appeals courts overruling lower courts in favor of protecting the pregnant woman's right to refuse treatment [22].

Conclusion

In seeking to override pregnant women's decision-making autonomy in refusing treatment, physicians have had a say in protecting the fetus, but not the final word.

Judges have also had a say, and, as the judicial decisions reveal, their final words have conflicted with one another. In a number of cases, higher courts have reversed the decisions of lower courts that found the pregnant woman guilty of some form of fetal abuse [17]. In general, the courts have been more protective of the rights of pregnant women than the states that have passed legislation restricting those rights. Those states are typically politically conservative, with legislative majorities that oppose abortion rights. Although judges may also be politically conservative, for the most part they look to legal precedents, and even judges who are elected rather than appointed are less beholden to constituencies than are legislators. A look at a recently compiled overview of state abortion laws confirms that politically conservative states have far more restrictions on abortion rights than politically liberal states like New York, California, Connecticut, and Oregon, for example [6]. But whether it is the right to a safe, legal abortion, the right to refuse a caesarean section, or other exercise of their autonomy, women should have the final say in matters relating to their pregnancies.

Table 1. Laws regarding abortion in effect in the US (as of August 1, 2014)

Law type	**Description**	**Number of states**
Requirements of physicians and clinics that go "beyond what is necessary to ensure patients' safety" [5]	Requirements that facilities where abortions are performed meet standards intended for outpatient surgical centers, which provide much riskier and more invasive procedures [5]	26
Restrictions on the gestational circumstances under which abortion can be performed	Prohibitions on abortions performed after viability of the fetus or another specified point in gestation, unless they are needed to protect the woman's health or life [4]	42
	Prohibitions on the intact extraction of a late-term fetus, called "partial-birth abortion" [6]	19, with 13 more states' laws struck down
Requirements about the content of the patient-physician encounter	• Requirement that women receive ultrasounds before abortions o Requirement that they view the results before proceeding [7]	• 12 o 3
	• Requirement that information that is either controversial or contradicted by evidence be provided as part of mandatory pre-abortion counseling o Requirement to tell women that personhood begins at conception. o Provision of written materials developed by the state health agency (which are in some cases	o 5 o 5

	required to be distributed) that inaccurately portray the risks of abortion for future fertility o Requirement to inaccurately assert a link between abortion and breast cancer [8]	o 5
	• Requirement of a specified waiting period between mandated counseling and the abortion procedure [8] o Requirement that counseling take place in person before the waiting period can begin [8]	• 26 o 3
Coverage restrictions	The Hyde Amendment (passed in 1976) prohibiting the use of federal funds to cover abortions, except when the woman is in mortal danger or conception has resulted from rape or incest [9]	federal
	• Restrictions on private insurance coverage of abortions [10] o Restrictions on this coverage for any insurance plan available in the state o Limitations or prohibitions on this coverage on insurance plans available through the health insurance exchanges established by the Affordable Care Act • Restrictions or prohibitions on this coverage for state employees	o 25 o 19 • 10
Protected refusal to provide abortions	The Weldon Amendment, also known as the "federal refusal clause," protecting from financial, professional, or legal consequences those who conscientiously refuse to perform abortions, or, crucially, to refer patients to those who will perform them [11]	federal
	• Allowance for individual clinicians to refuse to participate in abortions [5] • Allowance for institutions, including public hospitals, to decline to provide abortions • Allowance of this refusal for private and religious health care organizations, but not their public counterparts	• 42 • 27 • 16

Parental involvement in abortions for minors	Requirement of some combination of parental notification and permission for a minors to have an abortions [12]	38
	Exceptions for emergencies, rape, and judicial approval of waiving the consent requirement [12]	37

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SECOND THOUGHTS
Natural Childbirth—a Global Perspective
Lauri J. Romanzi, MD

Fresh out of ob-gyn residency in Brooklyn's Kings County Hospital, one of the busiest county hospitals in the US, I came close to being fired from my first academic posting for facilitating a tub birth in the Allen Pavilion of Columbia Presbyterian Medical Center. To rescue me from instant dismissal, the couple insisted that the tub was requested only for maternal relaxation, where precipitous birth ensued. Partially true—the patient did enter the tub for relaxation in the early transition phase, then delivered into the water some 20 minutes later while I neither dissuaded nor distracted her efforts beyond portable fetal heart monitoring. Did I collude with their birth preferences? Indeed so. Having birthed my own children in the East Side mansion basement delivery suite of Manhattan's Maternity Center Association (MCA) some few years earlier, I was no stranger to alternative and out-of-hospital birth advocacy for low-risk pregnant women [1, 2].

Data on Home Birth
In the United States, the battle over home birth is at fever pitch, reflected in one 2014 study from Weill Cornell Medical Center/New York Presbyterian Hospital and another, with contradictory data, from the Midwives Alliance of North American Statistics Project (MANA) [3, 4]. The first reviewed Centers for Disease Control and Prevention (CDC) data on neonatal and infant death, exclusive of congenital anomalies, in relation to type of birthing clinician and birth place [3]. This investigation said nothing reassuring about midwife home birth as opposed to midwife hospital birth, with final analysis revealing 0.9 more neonatal deaths per 1,000 births among home births than among hospital births [3].

Similar out-of-hospital birth concerns have been raised in European countries, particularly the Netherlands, which has been romanticized by the US home birth community and considered the mecca of optimal home birth policy among wealthy nations. In the Netherlands 22 percent of women deliver at home with certified midwives in a system designed to foster cooperation and facilitate transfers to hospital if needed [5]. In a 2008 review of 680,000 cases, home birth for low-risk women proved as safe as hospital births when there were no complications, but resulted in a disturbingly large 20 percent rate in neonatal morbidity and mortality when unexpected complications arose during home birth [6]. Other Dutch studies raise concerns about various perinatal mortality markers in which the Netherlands rank among the highest in Europe, with an overall perinatal death rate of 3.2 per 1,000 term births, which they identify as due to advanced maternal age and high rates of multiple pregnancies, without naming the country's home birth legacy as a

neonatal death risk factor [7]. Dutch midwifery itself came under direct fire in a prospective cohort study of birth morbidity and mortality related to pregnancy risk and caretaker (comparing midwife to obstetrician) that found a higher risk of perinatal death when labor started under midwife management than when it started under obstetrician management, regardless of whether the midwifery-managed labor began at home or in hospital [5].

These data stand in opposition to reassuring home birth studies embodied in one prospective cohort assessment of Swiss women choosing either home birth or hospital birth [8]. Following each cohort from antepartum to 3 months postpartum, including crossover patients (those who transferred to hospital birth during labor), no differences were found in neonatal or maternal clinical status, aside from lower rates of labor analgesia in the home birth group. Similar American findings on planned home birth outcomes was published this year by the Midwives Alliance of North American Statistics Project (MANA), with data from 2004-2010, a period in which stateside home births increased 41 percent [4]. Records from 16,924 women who planned home births showed 90 percent accomplished the goal, with low Apgar score in 1.5 percent of the births, intrapartum neonatal mortality in 1.3 births per 1,000, early neonatal mortality in 0.41 births per 1,000, and late neonatal mortality in 0.35 births per 1,000 [4]. Compared to the general US national neonatal mortality rate of 4 per 1,000 births, women in this study, high-risk or low, fared well [4, 9].

My Story

Now working year-round in Africa and Asia, I confess my preference for out-of-hospital birth for low-risk pregnancies has not changed. This despite an immersion in African maternal mortality and morbidity writ large; the wards full of women with foot drop, paraplegia, pelvic fibrosis, fistula, incontinence, stroke, coma, sepsis, necrotizing fasciitis, and all manner of iatrogenic injury; mothers with dead babies, babies with dead mothers; families with no money to pay, families with money who won't pay; obstetric morbidity sustained in hospital for lack of beds or staff or supplies or side-money when corruption demands extra payment for service; nomads with no access whether they have money or don't; and one camel herder who had given birth to more than 20 babies in the bush, angry that the twenty-first baby, in transverse-lie, warranted a caesarean, convinced even on the day of discharge home with a healthy baby in her arms that the hospital "just wanted my money." This Somali multipara's intense bias against hospital birth is reflected in Tanzanian and continental African data on the training and supervision of health care workers and the effect of negative delivery care experiences on the reputation of the health care system: they can lower community expectations of facility delivery and result in high rates of home deliveries [10, 11].

Euro-American strategists hoping to improve outcomes by restricting home birth have lessons to learn from African data. These factors involved in hospital avoidance for childbirth in Tanzania exist everywhere. Why would a Somali woman with access to hospital care birth 20 babies at home? Her perspective revealed a mix of reverence for tradition, nomadic living, and lack of faith in Western medicine. Why

would a New York City gynecologist deliver her own children in anything other than a major obstetric hospital setting with the highest level of neonatal care? Simple: I was terrified—of being tethered to constant fetal heart monitoring, of restriction to the labor bed, of pain without emotional support, of sedation, of epidural anesthesia, of medication errors, of nosocomial neonatal infection, of inadvertent bottle feeding, of every iatrogenic possibility, and of laboring and birthing in a dogmatic environment that deems every pregnancy an adversary to be conquered, lest it wreak obstetrical havoc and malpractice litigation.

My version of home birth was choosing New York City's Maternity Center Association (MCA) [1, 2]. I had full confidence in MCA because of its history as the country's first midwifery training institute, its stringent antepartum and intrapartum hospital referral protocols, and its time-tested, animosity-free relationship with the nearby covering hospital and obstetricians. Having witnessed countless women arrive to the labor ward only to descend into terror and labor arrest, confined to bed, attached to monitors, sedated into a stupor or immobilized by epidurals, I could not bring myself to elect birth inside a modern hospital without compelling circumstances. It seemed to me then, and still does, that the ideal role of modern obstetrics is to nourish a system in which women labor under expert surveillance, yet are able to move, to be monitored intermittently without strapped-on monitors, to be coached through the pain, to choose birth positions, with all the interventions at the ready should labor obstruct, the placenta abrupt, hemorrhage ensue, hypertension develop, infection threaten, or fetal distress erupt.

The Risks of Childbirth Today

The global state of pregnancy and childbirth today is one of obscene maternal and neonatal apartheid. In 2013, 800 maternal deaths occurred daily, 690 of which took place in sub-Saharan Africa and southeast Asia, with only 6 per day in wealthy nations [12]. In sub-Saharan Africa, maternal mortality ranges from 300-900 per 100,000 births and neonatal mortality is 32 per 1,000 births, in stark contrast to maternal (2-12 per 100,000 in Western Europe, 11 per 100,000 in Canada, and 28 per 100,000 in the US) and neonatal mortality (2-9 per 1,000 births) in industrialized nations [13, 14]. The struggle among developing nations to reduce these flagrant differences in odds involves improvements to medical infrastructure; increased numbers of trained birth attendants, obstetricians, and pediatricians; and educational outreach into communities favoring traditional birth to increase utilization of birthing centers and hospitals. All these are in keeping with the United Nations 2015 millennium development goals "4: Reduce Child Mortality" and "5: Improve Maternal Health" [15].

While in Europe and North America home birth is the province primarily of women who are educated, mature, multiparous, and economically privileged, data on developing nations show opposite correlations, with socioeconomic advantage associated with lower rates of home birth [16]. This intriguing home birth contrast between resource-poor and wealthy nations reveals an evolution of disenchantment with the exact methods that developing nations struggle to achieve, the very same

that have reduced Euro-American maternal and neonatal mortalities to unprecedented lows. Some few generations ago, the women of Europe and North America experienced pregnancy much as our African and Asian sisters do today—at great maternal risk from conception to delivery, with high rates of neonatal death. Why, then, would the most educated and privileged of women from wealthy nations, myself included, prefer to avoid immersion in modern obstetric technology during childbirth? Why would any woman anywhere want anything other than an obstetrician delivery with every possible intervention and monitoring device applied? Why hasn't the modern miracle of negligible obstetric and neonatal morbidity and mortality that is the new norm in wealthy nations reaped the seemingly obvious consequence of enthusiastic and universal adherence to in-hospital birthing? Can we expect universal adoption of hospital birthing at some future point in Africa and southeast Asia, when 100 percent hospital birth has failed to occur in wealthy countries? Perhaps we might begin by accepting that there will always be women delivering at home—by choice or by accident, through lack of access or lack of faith. We might discover new possibilities for upgrading home birth by following World Health Organization guideline for improved maternal and neonatal outcomes that advises, "increasing access...begins with mobilizing what you have" [17].

Let's Mobilize

In much of Africa and Asia, women lack access to modern obstetric care because of cultural traditions or deficiencies of medical infrastructure. If the global obstetric community were to consider the most challenging of lifestyles for obstetric and neonatal optimization, such as the nomadic herding cultures of Tuareg and Somali women of the African Sahel, would not strategies to reach those women improve access to obstetric and neonatal care everywhere that deficits exist?

Consider:

- Subsidized prenatal vitamins to all women from marriage—or whenever the onset of sexual activity is common in a given country—to menopause to reduce preventable congenital anomalies,
- Traveling birth attendants networked to communities by mobile phone; equipped with medications and portable sonography, ventilation, hydration, and other portable medical devices for the top five obstetric and neonatal mortality indicators; and linked into cellular communication with referral hospitals and mobilization teams for interventions beyond the scope of these portable implementations.

The benefits to be had from respectful collaboration with traditional birthing practices are already evident. One novel capacity-building program in Somaliland, for example, embraced traditional, often illiterate, birth attendants (TBA) in a system of clinical training, facility upgrade, and financial and implementation support [18]. It allowed the trusted community TBAs to control and introduce a new standard in which all women labor and birth in Maternal Health Centers networked to referral hospitals for transfer and staffed by trained midwives and trained traditional birth attendants. Prior to this program, TBAs delivered all women at home, calling for

help, often too late, only when complications arose. By validating existing pregnancy beliefs and community standards, a true transformation occurred that reduces maternal and neonatal risk.

Industrialized nations would benefit from extrapolations of such tactics emerging in developing nations. What steps might be taken to reduce risks for Euro-American mothers and babies birthing at home or in birth centers? Or even in hospital?

Consider:

- Engaging the home birth community by creating cooperative midwifery, obstetric, and pediatric professional guidelines for home birth,
- Equipping all birth centers and home birth midwives with portable sonography, maternal and neonatal ventilation and hydration supplies, and medications for the top five obstetric and neonatal mortality indicators,
- Adopting, for example, Mama Natalie and Helping Babies Breathe protocols used in poor countries for out-of-hospital births throughout the world [19, 20],
- Integrating communication between out-of-hospital births and maternity units in partnered hospitals to encourage remote intrapartum consultation and optimal stabilization and transfer to hospital when complications occur.

These two thought experiments are but a sample of the untapped potential for integrating maternal and neonatal-care practices. If the US obstetric community truly hopes to woo its educated and affluent home-birthers back into the fold, it may be time to create global obstetric guidelines that eliminate the stratification of policy between wealthy and poor countries, so that effective capacity-building and implementation concepts flow reciprocally between developed, middle-income, and developing nations. Lastly, it may be time to embrace home birth, in the US and in the world, rather than decry it.

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SECOND THOUGHTS

"We Can" Doesn't Mean "We Should": Aggressive Interventions to Prolong Pregnancy

Stephen T. Chasen, MD

Over the past several decades, there have been major advances in prenatal care. Fetal imaging can identify most major structural abnormalities, many of them early in pregnancy. Advances in genetic screening have led to detection of an increasing number of fetal genetic disorders through far less invasive methods. We can evaluate fetal health and identify conditions such as growth restriction and fetal anemia with greater precision.

Unfortunately, we have achieved relatively little progress in preventing spontaneous preterm birth. Therapies such as progesterone and cerclage can prevent some preterm births for certain high-risk patients [1, 2]. For patients whom we first see when they are already in labor, however, we can delay delivery barely if at all.

When patients present in labor or with ruptured membranes and the fetus is of a viable gestational age, obstetric interventions—glucocorticoids to hasten fetal lung maturity, magnesium sulfate for neuroprotection, and (more importantly) advances in neonatal care—have improved outcomes for premature newborns [3, 4]. For patients who present with advanced cervical dilation, ruptured membranes, or labor prior to fetal viability, however, there are no evidence-based interventions known to prolong pregnancy and improve survival.

A big problem in managing the care of patients in this latter group is that many inappropriate interventions can make intuitive sense to doctors and patients alike. Consider this scenario: A patient presents at 20 weeks due to pelvic pressure, cramping, and bleeding, and her cervix is found to be 3 cm dilated. Would suturing that cervix closed with a cerclage help to maintain her pregnancy? If that same patient then started contracting painfully, would medication that can prevent uterine contractions keep her from delivering? If her membranes then ruptured, and she developed oligohydramnios, which at that early stage of fetal development is highly correlated with pulmonary hypoplasia [5], can we instill sterile fluid into the amniotic sac and prevent this?

The answer to all these questions is: "Yes. We can." The missing question is "Should we?"

This is a real patient, who was pregnant following two cycles of in vitro fertilization necessitated by male-factor infertility. The pregnancy was greatly desired by a

couple who were not averse to aggressive therapy. Did they deserve every chance to achieve their goals?

This kind of thinking is flawed for several reasons. It assumes that any intervention can only help and not harm. It assumes that the health and well-being of a pregnant patient is not our main responsibility. And it assumes that an overwhelming desire for a good outcome, which is hardly unique to obstetrics, justifies disregarding sound medical judgment.

Most physicians would consider that a patient with vaginal bleeding and advanced cervical dilation several weeks before fetal viability is having an inevitable miscarriage. While patients with painless dilation and no signs or symptoms of intrauterine infection may be considered candidates for cerclage [2], this patient with bleeding and cramping should not have been considered a good candidate. Once she started contracting after cerclage placement, no evidence-based interventions could significantly prolong pregnancy; tocolysis can, at best, delay delivery for a few days [4]. At that time, removing the cerclage and allowing her to deliver would preserve maternal health without altering the fetal prognosis. Once her membranes had ruptured, delivery was clearly inevitable, and intrauterine infection, if not already present, was highly likely to develop. Offering her amnioinfusion, an experimental procedure with no good data to support its use under these circumstances [6], was reckless.

While the patient and her husband considered amnioinfusion, she began bleeding heavily from the vagina. Examination of her cervix revealed a laceration from dilation through the cerclage, and she miscarried a few minutes later. She lost approximately one liter of blood before her cervix was repaired. Placental pathology revealed severe acute chorioamnionitis consistent with intrauterine infection, which is the most common proximate cause of spontaneous preterm birth.

It is frustrating for any physician to be in the position of conveying bad news to a patient without being able to offer beneficial interventions. “Don’t just do something, stand there!” does not come naturally to physicians. Nevertheless, we must recognize when there are no good treatments available and when interventions have only the potential to harm.

How can we convey this to patients, especially to those who may have done their own “research” and discovered a “treatment” that is entirely experimental or may be indicated under clearly different circumstances? The first and most important obligation we have to our patients is to provide them with an honest and informed assessment. There are many areas of obstetrics in which good evidence based on randomized trials is not available, but interventions designed to prevent prematurity, such as progesterone, antibiotics, cerclage, and tocolysis are well studied. Resources such as PubMED and The Cochrane Library are readily available, as are practice bulletins from the American College of Obstetricians and Gynecologists (ACOG) with evidence-based recommendations.

We must make patients aware of the harms of intervention. Cerclage can cause complications, including cervical laceration, in a patient with signs of labor [2]. This may increase the risk of miscarriage or premature labor in the future. Tocolysis is associated with toxicity, hemodynamic changes, and postpartum hemorrhage [4]. Any intervention that delays delivery when an intrauterine infection is present can lead to sepsis. The risk of any of these complications can be justified when there is potential benefit, but never when intervention will not improve the patient's prognosis.

The importance of avoiding harmful interventions in futile situations is hardly unique to obstetrics. One added dimension, often unspoken, should be acknowledged. While natural processes like previable birth and miscarriage are clearly different than induced abortion, a patient and her family may conflate the two. Thus, forgoing any aggressive intervention can seem, to some, like a moral transgression. While access to safe and legal abortion is a cornerstone of women's health care and a major component of preventing maternal mortality and morbidity, some patients and their families may need assurance that the two sets of circumstances and actions are distinct—that withdrawing or withholding futile interventions is not the same thing as causing the end of the pregnancy.

There is an established model of care when the goals of a patient cannot be achieved, and care is redirected. While pregnancy is not an illness for which delivering a healthy child is the "cure," the hospice model can be applied here. When previable birth is inevitable and interventions designed to achieve viable birth will not stop it, we are obligated to provide excellent care to the patient and her family [7]. Care is redirected towards ensuring maternal health and comfort. Perinatal bereavement teams, consisting of physicians, nurses, social workers, and (when desired) clergy can help the patients and her family come to terms with their loss. In most cases, optimism for future pregnancies is not unwarranted.

Physicians who choose careers in women's health are attracted to obstetrics, a field in which happy outcomes are the norm. Anyone who specializes in obstetrics, however, will care for some women for whom this is not possible. It can be easy for our desire for a good outcome to cloud our better judgment. In these cases, we must be prepared to act honestly and ethically, and to always recognize the difference between "I can" and "I should."

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Related in VM

Natural Childbirth—A Global Perspective, October 2014

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Suggested Readings and Resources

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