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American Medical Association Journal of Ethics

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FROM THE EDITOR

Technology, Policy, and Personal Decision Making

The ability to make choices about whether, when, and how to have a family is a goal that people have sought since antiquity. For example, written records of contraceptive methods and techniques for performing abortions dating back to 1550 BCE have been found among artifacts of ancient Egyptian civilizations [1]. Of course, as our understanding of reproductive science has increased, newer, safer, more effective technologies for family planning have been developed and introduced. Regulation of fertility is now very common: between 2006 and 2008, 73 percent of Americans women aged 15-44 (or their sexual partners) were using a "modern method" of contraception, such as pills, condoms, intrauterine devices, injectables, and implants [2]. With the help of these methods, some people are choosing to delay having children or not to have children at all. In fact, the average age at which American women have their first child increased from 21.4 years in 1970 to 25 years in 2006 [3]. Despite this, about half of American women have an unplanned pregnancy and nearly one in three women are projected to have an abortion by the age of 45 [4].

The opportunity to make choices about family planning and access to safe and effective methods to carry out those choices are surely welcomed by many. It seems, however, that the development of these methods has outpaced our ability to reach consensus on what constitutes their ethical use. In halls of government, at kitchen tables, on blogs, and around the water cooler, debates rage about who should have access to emergency contraceptives, whether abortion should be legal, and who should or shouldn't be having children.

This month, we take a broad view of the ethical issues in family planning, past, present and future. We look back at the history of government intervention in childbearing with an article by Susan P. Raine, JD, MD, LLM, on the history of the federal sterilization program. We touch on a current hot-button issue in Rebecca C. Thilo's review of a journal article exploring the attitudes of emergency room clinicians about emergency contraception. Timothy F. Murphy, PhD, looks forward to the future in his op-ed, which explores whether it might be acceptable, or even ethically obligatory, to use prenatal genetic selection methods to ensure desirable traits in children.

Our clinical cases this month focus on some of the fundamental principles of medical ethics as they relate to family planning. Xiomara M. Santos, MD, examines how physicians can protect the confidentiality of a minor whose parents demand information about her sexual activity. Frank A. Chervenak, MD, and Lawrence

McCullough, PhD, provide guidance on counseling a patient who desires a pregnancy but whose ability to care for a child is in question. Lastly, Lusine Aghajanova, MD, PhD, and Cecilia T. Valdes, MD, comment on the obligations of a physician to a couple who desire a child of a particular sex.

Family planning is often thought of primarily or solely as a women's health issue, in part because fewer contraceptive options are available for men than for women. In her medicine and society article, Lisa Campo-Engelstein, PhD, examines the development and social implications of this disparity. In addition, Mara Y. Roth, MD, provides an update on the current state of research in the development of longacting reversible contraceptives for men.

Finally, we look at the role of law and government in regulating access to family planning services. Recent policies have raised several ethical questions in this area, as we see in the review by B. Jessie Hill, JD, of recent legislation restricting access to abortion services and an article by Adam Sonfield, MPP, on the conscience exemption to new requirements for health insurance coverage of family planning services. Kristina Tocce, MD, MPH, and Britt Severson, MPH, examine the impact that federal funding restrictions on abortion services have on the training of medical residents.

With so many options for family planning, and education about these issues often lacking, patients turn to their health care clinicians for information, guidance, and support as they make decisions about whether, when, and how to start or expand their families. Although many of the questions explored in this issue have no single right answer, we hope that these articles spur you to reflect on your own beliefs and opinions concerning what are often emotional subjects for both patient and physician and that they may provide a starting point as you guide your patients toward their decisions.

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Jennifer Braverman Baylor College of Medicine Houston, Texas

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CLINICAL CASE

Directive Counseling about Becoming Pregnant

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

Dr. Brooks picked up the first chart of the day at the free clinic where she had worked for just a few months since finishing her residency. Her first patient was Jessica, a 25-year-old, here for a new patient visit.

"Hi, Jessica. I'm Dr. Brooks, one of the primary care doctors here. What brings you in today?"

Jessica responded, "I just want to make sure that I'm as healthy as I can be before I get pregnant."

Dr. Brooks began to take Jessica's medical history. She seemed very healthy, with no major medical problems. Jessica had been pregnant twice and she had delivered two healthy infants without complications. But when Dr. Brooks asked about her kids, Jessica became quiet. As it turned out, Jessica and her boyfriend, the children's father, had not seen them in over a year, after they were removed from her home by child protective services. "They said we weren't caring for them properly, not feeding them enough, that sort of thing," said Jessica. "but I always thought they seemed OK."

Dr. Brooks was taken aback, but managed to say, "That must be really difficult."

"Yeah," agreed Jessica, "and that's why my boyfriend and I want to have another baby. I miss my babies, and I want to try again. In fact, I wanted to ask you, do you have any advice for me? Is there anything else I should do to help me get pregnant?"

Dr. Brooks paused. Jessica seems not to have known how to care for her first two children, but now she wanted to have another baby? What if this one were neglected and faced years of suffering or worse? Dr. Brooks didn't want to think about it. As she tried to gather her thoughts, Jessica waited for an answer.

Commentary

A general rule in obstetric ethics is that the decision to become pregnant is a personal decision that has a medical component. There are medical conditions, such as poorly controlled diabetes, that increase the risk of morbidity and mortality to the pregnant woman, fetal patient, and future child that should be considered. Recommending that a woman take such information into account in her decision making and that pregnancy be postponed until the medical condition is well managed are matters of

professional responsibility [1]. We emphasize that making recommendations, i.e., directive counseling when the recommendations concern the medical aspects of pregnancy and when they have a reliable evidence base, does not violate respect for the patient's autonomy, because recommendations do not control the woman's decision-making process. Nor is making recommendations coercive, because the concept of coercion includes the attempt to control decision making by making threats [2].

In this case, the patient has no medical condition that might justify directive counseling. However, based on past history (which appears to include negligence resulting in failure to thrive, which has deleterious, irreversible, long-term consequences for child development) the biopsychosocial well-being of a future child is at stake. Jessica's psychosocial well-being is also at stake, because the removal of a third child from her custody would be psychosocially traumatic.

These biopsychosocial considerations, while not medical conditions, are ethically significant in comprehensive clinical judgment about the patient's well-being and, with respect to a future child, that child's best interests, the protection of which is the core principle of pediatric ethics [3]. The latter ethical consideration creates an obligation on the part of the obstetrician to protect a future child from preventable harm, especially when that harm is serious, far-reaching, irreversible, and likely to occur.

The best interests of any child are protected and promoted when the child is raised by his or her birth mother, her partner or spouse, and involved family members. Being raised by foster or adoptive parents should not be judged to be harmful to a child's interests; the best (being raised by biological parents) should not become the enemy of the good. The pregnant patient's interests and the best interests of a future child will be furthered if she can have a successful pregnancy and keep her child. The future child's interests will be furthered by good parenting, including being cared for by foster or adoptive parents. Obviously, it is biopsychosocially in Jessica's interest to have a successful pregnancy and keep her child.

Achieving a successful pregnancy—i.e., adhering to an appropriate plan of self-care throughout pregnancy and delivery—is not unrelated to Jessica's addressing the causes of her neglect of her existing children and correcting them. Being able to keep the child from her next pregnancy will, in all likelihood, depend on addressing these causes. They could include undiagnosed and untreated mental illness, a history of abuse of the patient as a child, or abuse by her boyfriend. These and other potential reasons for Jessica's neglect of her children should be carefully investigated and a plan of care developed to ameliorate them. The plan should be coordinated with Child Protective Services, so that Jessica can be assured that she will indeed be able to keep her third child and possibly regain custody of her other children. Successful management of these factors will help improve the outcome of her pregnancy, because, now confident in her ability to parent a child, she will be more likely to

become an effective partner to her physicians in the management of a third pregnancy.

We emphasize that the scope of legitimate clinical ethical judgment does not include the obstetrician's deciding that Jessica should not become pregnant because she has been found to be an unfit parent by the courts. To be sure, obstetricians can contribute expert judgment about such matters as Jessica's adherence to an effective plan of self-care during pregnancy. Whether she should become pregnant again, however, is a judgment beyond the competence of obstetricians to make. The obstetrician also has no competence to decide whether being raised in a single-parent household is or is not consistent with the best interests of the child, for the simple reason that many single parents are successful in parenting their children. With adequate preparation and support, Jessica could be a successful parent.

There is an important obstetric ethics take-home lesson from this aspect of this case. Physicians, including obstetricians, get themselves into preventable ethical conflict very quickly when they go beyond the limits of the expertise supported by evidencebased reasoning and the scientific and clinical competence it creates. It would therefore be corrosive to Dr. Brooks's professional integrity for her to make any judgment about whether Jessica should become pregnant again. The above ethical argument supports only making recommendations as to the timing of and preparation for a successful pregnancy.

These clinical ethical considerations warrant a preventive ethics approach to giving Jessica directive counseling [4]. It is clearly in a future child's interest and in Jessica's interests for her to postpone pregnancy until she can become responsible for the rearing of a child. The physician should therefore recommend postponement of pregnancy and refer Jessica to appropriate social services counseling. She should also assure Jessica that she will have her full professional support in implementing this recommendation.

There are no legal tools available to the obstetrician to enforce such a recommendation. The obstetrician will therefore have to use the tools of ethics, especially respectful persuasion: developing a plan of care and recommendations that support Jessica's values concerning having a successful pregnancy and becoming a responsible parent. Such recommendations justifiably include effective prevention of pregnancy during the several months or more that Jessica will need to get her life better organized and to develop the support systems she will need during pregnancy and parenting.

Jessica might not cooperate and might become pregnant without waiting. Is this sufficient reason to end the patient-doctor relationship? The risks of pregnancy, should she cooperate with prenatal care, can be managed. It is not the case that the obstetrician can reliably predict that the fetal patient and future child will be at high risk of serious, far-reaching, and irreversible harm. The reasoned answer to our question is therefore no.

Should clinical ethical obstetric judgment change if Jessica were seeking medical help beyond ensuring that she is medically healthy to initiate a pregnancy? Suppose, for example, that her concern was infertility and that she is seeking assisted reproduction. In such circumstances, the physician has the power to control whether and when Jessica might attempt to initiate a pregnancy. What ethical considerations should guide the obstetrician in the use of such professional power?

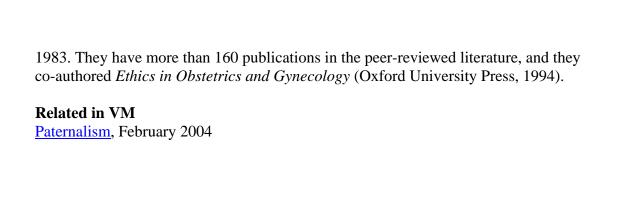
Again, the dual focus should be on Jessica's ability to undertake and successfully complete a pregnancy and the best interests of the future child, especially with respect to her keeping the child she will bear. The above ethical considerations apply. The obstetrician is not ethically justified in making the judgment that it would be better for Jessica and society that she not become pregnant; such a social judgment is beyond the obstetrician's competence. Recommending that Jessica postpone assisted reproduction, however, would be ethically justified. Assisted reproduction is an elective procedure and, therefore, the obstetrician has more latitude in deciding whether to offer it. However, the reasoning about such a decision should not appeal to personal judgments about Jessica's parental fitness but to expert clinical judgment that she has not adequately prepared to become pregnant.

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Frank A. Chervenak, MD, is the Given Foundation Professor of Obstetrics and Gynecology and chairman of the Department of Obstetrics and Gynecology at Weill Medical College of Cornell University in New York. He is also a member of the Institute of Medicine of the National Academies of Science. He has collaborated with Laurence B. McCullough on scholarly work and teaching ethics in obstetrics and gynecology since 1983. They have more than 160 publications in the peer-reviewed literature, and they co-authored *Ethics in Obstetrics and Gynecology* (Oxford University Press, 1994).

Laurence B. McCullough, PhD, holds the Dalton Tomlin Chair in Medical Ethics and Health Policy in the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston, Texas. He has collaborated with Frank A. Chervenak on scholarly work and teaching ethics in obstetrics and gynecology since



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CLINICAL CASE

Protecting the Confidentiality of Sexually Active Adolescents Commentary by Xiomara M. Santos, MD

Dr. Nelson was just about to leave the office for the day when her pager went off. She returned the call, and learned that one of her patients, Andrea, was in the emergency room with what looked like pelvic inflammatory disease (PID). Dr.

emergency room with what looked like pelvic inflammatory disease (PID). Dr. Nelson sighed. She had placed an intrauterine contraceptive device (IUD) for Andrea in the office last week, and the PID could be a rare complication of the procedure.

Andrea had come to the appointment last week by herself. She said that she had recently become sexually active with her boyfriend, and she really didn't want to get pregnant. Although Andrea was only 15, laws in her state allowed her to legally consent to contraceptive services. After reviewing Andrea's history and doing a physical exam and pregnancy test, Dr. Nelson found no medical contraindications to an IUD. Dr. Nelson counseled Andrea about the risks and benefits of the IUD and alternative methods. Andrea and Dr. Nelson agreed that the IUD was the best option.

When Dr. Nelson arrived in the emergency department, she was dismayed to hear yelling coming from Andrea's room.

"You're going to tell me that this isn't because you were having sex? Well, we'll see what the doctors have to say about that! You're my daughter and I'm not going to have you living under my roof if you're sleeping with that boy!"

Hoping that she could defuse the situation, Dr. Nelson headed into the room. She was met by an angry man who said he was Andrea's father.

"What's going on here?" he shouted. "This is because she had sex, right? Well, if she did, she's out of my house for good!" He stormed out.

After her father left the room, Andrea pleaded with Dr. Nelson not to tell him that she was sexually active. She said that his threat was real—he'd forced her older sister to leave home when she got pregnant at age 18. Andrea said that things at home were fine and that she and her father had always gotten along well, but that he had made it clear that he believed his daughters should wait to have sex until they were married. "Even if you don't say anything, he's going to think this is because I'm having sex," Andrea insisted. "Can't you just make up another reason why I'm sick?"

Commentary

Confidentiality protection is essential to providing quality health care to adolescents [1, 2]. The major causes of morbidity and mortality in this age group are related to high-risk behaviors such as unsafe sex and drug use and mental health problems like depression [3-5]. Studies find that adolescents were more likely to seek care and disclose sensitive information when they believed the physician would not disclose the information to their parents [6-8]. As stated in a position paper by the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the Society for Adolescent Medicine, it is *critical* for sexually active adolescents to receive appropriate *confidential* health care and counseling [9].

Clinicians who take care of adolescents should familiarize themselves with the state and local laws that affect the rights of minors to consent to health care services, as well as federal and state laws that affect confidentiality in the provision of their health care. Physicians should discuss confidentiality with the adolescent and the parent or guardian, if present, at the first clinic visit. The clinician should stress that he or she has the same goal as the parent: the health and well being of the adolescent. While physicians should respect patients' privacy and confidentiality, they should also encourage communication between the adolescent and his or her parents. Parental support can be a valuable tool in helping adolescents meet their health care needs [1, 9, 10].

Physicians cannot promise unconditional confidentiality to the adolescent, however. In situations where there is the potential for harm to the minor or others, such as abuse, suicidal ideation, or homicidal ideation, the physician is required by law to report the situation to the local child protective services agency. In addition, cases of certain sexually transmitted infections (STIs) must be reported to public health departments. Many state laws consider sexual activity involving a minor to be child abuse, depending on the age of those involved, and clinicians have the legal duty to report the case in accordance with the laws in their states [9, 11]. The physician should explain to the adolescent that their discussions are confidential unless the adolescent gives permission for disclosure or there is concern about serious harm to the patient or others [10, 12, 13].

Lying

Not only is Andrea requesting that Dr. Nelson protect her confidential information; she is also asking her to lie about the diagnosis. Since all states allow minors to consent to testing and treatment for STIs [14], treating Andrea in an outpatient setting without her father's consent would have been appropriate. But now that she is in the emergency department and her father is present, should Dr. Nelson lie to protect Andrea's confidentiality and safety? The simple answer is no, but Dr. Nelson has other ways of protecting her patient. While Dr. Nelson should still attempt to protect Andrea's confidentiality, she should not lie.

It might seem simple to Andrea to just "make up another reason" why she is sick, but it is not the ethical thing to do. In addition, how would Dr. Nelson retain Andrea's trust in the long run once Andrea knew she was capable of lying? Would you trust a physician who you knew was dishonest?

Lying to Andrea's father would only temporarily delay his finding out. Andrea is most likely going to be admitted to the hospital for treatment of PID, depending on how stable she is and how comfortable Dr. Nelson feels about managing her as an outpatient. Once she is admitted, her diagnosis cannot be kept a secret. Dr. Nelson could speak to the rest of her team and nursing staff about not disclosing information to Andrea's father, but the more opportunities there are for the information to slip out, the more likely it is to happen.

If Andrea's father does not already know the diagnosis, he will learn it when he receives the explanation of benefits. A treatment for which a minor consents is usually his or her financial responsibility [1, 15], but when a minor is in the hospital and her parent is at her bedside, we can assume her parent is the one giving consent for treatment and is the insurance plan holder. When Andrea's father gets the bills for her hospital care, he will see that PID is the diagnosis. Whenever he learns it, a quick internet search will make clear that PID is most commonly seen in sexually active women.

Protecting the Patient

Andrea's main concern is that her father threatened to make her leave the house if he knew she was sexually active. Every parent has the duty to provide his or her children with the basic necessities of life, including food, clothing, and shelter. This duty usually terminates when the child is emancipated, graduates from high school, enters the military, or marries. In most states, emancipation occurs for children still living at home at the age of 18 [16]. Since Andrea is 15 years old and living at home, her father could be charged with child abandonment, which is a criminal offense under state laws, if he does not provide shelter for her. Even if her father cannot legally throw Andrea out of the house, however, Dr. Nelson should not take his threat lightly. If she believes Andrea's father might take action on his threat, Dr. Nelson should involve social services to determine the need to contact Child Protective Services while Andrea is still in the hospital. Like most adolescents, Andrea most likely would prefer not to share her sexual history with her father even if he had not threatened her, and Dr. Nelson should still try to protect her confidentiality.

Andrea's father asked if "this" was because she had sex. What does the father know about "this"? Does he know she has a vaginal infection? Does he know it is pelvic inflammatory disease (PID)? Dr. Nelson should ask Andrea these questions to determine what her father already knows. Since Andrea might not know the answers, Dr. Nelson should ask the other clinicians involved and determine what information has already been given to the father. If he already knows it is PID, Dr. Nelson can truthfully tell him that there are different ways of getting this infection. If he does not know the diagnosis, Dr. Nelson could say that they are still doing their evaluation to determine the reason for her symptoms. If Andrea has other findings, like a urinary tract infection, Dr. Nelson could focus on those when talking to Andrea's father without actually lying.

If the father then specifically asks whether Andrea is sexually active, Dr. Nelson should inform him that is not her immediate concern in treating Andrea's infection and that it is something he should discuss with his daughter. While this statement does imply that she is sexually active, Dr. Nelson does not have many other options, because she should not lie to Andrea's father.

Dr. Nelson should also reassure the father that if there were anything life-threatening involving his daughter she would inform him. This is another challenging aspect of this case, since Andrea does have a serious medical condition that requires close monitoring and compliance with treatment, once she is discharged from the hospital. While PID is usually not life-threatening, lack of compliance with treatment can have serious short-term consequences, like development of tubo-ovarian abscesses, and long-term consequences, including infertility. Dr. Nelson should assess Andrea's maturity in understanding her diagnosis and future adherence with treatment to decide whether she feels the need to involve Andrea's parents to assure adequate compliance.

There is no mention of Andrea's mother in the case scenario. Dr. Nelson should also ask Andrea about her mother's involvement in the family dynamics and if she can talk to her mother about her diagnosis. If deemed appropriate, Dr. Nelson should encourage Andrea to be honest with her mother since she would benefit from her support.

Conclusion

Dr. Nelson is facing one of the most challenging aspects of taking care of adolescents. She needs to provide the best care for her patient, and protecting her confidentiality is an important and necessary part of that. Adolescents need to trust their doctors in order to be able to disclose sensitive information that might impact their care. Clinicians should always encourage communication between a minor and his or her parents, but they should not force it. Clinicians should also remind the parents that they share a common goal—the well-being of the adolescent. On many occasions the parents' reactions are not as extreme as the patient feared.

Dr. Nelson should do everything in her power to protect Andrea's confidentiality, but lying is never recommended and, in this particular case, it would be nearly impossible to keep the diagnosis a secret. If there *is* a concern about her patient's safety once she is discharged from the hospital, Dr. Nelson should involve other services prior to discharging her.

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Xiomara M. Santos, MD, is an assistant professor in the Department of Obstetrics and Gynecology at Baylor College of Medicine in Houston, Texas. She is board certified in obstetrics and gynecology and fellowship trained in pediatric and adolescent gynecology. Her research interests include adnexal masses in children and adolescents, pelvic inflammatory disease, menstrual disorders in adolescents, and congenital anomalies.

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CLINICAL CASE

Sex Selection for Nonhealth-Related Reasons

Commentary by Lusine Aghajanova, MD, PhD, and Cecilia T. Valdes, MD

Mr. and Mrs. Carter had been married for 6 years when they visited Dr. Jones, a well-known infertility specialist, to ask for help creating their family. Mrs. Carter had given birth to a beautiful, healthy baby girl 3 years earlier. She was the light of their lives, and they loved her dearly. Now that their daughter was in preschool, they had decided it was time for them to complete their family by having another child—a son.

They sat down in the plush chairs in Dr. Jones's office. Mr. Carter spoke first, "We've done a lot of research, Dr. Jones, and we think you can help us. A couple that we are friends with came to you to make sure they had a girl, since they have a disease in their family that runs in boys. We're here to see if you can help us conceive a son for our family."

Dr. Jones was confused about what they were asking for, and why. "Have you been having trouble getting pregnant?" he asked Mrs. Carter.

"Oh, no," she responded. "We haven't been trying. We wanted to wait to see you, so that we could make sure we had a boy. We love our daughter, and we always thought it would be perfect to have one of each. A balanced family."

"Hmm," Dr. Jones said. "We have done sex selection for patients in the past, but only based on medical conditions that occur in certain families, like what we did for your friends—"

"No, it's nothing like that," said Mr. Carter. "I just think we should have a boy and a girl. All my life I've envisioned having a kid I can take fishing and play ball with."

"So, what do you think?" Mrs. Carter pressed. "Does this sound like something you can help us with?"

Commentary

Use of assisted reproductive technologies (ART) for nonmedical reasons presents several ethical dilemmas. Issues that should be considered include: (i) indications for medical, as well as for elective, sex selection, (ii) methods for sex selection, (iii) relevant policies in different countries, (iv) arguments for and against sex selection for nonmedical reasons, and (v) risks associated with the procedures. This discussion should help us to work out the moral dilemma that Dr. Jones is facing with his patients in this case.

The desire to have a child of a particular sex tracks back through centuries. Kings were desperate to have a male heir to the throne, peasants desired sons to help with the work, while some families with many boys were longing for girls. However, until now, there were no effective means of sex selection, except for highly speculative and unproven methods relating to the timing of intercourse and positions of the partners during intercourse. The definitive method during the past few decades with the ultrasound era has been prenatal diagnosis and elective abortion of a fetus of undesired sex, which raises many ethical issues as well as risks to maternal health. Advances in assisted reproduction technologies allow many dreams to come true: infertile couples are able to experience parenthood, and parents affected by chromosomal mutation or carriers of an abnormal gene can select healthy embryos for implantation. With the implementation of new technologies, sex selection has become more precise and achieves the goal of avoiding a sex-linked genetic disorder.

Reasons for sex selection can be divided into two categories: medically indicated and elective (nonmedical) reasons [1]. What does that mean? In the former category, sex selection is used to avoid so-called sex-linked diseases, which male children inherit from their mothers, such as hemophilia A and B, Duchenne muscular dystrophy, Lesch-Nyhan syndrome and others. In some cases, conditions are more severely expressed in one gender (e.g., fragile X syndrome in males) than the other. Elective sex selection is not done for medical reasons, but to accord with a desire for "family balancing," as in the present case, or a strong preference for a child of a particular sex [2]. A situation in which parents who have lost a child desire another child of the same sex may be considered another nonmedical indication for sex selection.

There are two primary methods now available for sex selection: (1) the sperm-sorting technique, which is selection of sperm with the preferred sex chromosome (X or Y), followed by intrauterine insemination (IUI) or in vitro fertilization (IVF), and (2) pre-implantation genetic diagnosis (PGD) followed by IVF [3, 4].

Because the male gamete determines the gender of the offspring, sperm is an obvious target for selection. Sperm selection allows for prefertilization sex selection and is based on the flow cytometry technique. Prior to flow cytometric sorting, sperm are labeled with a fluorescent dye, Hoechst 33342, which binds to the DNA of each spermatozoon. Every man has one X and one Y chromosome. Because the X (female) chromosome is 2.8 percent larger (i.e., has more DNA) than the Y (male) chromosome, the spermatozoa bearing X chromosomes will absorb a greater amount of dye than those bearing Y chromosomes. Consequently, when they are exposed to UV light during flow cytometry, X-bearing spermatozoa fluoresce brighter than Y-bearing spermatozoa. As they pass through the flow cytometer in single file, they are separated by means of electrostatic deflection and collected in separate tubes for processing. This sperm-sorting technique has a success rate of 91 percent for selecting girls and 76 percent for selecting boys [5]. Once the sample is processed,

there is often only sufficient quality and quantity of sperm for laboratory-controlled IVF rather than the less costly and less invasive IUI.

Pre-implantation genetic diagnosis sex selection is the most reliable method, with almost 100 percent accuracy. This procedure is performed in the context of IVF, when embryos are created from eggs obtained from the female partner (after overstimulating her ovaries) and sperm collected from the male partner in the laboratory. When embryos are 3 days old and have about 8 cells, one of the cells is taken from each embryo for chromosomal analysis. Then, only the embryos of the preferred sex are transferred back to the mother or frozen for future use, and the rest are discarded. This procedure, however, is not risk-free and is associated with significant cost. Of note, the sperm-sorting method still requires subsequent IVF and possibly even PGD for 100 percent accuracy. Sperm sorting is associated with the minimum number of discarded embryos, less than the 50 percent resulting from the IVF-PGD-only method, since sperm sorting should produce a high percentage of embryos of the desired sex.

There is no country that explicitly permits sex selection. Five countries prohibit it for any reason, while 31 countries prohibit it for social or nonmedical reasons. Other countries either do not have any laws or policies regarding sex selection, or such policies are unknown [6]. There is no official policy in the United States of America. Israel allows nonmedical sex selection only if a family has 4 children of one sex and desires a child of the opposite sex [7].

As is clearly outlined in the latest statement of the ethics committee of the American Society for Reproductive Medicine (ASRM), PGD for sex selection to prevent the transmission of serious sex-linked genetic disease is acceptable and recommended [8]. There is no argument against medically indicated sex selection: the ASRM's position is that all families have a genuine right to healthy offspring, and they can implement all available technologies to avoid a known genetic disorder. Moreover, in such cases, no preference of one sex to another is expressed based on its supposed value. The ASRM committee advocates that use of PGD for nonmedical sex selection should not be encouraged but does not favor its legal prohibition [8]. The nonmedical reasons are the area of continuing debate.

Proponents of elective sex selection argue about one's right to reproductive choice including sex selection—in terms of constitutional rights. Family balance is considered to be another valid reason for sex selection. Interestingly, Judaism and Islam largely allow sex preselection, while it is forbidden by the Catholic Church even for medical use [9]. The strongest argument for pre-implantation sex selection is that it may be considered a lesser evil than prenatal diagnosis (ultrasound or amniocentesis) and abortion solely for unwanted sex. The latter carries more significant risks for the mother's health, not to mention stronger ethical concerns.

One of the concerns of elective sex selection is sex discrimination that results in an imbalance in the sex ratio within a given society. This already exists in China and India, where male children are particularly favored [10, 11], but is less likely to

happen in the Western world [12, 13], where "family balancing" is the usual reason for nonmedical sex selection [3]. Because of unavailability of sex selection in a majority of countries around the world, patients from China and India undertake "sex-selection traveling" to the clinics that provide such services in the U.S. The risk of population sex imbalance in the U.S. is not great, largely due to its ethnically mixed population, in which different preferences in sex selection balance each other. Asian and Middle Eastern couples often prefer sons, while Caucasian and Hispanic couples prefer daughters [14]. Nonetheless, nonmedical sex selection risks indulging or reinforcing sex discrimination and may even contribute to sex-based stereotyping [8].

Another argument against sex selection for nonmedical reasons is exposure to unnecessary medical risks. As mentioned above, IVF carries certain risks, such as ovarian hyperstimulation syndrome. The risks associated with sperm sorting are still unclear due to the lack of relevant research, though some studies have found that Hoechst dye can have a mutagenic effect on sperm [15]. These findings suggest caution when using sperm sorting as an elective procedure [15], as does the unknown risk associated with repeatedly freezing and thawing sperm. Further studies are warranted before recommending sperm sorting.

In the meantime, do providers and proponents of sperm sorting have an ethical obligation to fully disclose the unknown risks of the DNA labeling of sperm on the health of offspring?

These procedures also carry a large financial burden in countries where patients are usually responsible for treatment costs. Another issue in countries where patients pay treatments costs is the fairness of access to medical resources [8, 16].

Detailed informed consent before initiating ART for sex selection, including scenarios specific to this treatment modality, are of particular importance. Patients need to be informed of the small possibility of having a child of the unwanted sex despite the procedure or of having produced embryos only of the "unwanted" sex. It is better to agree beforehand if the couple will still choose to transfer healthy embryos even if they are of the "wrong" sex, or if they will donate those embryos if there are none of the desired sex. A significant ethical dilemma arising from IVF-PGD for the purpose of sex selection is subsequent discarding of the embryos of unwanted sex. In that case, couples are to be offered alternatives, such as donating their embryos to infertile couples or for research.

One multicenter study reported that some couples pursuing IVF-PGD for sex selection for nonmedical reasons view this procedure as an ethically complex decision and express considerable uncertainty about its ethical acceptability [17]. Discussions regarding the couple's wishes in these difficult situations should occur prior to beginning the IVF-PGD cycle to avoid presenting these dilemmas on the day of embryo transfer, when there is insufficient time for the couple to consider their decision carefully. Thus, detailed informed consent should be obtained prior to initiation of the whole process, because many couples seeking help with nonmedical

sex selection are usually not aware of the seriousness and full complexity of either IVF and PGD or flow cytometry sperm sorting procedures. This however, is not the case with the Carters, who are aware of IVF, but need to be informed about the specific risks and side effects of PGD for sex selection.

Due to patient demand and financial pressures, reproductive endocrinology and infertility physicians may consider providing ethically controversial services. However, it is important to know that practitioners who offer assisted reproductive services are under no legal or ethical obligations to provide nonmedically indicated preconception methods of sex selection [8]. Applying this to the current scenario, Dr. Jones should not feel any legal or ethical obligations to provide reproductive services to the Carters, if doing so conflicts with his own clinical judgment, values, or beliefs.

Thus, we can summarize the above discussion in a few points:

- Sex selection for sex-linked disease prevention is well established and not controversial.
- Sex selection for nonmedical reasons is not encouraged, but neither is it prohibited in the U.S., according to the latest guidelines.
- Based on available research data, we believe that sperm sorting should not be used until more safety data are available.

Dr. Mark Hughes, one of the pioneers of PGD in the U.S., expressed a clear opinion on the topic: "Your gender is not a disease, last time I checked. There's no pathology. There's no suffering. There's no illness. And I don't think doctors have any business being there" [18].

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Lusine Aghajanova, MD, PhD, is a resident in obstetrics and gynecology at Baylor College of Medicine in Houston, Texas. She obtained her doctoral degree from the Department of Obstetrics and Gynecology at the Karolinska Institute in Stockholm and completed her postdoctoral fellowship in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco. Because her particular interests are human reproduction and infertility, she has focused her research on human implantation and biomarkers of uterine receptivity, as well as on endometrial dysfunction in women with unexplained infertility and endometriosis.

Cecilia T. Valdes, MD, is an associate clinical professor with an appointment in the Department of Obstetrics and Gynecology and associate director of the Reproductive Endocrinology and Infertility (REI) Fellowship at Baylor College of Medicine in Houston, Texas. Dr. Valdes is certified in REI, and her clinical and research interests include assisted reproduction, polycystic ovarian syndrome, insulin resistance, and metabolism.

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MEDICAL EDUCATION

Funding for Abortion Training in Ob/Gyn Residency Kristina Tocce, MD, MPH, and Britt Severson, MPH

Suppose your patient, Jessica, has a routine ultrasound at 20 weeks gestation. She has picked out names and her husband is hoping for a boy. Instead, they learn they are expecting a girl...with anencephaly. Jessica is informed that this malformation is not compatible with life. She and her husband make an anguished decision to end the pregnancy. They then find out that Medicaid will not cover the cost of her abortion and she must postpone the procedure until she can collect the funds.

Situations like this are not unusual in the field of obstetrics and gynecology. Since the fetus has a lethal anomaly, continuing the pregnancy until the onset of spontaneous labor poses medical risks to Jessica with no benefits for the fetus. Therefore, some argue, not providing Jessica with the option of termination is unconscionable, and necessitating that she postpone a legal and time-sensitive medical procedure—complications of abortion increase with advanced gestational age—due to financial constraints is reprehensible.

Suppose further that, with significant effort, Jessica's entire family helps her acquire the necessary funds and she undergoes an uncomplicated dilation and evacuation at 23 weeks. Legislation intended to restrict abortion training may create a situation in which future physicians would not be competent in providing abortions, and patients will no longer have this option.

Abortion in the U.S.

In the United States, slightly more than one in five pregnancies ends in abortion [1]. Abortion is one of the most common surgical procedures undergone by U.S. women [2]. According to predictions based on the 2008 abortion rate, almost one-third of women will have an abortion by age 45 [3]. A substantial proportion of patients seen by physicians will have had an abortion or will have one in the future, yet acquiring the necessary skills to care for 30 percent of the female patient population has been made challenging for future physicians by a number of laws and amendments.

The original Hyde Amendment was passed September 30, 1976. It was introduced in response to the U.S. Supreme Court's 1973 *Roe v. Wade* decision to legalize abortion and represented the first major legislative success by the anti-abortion movement. The amendment, routinely attached to the annual appropriation bill for the Department of Health and Human Services (HHS) since 1973 [4], prohibits the use of certain federal funds to pay for abortions, with the exception of pregnancies that endanger the life of the woman or result from rape or incest. Hence, the amendment

primarily affects patients covered by Medicaid, military plans, and the Indian Health Service.

The first "conscience clause," known as the Church Amendment, was also enacted in 1973. This law established that public officials may not require individuals or entities who receive certain public funds to perform abortion or sterilization procedures or to make facilities or personnel available for the performance of such procedures if doing so "would be contrary to [the individual or entity's] religious beliefs or moral convictions" [5]. Such clauses were reaffirmed and expanded with the Hyde-Weldon Conscience Protection Amendment that was added to the HHS Appropriations Bill and signed into law in December 2004. The amendment prohibits federal, state, and local government agencies and programs from discriminating against health care entities because they do not offer, pay for, cover, or refer for abortion [6]. While previous clauses protected individual health care professionals from discrimination, this provision covers a diverse group of health care entities, including hospitals, insurance plans, and any kind of health care facility, organization, or plan [6].

Medical practices that offer abortions are singled out by so-called targeted regulation of abortion provider (TRAP) bills. These state laws are specifically designed to present obstacles to the provision of abortion by requiring various licensures and mandating features of the clinical facility. Requirements are more stringent than those imposed on other medical practices [7]. Compliance with specific conditions may make providing abortion services extremely difficult or impossible. Increased cost or scarcity of services limit both patient and trainee access to abortion care.

Medical Training, Government Funding, and the Foxx Amendment

The decision to perform abortions is personal and multifactorial, but, for obvious reasons, training opportunities are associated with future abortion provision, comprehensive options counseling, and referrals [8]. In 1995, responding to both the decline in residency training opportunities and the increasing shortage of abortion services, the Accreditation Council for Graduate Medical Education (ACGME) mandated explicit abortion training requirements for ob/gyn residents (though not for family medicine programs), specifying that

access to experience with induced abortion must be part of residency education. This education can be provided outside the institution. Experience with management of complications of abortion must be provided to all residents. If a residency program has a religious, moral, or legal restriction that prohibits the residents from performing abortions within the institution, the program must ensure that the residents receive satisfactory education and experience in managing the complications of abortion [9].

This ACGME mandate took effect January 1, 1996. The Coats Amendment to the Omnibus Consolidated Rescissions and Appropriations Act of 1996 soon followed [10], making it difficult to enforce the ACGME mandate. The amendment upholds the federal funding and legal status of medical institutions that do not offer abortion training or referrals for individuals seeking abortion training at another institution. Under the Coats Amendment, institutions and individuals no longer have to claim moral objections for their noncompliance [6]. The ACGME maintains that residency programs with religious or moral objections must not impede residents who do not share those objections from receiving education and experience in performing abortions at another institution. In addition, the program must publicize such a policy to all applicants to the residency program [9].

Medicare is the single largest source of funding for graduate medical education (GME). Second only to Medicare is Medicaid, another funder of GME [11]. This tax-based financing covers both direct medical education (DME) payments (for resident salaries and benefits) and indirect medical education (IME) payments (subsidies to teaching hospitals). This funding structure has become the focus of the most recent attempt to restrict abortion provision and training. Congresswoman Virginia Foxx, representing the 5th Congressional District of North Carolina, has proposed an amendment to H.R. 1216, a bill that would amend the Public Health Service Act by converting funding for GME in qualified teaching health centers from direct appropriation to an authorization of appropriations [12].

The Foxx Amendment explicitly prohibits this taxpayer-funded grant program from providing funds for abortions (except when the pregnancy puts the mother's life at risk or is the result of rape or incest) and training of abortion doctors [13]. The amendment also includes a clause ensuring that no funds are given to a "qualified teaching health center if such center subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions" [13]. Unlike the Hyde Amendment, which needs to be annually renewed, these prohibitions would be permanent. On May 24th, 2011, this amendment passed the House and was sent to committee in the Senate, where it awaits a vote.

Implications for the Future

If passed by the Senate, this bill will clash with the ACGME abortion training mandate and would raise the possibility that institutions could not finance resident salaries during abortion training. The need to obtain other funding for resident salaries will become a new, formidable barrier to abortion training access.

Supporters of such restrictive legislation may argue that ob/gyn residents will be able to get adequate training by learning similar techniques for nonabortion-related interventions (e.g., dilation and curettage for abnormal uterine bleeding), miscarriage management, rape, incest, and maternal medical conditions. Without exposure to a significant number of patients, however, future physicians may not be competent to perform such procedures in acute or challenging situations. Induced abortion also requires specific counseling and clinical care. Training in induced abortion affords residents the opportunity not only to learn abortion techniques but also to acquire skills they will use throughout their careers, including the performance of

ultrasounds and pelvic exams, administration of anesthesia, offering contraception counseling, placement of IUDs, and management of psychosocial aspects of abortion care. Abortion procedures are often thought of as confined to specialized off-site clinics, yet many aspects of comprehensive abortion care are essential to any ob/gyn physician's practice.

Even if the Foxx Amendment does not make it through the Senate, abortion training remains jeopardized in individual states. In April 2011, the governor of Arizona signed House Bill 2384 [14]. This bill not only denies tax deductions for donations made to charitable organizations that "provide, pay for, promote, provide coverage of or provide referrals for abortion," it also prohibits expending "public monies, tax monies, federal funds passing through the state treasury, monies paid by students as part of tuition or fees to a state university or community college" for training in performing abortions. It is too soon to evaluate the impact of these restrictions on residency training or how they will affect the ability of Arizona residency programs to remain in compliance with the ACGME mandate.

Despite the legislation that attempts to restrict or eliminate abortion training, there are initiatives that support the ACGME abortion training mandate. In the summer of 2002, New York City Mayor Michael Bloomberg's directive to improve residency training in city hospitals marked the first time a city government required medical and surgical abortion training in publicly funded hospitals; objecting residents are allowed to opt out [15, 16]. Also in 2002, California enacted a state law (AB-2194) requiring abortion training to be available at each of California's public medical schools [15, 16].

Such legislation is not the standard, and future laws echoing the Foxx Amendment and the Arizona house bill will continue to be proposed. Residencies may become more reliant on private funding to maintain abortion training opportunities and maintain compliance with the ACGME mandate. Since 1999, the privately funded Kenneth J. Ryan Residency Training Program in Abortion and Family Planning has supplied technical and financial support for residency programs to develop curricula and clinical opportunities for abortion training [16]. Ob/gyn residents can also pursue fellowships in family planning, which provide high-level research training and clinical skills in contraception and abortion. There are currently 23 privately funded fellowship programs available for ob/gyn physicians and 1 program for family medicine doctors [17]. Private funding, however, cannot be the answer to training future physicians in a legal procedure essential for women's health.

Conclusion

Restricting abortion training runs counter to the standards set forth by both the ACGME and the American Congress of Obstetricians and Gynecologists (ACOG), which

supports education in family planning and abortion for both medical students and residents and abortion training among residents. In

addition, ACOG supports availability of reproductive health services for all women, including strategies to reduce unintended pregnancy and to improve access to safe abortion services [18].

Current legislative efforts to eliminate funding for abortion training—an unprecedented restriction—have the potential to make it impossible for future physicians to meet the full scope of women's health care needs. Previously there may have been a need to prevent discrimination against those who wished to opt out of training; now the pendulum has swung to the other extreme. Those who desire training may face significant financial barriers and may not be competent to perform abortions after completing an ob/gyn residency program, ultimately leaving patients like Jessica without options.

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Kristina Tocce, MD, MPH, is an assistant professor in the Department of Obstetrics and Gynecology at the University of Colorado Anschutz Medical Center in Aurora. She is the student program director and the assistant family planning fellowship director. Her research interests include adolescent contraception, abortion techniques, and medical student family planning curricula.

Britt Severson, MPH, is a fourth-year medical student at Oregon Health and Sciences University in Portland. She received her MPH from Johns Hopkins Bloomberg School of Public Health. Her research interests include contraceptive counseling, tobacco cessation in pregnancy, and abortion training in medical school.

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THE CODE SAYS

The American Medical Association *Code of Medical Ethics*' Opinions on Confidential Care for Sexually Active Minors and Physicians' Exercise of Conscience in Refusal of Services

Opinion 5.055 - Confidential Care for Minors

Physicians who treat minors have an ethical duty to promote the autonomy of minor patients by involving them in the medical decision-making process to a degree commensurate with their abilities.

When minors request confidential services, physicians should encourage them to involve their parents. This includes making efforts to obtain the minor's reasons for not involving their parents and correcting misconceptions that may be motivating their objections.

Where the law does not require otherwise, physicians should permit a competent minor to consent to medical care and should not notify parents without the patient's consent. Depending on the seriousness of the decision, competence may be evaluated by physicians for most minors. When necessary, experts in adolescent medicine or child psychological development should be consulted. Use of the courts for competence determinations should be made only as a last resort.

When an immature minor requests contraceptive services, pregnancy-related care (including pregnancy testing, prenatal and postnatal care, and delivery services), or treatment for sexually transmitted disease, drug and alcohol abuse, or mental illness, physicians must recognize that requiring parental involvement may be counterproductive to the health of the patient. Physicians should encourage parental involvement in these situations. However, if the minor continues to object, his or her wishes ordinarily should be respected. If the physician is uncomfortable with providing services without parental involvement, and alternative confidential services are available, the minor may be referred to those services. In cases when the physician believes that without parental involvement and guidance, the minor will face a serious health threat, and there is reason to believe that the parents will be helpful and understanding, disclosing the problem to the parents is ethically justified. When the physician does breach confidentiality to the parents, he or she must discuss the reasons for the breach with the minor prior to the disclosure.

For minors who are mature enough to be unaccompanied by their parents for their examination, confidentiality of information disclosed during an exam, interview, or in counseling should be maintained. Such information may be disclosed to parents when the patient consents to disclosure. Confidentiality may be justifiably breached in situations for which confidentiality for adults may be breached, according to

Opinion 5.05, "Confidentiality." In addition, confidentiality for immature minors may be ethically breached when necessary to enable the parent to make an informed decision about treatment for the minor or when such a breach is necessary to avert serious harm to the minor.

Issued June 1994, based on the report "Confidential Care for Minors." Updated June 1996.

Opinion 2.015 - Mandatory Parental Consent to Abortion

Physicians should ascertain the law in their state on parental involvement to ensure that their procedures are consistent with their legal obligations.

Physicians should strongly encourage minors to discuss their pregnancy with their parents. Physicians should explain how parental involvement can be helpful and that parents are generally very understanding and supportive. If a minor expresses concerns about parental involvement, the physician should ensure that the minor's reluctance is not based on any misperceptions about the likely consequences of parental involvement.

Physicians should not feel or be compelled to require minors to involve their parents before deciding whether to undergo an abortion. The patient, even an adolescent, generally must decide whether, on balance, parental involvement is advisable. Accordingly, minors should ultimately be allowed to decide whether parental involvement is appropriate. Physicians should explain under what circumstances (e.g., life-threatening emergency) the minor's confidentiality will need to be abrogated.

Physicians should try to ensure that minor patients have made an informed decision after giving careful consideration to the issues involved. They should encourage their minor patients to consult alternative sources if parents are not going to be involved in the abortion decision. Minors should be urged to seek the advice and counsel of those adults in whom they have confidence, including professional counselors, relatives, friends, teachers, or the clergy.

Issued June 1994 based on the report "Mandatory Parental Consent to Abortion," adopted June 1992.

Opinion 2.12 - Genetic Counseling

Three primary areas of prenatal genetic testing are (1) screening or evaluating prospective parents for genetic disease before conception to predict the likelihood of conceiving an affected child; (2) analysis of a pre-embryo at the preimplantation stage of artificial reproductive techniques; and (3) in utero testing after conception, such as ultrasonography, amniocentesis, fetoscopy, and chorionic villus sampling, to determine the condition of the fetus.

Physicians engaged in genetic counseling are ethically obligated to provide prospective parents with the basis for an informed decision for childbearing. Counseling should include reasons for and against testing as well as discussion of inappropriate uses of genetic testing. Prenatal genetic testing is most appropriate for women or couples whose medical histories or family backgrounds indicate an elevated risk of fetal genetic disorders. Women or couples without an elevated risk of genetic disease may legitimately request prenatal diagnosis, provided they understand and accept the risks involved. When counseling prospective parents, physicians should avoid the imposition of their personal moral values and the substitution of their own moral judgment for that of the prospective parents.

The physician should be aware that where a genetic defect is found in the fetus, prospective parents may request or refuse an abortion. Physicians who consider the legal and ethical requirements applicable to genetic counseling to be in conflict with their moral values and conscience may choose to limit their services to preconception diagnosis and advice or not provide any genetic services. However, the physician who is so disposed is nevertheless obligated to alert prospective parents when a potential genetic problem does exist, so that the patient may decide whether to seek further genetic counseling from another qualified specialist.

Genetic selection refers to the abortion or discard of a fetus or pre-embryo with a genetic abnormality. In general, it is ethically permissible for physicians to participate in genetic selection to prevent, cure, or treat genetic disease. However, selection to avoid a genetic disease may not always be appropriate, depending on factors such as the severity of the disease, the probability of its occurrence, the age at onset, and the time of gestation at which selection would occur. It would not be ethical to engage in selection on the basis of non-disease-related characteristics or traits.

Issued June 1983; updated June 1994 based on the report "<u>Prenatal Genetic Screening</u>," adopted December 1992.

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Sex Selection for Nonhealth-Related Reasons, February 2012

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JOURNAL DISCUSSION

Barriers and Biases: Ethical Considerations for Providing Emergency Contraception to Adolescents in the Emergency Department Rebecca C. Thilo

Miller MK, Plantz DM, Dowd MD, et al. Pediatric emergency health care providers' knowledge, attitudes, and experiences regarding emergency contraception. Acad Emerg Med. 2011;18(6):605-612.

Several ethical issues relating to the distribution of emergency contraception (EC) to pediatric patients are brought to light in the Academic Emergency Medicine article "Pediatric Emergency Health Care Providers' Knowledge, Attitudes, and Experiences Regarding Emergency Contraception" [1]. Miller et al. conducted a multicenter focus group study that unveiled several opinions regarding EC among health care professionals in urban pediatric emergency departments (EDs). The varying levels of knowledge, diverse attitudes, and practices discussed in the article point to implied biases and health care disparities related to emergency contraception distribution among pediatric patients.

The article begins with background on the state of unintended adolescent pregnancies in the United States. Despite a slight overall decline since its peak in 1990, the birth rate among U.S. adolescents is the highest among industrialized nations [2]. Although emergency contraception is available over the counter to women as young as 17 years old, many adolescent patients find themselves in the emergency department following unprotected intercourse. The authors identify barriers these adolescents encounter, focusing specifically on the knowledge deficits and personal opinions of health care professionals (HCPs) and state laws regarding conscientious objection. Citing a lack of data describing nurses' attitudes and knowledge, the authors set out to ascertain clinicians' attitudes, beliefs, and experiences regarding emergency contraception in pediatric emergency room encounters. It should be noted that the authors focus on current beliefs without discussing trends or changes over time.

The authors conducted a multisite focus group study in three freestanding urban pediatric teaching hospital EDs across the country. It is important to consider the potential selection bias of this population, which may not reflect the typical U.S. adolescent emergency room visit (for example, according to U.S. News, only about 1 in 30 U.S. hospitals has "deep expertise" in pediatric critical care) [3]. The methods involved a psychologist's using a discussion guide with open-ended questions to moderate 60-90-minute sessions comprising approximately ten physicians, nurse practitioners, or nurses. Later in the article, the authors acknowledge the limitations

of qualitative methods and the varied discussion content in the nonreproducible, semistructured group setting. Despite the variations from group to group, Miller and colleagues identified three major themes of conversation, which bring to light important ethical implications for adolescents who visit the ED following unprotected intercourse [4].

1. Attitudes and Beliefs toward Adolescent Sex and Contraception

Though "most" HCPs in the study supported adolescent contraception, the nurses in particular raised concerns about societal norms shifting to become more accepting of teenage pregnancy. The article lists the barriers to emergency contraception for adolescents perceived by the participants: "fear, availability, knowledge deficits, side effects, cost, transportation, need for HCP contact and prescription, embarrassment, lack of planning, and privacy issues" [4]. It would be interesting to follow up this perceived list of barriers with a survey of sexually active adolescents to elicit their perceived and actual barriers to reproductive care and contraception.

2. Attitudes and Beliefs Toward Emergency Contraception

Several quotes illustrate personal anecdotes, experiences, and biases about adolescent use of emergency contraception inherent in the sample nursing population. The authors recount that the nurses "expressed punitive attitudes" toward the adolescents' "irresponsible behavior" [4]. Specifically, one nurse mentioned an adolescent niece getting kicked out of her parents' house after using Plan B, and another nurse asked, "If you play the game, don't you maybe have to pay?" Of course, pregnancy is a big price to pay for unprotected sex. Though it is understandable that clinicians may feel frustration with any patient noncompliance (whether in failing to take diabetes medication or birth control, failing to use the treadmill or condoms), it is ethically unacceptable for HCPs to penalize patients for their actions. Clinicians do not withhold insulin from patients in diabetic ketoacidosis to teach them a lesson; nor should a teenager be denied emergency contraception. Recognizing these attitudes and striving to thwart them in favor of the virtue of compassion is essential to providing appropriate and ethical patient care.

3. Barriers and Opportunities to Provision of Emergency Contraception

Social judgment. The authors note how most nurses in the study tended to favor assessing patients on an individual basis. It seems to be implied that the surveyed HCPs favor providing EC to smart, responsible patients like a Stanford-bound 17-year-old girl. What does this mean for patients of low socioeconomic status who cannot afford or receive regular birth control, much less support a child? Arbitrarily doling out emergency contraception to adolescents based on their status as upstanding citizens or their moral merit is ethically problematic. Professional integrity dictates that health care professionals have an obligation to practice medicine at the highest intellectual and moral standards, regardless of the socioeconomic or emotional level of the patient in question.

Provision of emergency contraception. Opinions about providing emergency contraception differed both by hospital location and between nurses, on the one

hand, and physicians and nurse practitioners, on the other. Adhering to the principle of justice requires that patients have equal access to care, which is at odds with the lack of nursing support for emergency contraception in the Midwest compared with the Northeast. Nurses seemed more inclined to put stipulations on access to emergency contraception such as the context of the intercourse. The article mentioned several comments in which rape or assault victims were considered more justified in receiving EC than patients who engaged in consensual intercourse. Again, the patient's intelligence or "head on her shoulders" affected nurses' perception of her and the treatment they were inclined to support [5]. The ethical duty to respect patients' autonomy necessitates that each patient's individual worth and value be acknowledged. Patients should be treated with dignity and due regard, and care should not be compromised by the clinicians' judgment. It should be noted that physicians and nurse practitioners did not seem to reflect these biased attitudes towards EC provision.

Emergency contraception knowledge and experience. Subjects reported confusion regarding "screening requirements, side effects, and legality of health care provision." Even physicians and nurse practitioners lacked comfort with knowing how and when to prescribe emergency contraception. Professionals are ethically obligated to know practice guidelines and be able to provide appropriate care. If HCP ignorance or discomfort is an issue, perhaps hospitals should make efforts to educate staff regarding care options, especially pregnancy prevention for adolescents.

Emergency contraception in the emergency department. While many HCPs identified preferable locations for the distribution of emergency contraception (namely, the patient's primary care physician [PCP]), the respondents seemed to understand why adolescents seek it in the emergency room. Even though the continuity-lacking ED may not be the ideal setting, the consequences of denying emergency contraception or referring patients to PCPs may be great, including the need for more invasive procedures or unwanted pregnancy. Data compiled by California's Healthy Families Program indicates that 6-27 percent of adolescents aged 12-18 may not visit a primary care practitioner on a regular basis [6]. For adolescents without a regular PCP, the ED may be the only place to turn.

Refusal. The article points out an important ideological dichotomy between nurses and the other HCPs. Nurses were more inclined to refuse providing emergency contraception on moral grounds, whereas nurse practitioners and physicians felt an obligation or "an oath" to provide information about it [7]. Ethically, the nurses are entitled to limit care obligations due to legitimate self-interests. The conscientious objection argument is, perhaps, the most compelling justification for refusing to offer emergency contraception to adolescents. The authors share a quote from the American Nursing Association's Code of Ethics, which prioritizes patient safety and the patient's best interest.

Education. The groups identified barriers to providing reproductive education including "time, HCP knowledge deficit, and lack of adolescent interest." Though time and disinterest may be difficult barriers to overcome, correcting the HCP's knowledge deficit is an important and attainable task. Assessment of the study participants' knowledge of EC found it to be generally poor and of especial concern in the Midwest and among nurses [8]. HCP knowledge deficits may limit patient autonomy if patients are poorly informed when making decisions. Providing emergency contraception education to all HCPs should be incorporated by emergency medicine departments throughout the country so that patients can make knowledgeable care choices.

Screening and advance prescription were also common themes among the group discussions. Most clinicians did not support either action. Though screening did not seem to be a part of every patient encounter, questions about sexual history and the need for emergency contraception were asked of high-risk patients. These areas may warrant further investigation, though they do not currently seem to play a central role in the ethical debate surrounding the availability of emergency contraception in emergency rooms.

The article summarizes current care inconsistencies and the need for education of HCPs. The authors warn that social judgment often affects patient care, and they conclude that future studies of emergency contraception for adolescent patients in the ED are warranted. Yet, the perceptions and barriers discussed in the article also indicate the need for a universal ethical framework to guide clinicians' actions and patient care. Not only should readers be informed of the biases and disparities, but action should be taken to avoid ethical injustices. Such actions should take the form of self-awareness on the part of health care professionals and educational efforts regarding EC.

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Rebecca C. Thilo is a fourth-year medical student in the Medical Ethics Track at Baylor College of Medicine in Houston, Texas. She is pursuing a residency in emergency medicine and is interested in medical humanities, women's health, and spirituality and healing.

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Virtual Mentor

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STATE OF THE ART AND SCIENCE Male Hormonal Contraception Mara Y. Roth, MD

Introduction

Throughout the world, including the United States, one-half of all pregnancies are unplanned, leading to unsafe abortions and the unnecessary deaths of thousands of healthy young women [1, 2]. While reversible contraceptive options for women have proliferated to include pills, patches, injections, intrauterine devices, and permanent sterilization [3], no new reversible contraceptive options have arisen for men since the development of condoms over 400 years ago. Despite expressions of interest in a reversible hormonal contraceptive for men by men and women of multiple races, religions, and ethnicities [4, 5], there is still no commercially available option. This article will review the theory, the current agents in development, and the potential risks and benefits of a reversible male hormonal contraceptive.

Physiology of Male Hormonal Contraception

The theory behind a reversible male hormonal contraceptive involves manipulation of the hypothalamic-pituitary-gonadal axis that regulates testicular steroidogenesis and spermatogenesis. In men with proper gonadal function (eugonadal men), pulsatile release of gonadotropin-releasing hormone stimulates the release of luteinizing hormone and follicle-stimulating hormone from the pituitary gland. Luteinizing hormone binds to Leydig cells to stimulate testosterone production, while follicle-stimulating hormone stimulates Sertoli cells to produce sperm [6]. Testosterone diffuses into the blood stream and serves to regulate its own production by providing negative feedback at the level of the hypothalamus and pituitary gland. In healthy, eugonadal men, this system of dual-hormonal control with luteinizing hormone and follicle-stimulating hormone allows for the production of nearly 1,000 sperm per second [7].

Male hormonal contraceptives capitalize on the neuroendocrine negative feedback loop by providing exogenous testosterone, which suppresses production of gonadotropin-releasing hormone, luteinizing hormone, and follicle-stimulating hormone, thereby blocking endogenous testosterone production in the testes and, subsequently, spermatogenesis. Cessation of male hormonal contraceptive regimens leads to universal return of normal testicular function including spermatogenesis [8, 9].

Sperm concentrations in healthy men exceed 14 million per ml of ejaculate produced [10]. Complete absence of sperm in the ejaculate, called "azoospermia," makes fertilization of ova impossible. Therefore the goal of a male hormonal contraceptive is to induce azoospermia in those men undergoing treatment. However, a sperm

concentration of less than 1 million per ml of ejaculate, called "severe oligozoospermia," has been associated with a risk of pregnancy of approximately 1 percent per year [11]. A goal of severe oligozoospermia has been defined as a reasonable goal for contraceptive development and regulatory approval, inasmuch as this would confer an efficacy similar to that of hormonal contraceptives for women [12, 13].

Testosterone-Based Regimens

While sperm concentration goals define "success" in most studies evaluating contraceptive regimens, "efficacy" is defined by pregnancy rates. The majority of studies evaluating contraceptive efficacy have used protocols containing only testosterone. The World Health Organization (WHO) conducted the first contraceptive efficacy trial using testosterone enanthate, 200 mg administered intramuscularly weekly. While sperm concentrations declined below 1 million per ml in 98 percent of subjects, 11 pregnancies occurred, accounting for an overall efficacy rate of only 94.7 percent [11]. More recent studies using testosterone undecanoate (TU), a long-acting testosterone formulation 500 mg of which is given intramuscularly each month, showed similarly high rates of spermatogenesis suppression; 95-97 percent of subjects achieved less than 1 million sperm per ml, and the efficacy rates were 94.2-96.7 percent [14, 15]. In addition, contraceptive options using testosterone alone have shown wide variation based on ethnicity when looking at suppression of spermatogenesis [16].

Addition of a progestin agent to testosterone-containing regimens has been shown to increase rates of suppression of spermatogenesis among all ethnic groups [8]. Several long-acting progestin agents have been used in combination with TU with very promising results. Etonogestrel, initially designed as a long-acting implantable contraceptive for women, shows a 94 percent rate of suppression of spermatogenesis to less than 1 million per ml when used with TU in an international randomized controlled trial [17]. Similarly, norethistrone enanthate, a long-acting injectable progestin, showed great promise when combined with TU in a small trial of 40 men [18]. The WHO sponsored a large international contraceptive trial enrolling 400 couples to further explore this combined regimen for hormonal contraceptive efficacy in men. The WHO recently stopped this trial early due to concern that the risk of side effects from the regimen may outweigh the potential contraceptive benefits to the study participants [19].

Transdermal testosterone gels provide more consistent, stable serum testosterone concentrations than some injectable forms of testosterone [20]. While only 90 percent effective at suppressing sperm concentrations to less than 1 million per ml when used in combination with injectable medroxyprogesterone acetate [21], a gel formulation appears to be quite acceptable to men and may provide a reasonable contraceptive option in the future [22]. Testosterone gel has also been used in combination with nestorone gel, a progesterone derivative, to create a completely topical form of male hormonal contraception. Shown to be highly effective at gonadotropin suppression [23], the combination of testosterone gel and nestorone gel are currently being tested in a 6-month randomized, multicenter contraceptive study looking at suppression of spermatogenesis as the primary outcome.

Alternative Androgens for Hormonal Contraception

Testosterone-based male hormonal contraceptive regimens have not yet achieved a consistent enough level of efficacy in all subjects to allow drug development to progress to widespread use. In addition, the majority of likely testosterone-based regimens require the addition of a progestin agent to improve rates of suppression of spermatogenesis. In an attempt to circumvent the need for a multidrug contraceptive regimen, alternative synthetic androgens have been developed for possible use as contraceptive options.

Dimethandrolone undecanoate (DMAU) is a potent synthetic androgen with activity at both the androgen and progesterone receptors, and can be administered both orally and by injection [24]. While studies in humans have not yet been done, early studies of DMAU in rabbits have been promising. A 60-day study showed suppression of gonadotropins and severe oligozoospermia in all rabbits receiving 2.5 mg per kg per day [25]. In addition, mating trials showed that all oligozoospermic rabbits receiving DMAU were rendered infertile, and all recovered to normal levels of spermatogenesis within 18 weeks of stopping DMAU. Studies testing this promising compound in humans are in the planning stages and will, it is hoped, begin soon.

Another synthetic androgen, 7-alpha-methyl-19-nortestosterone (MENT), is significantly more potent than testosterone and can be administered annually as a subdermal implant [26]. MENT is resistant to 5-alpha-reduction, both contributing to its high potency at the androgen receptor and also helping to prevent possible risk to prostate health by avoiding increased exposure to dihydrotestosterone (DHT) [27]. Initially studied for 4 weeks to assess safety in healthy, eugonadal men [28], and for 6 weeks as treatment for hypogonadal men [29], a small dose-finding study looking at MENT as a single-agent contraceptive for men was extremely promising. Eighty-two percent of men in the highest dose group achieved azoospermia during the study, and 100 percent of men in this group became oligozoospermic (defined as less than 3 million per ml) during the study [26]. Given these promising results, a larger randomized controlled trial looking at MENT for male hormonal contraception should begin in 2012.

Risks and Benefits of Male Hormonal Contraception

While it is hard to accurately predict the true risks and benefits of long-term hormonal contraception for men when no FDA-approved contraceptive option exists, the potential risks and benefits of a contraceptive regimen can be inferred from our knowledge of long-term hormonal replacement in men and from contraceptive trials. Aside from the benefits of improved contraceptive efficacy, testosterone therapy in hypogonadal men significantly increases lean body mass and decreases fat mass [30] and affects healthy men on a testosterone-only contraceptive regimen similarly [31]. The beneficial effects on body composition appear to be partially attenuated by the addition of a progestin agent, levonorgestrel (LNG). In a randomized trial comparing testosterone enanthate to testosterone plus LNG, subjects receiving LNG still showed

an increase in lean body mass, but also had an increase in abdominal fat mass, as compared to a decrease seen in the testosterone-only group [32]. Testosterone therapy in hypogonadal men significantly increases bone mineral density for up to 16 years [33]. When administered as a single-agent contraceptive to healthy young men, testosterone enanthate also increases bone mineral density [31], but long-term effects in healthy men, and the effects of a contraceptive regimen when a progestin agent is added, remain unknown.

Evaluating the risks of a male hormonal contraceptive regimen can often be challenging, both because of the limited duration of studies and the lack of a control group in most studies. In addition, the range of common side effects varies dramatically and may be reflective of the progestin agent used. In the largest male hormonal contraceptive study, using testosterone undecanoate injections monthly for 30 months in more than 1,000 men, 7 percent reported an increase in acne and less than 1 percent reported mood changes or skin irritation [15]. Alternatively, in a trial comparing a testosterone-and-etonogestrel contraception regimen to placebo, rates in the treatment group were significantly higher than in the placebo group for acne (26 percent versus 10 percent), increase in body weight (24 percent versus 10 percent), change in libido (13 percent versus 0), and night sweats (27 percent versus 8 percent), but rates of mood changes (19 percent versus 10 percent) were similar in both groups [17]. Testis volume is known to decrease by about 4-5 ml when testosterone is used for contraception due to the effect of gonadotropin suppression on seminiferous tubule volume and Leydig cell volume [15]. Given that all men on contraceptive regimens recover their sperm output after discontinuing the contraceptive regimen (the exact timing depends on the drug and the individual), the testis volume is also expected to return to baseline [8]. Erythrocytosis, also a known side effect of testosterone therapy in hypogonadal men, appears to be dose-related and to affect men differently based on age, and it has not been a frequent adverse event reported in contraceptive trials [34].

The potential impact of male hormonal contraceptive regimens on metabolism and cardiovascular risk are of concern when considering long-term treatment of otherwise healthy men. The overall impact of testosterone on lipids when used for hypogonadism therapy appears to be a small decrease in high-density lipoprotein [35], but the clinical significance of this alteration is unclear. Conflicting data reports both higher rates of cardiovascular mortality in men with low serum testosterone [36], and significantly higher rates of cardiovascular events in men treated with testosterone therapy [37]. The implications of this information gathered in a population of men that is not likely to use long-term contraceptive therapy are difficult to apply to young, eugonadal men and highlight the need for additional studies of the cardiovascular implications of contraceptive therapy.

Similarly, the potential risk of contraceptive therapy to prostate growth and prostate cancer remains undefined. A large meta-analysis of testosterone therapy for up to 3 years showed no increase in adverse prostate outcomes [35], yet the potential impact of a contraceptive regimen on prostate health over a longer period of time has not been studied.

Conclusions

The development of a reversible male hormonal contraceptive would offer a monumental improvement in reproductive choices for both men and women. While many options have been tested, no pharmaceutical company has applied to the Food and Drug Administration for permission to bring any of those regimens to market. The development of new, synthetic androgens offering the potential for a single-agent contraceptive regimen are promising, but further research including larger phase III trials and more exploration of potential long-term risks needs to be pursued.

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Mara Y. Roth, MD, is an assistant professor in the Department of Medicine, Division of Endocrinology, at the University of Washington in Seattle. Dr. Roth's research focuses on the development of a male hormonal contraceptive, looking specifically at intratesticular hormone requirements necessary for spermatogenesis as a means of identifying nonresponders to contraceptive regimens.

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Virtual Mentor

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HEALTH LAW Legislative Restrictions on Abortion B. Jessie Hill, JD

More anti-abortion legislation was passed in 2011 than in any other year since *Roe v*. Wade was decided in 1973 [1]. In the first half of the year, when most of the legislative activity took place, more than 80 abortion-related restrictions were enacted across the United States [1, 2]. Though this statistic encompasses a wide array of rules and regulations, a few trends clearly emerge. Many of these laws are more extreme than any we have seen in decades. The following are a few of the most common or most notable types of laws to appear this year.

Banning Abortion before the Fetus Is Viable

In April 2010, Nebraska passed a law banning all abortions after the twentieth week of pregnancy, except to save the life of the woman or protect her from a severe threat to her physical health [3]. In 2011, five more states (Alabama, Idaho, Indiana, Kansas, and Oklahoma) followed suit. These laws are sometimes justified by the legislators' view that fetuses can feel pain at or around 20 weeks' gestation—a view that is mostly rejected by the medical literature [4, 5].

Regardless of the state of the medical evidence on fetal pain, the U.S. Supreme Court has made it clear that states may not ban abortion outright before the fetus is determined to be viable [6]. Viability must be determined by the individual physician but is generally understood to occur at approximately 24 weeks' gestation. Yet, despite their apparent unconstitutionality, such laws are currently in effect in the six states named. Only one—Idaho's—has been challenged in court, and it was not struck down because the woman challenging the law did not have the legal "standing" to challenge it; that is, she was neither a patient seeking a late-term abortion nor a doctor who performs them, and therefore she was not directly affected by the law [7].)

In Ohio, legislators introduced the so-called "Heartbeat Bill," which would ban all abortions (except to save the life of the woman or prevent severe physical harm) after the fetal heartbeat could be detected—which can be as early as 6 weeks' gestation [8]. This bill would be the most stringent abortion law in the country, prohibiting virtually all abortions. The bill has not yet become law, however, and if it does pass, several abortion-rights groups have stated their intention to challenge it immediately in court.

Informed Consent and Waiting Periods

Although informed consent is a standard requirement before providing medical treatment of any kind, many states have abortion-specific informed consent laws that can be burdensome or inappropriate. For example, a law passed this year in South Dakota created a 72-hour waiting period before an abortion may be performed and requires any woman seeking an abortion to visit a pro-life crisis pregnancy center, which is specifically defined in the law as an entity with the principal mission of "help[ing] a pregnant mother maintain her relationship with her unborn child" [9]. Before the law went into effect, however, a federal judge blocked it, finding that it violated women's constitutional rights.

Other states besides South Dakota have passed laws requiring the provision of medically irrelevant or inaccurate information. Indiana amended its existing informed consent law to require abortion providers to inform women that "human physical life begins when a human ovum is fertilized by a human sperm" and that "objective scientific information shows that a fetus can feel pain at or before twenty (20) weeks of postfertilization age" [10]. A legal challenge to the Indiana law has not succeeded so far in lifting these requirements.

A North Dakota law passed in 2011 requires women be given information such as "the possible increased risk of breast cancer" and "the possible adverse psychological effects associated with an abortion" [11]. Neither breast cancer nor adverse mental health effects have been shown to correlate with abortion, however.

Restrictions on Medication Abortion

Several states acted in 2011 to restrict abortions that are performed medically rather than surgically with the abortifacient mifepristone (also known by its brand name Mifeprex or RU-486). Three states (Kansas, North Dakota, and Oklahoma) passed laws requiring mifepristone abortions to be provided using the same protocols that were used in clinical testing when the drug was approved by the FDA in 2000. The evidence-based protocol adopted by the overwhelming majority of clinicians today involves a significantly smaller dosage of mifepristone than that used in the earlier FDA protocol and allows medication abortions to occur up to 63 days' gestation, rather than only up to 49 days, as in the clinical trials. States have nonetheless passed legislation preventing doctors from applying their best medical judgment with respect to dosage and timing of the abortion drug. These state laws are similar to an Ohio law, the constitutionality of which continues to be litigated, that was passed in 2004 but only recently allowed to go into effect by a federal judge.

Finally, a number of states have taken aim at medication abortion by outlawing the use of telemedicine for this purpose. Telemedicine has given many women access to medication abortion without an in-person meeting with a physician. Women could receive the medication from on-site staff at the abortion clinic after counseling via videoconference from a physician who is off-site. Telemedicine is a particularly valuable technology for women in rural or remote areas, to whom abortion would otherwise be inaccessible.

Bans on Insurance Coverage for Abortion

Another prominent area of legislative activity in 2011 was insurance coverage for abortion. Five states (Florida, Idaho, Indiana, Ohio, and Virginia) passed laws restricting insurance coverage for abortion in plans that will be offered in state health insurance exchanges under the Affordable Care Act, beginning in 2014 [1, 2, 12]. Four additional states (Kansas, Nebraska, Oklahoma, and Utah) went further, banning insurance coverage not only in the state-sponsored exchanges but in all private insurance plans [1, 2].

Other Efforts on the Cutting Edge of Abortion Regulation

Many other types of initiatives have been introduced or are likely to be introduced in various states. For example, voters in Mississippi rejected a proposed amendment to the state constitution that would define a fetus or embryo as a "person" beginning at the moment of fertilization. This measure was widely understood to threaten the legality not only of abortion but also of any method of contraception with a possible post-fertilization effect (such as emergency contraception and progestin-only birth control pills), as well as any in vitro fertilization methods or stem cell research that results in the destruction of embryos. Despite the law's defeat in Mississippi, its backers will likely attempt to introduce similar measures in other states, including California, Florida, Montana, Nevada, Ohio, and Oregon in 2012 [13].

Legislatures continue to target abortion providers in other ways as well. Though not new, so-called TRAP laws (targeted regulations of abortion providers) continue to be put in place, imposing onerous requirements specific to abortion clinics, such as precise room temperatures, minimum dimensions for waiting rooms and recovery rooms, and hospital admitting privileges for all physicians who perform abortions [14]. Some states have cut funding to Planned Parenthood and other family planning organizations, affecting not only abortion services, but also the provision of other core reproductive health services such as contraception and screening for cervical cancers and STDs.

If 2011 is any indication, a new era of attacks on abortion rights has begun, with very little resistance from the courts. Though only a small number of physicians in the country will be directly affected in their practices by these restrictions, all physicians should be profoundly concerned. These measures represent an unprecedented level of intrusiveness in the doctor-patient relationship and a thorough disregard for the exercise of independent medical judgment. Regardless of beliefs concerning abortion, all physicians have reason to object on professional grounds to state interference with the practice of medicine.

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- B. Jessie Hill, JD, is a professor of law at Case Western Reserve University in Cleveland. She received her law degree from Harvard Law School. Her research focuses on constitutional law, with a particular emphasis on reproductive and religious rights. Previously, Ms. Hill worked for the Reproductive Freedom Project of the American Civil Liberties Union (ACLU).

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POLICY FORUM

The Religious Exemption to Mandated Insurance Coverage of Contraception Adam Sonfield, MPP

Accepting the recommendation of an Institute of Medicine (IOM) expert advisory panel, the U.S. Department of Health and Human Services (HHS) in August 2011 designated contraceptive services, supplies and counseling as women's preventive health care that private health plans are obligated to cover without consumer costsharing under the Patient Protection and Affordable Care Act (ACA) [1, 2]. In announcing its decision, HHS also announced its intent to exempt certain religiously affiliated employers from this requirement [3]. A substantial body of evidence indicates that expanding insurance coverage of contraception has considerable potential for improving its use and, in turn, a host of subsequent health outcomes, in the United States. At the same time, the unilateral decision by HHS to include a religious exemption raises serious questions—namely, whether it is merited at all and, when it is finalized, whether it appropriately balances the beliefs, rights, obligations, and needs of all affected parties.

The Requirement to Cover Contraceptive Services

The goal behind the ACA provision on preventive health care services is to eliminate financial disincentives to using effective preventive care, thereby improving health. Numerous studies have found that even modest cost-sharing requirements can dramatically reduce use of preventive health services, particularly among lowerincome Americans [4].

The ACA refers to three sets of existing guidelines on preventive care that include, among many others, services such as breast and cervical cancer screening, screening and counseling for HIV and other sexually transmitted infections (STIs), vaccination for human papillomavirus, specified aspects of prenatal care, and reproductive health counseling for adolescents [5]. During consideration of the legislation in December 2009, the Senate approved an amendment that added "women's preventive care and screenings" as a fourth category of mandated preventive services, to fill gaps in the existing three. Although those three sets of guidelines include a range of services for women, none of the three is designed to meet all of women's preventive health care needs.

Because there were no comprehensive guidelines on women's preventive health to draw upon, HHS turned to the IOM to evaluate the evidence and advise it on what services should be included. The resulting recommendations include "the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling" [1]. They also specify wellwoman visits, counseling and equipment to support breastfeeding, and screening and counseling for domestic violence, as well as enhancements to insurance coverage related to HIV, other STIs, cervical cancer, and pregnancy care.

The new requirements affect private health plans starting in August 2012, except for those that have been "grandfathered"—exempt from the requirement—so long as they make no significant, negative changes, such as cutting benefits or raising cost-sharing. HHS projects that most plans will lose grandfathered status by making those types of changes within a few years [6].

Potential Benefits of the Requirement

The HHS decision builds on major changes in private-sector contraceptive coverage over the past two decades. Since the late 1990s, 28 states have required plans to cover contraception when other prescription drugs are covered [7]. And in December 2000, the U.S. Equal Employment Opportunity Commission first made it clear that an employer's failure to cover contraception when it covers other prescription drugs and preventive care violates protections against sex discrimination under Title VII of the Civil Rights Act [8]. By 2002, the vast majority of private insurance plans were covering a comprehensive array of contraceptive services and supplies, a substantial shift from coverage practices in 1993, when the issue was first studied [9].

The result of the new requirement, therefore, will be to close most of the remaining gaps in coverage, such as in the individual and small-group markets, and bring private insurance in line with Medicaid's decades-old practice of exempting family planning—along with other key services, such as pregnancy-related care—from cost-sharing [10].

In doing so, the requirement has the potential to provide the substantial benefits for the health and well-being of women and families that come from helping women plan and space their pregnancies [11]. Correct and consistent contraceptive use dramatically reduces the risk of unintended pregnancy: in any given year, the two-thirds of U.S. women at risk (i.e., sexually active, fertile, and not seeking to become pregnant) who use contraception consistently and correctly throughout the year account for only 5 percent of unintended pregnancies [12]. Numerous studies, in turn, point to a causal link between pregnancies that are too close together and three birth outcomes that influence the future health of the child: low birth weight, preterm birth, and small size for gestational age [13, 14]. Similarly, unintended pregnancy has been linked to delayed initiation of prenatal care and reduced breastfeeding after a child is born—maternal behavior that can influence health outcomes throughout the child's life [15]. Moreover, unintended pregnancy can hinder women's educational and financial success and deprive women and couples of the ability to prepare before having children [16-19].

Despite the well-documented benefits of contraception, many women face problems using contraceptives consistently over several decades. The result is that nearly half of U.S. pregnancies—more than 3 million annually—are unintended, and unintended

pregnancy rates increased by 50 percent among poor women between 1994 and 2006 [20, 21]. Although there are myriad reasons behind these statistics, cost is one important access barrier, particularly with respect to long-acting, reversible methods (such as the IUD and the implant) that are extremely effective and cost-effective in the long run, but have high up-front costs.

Removing that barrier not only makes it easier for women to use contraception, but also allows them to choose the most effective methods. Three recent studies have found that lack of insurance is significantly associated with reduced use of prescription contraceptives [22-24]; one of those studies found, for example, that after controlling for socioeconomic characteristics and self-reported overall health, uninsured women were 30 percent less likely to report using prescription contraceptive methods than women with private or public health insurance [23]. And several other studies showed that when out-of-pocket costs were eliminated, women's use of long-acting methods increased substantially [25, 26].

In recognizing contraceptive services as an important aspect of preventive care, the IOM guidelines are in harmony with numerous precedents from federal programs, including Medicaid [10], the federally qualified health centers program [27] and HHS's Healthy People goals for the nation [28]. They also concur with the position of the American Medical Association [29] and many other health care professional and health promotion associations, such as the March of Dimes [30] and the National Business Group on Health [31].

The Exemption for Religiously Affiliated Employers

When it made its decision in August 2011 on women's preventive services, HHS also put forward an exemption to the required coverage of contraception for health plans provided by "religious employers" [3]. That key term is defined as an organization that has the inculcation of religious values as its purpose, primarily employs and serves people who share its religious tenets, and is a nonprofit organization under sections of U.S. law that refer to "churches, their integrated auxiliaries, and conventions or associations of churches" and to "the exclusively religious activities of any religious order" [32]. The language mirrors the religious exemptions to contraceptive coverage laws established, and upheld by courts, in California and New York [33, 34]. Public comments on this proposal were accepted through September 2011.

Reproductive health advocates and clinicians have criticized the decision to establish a religious exemption at all [35]. They noted that such an exemption was called for repeatedly during ACA debates by policymakers and advocates opposed to contraception, but Congress did not agree to include one for contraception, despite including several other religious exemptions as part of the ACA.

In fact, the decision by Congress not to include a religious exemption in this case was far from unprecedented. Nine of the 28 states that have required insurance coverage of contraception have done so without including any religious exemption for employers [7]. Neither are religious employers exempt from the Title VII protections against sex discrimination [8].

Finally, these critics point out that the definition of religious employer established by HHS is not precisely tailored to its stated purpose, to "provide for a religious accommodation that respects the unique relationship between a *house of worship* and its employees *in ministerial positions*" (emphasis added) [3]. Rather, this exemption would also affect numerous other employees, including clerical and administrative staff, cafeteria workers, and custodians.

The Catholic hierarchy and some conservative "pro-family" groups—which oppose contraceptive use more broadly on doctrinal or social grounds and objected to its inclusion as required preventive care—have criticized the exemption from a different perspective [36-38]. They argue that it should encompass a far broader range of employers, including religiously affiliated schools, universities, hospitals, and charities that serve and employ the general public, suggesting that the current definition of "religious employer" could force them to limit whom they hire and serve. Such groups also assert that the exemption should be expanded to include insurers and even individual purchasers with religious or moral objections, arguing that a requirement to provide or purchase coverage for contraception amounts to religious discrimination and violates their conscience rights. Some have also called for an exemption for health care providers, although the coverage requirement imposes no obligations on clinicians or institutions to provide the care itself.

Analysis of the Objections

These arguments do not stand up well to scrutiny. Although the founders or sponsors of an institution may have a religious motivation, it does not follow that the institution is serving a religious function *per se*. Religiously affiliated schools, hospitals, social service agencies, and insurers serve and employ members of the general public and are a part of the public arena, with an obligation to abide by public rules.

Moreover, it is not clear why the religious beliefs of any employer or insurer should take precedence over those of its employees or enrollees. Expanding the exemption would affect millions of teachers and guidance counselors, doctors and nurses, clerks and janitors, by interfering with their access to preventive health care that they deem necessary and in line with their *own* religious and moral beliefs. Indeed, the opposition to contraceptive use by some religious leaders does not reflect the beliefs of the laity: 99 percent of U.S. women who have ever had sex with a man have used a contraceptive method other than natural family planning, and that figure is virtually the same across religious groups, including 98 percent among sexually experienced Catholic women [39]. For those employees who do adhere to their employer's religious position on contraception, providing coverage of contraception would not in any way force them to use it in violation of their beliefs.

Objections to financial entanglement with someone else's use of contraception are also problematic. It is difficult to see why an employer has any more right to veto an employee's use of her health benefits than it does to veto her use of her salary, sick leave, or other aspects of her compensation for the same contraceptive services. Moreover, everyone paying for insurance is paying for some services they expect never to need or use, and allowing individuals to pick and choose what specific benefits to cover would undermine the ability of insurance to pool peoples' risks. That type of self-selection is what leads insurers to impose the sort of restrictions on coverage—such as limitations for preexisting conditions or maternity care—that the ACA was designed to eliminate.

Protections for Patients Under a Religious Exemption

The benefits to women and families of the contraceptive coverage requirement will be undercut by a religious exemption, and simple math says that the broader the exemption, the greater the potential harm. In that regard, an HHS announcement in January 2012 that it would retain the narrow definition of a religious employer exempt from the coverage requirement that it proposed in August 2011 is highly significant [40]. The HHS press release also announced a 1-year grace period (until August 2013) for compliance with the requirement for other nonprofit employers certifying that, based on their religious beliefs, they do not currently provide coverage of contraception. (Final regulations have not been issued as of this writing but are expected shortly; in addition, HHS could choose to release additional subregulatory guidance.)

Meanwhile, the fact remains that some people will be harmed even by the narrow religious exemption to the contraceptive coverage requirement. In implementing the requirement and the religious exemption, HHS could and should mitigate harm by explicitly including three key protections.

First, employees and their dependents should still be able to acquire coverage for contraception without cost-sharing through an alternate means. Under several state laws, for example, enrollees of an employer invoking a religious exemption are given the right to purchase contraceptive coverage directly from an insurer. In its January 2012 announcement, HHS pointed to safety-net providers, such as community health centers, as an alternative source of affordable care for those women affected by the religious exemption.

Second, any entity invoking a religious exemption should be required to provide advance notice of that decision. That includes notice to current and potential enrollees about what is excluded and alternate means of accessing coverage and notice to the appropriate regulatory agency, certifying eligibility for the exemption to allow for transparency and enforcement. The January 2012 announcement addressed this issue in part, stating that HHS intended to require employers who do not cover contraception to notify their employees.

Not addressed at all by HHS so far, however, is the critical issue of enforcement of the religious exemption and the preventive services requirement more broadly. For the religious exemption specifically, that includes guarding against abuse, such as allowing ineligible employers to invoke the exemption (for example, by acquiring health coverage through another organization that does qualify for the exemption).

Such protections would constitute the minimum effort necessary to uphold and honor the beliefs, rights, obligations, and needs of all affected parties.

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Adam Sonfield, MPP, is a senior public policy associate at the Guttmacher Institute and a managing editor and regular contributor to its journal, the *Guttmacher Policy Review*. He also writes a quarterly Washington Watch column for *Contraceptive Technology Update*. His portfolio includes research and policy analysis on public and private financing of reproductive health care in the United States, the rights and

responsibilities of health care providers and patients, and men's sexual and reproductive health.

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MEDICINE AND SOCIETY

Contraceptive Justice: Why We Need a Male Pill

Lisa Campo-Engelstein, PhD

The invention of the birth control pill was a significant milestone in the women's rights movement. Since then, other long-acting, reversible contraceptives (LARCs) have been developed for women, and women now have a total of 11 methods to choose from, including barrier methods, hormonal methods, and LARCs [1]. In contrast, men only have 2 options—male condom and vasectomy—and neither are hormonal methods or LARCs. The disparity between the number and types of female and male LARCs is problematic for at least two reasons: first, because it forces women to assume most of the financial, health-related, and other burdens of contraception, and, second, because men's reproductive autonomy is diminished by ceding major responsibility for contraception to women. A more just contraceptive arrangement can only be achieved through the development of male LARCs and reconceptualizing the responsibility for contraception as shared between men and women [2].

Women currently bear most of the financial and health-related burdens of contraception. On the whole, female methods tend to be more expensive than male methods [3] because most require at least one physician visit, and some involve a renewable prescription. Currently many insurance plans do not cover contraception and, of the 28 states that mandate insurance plans to cover contraception, 20 of them have opt-out clauses for religious or ethical reasons [4]. However, beginning August 1, 2012, new insurance plans will have to cover contraception without a co-pay to comply with the Patient Protection and Affordable Care Act of 2010 [5].

In addition to being more expensive, female methods have more serious side effects than male methods, as well, in part because various contraceptive methods for women involve hormones, while no methods for men do [6]. The most common reason women discontinue contraceptive use is unwanted side effects [7, 8], and most forms of contraception have discontinuation rates approaching 50 percent after 1 year of use [9]. Finally, the two available male forms of contraception, condoms and vasectomy, also carry fewer health risks than their corresponding female methods, female barrier contraceptives and tubal ligation [10].

Beyond the health-related and financial considerations, there are also nontrivial inconveniences and burdens associated with contraceptive use: dedicating time and energy to contraception care (e.g., doctor visits), acquiring the knowledge about contraception and reproduction needed to effectively prevent pregnancy (e.g. knowing which medications can interfere with the effectiveness of contraception),

dealing with the medicalization of one's reproductive health, undergoing invasive procedures by physicians (e.g., pelvic exam) and by contraceptives (e.g., IUDs, Norplant), feeling stress and anxiety about the possibility of unintended pregnancy, and facing the social repercussions of contraceptive decisions and the possible moral reproach for contraceptive failures.

While not being responsible for some or all of these burdens is a significant boon for men, at the same time, men's reproductive autonomy is inhibited by the dearth of male contraceptives, especially LARCs. Given the condom's high failure rate of 16 percent during typical use, men who want to maintain the possibility of having biological children are not able to regulate their reproduction as effectively as women are—many female LARCs have failure rates under 3 percent [11]. The lack of effective and reversible options for men forces many men to rely on their partners for contraception. Men have to trust that their partners are correctly and consistently using contraception. Regardless of the circumstances under which pregnancies occur, men are still held socially and financially responsible for any children they father.

Why Are There So Few Male LARCS?

Historically, contraceptive use was tied to the actual sex act, and for this reason men had to participate in it (for example, by using a condom or withdrawing). Additionally, men were generally involved in decisions about and use of contraception because of their traditional role as heads of their households [12]. Well before the invention of the birth control pill, contraceptive use began to shift from a shared (or even male-dominated) responsibility to a woman's responsibility. Due to the Comstock Law of 1873, an anti-obscenity act that explicitly includes contraceptives as obscene material and prohibits their distribution via mail or interstate commerce, women had trouble acquiring contraceptives because clinics and private doctors were often not very convenient, discreet, or affordable.

Seeing an opportunity to make a lot of money (and they did—in 1938 alone, they earned \$250 million), the contraceptive industry began a campaign to encourage women to use their "feminine hygiene" products [13]. These new alignments between women and contraception responsibility and between contraception and private companies paved the way for the success of the pill—whose overnight popularity reinforced women's role as contraceptive consumers. The association of contraception with women led researchers to focus almost exclusively on womenonly methods. Indeed, scientists did not begin researching new types of male contraceptives until the 1970s, 50 years after they first started researching "modern" female contraceptives [14].

The immense and rapid popularity of the pill as well as the subsequent focus of contraceptive research and development on female methods led to a shift in ideology: women became the locus of responsibility for contraception. After the invention of female LARCs, "men, no longer required to use condoms or to practice withdrawal, were essentially absolved from contraceptive decisions. Consequently,

both researchers and service providers have focused almost exclusively on women" [15].

Another reason there are no male LARCs is the dominant perceptions that men do not think they should be responsible for contraception and are not interested in using it—therefore there is no market for the product. Yet empirical evidence often suggests otherwise. For example, one study revealed that more than 70 percent of men think men should take more responsibility for contraception [8]. Furthermore, there is evidence that men are not only interested in using current male contraceptives [16, 17], but also that between 44 and 83 percent of men would use hormonal methods [18-20].

There is also a perception that women will not trust men to use contraception. Many mainstream news articles assert this by claiming that most women's response to male contraceptives would be something like, "Are you kidding? I can't even trust him to take out the garbage!" [21]. In contrast, academic studies show that women in committed relationships would trust their male partners to use new contraceptives [8, 19, 20]. Furthermore, while they may not be a representative sample, it seems safe to assume that women who have agreed to join clinical trials for male contraceptives, knowing it meant they could not use any other forms of contraception, trusted their partner to use the new contraceptives [22]. And many couples already rely on male contraception, which presumably means these women trust their male partners to use it [10, 23]. This disconnect between mass media stories and empirical studies can be explained by distinguishing between trust for individuals and trust for groups [24]: "On the whole many women have rather cynical views of men in general which do not reflect their views of individual men—especially their partner" [18].

Some claim men are less motivated to use contraception because pregnancy entails fewer consequences for them than for women [25, 26]. Besides the fact that it is women who actually carry a child, though, the main reason a pregnancy is thought to have more long-term consequences for women is that women are assumed to be the primary caretakers of children. This assumption is based on socially constructed gender roles. If men were expected to be the primary caretakers of children (or at least to equally share the role of primary caretaker with women), then pregnancy would also carry significant consequences for them. Today men are more actively involved in childrearing than previous decades; for example, 71 percent of children under 6 eat dinner with their fathers every day [27], 15 percent of single parents are men, and 154,000 men in the U.S. are stay-at-home dads [28]. This increased involvement shows that pregnancy does indeed have significant consequences for men—a good reason for men to want more control over their reproductive autonomy.

Shared Contraceptive Responsibility

There is no question that, due to contraceptive advances, the contraception situation women in the U.S. face today is vastly better than it was 60 years ago. That said, however, the current contraceptive situation is still unjust. Women bear the majority of contraception responsibility and the burdens it entails while men have limited

reproductive autonomy. In a way, the current contraception arrangement is more problematic than the previous one because its injustices are often hidden, or at least sidelined, by the dominant rhetoric of women's empowerment and equality. This dominant rhetoric sends the message that women should be content and grateful for the current situation, thus marginalizing and even silencing any complaints or suggestions for improvements.

As a matter of social justice, we should move toward shared contraception responsibility. In order to do this, we need to devote more resources to developing male LARCs. However, developing male LARCs is not enough: without any changes in dominant gender norms for contraception responsibility, it seems unlikely men will use contraception at the same rates women do. As epitomized by the case of sterilization, the mere existence of a particular technology is not enough to change our current contraceptive arrangement. Although surgical sterilization is available for both women and men, tubal ligation is nearly three times more common in the United States than vasectomy, and this trend is repeated worldwide. The differing rates cannot be attributed to availability of technology, nor to the procedures themselves—vasectomies are quicker, easier, safer, and cheaper than tubal ligations. The alignment of femininity with responsibility for contraception, and with reproduction more broadly, mostly explains why tubal ligation is far more popular [29, 30].

In short, we need both a change in technology—the development of male LARCs and a change in ideology—the belief that both women and men should be responsible for contraception—to achieve the more just contraceptive arrangement.

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Lisa Campo-Engelstein, PhD, is a bioethicist with a special interest in reproductive ethics. She is an assistant professor at the Alden March Bioethics Institute of Albany Medical College in New York and the co-editor of a book on the emerging field of oncofertility. She has been published in several medicine, science, and bioethics journals, including the Journal of Clinical Oncology, Science, The Hastings Center Report, and The American Journal of Bioethics. She earned her PhD in philosophy from Michigan State University and completed a postdoc with the Oncofertility Consortium at Northwestern University.

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HISTORY OF MEDICINE

Federal Sterilization Policy: Unintended Consequences

Susan P. Raine, JD, MD, LLM

On July 19, 1989, a commercial airliner crashed in Sioux City, Iowa. Four "lap" children were on that flight, the youngest of whom was 26 months old. As the plane crashed, two mothers were unable to hold onto their children due to the forces generated by the impact. Both children, including the 26-month-old, perished [1]. Subsequently, the National Transportation Safety Board (NTSB) accident report recommended that the Federal Aviation Administration (FAA) mandate child restraint systems for all children during airline travel. In fact, just two months before the Sioux City crash, the NTSB added mandatory child safety seats to its list of "most wanted" improvements from the FAA.

Despite these recommendations and requests, the debate over the use of mandatory child restraint systems for children during air travel continued, largely due to concern over the possible unintended consequences of such a policy. It has been estimated that universal use of child restraint systems could prevent 0.4 child air crash deaths per year in the United States; however, if due to increased costs, even as few as 5-10 percent of parents were to switch their mode of travel to the roadways, the number of deaths that might result from highway travel would outweigh the benefit gained from mandatory child restraint systems in the air [2]. While there is no question that "lap" children continue to be placed in jeopardy when they fly unrestrained, policy makers should be commended for their unwillingness to institute a policy with such serious possible consequences—in an effort to protect some of the most vulnerable members of society, children would inadvertently be put at increased risk. In November 2006, the NTSB removed mandatory child restraint seats from their wish list.

The discussion of women's reproductive rights and access to care has not seen the same considered debate, and the consequences of sterilization policies are overlooked or ignored, often for decades. In the late 1970s, in an effort to protect women's reproductive rights, federal legislation preventing sterilization of women without their consent was passed. One of the most important features of this legislation is that it applies only to women who receive government assistance for their medical care. The history of the Federal Sterilization Policy is one of unintended consequences, best understood in the historical context of the eugenics movement.

The term eugenics derives from the Greek word *eugenes*, which means "well born" and refers to the promotion of breeding among the most fit of citizens in an attempt to produce the most desirable offspring [3]. There are two types of eugenic

programs: positive and negative. Positive eugenics programs are designed to maximize the spread of desirable genetic traits, while negative eugenics programs work to prevent transmission of undesirable traits.

The eugenics movement in the United States gained ground in the late nineteenth and early twentieth centuries as a result of four independent factors: rediscovery of Gregor Mendel's laws of inheritance, increasing crime rates and other social problems, the rise of unemployment, and increased immigration. In 1907, Indiana became the first state to implement a sterilization policy based on eugenic principles, requiring sterilization of inmates at state institutions who were deemed to be "insane, idiots, imbeciles, feeble-minded, convicted rapists, or habitual criminals" [4].

Virginia's law, passed on March 20, 1924, provided for the "sterilization of mental defectives" to promote the "health of the patient and the welfare of society" [5]. The statute applied to both males and females; men were to be sterilized by vasectomy and women by salpingectomy [6]. The rationale for the statute was twofold: (1) that "defective persons" if sterilized prior to discharge "might become self-supporting with benefit to themselves and to society" and (2) that "heredity plays an important part in the transmission of insanity, imbecility, etc." [7]. Provisions were made for the protection of these individuals, including a formal appeals process.

In 1924, 18-year-old Carrie Buck was committed to the Virginia State Colony for Epileptics and Feeble Minded. Due to her status as a "feeble-minded" woman, daughter of a "feeble-minded mother in the same institution, and the mother of an illegitimate feeble-minded child," the superintendent of the State Colony petitioned for her sterilization by salpingectomy [8]. She appealed the decision, and the case reached the United States Supreme Court. In an opinion penned by one of the most learned legal scholars of the twentieth century, Oliver Wendell Holmes Jr., the Court found.

We have seen more than once that the public welfare may call upon the best citizens for their lives. It would be strange if it could not call upon those who already sap the strength of the state for these lesser sacrifices, often not felt to be such by those concerned, in order to prevent our being swamped with incompetence. It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind [9].

In sum, the Court concluded, "three generations of imbeciles are enough" [9]. Carrie Buck was subsequently sterilized on October 19, 1927 [10]. Of course, many interesting facts were omitted from Carrie Buck's appeal. Her foster parents committed Carrie to the Colony after she gave birth to an illegitimate daughter. Furthermore, Carrie's daughter, Vivian, was not the product of her mother's promiscuity nor was she feeble-minded [11]. Rather, Vivian was born following the rape of her mother by the nephew of her foster parents. Unfortunately, Vivian died at a young age, but prior to her death, she was a solid "B" student in the first grade. Even more disturbing is the fact that the Supreme Court's decision in *Buck v. Bell* is still on the books; the decision has never been challenged or overturned.

Once the Virginia law was upheld by the Supreme Court, involuntary sterilization movements in the United States continued to grow. By 1931, 30 states had eugenic laws, laws that would target and systematically discriminate against some of the most vulnerable members of society. It was not until the 1940s that eugenics came under close scrutiny for its lack of scientific basis and its disproportionate effects on the poorest and most disenfranchised citizens. By the 1950s, most states had abandoned involuntary sterilization programs. Despite this, it would be another 2 decades before the federal government issued its own protections in an attempt to prevent sterilization of incompetent persons.

Regulations governing sterilization under federally funded programs went into effect on March 8, 1979, eliciting a great deal of controversy; proponents favored protection of vulnerable persons otherwise destined to undergo involuntary sterilization, while detractors believed that the policy interfered with use of sterilization for population control. Sterilization was a popular method of birth control in the United States in the 1970s, second only to oral contraceptive pills [12]. By 1976, 30 percent of all women in the United States between the ages of 15 and 44 were surgically sterilized [13]; estimates by the Association for Voluntary Sterilization state that approximately 10 million men and women had undergone sterilization procedures in the United States by 1977 [13].

The 1979 federal sterilization regulations provide a number of protections for individuals covered by federally funded programs who desire sterilization, including a standardized consent form with an attestation that the individual appeared mentally competent and knowingly and voluntarily consented to the procedure [14]. Furthermore, official documentation must be signed at least 30 days but not more than 180 days before the procedure [15]. If an individual who desires sterilization undergoes premature delivery or an emergency abdominal surgery within 30 days, at least 72 hours must have elapsed between the time the consent was signed and the time the procedure is performed [15]. In addition, an emergency abdominal surgery must be described or, in the case of a premature delivery, the expected estimated date of delivery must be noted.

The desired result of the federal sterilization policy was to prevent sterilization of mentally incompetent individuals or of women who do not voluntarily consent to sterilization; the policy would protect an individual's autonomy by ensuring (1) that the individual was competent and (2) that informed consent for the procedure was obtained. However, there have been other consequences of that policy for women who receive federal financial assistance for their health care. For example, such a woman cannot have a tubal sterilization performed if she fails to sign the consent form at least 30 days prior to her procedure or if she inadvertently leaves her papers at home.

A woman covered by private insurance or one who pays out of pocket can present to the hospital, deliver her child, and have a sterilization procedure performed without any prior preparation or any negative financial repercussions to the physician or hospital. Whether the delivering physician would choose to perform a sterilization procedure for a woman without previous discussion is a separate question, particularly considering the risk of regret among those undergoing permanent sterilization.

Conversely, if a woman of limited resources, whose care is supported in whole or part by federal financial assistance, presents to labor and delivery and requests a sterilization procedure, she will be, in effect, denied access to that procedure if she has not signed federal sterilization papers at least 30 days prior to delivery. In fact, even women who have had consistent prenatal care and discussed the desire for sterilization with their clinicians will be unable to undergo a sterilization procedure without the appropriate documentation, even if the clinician failed to alert them to the regulations. While not physically prevented from performing the procedure for the woman, physicians face a significant financial disincentive—lack of reimbursement—for performing the sterilization without proper documentation.

A 2008 study published in *Contraception* reported that 4 of the 34 women who did not receive desired postpartum sterilization were denied the procedure because they lacked a valid Medicaid consent form [16]. The study was performed on the west side of Chicago in a university-based hospital serving a low-income population. In one case, a woman left her signed Medicaid papers at home because she mistakenly believed they would be on file at the hospital. Another woman, who attempted use of a reversible contraceptive after she was unable to have her tubal ligation due to lack of a valid standardized consent form, became pregnant and summed up her experience with the following statement: "Actually, I think I should have had it done because um it just that since then I have gotten pregnant again and I think that if I had had the tubal ligation done, I would never have gotten pregnant again...I had an abortion" [17]. In fact, all four women who were unable to have their sterilization procedure due to lack of signed Medicaid papers expressed anxiety regarding prevention of future pregnancy.

Thus, the unintended consequence of the federal sterilization policy is to treat women who are the most financially vulnerable quite differently from women of means. The irony here is that the women who may most need a sterilization procedure, due to the financial inability to provide for more children and the lack of access to routine medical care, are the least able to obtain it. As a result, rather than protecting women's autonomy, the federal sterilization policy may in fact prevent a physician from carrying out a woman's value-based decision to undergo permanent sterilization. Not only is a woman's autonomy not respected in this scenario, but if she goes on to have an unintended pregnancy, there is an additional violation of the principle of nonmaleficence insofar as the physician could have prevented harm to the patient. Unquestionably, the federal policy was intended to protect women from

the abuses of the past. Regrettably, the very attempt to protect this vulnerable group has resulted in a frequently insurmountable obstacle and a reduction in reproductive freedom for these women. An unfortunate consequence, indeed.

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Susan P. Raine, JD, MD, LLM, is an associate professor in the Department of Obstetrics and Gynecology and the Center for Medical Ethics and Health Policy, residency program director, and vice chairman for education at Baylor College of Medicine in Houston, Texas. Dr. Raine's clinical practice focuses on obstetrics and gynecology. Her research interests include family planning, simulation, and medical education.

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OP-ED

Selecting the Traits of Children Prior to Birth

Timothy F. Murphy, PhD

Early in 2011, the Food and Drug Administration (FDA) directed a Virginia fertility clinic to stop offering MicroSort to people wanting to use it to select boys or girls in order to balance the children in their families. MicroSort is a sperm-sorting technology that stratifies X-bearing and Y-bearing gametes, allowing clinicians to offer a degree of control over the sex of a child. The FDA licenses this technology for use by parents who wish to avoid sex-linked genetic disorders in their children, so it is safe and effective. However, the FDA said that the fertility clinic could not offer it to parents who want to blend their families in a particular way because that would serve "no public health benefit" [1].

The law in the United States does not require practitioners to provide preconception methods of sex selection for reasons unrelated to the medical welfare of the child, which throws up another obstacle for parents wanting to select boys or girls. Professional organizations and public opinion are, however, making inroads in favor of the right to select the sex of children under some circumstances. In 2001, the Ethics Committee of the American Society of Reproductive Medicine advised that if sperm-sorting technologies could be demonstrated as safe and effective, clinicians should be able to offer them for parents wishing to blend their families by sex [2]. Not only that, but that same ethics committee held the door open to sex selection for other reasons, saying that if the social, psychological, and demographic effects of sex selection fall within an acceptable range, "then other nonmedical uses of gender selection might be considered." On this interpretation, parents might choose, for example, to have only boys or only girls, or boys and girls in a particular order.

By contrast, some commentators object to sex selection for any reason. In the early 1980s, philosopher Michael Bayles argued that "a preference for one sex over the other, for its own sake, is simply sexism: It implies that one sex is intrinsically more valuable than another" and this preference is "irrational" [3]. This preference is sexist, Bayles believed, because parents' expectations for their children can be met no matter their sex; both boys and girls can find their way to meaningful relationships and lives. This preference is irrational, Bayles believed, it is based on an unfounded belief, and he thinks that most preferences regarding the sex of children are just that. Suppose parents had two boys and wanted to have a girl. Bayles sees no rational basis for that preference, since he sees nothing inherently valuable in having two boys and one girl rather than any other combination. By his interpretation, trying to have children of a particular sex necessarily involves

unfounded beliefs about the comparative value of boys and girls, birth order, and the overall number of boys and girls in a family.

Bayles doesn't think any important good is achieved for parents or families by letting parents choose the sex of their children. On his account, children of any sex and in any birth order are good enough for what people need in families and relationships. Yet this come-what-may approach is too restrictive as a matter of moral argument. Some parents may have no sexist motives in wanting both boys and girls in a family, and there may be no sexist effects from blending families in a particular way. It is perhaps for these reasons that not even Bayles argues for the legal prohibition of sex selection. He says the harms involved don't rise to a level that justifies state remedy.

Against this background, we can also ask whether arguments about sex selection stand in for selecting other traits in children through prenatal interventions. Some commentators have argued that not only is the selection of certain traits in children morally permissible, it is morally obligatory if the choice is within the parents' power and the traits in question will confer advantages on the children [4]. Taking this position to a logical extreme, one commentator has argued that parents are morally required to choose girls over the boys, always, if they have the power to make that choice. This position is based on the theory that women have better lives than men because they live longer generally and can have experiences men cannot, such as childbearing [5].

We don't have to actually make that choice, however, because all arguments about choosing the traits that will give children the best possible lives run into the trouble of establishing which possible life is better than the others. Even faced with that problem, it remains hard to argue that parents should not be entitled to confer benefits on their children through prenatal interventions, in much the same way they will do so after their birth.

In general, most discussion about using prenatal interventions to choose traits of children involves selecting traits that will contribute to intelligence, athleticism or strength, resistance to disease, and longevity. If the choice were available to us here and now, I think most people would be hard pressed to say that they would not want a bit more intelligence for themselves, longer endurance in exercise and sports, genetic immunity to certain viral infections, and the prospect of a longer life. If those outcomes are desirable for us here and now, how would those be any less desirable for children? How would it be immoral to work toward those outcomes for children just because the interventions took place before birth?

Some commentators worry that selecting the traits of children 'commodifies' them and turns them into commercial products. On this view, children are desired and loved only so far as they conform to their parents' expectations. It is hard, however, to give this argument much credence since—after birth—parents go to extraordinary lengths to shape children in terms of their language, social skills, the relationships they have, as well as their political and religious views. How is it possible to accept

that degree of influence over a child but reject the use of prenatal interventions that could confer benefits similar in kind and equal in importance?

As things stand, it is mostly genetic natural lottery that gives children the traits they have, but we have to ask why that status quo should prevail as the standard by which parents must abide as safe and effective interventions come along capable of conferring benefits on children. In other words, why are parents obliged to have children *only* as chance dictates? Some commentators have argued that intervening against chance usurps the choices ahead for children, by entraining them into futures of their parents' design [6]. This argument is not persuasive either: a human being has enough choices ahead of him or her to render that worry irrelevant. All human beings face enough choices and circumstances to be able to author a meaningful life, regardless of what their parents originally intended, and that outcome would persist even if parents selected some traits prior to birth.

In 2010, Dutch researchers reported that women who rely on low-sodium, high-calcium diets and who have intercourse in a particular window of time following ovulation can increase their odds of having a girl [7]. The method is not foolproof, but what if it worked routinely? What if a comparable diet to increase the odds of having a boy were found? It would be hard to make the case that the method involved here, eating particular kinds of food, was objectionable in itself. It would be hard to make the case either that the motives of parents for wanting boys or girls are always objectionable. Unless there were some wild swing in the sex ratio caused by eating one's way to children of the preferred sex, it would also be hard to make the case that this option would be objectionable in its effects either.

Human beings take steps all the time to order events in nature in ways that protect and enrich their lives. If the motives for selecting traits in children through prenatal interventions are not objectionable in themselves, if the interventions are safe and effective, and if no social harm comes from their use, it is possible to defend the selection of traits in children and maybe even, sometimes, call it an obligation.

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Timothy F. Murphy, PhD, is a professor of philosophy in the biomedical sciences at the University of Illinois College of Medicine at Chicago.

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American Medical Association Journal of Ethics February 2012, Volume 14, Number 2: 162-177.

Suggested Readings and Resources

A statement by U.S. Department of Health and Human Services Secretary Kathleen Sebelius [news release]. Washington, DC: Department of Health and Human Services; January 20, 2012.

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About the Contributors

Theme Issue Editor

Jennifer Braverman is a fourth-year medical student at Baylor College of Medicine in Houston, Texas. She obtained a bachelor's degree cum laude in sociology from Rice University, where she conducted research on children's access to preventive health care. While in medical school, Jennifer conducted research on cognitive biases in medical decision making. She plans to pursue a career in obstetrics and gynecology.

Contributors

Lusine Aghajanova, MD, PhD, is a resident in obstetrics and gynecology at Baylor College of Medicine in Houston, Texas. She obtained her doctoral degree from the Department of Obstetrics and Gynecology at the Karolinska Institute in Stockholm and completed her postdoctoral fellowship in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco. Because her particular interests are human reproduction and infertility, she has focused her research on human implantation and biomarkers of uterine receptivity, as well as on endometrial dysfunction in women with unexplained infertility and endometriosis.

Lisa Campo-Engelstein, PhD, is a bioethicist with a special interest in reproductive ethics. She is an assistant professor at the Alden March Bioethics Institute of Albany Medical College in New York and the co-editor of a book on the emerging field of oncofertility. She has been published in several medicine, science, and bioethics journals, including the *Journal of Clinical Oncology, Science, The Hastings Center Report*, and *The American Journal of Bioethics*. She earned her PhD in philosophy from Michigan State University and completed a postdoc with the Oncofertility Consortium at Northwestern University.

Frank A. Chervenak, MD, is the Given Foundation Professor of Obstetrics and Gynecology and chairman of the Department of Obstetrics and Gynecology at Weill Medical College of Cornell University in New York. He is also a member of the Institute of Medicine of the National Academies of Science. He has collaborated with Laurence B. McCullough on scholarly work and teaching ethics in obstetrics and gynecology since 1983. They have more than 160 publications in the peer-reviewed literature, and they co-authored *Ethics in Obstetrics and Gynecology* (Oxford University Press, 1994).

B. Jessie Hill, JD, is a professor of law at Case Western Reserve University in Cleveland. She received her law degree from Harvard Law School. Her research

focuses on constitutional law, with a particular emphasis on reproductive and religious rights. Previously, Ms. Hill worked for the Reproductive Freedom Project of the American Civil Liberties Union (ACLU).

Laurence B. McCullough, PhD, holds the Dalton Tomlin Chair in Medical Ethics and Health Policy in the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston, Texas. He has collaborated with Frank A. Chervenak on scholarly work and teaching ethics in obstetrics and gynecology since 1983. They have more than 160 publications in the peer-reviewed literature, and they co-authored Ethics in Obstetrics and Gynecology (Oxford University Press, 1994).

Timothy F. Murphy, PhD, is a professor of philosophy in the biomedical sciences at the University of Illinois College of Medicine at Chicago.

Susan P. Raine, JD, MD, LLM, is an associate professor in the Department of Obstetrics and Gynecology and the Center for Medical Ethics and Health Policy, residency program director, and vice chairman for education at Baylor College of Medicine in Houston, Texas. Dr. Raine's clinical practice focuses on obstetrics and gynecology. Her research interests include family planning, simulation, and medical education.

Mara Y. Roth, MD, is an assistant professor in the Department of Medicine, Division of Endocrinology, at the University of Washington in Seattle. Dr. Roth's research focuses on the development of a male hormonal contraceptive, looking specifically at intratesticular hormone requirements necessary for spermatogenesis as a means of identifying nonresponders to contraceptive regimens.

Xiomara M. Santos, MD, is an assistant professor in the Department of Obstetrics and Gynecology at Baylor College of Medicine in Houston, Texas. She is board certified in obstetrics and gynecology and fellowship trained in pediatric and adolescent gynecology. Her research interests include adnexal masses in children and adolescents, pelvic inflammatory disease, menstrual disorders in adolescents, and congenital anomalies.

Britt Severson, MPH, is a fourth-year medical student at Oregon Health and Sciences University in Portland. She received her MPH from Johns Hopkins Bloomberg School of Public Health. Her research interests include contraceptive counseling, tobacco cessation in pregnancy, and abortion training in medical school.

Adam Sonfield, MPP, is a senior public policy associate at the Guttmacher Institute and a managing editor and regular contributor to its journal, the Guttmacher Policy Review. He also writes a quarterly Washington Watch column for Contraceptive Technology Update. His portfolio includes research and policy analysis on public and private financing of reproductive health care in the United States, the rights and responsibilities of health care providers and patients, and men's sexual and reproductive health.

Rebecca C. Thilo is a fourth-year medical student in the Medical Ethics Track at Baylor College of Medicine in Houston, Texas. She is pursuing a residency in emergency medicine and is interested in medical humanities, women's health, and spirituality and healing.

Kristina Tocce, MD, MPH, is an assistant professor in the Department of Obstetrics and Gynecology at the University of Colorado Anschutz Medical Center in Aurora. She is the student program director and the assistant family planning fellowship director. Her research interests include adolescent contraception, abortion techniques, and medical student family planning curricula.

Cecilia T. Valdes, MD, is an associate clinical professor with an appointment in the Department of Obstetrics and Gynecology and associate director of the Reproductive Endocrinology and Infertility (REI) Fellowship at Baylor College of Medicine in Houston, Texas. Dr. Valdes is certified in REI, and her clinical and research interests include assisted reproduction, polycystic ovarian syndrome, insulin resistance, and metabolism.

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