GYNECOLOGY

Health care justice and its implications for current policy of a mandatory waiting period for elective tubal sterilization

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Tubal sterilization during the immediate postpartum period is 1 of the most common forms of contraception in the United States. This time of the procedure has the advantage of 1-time hospitalization, which results in ease and convenience for the woman. The US Collaborative Review of Sterilization Study indicates the high efficacy and effectiveness of postpartum tubal sterilization. Oral and written informed consent is the ethical and legal standard for the performance of elective tubal sterilization for permanent contraception for all patients, regardless of source of payment. Current health care policy and practice regarding elective tubal sterilization for Medicaid beneficiaries places a unique requirement on these patients and their obstetricians: a mandatory waiting period. This requirement originates in decades-old legislation, which we briefly describe. We then introduce the concept of health care justice in professional obstetric ethics and explain how it originates in the ethical concepts of medicine as a profession and of being a patient and its deontologic and consequentialist dimensions. We next identify the implications of health care justice for the current policy of a mandatory 30-day waiting period. We conclude that Medicaid policy allocates access to elective tubal sterilization differently, based on source of payment and gender, which violates health care justice in both its deontologic and consequentialist dimensions. Obstetricians should invoke health care justice in women's health care as the basis for advocacy for needed change in law and health policy, to eliminate health care injustice in women's access to elective tubal sterilization.

Key words: ethics, health policy, health care justice, medicine as a profession, tubal sterilization

Elective tubal sterilization during the immediate postpartum period is one of the most common forms of contraception in the United States. This timing of the procedure has the advantage of 1-time hospitalization, which

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results in ease and convenience for the woman. The US Collaborative Review of Sterilization Study indicates the high efficacy and effectiveness of postpartum tubal sterilization.[1] Besides providing the desired contraception, tubal sterilization reduces the risk of ovarian cancer and pelvic inflammatory disease.[2]

Both oral and written informed consent is the ethical and legal standard for the performance of tubal sterilization for elective tubal sterilization for all patients, regardless of source of payment. However, current health care policy and practice regarding elective tubal sterilization for Medicaid beneficiaries place an additional requirement on these patients and their obstetricians: a mandatory waiting 30-day period. This requirement is especially problematic during pregnancy when the woman is a late registrant, when there is a complication of pregnancy that necessitates early delivery, when the woman requests permanent sterilization late in pregnancy, or when the consent form that the woman had signed previously is misplaced.

The mandatory waiting period originates in decades-old legislation. Although well intentioned, this policy has now come to have the effect of restricting women's access to elective tubal sterilization. In the contexts of the long history of efforts to enable female reproductive choice and access to care and of the changing role of women in society, this restricted access is at least ironic, given the intention of the legislation. The purpose of this article is to go further and show that current restrictions are ethically impermissible because they are incompatible with the concept of health care justice in professional obstetric ethics. Obstetricians therefore should advocate for policy change.

We begin with a brief account of the origins of current health policy. We

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then present an ethical framework that is based on a concept in professional obstetric ethics that heretofore has not been elucidated in the literature of obstetric ethics: health care justice. We close by identifying the implications of health care justice for the current requirement of a waiting period only for Medicaid beneficiaries and how obstetricians should respond to it.

Brief history of federal legislation

Up until the middle decades of the 20th century, compulsory sterilization programs existed in the United States.[3] Initially, these programs targeted intellectually disabled and mentally ill patients; however, many African American women and deaf, blind, epileptic, physically deformed, and low-income women were sterilized against their will.[4] One legacy of this history is persistent racial disparities in access to and use of contraception.[5] In 1979, US federal legislation was enacted that aimed to enhance women's health rights by regulating the process of consent and documentation before receiving surgical sterilization (both tubal sterilization and hysterectomy) that is publicly funded. The intent was good: to protect the autonomy of women and men by requiring that consent be obtained and documented. One justification for this change in health policy was that women were undergoing nonelective, possibly eugenic, sterilizations that were inherently nonconsensual in nature.[6] Such forced treatment under the sanction of state power is a form of coercion.

To this day, federal law mandates that appropriate Medicaid consent forms must be signed at least 30 days before the service date and must be completed in their entirety, inclusive of both the woman and her health care provider's signature after disclosure of the risks, benefits, alternatives, and limitations to elective tubal sterilization. The consent form is valid for 180 days (human pregnancy being approximately 280 days). Signed consent therefore is obtained after the mid gestation. An exception can be made to the 30-day preprocedural interval if the consent form has been signed and at least 72 hours have elapsed and if the recipient requires emergency abdominal surgery or if the recipient has a premature delivery. In this case, informed consent must have been obtained at least 30 days before the documented "due date" or expected date of delivery. The expected date of delivery must be stated on the claim, and the consent must be signed and dated in the presence of the woman and her provider.[7] Risk of maternal morbidity in a future pregnancy is not considered in the federal form.

Understanding the legal and legislative context and history of elective tubal sterilization is necessary for a critical ethical appraisal of whether the justification for current law and regulations continue to apply in current clinical practice. The reality of clinical practice is that nearly 50% of annual deliveries are paid for by Medicaid and therefore necessitate the signed federal consent form and waiting period.[8] Although the initial intent was to protect patient autonomy by preventing forced sterilization, the unintended consequence 4 decades later is restricted access based on source of payment; elective tubal sterilization is readily available to women with a private source of payment but not readily available to Medicaid beneficiaries. Previous studies showed that insurance coverage exceptions, immigration status, and Medicaid sterilization-consent paperwork present potential barriers to obtaining postpartum tubal sterilization, which is one of the safest and most effective methods of contraception.[8-12] Moreover, a new study showed that the Medicaid policy has resulted in obstacles that are clinically significant: up to 62,000 unfulfilled requests for postpartum sterilization, 10,000 abortions, 19,000 unintended births in the subsequent year, and an economically significant public cost of $215 million.[13]

Ethical framework

Health care justice

Brown and Chor[14] recently have argued against the mandatory 30-day waiting period on the basis of the ethical principles of beneficence, nonmaleficence, and justice. We propose a complementary approach, based on the concept of health care justice, that has not been elucidated previously. The concept of health care justice is based on the ethical concepts of medicine as a profession and of being a patient[15-17] and has both deontologic and consequentialist dimensions, the implications of which for the mandatory waiting period we will explain.

The ethical concept of medicine as a profession was introduced into the history of medical ethics at the end of the 18th century by 2 British physician-ethicists, the Scotsman John Gregory (1724-1773) and the Englishman Thomas Percival (1740-1804). For Gregory and Percival the physician-patient relationship is created when physicians make 2 commitments: to the scientifically and clinically competent practice of medicine and to the primacy of professional responsibility over self-interest. These twin commitments make the physician a professional, rather than a self-interested practitioner, which was the model that had come to dominate British medicine at that time. Making these 2 commitments makes it possible for an individual human being to become a patient. When an individual human being is presented to a physician and there exist clinical interventions that in deliberative (evidence-based, rigorous, transparent, and accountable) clinical judgment are expected to benefit that individual clinically, that individual becomes a patient under the care of a professional physician.[14]

This concept is both elegant and simple. Its simplicity excludes such criteria as ability to pay, more precisely the source of payment for a patient's clinical care. It also excludes gender as a criterion.

The ethical concepts of medicine as a profession and of being a patient have important implications for the meaning of the ethical principle of justice in health care. In its most general formulation, the principle of justice requires that like cases be treated alike. The key to the application of justice in clinical practice is specifying the meaning of "like" and "alike." Without such specification, justice remains an abstract concept without clinical application.[18,19] In health care, the concepts of medicine

as a profession and being a patient supply the basis for the specification. Justice in health care, the concept of health care justice, requires that all patients receive clinical management based on their clinical needs, which are defined by deliberative (evidence-based, rigorous, transparent, and accountable) clinical judgment.

Health care justice also protects the informed consent process, which is intended to empower the exercise of patient autonomy in the decision-making process about patient care. In the context of health care justice, the informed consent process should not be influenced by ethically irrelevant factors.

Implications of health care justice

The concept of health care justice has both deontologic and consequentialist dimensions. The deontologic dimension of health care justice appeals to reasons for the rightness or wrongness of actions based on the ethical concept of being a patient and professional responsibility to the patient that is independent of consequences. The consequentialist dimension of health care justice appeals to reasons for the rightness or wrongness of actions based on their clinical consequences and the professional responsibility to produce net clinical benefit and therefore to prevent clinically unnecessary harms. We turn now to the task of identifying the clinical ethical implications of health care justice in its 2 dimensions.

Deontologic implications regarding source of payment

Current requirements for advance consent for elective tubal sterilization allocate access to this procedure on the basis of the ability to pay, which is ethically irrelevant to being a patient. This is incompatible with deontologic professional responsibility to and for patients. There is no other example that we are aware of whereby consent differs by source of payment.[20] This feature of the current policy violates health care justice.

Deontologic implications regarding gender

Both men and women can choose to undergo elective tubal sterilization. Vasectomy (male elective sterilization) is permanent (though potentially reversible), and consent for it is potentially at risk for being forced rather than voluntary (ie, free of internal and external controlling constraints). The mandated interval after consent for eligible men who are enrolled in Medicaid program is the same as for tubal sterilization for female patients. It should be noted that women take most of the financial and health-related burdens of contraception.[21] According to the National Survey of Family Growth data 175,000-354,000 vasectomies were done yearly; in the same period, 546,000-789,000 tubal sterilizations were done annually in the United States. One-half of the annual bilateral tubal sterilizations are performed postpartum.[22,23] Vasectomy also has fewer health risks than tubal sterilization, and almost always vasectomy is performed as an ambulatory procedure,[18] because it is comparatively less invasive. The result is different clinical practices based on gender, which, in this clinical context, is ethically irrelevant to being a patient. This violates health care justice in its deontologic dimension.

Consequentialist implications of increased clinical risk based on source of payment

In a longitudinal study, it was found that women who did not receive a desired postpartum tubal sterilization were more likely than were those who did not request permanent sterilization (control group) to be discharged from the obstetric service without contraception, and 18% of these women became pregnant within 1 year after delivery.[8,9] The American College of Obstetricians and Gynecologists committee opinion declares that approximately 50% of women with an unmet need of postpartum sterilization have had a repeat pregnancy.[2]

The effect of current health policy is to increase unnecessarily the clinical risks of an unwanted pregnancy for female patients with public funding compared with patients with other sources of payment. These risks may be compounded for women who are at risk for partner violence[24] and for adolescents with mental disorders.[25] This clinically unnecessary increased risk is incompatible with health care justice in its consequentialist dimension. This same conclusion can be applied to policies that prohibit tubal sterilization at the time of abortion.[26,27]

A theoretic but impractical alternative

A mandatory 30-day waiting period for all men and women who elect elective tubal sterilization, regardless of source of payment, would address the deontologic implications of health care justice identified earlier, but not the consequentialist implications of unwanted pregnancy. This alternative is impractical, because no local, state, or federal government has the authority to create such a national policy that affects all patients who are considering elective tubal sterilization. In addition, such a policy would need, as a matter of treating like cases alike, to be extended to all nonemergent surgical procedures.

Conclusion

From the perspective of health care justice in professional obstetric ethics in both its deontologic and consequentialist dimensions, the law of unintended consequences clearly applies to the well-intended legislation of the 1970s. Legislation that was designed to promote health care justice has resulted in policies and practices that, 4 decades later, violate health care justice. Access by many women to elective tubal sterilization is based on source of payment, differs from that of men, and entails increased clinical risks of unwanted pregnancy based on source of payment. From the perspective of health care justice, current policy has resulted in disparities that are unacceptable because they are based on ethically irrelevant differences in sources of payment. Obstetricians should therefore invoke health care justice in women's health care as the basis for advocacy for needed change in law and health policy, to eliminate health care injustice in women's access to elective tubal sterilization. ■

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