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Committee on Ethics

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Informed Consent and Shared Decision Making in Obstetrics and Gynecology

ABSTRACT: Meeting the ethical obligations of informed consent requires that an obstetrician–gynecologist gives the patient adequate, accurate, and understandable information and requires that the patient has the ability to understand and reason through this information and is free to ask questions and to make an intentional and voluntary choice, which may include refusal of care or treatment. Shared decision making is a patient-centered, individualized approach to the informed consent process that involves discussion of the benefits and risks of available treatment options in the context of a patient's values and priorities. Some informed consent challenges are universal to medicine, whereas other challenges arise more commonly in the practice of obstetrics and gynecology than in other specialty areas. This Committee Opinion focuses on informed consent for adult patients in clinical practice and provides new guidance on the practical application of informed consent through shared decision making. The principles outlined in this Committee Opinion will help support the obstetrician–gynecologist in the patient-centered informed consent process.

Recommendations and Conclusions

On the basis of the principles outlined in this Committee Opinion, the American College of Obstetricians and Gynecologists offers the following recommendations and conclusions:

- The goal of the informed consent process is to provide patients with information that is necessary and relevant to their decision making (including the risks and benefits of accepting or declining recommended treatment) and to assist patients in identifying the best course of action for their medical care.
- Shared decision making is a patient-centered, individualized approach to the informed consent process that involves discussion of the benefits and risks of available treatment options in the context of a patient's values and priorities.
- The informed consent conversation, including the required elements of consent and any challenges to the requirements, should be documented in the medical record.
- A signed consent document, however, does not guarantee that the patient's values and priorities have been taken into consideration in a meaningful way and that the ethical requirements of informed consent have been met.
- Meeting the ethical obligations of informed consent requires that an obstetrician–gynecologist gives the patient adequate, accurate, and understandable information and requires that the patient has the ability to understand and reason through this information and is free to ask questions and to make an intentional and voluntary choice, which may include refusal of care or treatment.
- Adult patients are presumed to have decision-making capacity unless formally determined otherwise, and physicians generally can determine a patient's capacity to make informed decisions through typical patient–physician interactions. An adult patient with decision-making capacity has the right to refuse treatment, including during pregnancy, labor, and delivery and when treatment is necessary for the patient's health or survival, that of the patient's fetus, or both.

- The highest ethical standard for adequacy of clinical information requires that the amount and complexity of information be tailored to the desires of the individual patient and to the patient's ability to understand this information. The legal standard for adequacy of the amount of clinical information or content given to the patient during an informed consent process may vary from state to state; obstetrician–gynecologists should be familiar with their state and institutional requirements for informed consent.
- Using decision aids may increase patient knowledge and understanding of risk, reduce decisional uncertainty, and lead to care that more closely represents patient values. However, decision aids are intended to complement the discussion and do not replace the deliberative and supportive responsibilities of the obstetrician–gynecologist throughout the process.

Introduction

This Committee Opinion focuses on informed consent for adult patients in clinical practice and provides new guidance on the practical application of informed consent through shared decision making. Ethical issues related to informed consent for research, clinical situations that involve adolescent and pediatric patients, medical treatment during pregnancy, and pelvic examinations under anesthesia in medical education are addressed elsewhere (1–5).

Background

Informed Consent

Informed consent is a practical application of the bioethics principle of respect for patient autonomy and self-determination as well as the legal right of a patient to bodily integrity. Although informed consent has legal implications, this Committee Opinion focuses on obstetrician–gynecologists' ethical obligations surrounding informed consent. Respect for patient autonomy is one of the four pillars of principle-based medical ethics (autonomy, beneficence, nonmaleficence, and justice) and is considered by some to be the "first among equals" of these four principles because of the value placed in modern Western society on individualism and liberty (6). The essential components of the informed consent process are listed in Box 1 (7). The goal of the informed consent process is to provide patients with information that is necessary and relevant to their decision making (including the risks and benefits of accepting or declining recommended treatment) and to assist patients in identifying the best course of action for their medical care.

Meeting the ethical obligations of informed consent requires that an obstetrician–gynecologist gives the patient adequate, accurate, and understandable information and requires that the patient has the ability to understand and reason through this information and is free to ask questions and to make an intentional and voluntary choice, which may include refusal of care or treatment. The information provided to the patient does not need to include an exhaustive list of all possible courses of action and outcomes but rather those that are relevant to the patient's situation. The highest ethical standard for adequacy of clinical information requires that the amount and complexity of information be tailored to the desires of the individual patient and to the patient's ability to understand this information (8). The legal standard for adequacy of the amount of clinical information or content given to the patient during an informed consent process may vary from state to state; obstetrician–gynecologists should be familiar with their state and institutional requirements for informed consent.

To meet the requirement of disclosure of accurate and comprehensible information, the counseling obstetrician–gynecologist should engage in effective patient-centered and culturally responsive communication (9), and patients should have adequate understanding of the language used by their obstetrician–gynecologist during this informed consent process.

Box 1. Essential Elements of the Informed Consent Process

In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision making capacity or declines to participate in making decisions), physicians should do the following:

- Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.
- Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about the following:
  - The diagnosis (when known)
  - The nature and purpose of recommended interventions
  - Treatment alternatives, including options for nonoperative care in the setting of a consent process for surgery
  - The burdens, risks, and expected benefits of all options, including forgoing treatment
- Document the informed consent conversation and the patient's (or surrogate's) decision in the medical record in some manner. When the patient/surrogate has provided specific written consent, the consent form should be included in the medical record.

Adapted from Opinion 2.1.1, Informed Consent of the American Medical Association Code of Medical Ethics. Full original text is available at https://www.ama-assn.org/delivering-care/ethics/informed-consent. Retrieved July 27, 2020.

Ambiguities in communication of medical information because of cultural or language differences between physicians and patients present a challenge to the informed consent process that disproportionately affects people of color, immigrants, and other marginalized groups, adding to health disparities (10). To help avoid miscommunication related to language differences, a professional medical interpreter should be made available in person, by phone, or through video remote technology to assist with the informed consent process (9, 11). More information on racial and ethnic disparities in obstetrics and gynecology and the importance of social determinants of health and cultural awareness is available in other ACOG documents (10, 11).

The informed consent conversation, including the required elements of consent and any challenges to the requirements, should be documented in the medical record. Any refusal of recommended testing or treatment should be included in this documentation. If written consent has been part of this process, a copy of this document should be included in the records (Box 1) (7). A signed consent document, however, does not guarantee that the patient's values and priorities have been taken into consideration in a meaningful way and that the ethical requirements of informed consent have been met.

A physician's freedom to decline to provide a patient with standard or potentially beneficial care to which the physician ethically objects is sometimes called a right to "conscientious refusal," although this right is limited (12). Even in the context of conscientious refusal, physicians must provide the patient with accurate and unbiased information about the patient's medical options and make appropriate referrals. More information on conscientious refusal in obstetrics and gynecology is available in a separate ACOG publication (12).

Shared Decision Making

It is important for obstetrician–gynecologists to acknowledge that the information and options that a physician shares with patients during the informed consent process are often a reflection of the physician's own values, priorities, and culture, and that these do not always align with the values, priorities, and culture of their patient population. Shared decision making is a patient-centered, individualized approach to the informed consent process that involves discussion of the benefits and risks of available treatment options in the context of a patient's values and priorities. During the shared decision-making process, patients are encouraged to share information, express value-based preferences, and provide input on a treatment plan. A shared decision-making approach facilitates meeting the highest ethical standard for the informed consent process.

A shared decision-making model of informed consent encourages physicians to reframe autonomy as "relational," that is, informed by a patient's interpersonal relationships and broader social environment (13). Thus, shared decision making allows patients to obtain personalized information about their treatment options with the goal of improving their ability to make an autonomous decision. This practice has been shown to improve patient knowledge around their care, allow for better understanding of risk, and improve patient outcomes and satisfaction (14, 15).

From the standpoint of the obstetrician–gynecologist, the process of shared decision making involves a complex interplay of ethical obligations: respect for patient autonomy, beneficence and nonmaleficence, professional responsibility and integrity, stewardship, and the fiduciary responsibility to refer or consult with other physicians when in the best interest of the patient (13). An example of the shared decision-making model, the SHARE approach, is illustrated in Figure 1 (16). The implementation of informed consent through a shared decision-making framework should be taught and modeled early and often for medical trainees.

Decision aids are multimedia tools, such as printed information or educational videos, that may be used to facilitate physician counseling and shared decision making. Using decision aids may increase patient knowledge and understanding of risk, reduce decisional uncertainty, and lead to care that more closely represents patient values (14, 17). However, decision aids are intended to complement the discussion and do not replace the deliberative and supportive responsibilities of the obstetrician–gynecologist throughout the process.

Ethical Issues and Considerations

Decision-Making Capacity

Individuals demonstrate decision-making capacity when they are able to understand their clinical condition as well as the benefits, risks, and alternatives to their treatment options; to appreciate the potential consequences of their decision on their own health and welfare; to reason logically through the options and possible outcomes; and to communicate a choice clearly and consistently (18). Adult patients are presumed to have decision-making capacity unless formally determined otherwise, and physicians generally can determine a patient's capacity to make informed decisions through typical patient–physician interactions. An adult patient with decision-making capacity has the right to refuse treatment, including during pregnancy, labor, and delivery and when treatment is necessary for the patient's health or survival, that of the patient's fetus, or both (4).

If there is doubt about a patient's decision-making capacity, consultation with ethics, legal, and psychiatric experts is recommended. Such efforts should always be made in the interest of respecting patient autonomy and never with the goal of coercing a patient to accept medically recommended treatment that the patient has declined (4).

For patients who have either temporarily or permanently lost the capacity to make an informed decision, respect for autonomy is best demonstrated by adhering

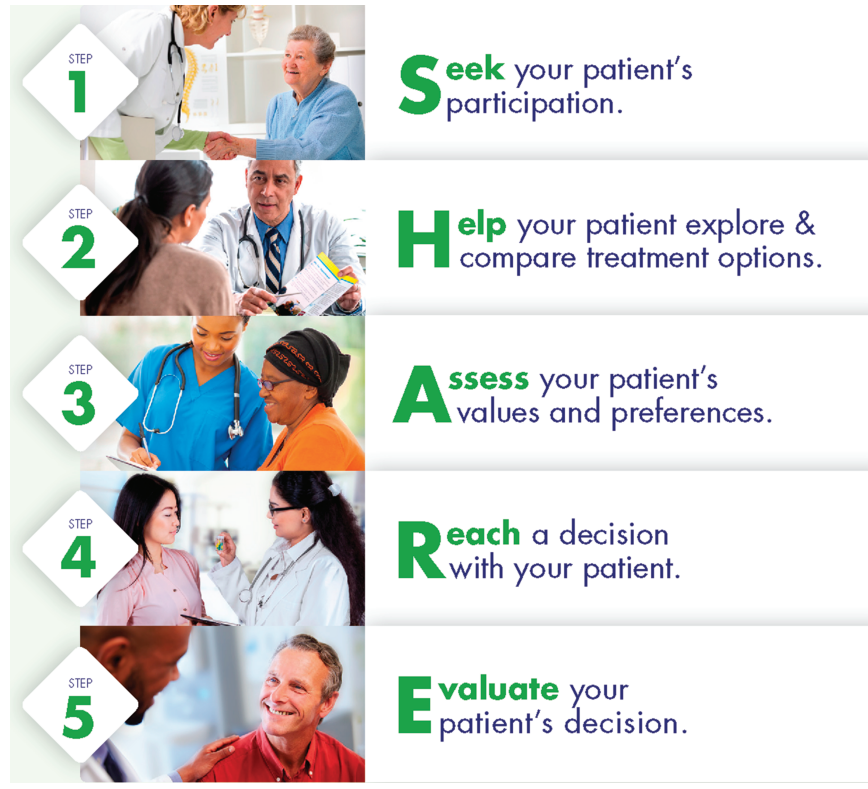

Figure 1. Reprinted with permission from The SHARE Approach: A Model for Shared Decisionmaking - Fact Sheet. Agency for Healthcare Research and Quality, Rockville, MD. Available at: https://www.ahrq.gov/health-literacy/professional-training/shared-decision/tools/factsheet.html

to advance directives, when available. Advance directives are valid regardless of pregnancy status and throughout labor and delivery. State laws that suggest otherwise are problematic because they conflict with obstetrician–gynecologists' ethical obligation to respect patient autonomy. When clinically relevant advance directives do not exist, appropriate surrogate decision makers should take part in the informed consent process and endeavor to make decisions in line with the patient's values and in light of the patient's particular context. In other words, a surrogate decision maker should be identified to provide a "substituted judgment" (a decision based on what the patient would have wanted, assuming some knowledge of what the patient's wishes would be). If the patient's wishes are unknown, the surrogate should make a decision according to the "best interests" of the patient. A surrogate decision maker who is legally designated as such by the patient (eg, an individual with a durable power of attorney for health care) is the first-line surrogate (19). In the absence of such a person, next of kin are often asked to fulfill this duty, and there may be a hierarchy of next-of-kin and nonrelatives (specified in many states' statutes) who have this responsibility (19, 20). If there is any doubt in a particular situation, consultation with local ethics and legal experts is encouraged.

Adult patients who have never had the intellectual capacity to make informed decisions related to their health care should have a legal or court-appointed guardian to represent their best interest when making health care decisions (19–21). It is important to note that a guardian may not have the legal standing to make certain health care decisions for the patient depending on the patient's age and the details of the guardianship agreement; examples include sterilization (permanent contraception) and withdrawal of life-prolonging treatments (22–24). In these cases, an independent guardian ad litem may be assigned by the courts with the goal of providing further unbiased representation of the patient's interests. Obstetrician–gynecologists should be aware of the legal environment that surrounds guardianship and the limits of decision making for dependents in their home state and institution.

The ethical considerations regarding informed consent and confidentiality in the setting of adolescent health care, including counseling regarding contraceptive options, are complex and beyond the scope of this document. For more information, please see ACOG's other publications on these topics (2, 25).

Emergency Situations

In life-threatening emergency situations in which the patient is unable to give consent and an appropriate advance directive or surrogate is not available, it is ethically acceptable for physicians to provide life-saving treatment to the patient using presumed consent (26,

27). Even in these situations, efforts to contact a surrogate should continue, and the treating physician must update the patient (if capacity is restored) or surrogate as soon as possible (26). However, if the patient has an appropriate advance directive that specifically directs against active life-saving efforts in the setting of chronic life-limiting illness, the directive must be respected even in emergency situations.

Therapeutic Privilege

Therapeutic privilege refers to a physician's withholding of medical information from a patient because of concern that it may cause psychological or emotional harm to the patient. The concept of therapeutic privilege has been misinterpreted in the past to be an exception to the ethical requirement of providing adequate, accurate, and comprehensible information to a patient with decision-making capacity. Invoking therapeutic privilege is ethically unacceptable because it suggests that physicians always know what is best for their patients, requires a physician to predict the future, and opens the door for coercive misuse under the guise of the patient's best interest (28). The American College of Obstetricians and Gynecologists and the American Medical Association assert that although it is never ethically acceptable to withhold information without the patient's knowledge and consent, it is acceptable to communicate information over time based on the patient's stated preferences and ability to understand the information (26).

Patient Testing

Just as in the case of medical treatment, informed consent for any patient testing (eg, laboratory testing of serum or salivary samples, imaging, or pathology evaluations) requires explanation of risks and benefits, including those associated with declining the test. Counseling about more complex testing options can be particularly challenging as technology rapidly advances, and in these situations the informed consent process is optimized by using a shared decision-making model. Referral for comprehensive counseling may be needed in complex situations such as those that involve the multigenerational and variable effects of genetic abnormalities. Additional information about patient counseling regarding genetic testing is available in other ACOG publications (29, 30). For more routine testing, such as HIV testing during prenatal care, patient counseling should include the fact that certain tests are standard and that patients may refuse, or "opt out" of, such tests. Additional information on HIV testing is available in other ACOG publications (31, 32).

Physicians must be aware of relevant laws and regulations related to mandatory reporting of test results to local or state agencies, and patients must be informed about this necessity when applicable. Testing at the request of third parties such as family members, social contacts, or health care professionals or institutions that are concerned about exposure to infectious agents, should be done only when the patient understands the risks and benefits and gives consent for such testing.

Innovative Practice

Innovative practice involves providing medicines, procedures, or tests that show therapeutic promise but have not yet become standard practice and have a limited evidence base (33). Although innovative procedures, tests, and treatment strategies may benefit individual patients and lead to advancement in medical care more broadly, obstetrician–gynecologists must consider the unique ethical obligations that arise when they offer clinical techniques that have yet to be adequately tested or validated and are not part of a formal research protocol. In keeping with the obligation to inform patients of all information relevant to their decision about a treatment option, the informed consent process in this scenario must include the innovative nature of the practice, the experience of the individual obstetrician–gynecologist and cumulative experience with this practice, and potential risks yet to be quantified (33). Physicians have a particular obligation to protect the patient from potential harms that are not proportionate to expected benefits, a role that an institutional review board assumes with respect to formal research protocols (33). Obstetrician–gynecologists also must recognize their own motivations for offering this innovation and ensure that the patient's best interest is a priority. If there are any economic motivations or potential conflicts of interest involved, these also must be disclosed to the patient as part of the informed consent process (34).

Legislative Interference

Examples of legislative interference in the informed consent process include state-mandated consent forms; laws that require physicians to give, or withhold, specific information when counseling patients before undergoing an abortion; and laws that prohibit physicians from speaking to their patients about firearms and gun safety (35–38). Laws should not interfere with the ability of physicians to have open, honest, and confidential communications with their patients. Nor should laws interfere with the patient's right to be counseled by a physician according to the best currently available medical evidence and the physician's professional medical judgment (35). Absent a substantial public health justification, government should not interfere with individual patient–physician encounters (35). Despite differing legal requirements, in all cases, physicians continue to have an ethical obligation to provide each patient with information that is evidence-based, tailored to that patient, and comprehensive enough to allow that patient to make an informed decision about care and treatment.

Situations Unique to Obstetrics and Gynecology

The informed consent process may become more complicated during pregnancy because of the presence of the fetus and the obstetrician–gynecologist's dual concern for maternal and fetal well-being. However, the ethical obligation to obtain informed consent using shared decision making does not change based on pregnancy or parenting status (4, 39). A patient who is pregnant is fully capable of making medical care decisions during pregnancy and during labor and delivery, even if those decisions are in disagreement with obstetrician–gynecologists or family members, involve withdrawal of life-sustaining treatment, or may adversely affect the health of the fetus (4). It is commonplace for clinical decisions to be made quickly during labor and delivery, such as when obstetricians must respond to fetal distress with a change in delivery plans, thus challenging an optimal shared decision-making process. Whenever feasible, it is particularly important to initiate anticipatory conversations about delivery possibilities during prenatal care and to continue these conversations early in admission. Regardless of anticipatory conversations, physicians are expected to initiate as full an informed consent process as possible in time-limited scenarios.

The informed consent process for other unique clinical scenarios in obstetrics and gynecology, such as sterilization (permanent contraception) and fertility-restricting treatments, can be negatively influenced by practitioner-level factors, including racism and biases about culture, religion, gender, reproduction, sexuality, family, and parenting (40, 41). A patient-centered, shared decision-making approach that focuses on the reproductive desires of individual patients within the context of their beliefs, values, and culture can help to mitigate some of the potentially negative effects of conscious or unconscious biases and of the larger social climate of race and class inequality in which health care is carried out (40). For more information on the ethical complexities of informed consent for sterilization and fertility-restricting treatments, as well as the importance of cultural and racial awareness in the delivery of reproductive health care, please see separate publications on these topics from ACOG and others (10, 11, 40, 41).

Conclusion

Informed consent is the practical application of the foundational bioethics principle of respect for autonomy. It is not an end in itself, but rather a means to responsible participation by patients in their own medical care and to a stronger therapeutic relationship with their obstetrician–gynecologist. In practice, a shared decision-making framework can operationalize the informed consent process in a way that is relational and patient-centered and does not nullify the contributions of the obstetrician–gynecologist to medical decision making. Some informed consent challenges are universal to medicine, whereas other challenges arise more commonly in the practice of obstetrics and gynecology than in other specialty areas. In each case, the principles outlined in this Committee Opinion will help support the obstetrician–gynecologist in the patient-centered informed consent process.

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