

Informed consent in assisted reproduction: an Ethics Committee opinion

Ethics Committee of the American Society for Reproductive Medicine

American Society for Reproductive Medicine, Washington, DC

Informed consent is a process in which the patient is supported in developing an understanding of medical options (including risks, benefits, and alternatives) and coming to a voluntary and autonomous decision. (Fertil Steril® 2023;119:948-53. ©2023 by American Society for Reproductive Medicine.)

El resumen está disponible en Español al final del artículo.

Key Words: Informed consent, assisted reproduction, ethics, disclosure

KEY POINTS

- Providers should understand the differences between the ethical and legal requirements for informed consent.
- Providers should understand the differences between informed consent for clinical care and informed consent for participation in research.
- American Society for Reproductive Medicine ethics opinions emphasize the value of fully informed consent, including information about facility policies that may be important to patients in making decisions about their care.
- Education is an important prerequisite to informed consent but is not a substitute for it.
- Informed consent for clinical care typically is a process in which the patient is supported in developing an understanding of medical options (including risks, benefits, and alternatives) and coming to a voluntary and autonomous decision.
- Best practices for the process of informed consent include a model of shared decision-making that in-

cludes: ensuring the patient understands the medical condition; presenting accurate and unbiased information about the risks, benefits, expected outcomes, and alternatives of the proposed intervention, including no treatment; eliciting the patient's values; considering how the available options may or may not realize these values; and ensuring the patient is able to make an informed, voluntary decision.

- Additional efforts may be needed to ensure informed consent when patients are in stressful situations, such as: when they may be subject to pressures from partners or family; when they lack experience with what they may undergo (such as pregnancy or childbirth); when the risks, benefits, and processes of care are difficult to explain and understand; and when their first language is not English.

SUMMARY

Informed consent is a complex topic in bioethics and clinical practice. This opinion focuses on the ethical princi-

ples underpinning the provision of informed consent for the clinical care of patients seeking fertility treatment. Although there may be an overlap in the ethical and legal requirements for informed consent, this opinion will focus specifically on the ethical requirements for informed consent. Moreover, unlike legal requirements that may vary by jurisdiction, ethical requirements are universal. Ethical analyses of informed consent also must distinguish whether the consent is for clinical care or for research, because the research goals of obtaining knowledge differ from the goals of treatment. Ethical informed consent for fertility care requires sufficient understanding on the part of the patient to make a well-reasoned decision in furtherance of their values. It is a process in which the patient is supported in developing understanding and coming to an informed, voluntary, and carefully considered decision. Best practices for this process include understanding the patient's condition; discussing without bias the known and potential risks, benefits, and likely outcomes of available alternatives, including no treatment; eliciting the patient's values; and considering how alternatives may or may not realize these values. Special care may need to be taken when patients are in stressful situations, such

Received March 8, 2023; accepted March 9, 2023.

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Fertility and Sterility® Vol. 119, No. 6, June 2023 0015-0282/\$36.00

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<https://doi.org/10.1016/j.fertnstert.2023.03.009>

as when they may be subject to pressure from partners or family; when they lack experience with what they may undergo (such as pregnancy or childbirth); when the risks, benefits, and processes of care are difficult to explain and understand; or when their first language is not English. Ethical informed consent may also require the disclosure of information specific to a particular facility, such as conflicts of interest, prior experience, or policies that may be important to patients in making decisions about their care. Education is an important prerequisite to informed consent but is not a substitute for it.

Informed consent for clinical care is a complex and important topic in bioethics. This is the means through which patient choices are realized. Patient autonomy is at the core of informed consent. Respect for patient autonomy requires that relevant information about a given patient's medical condition and the options to manage it be provided to the patient. In addition, respect for patient autonomy requires allowing patients the opportunity to consider this information within their values and beliefs, as well as to make a decision free of coercion. This opinion deals with the ethical standards for informed consent for clinical care. Legal standards may be different from these ethical standards. In many jurisdictions, patient harm caused by failure to meet the relevant standard for informed consent may serve as the basis for tort liability. Jurisdictions vary on what the relevant standard is, with some pegging the standard to what reasonable providers do and others pegging it to what reasonable patients would want to know (1). Jurisdictions also vary on the significance they attach to a signed consent form. One retrospective review of claims data for a malpractice carrier covering 10 practices and 184,015 in vitro fertilization (IVF) cycles indicated that misdiagnosis and lack of informed consent were the claim categories associated with the highest total award amounts (2). Providers should seek legal advice when they have questions about the law of informed consent in their jurisdiction.

Although this opinion is primarily concerned with the ethical standards for informed consent in clinical care, providers should be aware that approaches for informed consent for participation in research differ from those used in clinical care. The presumption is that research has the goal of obtaining knowledge to inform the development of accepted treatments. In contrast to clinical care, the person participating in research may not directly benefit from their participation in the study. Research centers on the development and assessment of experimental procedures, although they may also include studying an established treatment approach as a comparator or comparing established treatments to determine whether one is superior to the other. The standards for informed consent in research were set out in the Belmont Report (3) and incorporated into the federal regulations governing research with human subjects. Although the federal regulations formally apply only to federally funded research or to research to be submitted for approval of drugs or devices by the Food and Drug Administration, many institutions apply the regulations to all research they conduct. Some states also have laws that implement additional requirements for research. American Society for Reproductive Medicine (ASRM) Ethics Committee opinions discuss several aspects

of informed consent in research, including the donation of embryos for human embryonic stem cell research (4); the use of gametes or embryos for research (5, 6); and the move from innovation to practice (7). To the extent that they are involved in research, providers should be careful to follow any applicable requirements of their institution, the laws of their state, and federal laws.

ETHICAL INFORMED CONSENT

Ethically, informed consent for clinical care is a process in which patients are supported in developing the understanding necessary to make a well-informed, voluntary, and autonomous decision in furtherance of their goals and values. Shared decision-making is a highly regarded approach to achieving informed consent. This process typically requires that the patient be aware of available alternatives, including no treatment. These alternatives must be presented and discussed without bias. Implicit bias, in particular, is important to recognize because it can negatively affect patient outcomes (8, 9). Although implicit bias is a critical issue in healthcare in general, there may be nuanced considerations for achieving informed consent for the provision of assisted reproductive care. As in other specialties, disparities in access to healthcare exist in the field of reproductive medicine, affecting patients of different races, ethnicities, sexes and gender self-identification, and family structures who seek assistance in building their families. Informed consent also involves understanding the risks, benefits, and likely outcomes of these alternatives to the extent they are known. Where information is lacking, particularly information about long-term outcomes, this must be explained carefully to patients. Patients must then consider which of the alternatives may best realize their values.

Many discussions of informed consent point out that it should be seen as an ongoing process rather than a single event. Patients' understanding may develop over time, and their values and goals may shift. Patients' situations may change, too; for example, patients who have had one or more failed IVF cycles may need additional information before deciding whether to proceed with additional cycles or other forms of care (10). Decision aids, videos, and interactive technologies may be helpful in developing understanding (11).

Reliance on consent forms may have the unanticipated consequences that patients perceive them as a needed formality to obtain treatment or as protective of the practice rather than truly informative (10). Instead, forms are only a part of the process and should be viewed as documents for patients to memorialize the information and choices they make. When it is legally important to document choices, such as the planned disposition of embryos that will not be used by the couple for reproduction, these should be presented clearly as a matter separate from the overall informed consent process (4).

As a process developing over time, informed consent involves conveying information, helping patients understand the significance of that information for them, and working with patients to ensure that their decision is informed,

voluntary, and reflective of their values and preferences. Interviews with providers also indicate the perception that patients, too, have a role to play in the informed consent process, including asking questions when they are unsure. Thus, practices should ensure that patients have the time and encouragement they need for the process to succeed (10).

Models of shared decision-making, in which the patient's values are elicited and the provider and the patient work together to achieve understanding and reach a decision in accordance with the patient's values, are especially helpful in achieving informed consent (11, 12).

In the informed consent process, patients should have a clear understanding of their conditions and available courses of action. In presenting for care, patients may be focused particularly on the possibility of a healthy child. They should understand the risks, including those related to pregnancy and those related to offspring, such as congenital anomalies and inherited disease. Fertility treatment potentially involves physical risks, psychological risks, and economic risks that patients may find challenging to discuss. The consideration of treatment options other than direct efforts to achieve a pregnancy may be difficult for some patients. Several ASRM ethics opinions; however, underscore the importance of discussions with patients about alternatives such as the use of a gestational carrier, adoption, or child-free living (13–17).

Additional efforts may be needed to ensure informed consent when patients face complex reproductive situations or when they may be subject to pressures from partners or family members regarding family planning efforts. Examples include IVF when the prognosis is poor or futile (15) or when the risks of treatment are high because of underlying medical conditions (16) or advanced age (17). The ASRM ethics opinion on posthumous use of gametes or embryos (18) emphasizes the importance of delaying the process to allow for time to grieve and think in a considered way about whether to proceed. Special efforts in achieving understanding also may be necessary when the patient's primary language is not English (10) or when other challenges to communication using the written or spoken word may exist. Providers should also be attentive to how differences in cultural backgrounds may affect patients' understanding or participation in the informed consent process.

Patients may have profound responses to infertility diagnosis and management options that may influence how they acquire and process information central to informed consent. Information may be especially difficult for the patient to process when they or their partner are deeply committed to having a biologically related child, yet their prognosis is poor or treatment poses risks (15). Emotional and psychological pressures may also impact decision-making when patients face a serious or terminal illness or the death of a partner. In such circumstances, patients should be given the time and support needed in coming to a decision that is informed by the medical facts of the condition and their options, in addition to being in accord with their wishes.

At times, information may be lacking, particularly about long-term outcomes or when there is a dearth or absence of studies regarding a particular treatment. In such circumstances, care must be taken to explain uncertainties to pa-

tients. The failure to discuss the absence of evidence with patients may be erroneously understood by them to mean that there is evidence that is reassuring. It is important to guard against this misunderstanding and to be fully candid about what is known and what is not known.

An inherent part of the informed consent process is a decision-making capacity. This is a threshold criterion for establishing whether a patient can make informed healthcare decisions for themselves. In the field of medicine, decision-making capacity is most often presumed to be present unless a patient demonstrates an acute or longstanding impairment in their decision-making ability. It is important for reproductive healthcare physicians to be aware of the importance of decision-making capacity in the informed consent process and the need for a formal assessment if there is concern about a patient's decision-making capacity. Special considerations apply to minors, in particular to those who are not deemed "mature minors" by the law, and programs should be aware of the unique ethical and legal issues surrounding consent and assent by and on behalf of minor patients. Referrals for a formal capacity assessment should be guided by authentic concerns about the patient's decision-making capacity and ability to provide informed consent for an assisted reproductive procedure. The consultation should be based on well-grounded reasons and not be driven, biased, or influenced by the personal beliefs of the healthcare provider regarding the reproductive healthcare decisions of the patient.

Many ASRM Ethics Committee opinions suggest that counseling may be helpful to patients confronting difficult decisions (13, 15, 19). Many forms of counseling may assist the informed consent process, including genetic, psychological, and legal counseling. Genetic counseling can help patients understand their values and consider carefully which options may further these values. It may also give patients more specialized information, such as meeting with a genetic counselor before testing for monogenic defects in adult-onset conditions (20). Psychological counseling may also offer patients help in developing an independent perspective on their situation and may be especially important when patients are in circumstances of stress or potentially facing pressures from family members to enter into an arrangement that they may find concerning (21–23). However, counseling should be viewed as helpful to the process of informed consent, not as a substitute for it.

In some situations, obtaining informed consent may be difficult for reasons of confidentiality. For example, intimate partners may be unwilling to disclose clinically relevant information to one another. When one partner requests that information that could impact their partner's decision-making not be shared, fully informed consent may not be possible. An example would be a male partner's request not to provide information about his HIV status to a partner or gestational carrier when his sperm are to be used in fertility treatment, or a female not sharing the fact that she carries an X-linked disorder. In such cases, when informed consent cannot be obtained, providers should ethically decline to provide care (24).

Informed consent may also require the disclosure of information that is specific to the facility providing care, including policies regarding the disposition of embryos that

will no longer be used in infertility care (4), the transfer of embryos with genetic anomalies (19), or sex selection for nonmedical reasons (22). Such disclosures should be shared with patients before starting treatment because this knowledge may affect their decisions about whether to pursue care at that facility or seek care elsewhere. Some decisions rely heavily on an assessment of likely prognosis, for example, when deciding whether to become part of a financial risk-sharing program or when treatment is not likely to succeed (15, 25). Patients should also be aware of the experience of the facility with any planned procedures, to the extent that such information is available and may impact their decisions.

CONCLUSION

Informed consent, although often a complex process, is essential to patient autonomy and the ethical practice of medicine. It represents a fundamental value in patient care. Informed consent discussions should be introduced as early as possible when making decisions regarding reproductive care. In this way, patients will benefit from maximizing the time they have to fully understand the risks and benefits of, and alternatives to, their decisions as they pursue or forego treatment.

Acknowledgments: This report was developed under the direction of the Ethics Committee of the American Society for Reproductive Medicine as a service to its members and other practicing clinicians. Although this document reflects appropriate management of a problem encountered in the practice of reproductive medicine, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Other plans of management may be appropriate, taking into account the needs of the individual patient, available resources, and institutional or clinical practice limitations. The Ethics Committee and the Board of Directors of the American Society for Reproductive Medicine have approved this report.

This document was reviewed by ASRM members, and their input was considered in the preparation of the final document. The following members of the ASRM Ethics Committee participated in the development of this document: Sigal Klipstein, M.D.; Deborah Bialis-Anderson; Ricardo Azziz, M.D., M.P.H., M.B.A.; Kavita Shah Arora, M.D., M.B.E.; Tolulope Bakare, M.D.; Katherine Cameron, M.D.; Susan Crockin, J.D.; Ruth Farrell, M.D.; Elizabeth Ginsburg, M.D.; Mandy Katz-Jaffe, Ph.D.; Jennifer Kawwass, M.D.; Edward Martinez, M.D.; Joshua Morris, M.D.; Catherine Raczowski, Ph.D.; Robert Rebar, M.D.; Mary Samplaski, M.D.; Chevis N Shannon, Dr.P.H., M.P.H., M.B.A.; Hugh Taylor, M.D.; Sean Tipton, M.A.; Lynn Westphal, M.D.; Julianne Zweifel, Ph.D. The Ethics Committee acknowledges the special contributions of Ruth Farrell, M.D., and Susan Crockin, J.D., in the preparation of this document. All committee members disclosed commercial and financial relationships with manufacturers or distributors of goods or services used to treat patients. Members of the committee who were found to have conflicts of interest on the basis of the relationships disclosed did not participate in the discussion or development of this document.

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El consentimiento informado en reproducción asistida: opinión del Comité Ético

El consentimiento informado es un proceso por el cual se asiste a la paciente en el desarrollo de la comprensión de las opciones médicas (incluyendo riesgos, beneficios y alternativas) y en la toma de una decisión voluntaria y autónoma.