

Disclosure of medical errors involving gametes and embryos

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Medical providers have an ethical duty to immediately disclose clinical errors involving gametes or embryos; clinics should have written policies in place for reducing and disclosing errors. This document was reviewed and affirmed in 2011 and replaces the earlier document of the same name. (*Fertil Steril*® 2011;96:1312–4. ©2011 by American Society for Reproductive Medicine.)

Clinics have an ethical obligation to disclose errors out of respect for patient autonomy and in fairness to patients.

Errors that affect the number or quality of gametes or embryos should be disclosed unless they clearly have a minimal effect on patient interests.

It is obligatory to disclose immediately errors in which the wrong sperm are used for insemination, or gametes or embryos are mistakenly switched resulting in embryo transfer, conception, or the birth of a child with a different genetic parentage than intended.

Clinics should promote a culture of truth-telling and should establish written policies and procedures regarding disclosure of errors to patients.

Fertility programs should have in place rigorous procedures to prevent the loss of gametes and embryos and to ensure proper identification of all gametes, embryos, and patients.

Medical errors are mistakes that have potentially negative consequences for patients (1, 2). Harm can occur from something done to the patient (errors of commission) or from something not done (errors of omission). Because some errors may be inconsequential, practitioners at times may be uncertain whether to inform the patient of an error and whether disclosure is always practical or always serves the interests of the patient. Although sometimes difficult, fairness to patients and respect for their autonomy require open and honest disclosure of errors immediately upon recognition. This document reviews conditions under which it is ethically obligatory to disclose errors to patients and how and when this might be done.

This document addresses the duty to disclose errors in assisted reproductive settings. It focuses on two types of errors: [1] errors that lead to gametes or embryos being lost, with the diminished reproductive opportunity that such errors can bring; and [2] situations in which the gametes or embryos of one person or couple are mistakenly transferred to another person or couple, potentially leading to the birth of a child with an unintended genetic parentage. We believe that physicians in the first instance are obligated to disclose errors

that affect the number or quality of gametes or embryos, except in those instances in which the error is so clearly minimal that it could not possibly affect the couple's interests (see below). In the second instance in which gametes or embryos are inadvertently mixed the obligation to disclose errors is without exception. Here the patient's right to know is compelling; physicians are obligated to disclose to patients as soon as discovered any error that could lead to a child being born with a mistaken paternity or maternity.

MEDICAL ERRORS IN FERTILITY PRACTICE

Although errors in fertility practice can take many forms, we focus on two types of errors. In one, the mistake leads to the loss of sperm, eggs, or embryos intended to be used for reproduction. Some of these errors clearly may have no adverse consequences for patients. Such would be the case, for example, if a small portion of a semen sample were accidentally spilled in the laboratory but enough remained to provide a suitable specimen for insemination, or if atretic oocytes or noncleaving embryos were lost.

A difference of opinion exists as to whether mistakes involving the number or quality of gametes or embryos should always be disclosed. According to one point of view, disclosure is discretionary if such errors do not harm the patients. According to another, "even trivial medical errors should be disclosed to patients, and decisions to withhold information need ethical justification" (3). We believe that the presumption should be to disclose, rather than not to disclose, mistakes that have potentially adverse effects for patients, even if the mistakes are seemingly minor. If, on the other hand, there is clearly no adverse effect, and if disclosure may unnecessarily compound the stress of patients, disclosure may be considered to not be obligatory.

Other errors, however may, or do, have an adverse effect by affecting the patient's ability to have a biologically related child. For example, some errors may require the couple to undergo another treatment cycle, with its corresponding costs and burdens. Such would be the case if an error resulted in an insufficient number or inadequate quality of gametes or embryos available for fertilization or implantation or prevented the couple from having a genetically related child. In such circumstances, we believe that the best ethical practice is to disclose errors that affect the number or quality of gametes or embryos. If the error is something that would or should be entered in the medical record, it should be disclosed.

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A second type of error, considerably less common, occurs when gametes or embryos of one person or couple are mistakenly used with the gametes or embryos of another person or mistakenly transferred to the uterus. This would include inseminating a patient with the wrong sperm, combining the wrong sperm with the wrong eggs in the laboratory, or transferring the wrong embryos to a patient. In such cases, couples face not only the loss of gametes or embryos that would have enabled them to reproduce but also the possibility that a child from the gametes or embryos will result in a child intended for another couple. If that happens, couples face potential legal disputes to determine the child's parentage and custody arrangements. Discovery of the error may occur shortly after the gametes are used or the embryos are transferred, or discovery may occur later. In one particularly unfortunate scenario, discovery will take place after the child is born and has been raised for some time by the couple who is not the child's intended parents.

Disclosure should take place even if the embryo has not implanted or a child has not been born. Some might argue that the ethical duty to minimize harm justifies not telling the patients of the error because disclosure may be harmful, such as leading to a pregnancy termination or creating stress. We believe this view is misguided. Disclosure of the error will enable the persons most directly affected to decide on a course of action. If a pregnancy has been established, this course of action may involve continuing the pregnancy, making advance arrangements about parentage, and securing legal counsel to take steps to develop a workable solution for this unforeseen outcome. An alternative course of action may be a decision to terminate the pregnancy. The duty to disclose also holds if the child has been born and some time elapses before the error is discovered. Realizing the complexity of disclosure in such a case, careful assessment and planning should be undertaken, but disclosure should still take place as soon as possible.

REASONS FOR DISCLOSING ERRORS

A fundamental principle of medical ethics is to respect patients by treating them as autonomous individuals. This means dealing with patients honestly and openly, and it includes the duty to provide patients with information necessary to understand their diagnosis, course of treatment, and risks and benefits so they can make knowing and informed decisions. The ethical dictum of "first do no harm" includes harm to the patient's status as an autonomous individual.

Respect for patients means providing them with information necessary to understand their situations and to make choices about future courses of treatment. Such information includes telling patients when physicians or other members of the medical team have made an error or mistake that affects the well-being or goals of the patient. In such cases there is an ethical duty to disclose the mistake and enable steps to prevent harmful effects, if possible. Disclosure also guards against an erosion of trust because failure to disclose "potentially involves deception and suggests preservation of narrow professional interests over the well-being of patients" (1).

The principle of informed consent and the need for disclosure of mistakes is recognized directly or indirectly in ethical statements of the American Medical Association, the American College of Physicians, the American College of Obstetricians and Gynecologists, the Joint Commission on the Accreditation of Health Care Organizations, and many other professional associations. In addition to a duty to disclose relevant information to patients, there is also a moral duty not to lie, falsify records, or ask or require team or staff members to engage in deception or actions that prevent patients from being properly informed about their situation.

Principles of open and honest communication with patients have special significance in reproductive medicine. Fertility treatments are often stressful, and patients may be particularly sensitive to the statements of their doctors. In addition, errors in reproductive medicine may affect the couple's ability to have a child. In errors that are particularly serious—where embryos are mistakenly transferred to the wrong couple—the error may lead to the birth of a different child than was intended. Such births can lead to significant emotional turmoil and the burdens of custody lawsuits, which can adversely affect all involved parties, including the children.

THE PROCESS OF DISCLOSING ERRORS

Clinic personnel may be reluctant to disclose errors for various reasons. They may be concerned about negative consequences to them or their practice, including concerns about losing patients, facing compensation demands, implicating other members of the medical team, being sued, harming the clinic's reputation, and complaints to medical licensing boards. Practitioners may also feel discomfort about admitting mistakes (2).

Although admitting a medical error might be difficult, disclosing rather than hiding the error is ethically and legally appropriate, both to avoid further harm to the patient and to avoid the additional wrongs that an attempt at secrecy might entail. Practitioners who hide their error may gamble that the error will not be discovered. For example, a practitioner may try to keep secret the error of inseminating a patient with the wrong sperm, hoping that a pregnancy is not established. Yet such an act may further injure patients by depriving them of the opportunity to take corrective or other remedial action. It is recognized that "errors do not necessarily constitute improper, negligent, or unethical behavior, but failure to disclose them may" (4). Covering up an error may also lead to penalties for practitioners, including the loss of a physician's medical license (5).

Some studies suggest that patients are less likely to take legal action if they are informed honestly about mistakes (1). If one does not tell and the patient later learns of the error, then the patient "is likely to be more hostile and suit-prone" because of the perceived violation of the practitioner's obligations to the patient (2). Disclosure is also important if the clinic uses it as an opportunity to prevent future similar mistakes or to improve the quality of care (6). Clinicians should, however, be prepared for negative consequences from disclosure, such as losing patients to other clinics, expectations of compensation, or initiation of a legal suit.

Health care workers may not know how or when to inform patients (7). As such, clinics should have a basic policy of disclosing all important clinical events to patients. In addition, guidelines and written clinic policies may be helpful (8, 9). Such policies should include the definitions of key events and terms, statements about who should be informed, how further investigation will be conducted, and when and how information will be discussed with patients. Clinic policies should also reflect a culture of encouraging disclosure of and discussion about errors in the clinic itself. A culture of openness includes conveying to the medical team awareness of the harm that can come from hiding errors, of the consequences of secrecy to staff members, and of policies in place to minimize errors.

It is also important for written policies to include rigorous procedures to prevent the loss of gametes and embryos and to ensure proper identification of all gametes, embryos, and patients. This should include written labeling as well as verbal identification at the initiation of embryo transfer. Clinics may also choose to

distinguish between individual errors and system errors. Recognizing system errors can help lessen the odds of a similar systemic mistake in the future. This can be part of the culture of encouraging disclosure of and discussion about errors in the clinic itself.

Clinic policy should include suggestions for facilitating the process of disclosure. For example, it is advisable for practitioners to: a) initiate the disclosure rather than waiting for the patient to ask and, b) regard disclosure as a process involving more than one discussion (1). Clinic personnel should also let the patient know what steps are being taken to prevent recurrences. Those who have studied disclosure of errors recommend that an apology and empathy can help; to express condolences is not necessarily to admit fault (6). Conversely, the lack of an apology may be distressing to the patients (5). Personnel should disclose what is known and what is uncertain and then provide updates if more is learned about the error (10).

We conclude that the best ethical practice is for programs to have in place rigorous procedures to prevent errors. To prepare for the possibility that errors may occur despite these procedures, programs should foster an environment of truth-telling that will allow prompt identification and disclosure of errors to patients. It is recommended that clinics have written policies and procedures that outline how to reduce and disclose medical errors.

This report was developed by the Ethics Committee of the American Society for Reproductive Medicine as a service to its members and other practicing clinicians. Although this document reflects the views of members of that Committee, it is not intended to be the only approved standard of practice or to dictate an exclusive course of

treatment in all cases. This report was approved by the Ethics Committee of the American Society for Reproductive Medicine and the Board of Directors of the American Society for Reproductive Medicine.

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REFERENCES

1. Hebert PC, Levin AV, Robertson G. Bioethics for clinicians: 23. Disclosure of medical error. *CMAJ* 2001;164:509–13.
2. Thurman AE. Institutional responses to medical mistakes: ethical and legal perspectives. *Kenn Inst Ethics J* 2001;11:147–56.
3. University of Washington School of Medicine. Ethics in medicine: mistakes. Available at: <http://depts.washington.edu/bioethx/topics/mistks.html>. Accessed May 4, 2011.
4. Snyder L, Leffler C. Ethics and Human Rights Committee, American College of Physicians. Ethics manual: fifth edition. *Ann Int Med* 2005;142:560–82.
5. In the matter of accusation against Steven L. Katz. Case no. 03-2001- 122617. OAH no. N2004080093. Sacramento, CA: Medical Board of California Department of Consumer Affairs; 2005.
6. University of Toronto Joint Centre for Bioethics. Sunnybrook and Women's College Health Sciences Centre administrative manual. Available at: http://www.jointcentreforbioethics.ca/research/documents/sunnybrook_policy.pdf. Accessed October 6, 2011.
7. DeVita MA. Honestly, do we need a policy on truth? *Kenn Inst Ethics J* 2001;11:157–64.
8. University of Pittsburgh Medical Center–Presbyterian Hospital. Policy and procedural manual. Guidelines for discussion and disclosure of conditions and events with patients, families, and guardians. *Kenn Inst Ethics J* 2001;11:165–8.
9. Vincent C. Understanding and responding to adverse events. *New Engl J Med* 2003;348:1051–6.
10. American Medical Association Council on Ethical and Judicial Affairs. Code of medical ethics. Available at: <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page>. Accessed May 4, 2011.