Disclosure of medical errors involving gametes and embryos: an Ethics Committee opinion

Ethics Committee of the American Society for Reproductive Medicine

American Society for Reproductive Medicine, Birmingham, Alabama

Medical providers have an ethical duty to disclose clinically significant errors involving gametes and embryos as soon as they are discovered. Clinics also should have written policies in place for reducing and disclosing errors. This document was reviewed and affirmed in 2015 and replaces the earlier document of the same name (Fertil Steril 2011;96:1312–4). (Fertil Steril® 2016;■:■–■. ©2016 by American Society for Reproductive Medicine.)

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KEY POINTS

- The practice of reproductive medicine can involve medical errors in which gametes and embryos are lost, degraded, or misdirected, as well as near misses in which errors are averted before producing any clinical impact.
- Fertility programs should have in place rigorous procedures to prevent the loss, degradation, or misdirection of gametes and embryos and to ensure proper identification of all gametes, embryos, and patients.
- Clinics should address medical errors and near misses by conducting a root-cause analysis aimed at revealing any systems failures.
- Clinics have an ethical obligation to disclose errors out of respect for patient autonomy and in fairness to patients.
- Clinics must disclose errors in which the wrong sperm are used for insemination, or gametes or embryos are mistakenly switched resulting in fertilization, embryo transfer, implantation, or the birth of a child with a different genetic parentage than intended, as soon as they are discovered.
- Clinics should promote a culture of truth telling and should establish written policies and procedures regarding disclosure of errors to patients.

The practice of reproductive medicine involves the retrieval, processing, transfer, and storage of human gametes and embryos. Manipulation of the elements of conception outside the body creates opportunities for the loss, degradation, or misdirection of gametes and embryos in the course of fertility care. Any instance in which gametes or embryos are lost, degraded, or misdirected constitutes an adverse event and will likely be considered a medical error. "Near misses," that is, possible errors averted before producing any clinical impact that reaches the patient, also occur. This document reviews the conditions under which it is ethically obligatory to disclose to patients such medical errors or near misses involving gametes and embryos. It also considers how and when disclosure might be done.

Medical errors are mistakes that have potentially negative consequences for patients (1–3). Harm can occur from something done to the patient (errors of commission) or from something not done (errors of omission). Some medical errors may be judged clinically inconsequential. Where harm is believed minimal, practitioners may be uncertain whether to inform the patient and whether disclosure is always practical or serves the interests of the patient. In these cases, the Ethics Committee of the American Society for Reproctive Medicine (ASRM) believes that there should be a strong presumption in favor of disclosure. Physicians and patients may differ in judgments about whether harm is minimal. Moreover, the many factors discouraging physicians from error

Received March 4, 2016; accepted March 7, 2016.
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Fertility and Sterility® Vol. ■, No. ■, ■ 2016 0015-0282/$36.00
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http://dx.doi.org/10.1016/j.fertnstert.2016.03.018

disclosure counsel in favor of a presumption favoring disclosure in these cases.

In the provision of fertility care, other errors involving gametes and embryos harm the patients who supply these reproductive materials. When errors are clinically relevant, fairness to patients, protection from harm, and respect for patient autonomy require open and honest disclosure of errors immediately upon recognition, even though disclosure may be difficult for clinicians. The scope of disclosure also includes other health-care providers who are involved in a fertility patient's care, including treating physicians within the clinic's practice or those independent of the clinic who provide necessary ancillary services such as surgical sperm extraction. Shared knowledge of errors by all members of a patient's health-care team allows for any adjustments in the treatment plan to proceed in a coordinated and consistent manner.

With near misses, the possibility of harm is averted before it reaches the patient. Reasons for disclosure of near misses may include patient autonomy and the importance of assessing clinic procedures for reducing systemic possibilities for error. The ASRM Ethics Committee believes that disclosure should be considered in these cases but is not obligatory. In addition, clinics should have policies in place to conduct a root-cause analysis when medical errors and near misses occur to guard against system error. Clinics should periodically review these policies for adequacy and for compliance with them.

While medical error can occur at any point in the delivery of assisted reproductive care, this document focuses on two specific types of errors: [1] errors that lead to gametes or embryos being lost or degraded, with the diminished reproductive opportunity that such errors can bring; and [2] situations in which the gametes or embryos employed in fertility care are not those originally intended for use in the patient undergoing treatment, potentially leading to the birth of a child with an unplanned 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's impact is so clearly minimal that it could not possibly affect the patient's interests, as discussed below. In the second instance in which gametes or embryos are misdirected, the obligation to disclose errors is without exception. Here the patient's right to know is compelling; physicians are obligated to disclose to patients any error as soon as discovered that could lead to a child being born with an unintended paternity or maternity.

MEDICAL ERRORS LEADING TO GAMETES OR EMBRYOS BEING LOST OR DEGRADED

Medical errors in fertility practice involving gametes or embryos can be devastating to patients and clinic personnel, often raising legal, ethical, and practical concerns in their wake (4). This section discusses circumstances in which the mistake leads to the loss or degradation of sperm, eggs, or embryos intended to be used for reproduction.

Some errors leading to the loss or degradation of gametes or embryos clearly have no adverse clinical 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. Because the patient has not been harmed and disclosure may cause needless worry or mistrust, it may be argued that disclosure is not required in these cases. This argument defers to a clinician's individual judgment about the minimal nature of the harm and the value of disclosure in these situations.

Arguments in favor of disclosure, even of errors with minimal clinical impact, raise concerns about deferring to physicians' judgments about whether errors are of clinical consequence. Disclosing errors is difficult and many physicians are reluctant to engage in disclosure discussions (5). Physicians thus may be overly likely to justify nondisclosure on the basis that the error was of little clinical importance. Critics also question whether physicians are the best judges of the meaning of "harm" in such cases and argue that respect for patient autonomy means that patients should be informed about events that they might judge to be harmful to them. These concerns weigh in favor of disclosure in cases in which the error reached the patient but is judged to have been inconsequential by the physician.

This second approach thus advises, ''even trivial medical errors should be disclosed to patients, and decisions to withhold information need ethical justification'' (6). The ASRM Ethics Committee believes 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.

There are also near misses surrounding loss or degradation of gametes or embryos. Examples are errors in the identification of gametes or embryos for disposal, or errors in the management of preservation techniques. Backup checking or other system methods may catch these errors before they are implemented. With near misses, the errors are caught before they actually occur, so that there is by definition no effect on the patient. However, near misses may indicate systemic difficulties clinics need to address so that errors do not occur in the future. They also illustrate the importance of having effective system methods to catch errors. Advocates of disclosure contend that disclosure may encourage practitioners to recognize systemic errors and take remedial steps that may reduce risks of harmful errors to subsequent patients (7). In these cases, the ASRM Ethics Committee believes that disclosure is not required but that clinics should have policies to identify near misses and to take steps to guard against them.

Other errors may, or do, have an adverse effect on patients by affecting their 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 transfer 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.

ERRORS INVOLVING MISDIRECTION OF GAMETES OR EMBRYOS

A second type of error, considerably less common, occurs when the gametes or embryos used in infertility treatment are not those originally intended for a particular patient. This might occur when the 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. When gametes or embryos are banked, it might involve the use of different materials than those originally intended for the patient.

In cases in which gametes or embryos of one person or couple are misdirected to another, patients face not only the loss of gametes or embryos that would have enabled them to reproduce but also the possibility that the gametes or embryos will result in a child intended for another couple. If the latter case, couples face potential legal disputes to determine the child's parentage and custody arrangements (8). Discovery of the error may occur shortly after the gametes are used or the embryos are transferred, or discovery may occur later. A particularly unfortunate scenario involves discovery of the error after the child is born and has been raised for some time by the couple who is not the child's intended parents (9).

Gamete or embryo banking also creates the possibility of use of materials different from those originally selected for a patient. In cases of donor gametes, the result might be the conception or birth of a child with different genetic characteristics than those originally intended.

Disclosure of any identified misdirection should take place immediately after discovery. Respect for patient autonomy requires disclosure 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" (2).

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 Congress of Obstetricians and Gynecologists, the Joint Commission, 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 health-care providers. In addition, errors in reproductive medicine may affect the couple's ability to have a child. In situations in which errors are particularly serious—where embryos are mistakenly transferred to the wrong patient—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 parentage or 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 having complaints filed to medical licensing boards. Practitioners may also feel discomfort about admitting mistakes (3, 7). Encouraging a climate of

transparency and nonretribution is important to counteract this reluctance.

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" (10). Covering up an error may also lead to penalties for practitioners, including the loss of a physician's medical license (11). Moreover, with contemporary forms of genetic testing, errors of misdirection are unlikely to remain undiscovered.

Some studies suggest that patients are less likely to take legal action if they are informed honestly about mistakes (2). 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 (3). Disclosure is also important if the clinic uses it as an opportunity to prevent future similar mistakes or to improve the quality of care (12). Clinicians should, however, be prepared for negative consequences from disclosure, such as loss of 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 (13). 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 (5, 14). 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 or degradation 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 (7). 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 (2). 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 (12). Conversely, the lack of an apology may be distressing to the patients (11). Personnel should disclose what is known and what is uncertain and then provide updates if more is learned about the error (15).

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.

Acknowledgments: 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. While 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 ASRM and the Board of Directors of the ASRM.

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. 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 based on the relationships disclosed did not participate in the discussion or development of this document.

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REFERENCES

1. Institute of Medicine. To Err is Human: Building a Safer Health System. Washington, DC: National Academies Press. Available at: http://iom.nationalacademies.org/Reports/1999/To-Err-is-Human-Building-A-Safer-Health-System.aspx; 1999. Last accessed March 1, 2016.
2. Hebert PC, Levin AV, Robertson G. Bioethics for clinicians: 23. Disclosure of medical error. CMAJ 2001;164:509–13.
3. Thurman AE. Institutional responses to medical mistakes: ethical and legal perspectives. Kenn Inst Ethics J 2001;11:147–56.
4. Vaughn M, Hossain A, Phelps JY. Liability for mismanagement of sperm specimens in fertility practices. Fertil Steril 2015;103:29–32.
5. Vincent C. Understanding and responding to adverse events. New Engl J Med 2003;348:1051–6.
6. University of Washington School of Medicine. Ethics in medicine: mistakes. Available at: http://depts.washington.edu/bioethx/topics/mistks.html. Last accessed March 1, 2016.
7. Chamberlain CJ, Koniaris LG, Wu AW, Pawlik TM. Disclosure of "nonharmful" medical errors and other events. Arch Surg 2012;147:282–6.
8. Perry-Rogers v. Fasano, 715 N.Y.S.2d 19 (2000).

9. Robert B. v. Susan B., 109 Cal. App. 4th 1109 (2003).
10. Snyder L, Leffler C, Ethics and Human Rights Committee, American College of Physicians. Ethics manual (fifth edition). Ann Int Med 2005;142:560–82.
11. 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.
12. 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. Last accessed July 16, 2015.
13. DeVita MA. Honestly, do we need a policy on truth? Kenn Inst Ethics J 2001; 11:157–64.
14. 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.
15. 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? Last accessed March 1, 2016.

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