

Recommendations for development of an emergency plan for in vitro fertilization programs: a committee opinion

Practice Committees of the American Society for Reproductive Medicine, the Society for Assisted Reproductive Technology, and the Society of Reproductive Biologists and Technologists

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All in vitro fertilization programs and clinics should have a plan to protect fresh and cryopreserved human tissue (embryos, oocytes, sperm) and to provide for continuation of patient care in the event of an emergency or natural disaster. This document was reviewed and affirmed by the Practice Committee in 2015. (Fertil Steril® 2016;105:e11–3. ©2016 by American Society for Reproductive Medicine.)

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All in vitro fertilization (IVF) programs and clinics should have a plan to protect fresh and cryopreserved human tissue (embryos, oocytes, sperm) and to provide for continuation of patient care in the event of an emergency or natural disaster. The American Society for Reproductive Medicine (ASRM) encourages each IVF program to develop and implement its own individual emergency preparedness plan (Emergency Plan) appropriate for its geographic location, which specifies the actions to be taken to protect patients, personnel, and specimens in the case of a natural disaster or other potentially devastating event. Below is a discussion of some key components to consider in developing your own Emergency Plan.

DEVELOPING AN EMERGENCY PLAN

An effective Emergency Plan sets out, in writing, the actions to be taken by an IVF program during an emergency or natural disaster. Those actions include providing for [1] the safety and protection of program personnel and patients; [2] the safety and preservation of fresh and cryopreserved human tissue; and [3] the protection and security of important IVF program materials, such as patient records, laboratory records, financial and operational documents, facility equipment, etc.

In order to develop an Emergency Plan appropriate for its needs, an IVF program should take into account the possible scenarios that may lead to or cause disruption to its operations. This

includes both natural disasters that are prone to occur in the program's location (e.g., hurricanes, tornadoes, earthquakes, etc.) and emergencies that can occur anywhere, such as fires, floods, power outages, terrorist attacks, etc. An IVF program should also take into consideration the possibility that ordinary means of communication (e.g., phone, fax, cell phone, email, etc.) may not work during an emergency or natural disaster and that patients and staff may be forced to evacuate to other cities or states and remain there for extended periods of time.

Once an IVF program has developed its written Emergency Plan, the plan should be distributed among the staff and tested. All program personnel should read and familiarize themselves with the Emergency Plan and, as appropriate, receive emergency preparedness training tailored to their job responsibilities. In addition, an IVF program should review and practice on a routine basis its Emergency Plan

Received January 6, 2016; accepted January 6, 2016; published online January 15, 2016.
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Fertility and Sterility® Vol. 105, No. 5, May 2016 0015-0282/\$36.00
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<http://dx.doi.org/10.1016/j.fertnstert.2016.01.004>

to ensure that personnel are capable of carrying out their assigned tasks during an emergency event.

ESSENTIAL ELEMENTS OF AN EMERGENCY PLAN

Outlined below is a list of suggested elements for an Emergency Plan. All IVF programs should consider incorporating these elements, as well as any emergency preparedness requirements mandated or suggested by local, state, and federal authorities and/or by accrediting and licensure bodies (such as The Joint Commission, the College of American Pathologists [CAP], the Clinical Laboratory Improvement Amendments [CLIA], the Federal Emergency Management Agency [FEMA], public health boards, etc.). Additionally, FEMA has a website that contains material that supplements the information contained in this committee opinion. The FEMA website offers general information about disaster planning (<http://www.fema.gov/>) and specific information about business disaster plans (<http://www.ready.gov/business>) that includes a "fill-in-the-blank" business plan that is a helpful starting point for an IVF emergency plan.

As with any planning protocols, the following recommendations are intended to provide IVF programs with some forethought about what to do in the event of an emergency.

Safety of Clinic Personnel and Patients

- I. The safety and security of persons working in the clinic and patients who may be in the clinic at the time of the emergency or disaster are of primary concern. An Emergency Plan should include provisions for the safe evacuation from the clinic premises.
- II. Clinic personnel should have knowledge of the Emergency Plan and understand their responsibilities in the event of an emergency or natural disaster.
- III. Clinic personnel should know whom they are to contact during and following an emergency in order to report their status (i.e., their safety, contact number, whereabouts, ability to return to work, etc.). Such contact should be made by clinic personnel as soon as possible after reaching a place of safety.

Cryopreserved Oocytes, Sperm, and Embryos

- I. Reasonable efforts should be made to maintain a stable cryoenvironment for cryopreserved oocytes, embryos, sperm, and other human tissue.
- II. A set of duplicate records identifying ownership of the tissue should be kept at a site separate from the location where the liquid nitrogen tanks containing the reproductive tissue are housed. While attempts should be made to keep duplicate records at a remote location or secure web server, it is understood that in the event of a catastrophic disaster, there may be no alternative location available.
- III. When there is sufficient prior warning of an emergency situation (e.g., approaching hurricane, rising flood waters, severe snowstorm, etc.), liquid nitrogen tanks containing

reproductive tissue should be "topped-off" and moved, if necessary, to an alternative location.

- IV. When cryopreserved tissues are moved to a location that they do not ordinarily occupy, an attempt should be made to notify appropriate personnel that the tissue has been moved. If time permits, the new location should be secured and the tanks marked appropriately so that they can be easily identified by nonmedical personnel (e.g., fire, police, etc.).
- V. When feasible, police and other institutional and/or municipal authorities should be notified that human tissue is stored at the clinic site and may need to be moved to safety in case of an emergency or natural disaster. The location to which cryopreserved tissues are to be moved should be determined for different types of disasters. A sign should be posted in the current tissue storage area specifying the location to which tanks are to be moved, the persons who are to be notified about the move, and the location of the duplicate identification records.
- VI. Following the emergency, and when it is safe to do so, efforts should be made to replenish the nitrogen in the tanks containing the reproductive tissue. It is recognized that in some circumstances, obtaining a source of liquid nitrogen for this purpose may not be possible.
- VII. Reasonable efforts should be made to notify patients regarding the location and status of their cryopreserved tissue in as timely a manner as possible. If the tissue has been compromised or destroyed, this information should be communicated to the patient and documented in the medical record. Efforts to contact patients and the results of this communication should be documented in each individual patient's medical record.
- VIII. Informed consent prior to the cryopreservation of patients' gametes/tissue should include a statement that the clinic will make efforts to maintain the cryopreserved state of the tissue but that the program cannot be held responsible for the loss of viability due to natural disasters or other emergencies beyond the control of the clinic. Furthermore, the consent form should indicate that the patient will be informed if their tissue is moved to an alternate location due to an emergency situation.

Continuation of Treatment

- I. The most prudent course of action in the event of a catastrophic disaster may be to discontinue treatment for that cycle. If the patient wishes to continue treatment, and the treating facility is not able to safely do so, patients can be given the option of completing their IVF or intrauterine insemination cycle at another center. Patients may be either directed to a specific facility or instructed to locate a clinic in the area to which they have relocated. They may also contact the Society for Assisted Reproductive Technology (SART) at <http://www.sart.org> or by telephone at 205-978-5000 ext. 109.
- II. If the emergency situation arises and if time permits subsequent to the oocyte retrieval and prior to the

embryo transfer, options regarding the transfer of embryos; cryopreservation of oocytes, zygotes, or embryos; or abandonment of the cycle altogether should be discussed with the patient and her partner. Depending on the nature of the disaster, not all options may be feasible.

III. Patients should be instructed to carry all necessary medical supplies and copies of their cycle and clinic records with them if they evacuate to safety, since in an emergency it may not be possible to obtain this information from their original clinic.

IV. Reporting of IVF cycles in which the care has been transferred in these emergency situations should be done according to SART guidelines. The practice that agrees to accept the patient in the middle of the cycle (prior to oocyte retrieval) must report that cycle as its own. In this situation, the requirement for prospective reporting will not be enforced.

Clinic and Patient Records

I. Clinic and patients' records should be copied or backed up periodically and kept in a secure (preferably remote), predetermined location.

II. Laboratory log books and records should be duplicated or backed up at appropriate intervals and the duplicates kept in a secure (preferably remote), predetermined location.

III. Records maintained electronically should be backed up and maintained in a suitable manner, preferably at an off-site and secure location.

IV. Medical record privacy and security should be maintained in accordance with state and federal law, including the Privacy and Security Rules issued pursuant to the Health Insurance Portability and Accountability Act of 1996.

Specific Emergencies and Events

I. Specific policies and procedures should be developed as part of a clinic's Emergency Plan, which addresses both natural disasters that are prone to occur in the clinic's location (e.g., earthquakes, snowstorms, tornadoes, etc.) and emergencies that can occur anywhere at any time, such as fires, floods, power outages, terrorist attacks, etc.

II. These policies and procedures should set out, among other things, plans for evacuation or lockdown of the clinic (as appropriate), whom to contact and notify in

the event of an evacuation, and action plans to be carried out by the clinic administration and/or personnel during the emergency.

SUMMARY AND RECOMMENDATIONS

- The primary objective of an emergency action plan should be to provide for the safety of program personnel and patients, fresh and cryopreserved human tissues, and critical equipment and records.
- All IVF programs and clinics should have a plan to protect fresh and cryopreserved human tissue (embryos, oocytes, sperm) and to provide for continuation of patient care in the event of an emergency or natural disaster.

Acknowledgments: This report was developed under the direction of the Practice Committees of the American Society for Reproductive Medicine (ASRM), the Society for Assisted Reproductive Technology (SART), and the Society of Reproductive Biologists and Technologists (SRBT) 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 Practice Committees and the Board of Directors of ASRM, SART, and SRBT have approved this report.

The following members of the ASRM Practice 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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