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 specimens (embryos, oocytes, sperm) and to provide contingencies for continuation or cessation of patient care in the event of an emergency or natural disaster. This document replaces the document titled "Recommendations for development of an emergency plan for in vitro fertilization programs: a committee opinion," last published in 2016 (*Fertil Steril* 2016;105:e11–3). (Fertil Steril® 2021;115:870–3. ©2021 by American Society for Reproductive Medicine.)

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Il in vitro fertilization (IVF) programs and clinics should implement their own individual emergency preparedness plan (the "Emergency Plan") appropriate for their geographic locations, which specifies the actions to be taken to protect patients, personnel, and specimens (embryos, oocytes, and sperm) in the case of an emergency, natural disaster, pandemic, or other potentially devastating event. This document includes a discussion of some key components to consider in developing such an 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 the safety and protection of program personnel and patients; the safety and preservation of fresh and cryopreserved human tissue; and the protection and security

of important IVF program materials, such as patient records, laboratory records, financial and operational documents, and facility equipment.

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 at the program's location (e.g., hurricanes, tornadoes, earthquakes) and emergencies that can occur anywhere (e.g., pandemics, fires, floods, power outages, terrorist attacks). An IVF program should also take into consideration the possibility that ordinary means of communication (e.g., phone, fax, cell phone, email) may not be available during an emergency or natural disaster and that patients and staff may be forced to remain at home and work remotely or evacuate to other cities or states and remain there for extended periods of time. These policies and procedures should set out, among other things, plans for evacuation or lockdown of the clinic (as appropriate) and whom to notify in the event of an evacuation.

Once an IVF program has developed its written Emergency Plan, the plan should be distributed among the staff and reviewed annually. All program personnel should read and familiarize themselves with the Emergency Plan on a regular basis and, as appropriate, receive emergency preparedness training tailored to their job responsibilities. Practicing the Emergency Plan annually is essential to ensure that personnel are capable of carrying out their assigned tasks during an emergency event.

ESSENTIAL ELEMENTS OF AN EMERGENCY PLAN

All IVF programs should consider incorporating the elements from the list outlined herein, as well as any emergency preparedness requirements mandated or suggested by local, state, and federal authorities or by accrediting and licensure bodies. Additionally, the US Federal Emergency Management Agency has a website that contains material that supplements the information contained in this committee opinion. The Federal Emergency Management Agency website offers

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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 recommendations that follow 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 after an emergency in order to report their status (i.e., their safety, contact number, whereabouts, ability to return to work). Such contact should be made by clinic personnel as soon as possible after reaching a place of safety.
- IV. The "return to the workplace" planning should be preceded by a formal risk assessment accompanied by a risk mitigation plan.

Cryopreserved Oocytes, Sperm, and Embryos

- I. Reasonable efforts should be made to maintain a stable cryoenvironment for cryopreserved oocytes, embryos, sperm, and other human specimens.
- II. A set of duplicate records identifying ownership of the specimen should be kept at a site separate from the location where the liquid nitrogen tanks containing the reproductive specimens are housed. Although attempts should be made to keep duplicate records at a remote location or on a 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), liquid nitrogen tanks containing the reproductive specimens should be topped-off and moved to an alternative location, if necessary.
- IV. When cryopreserved specimens are moved to a location that they do not ordinarily occupy, an attempt should be made to notify appropriate personnel that the specimen 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).
- V. When feasible, police and other institutional or municipal authorities should be notified that human specimens are 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 specimens are to be moved should be

- determined for different types of disasters. A sign should be posted in the current 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. After the emergency, and when it is safe to do so, efforts should be made to replenish the liquid 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. If the specimens are anticipated to be off-site for a prolonged period, reasonable and timely efforts should be made to notify patients regarding the location and status of their cryopreserved specimen(s). If the specimen 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 before the cryopreservation of patients' gametes or tissue should include a statement that the clinic will make efforts to maintain the cryopreserved state of the specimen 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 specimen is moved to an alternate location long-term because of an emergency situation.

Continuation or Cessation of Treatment

- I. The most prudent course of action in the event of an emergency or catastrophic disaster may be to discontinue treatment for that cycle. This may be the only option available, as provision of care may be restricted by local, state, or federal authorities. If the patient wishes to continue treatment, and the treating facility is not able to do so safely, patients can be given the option of completing their fertility treatments at another center, depending on the nature and scope of impact of the situation. 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 for guidance.
- II. Upon the development of an emergent situation, if there is time subsequent to the oocyte retrieval and before the embryo transfer, options such as the transfer of embryos, cryopreservation of specimens (oocytes, zygotes, or embryos), or abandonment of the cycle altogether should be discussed with the patient. Depending on the nature of the disaster, not all options may be feasible.
- III. Patients should be instructed, when possible, to carry all necessary medical supplies and copies of their cycle and clinic records with them if they evacuate to safety, since it may not be possible to obtain this information from their original clinic in an emergency.
- IV. Reporting of IVF cycles should be done according to SART guidelines for cycles in which care has been

transferred in response to an emergency situation. The practice that agrees to accept the patient in the midst of their cycle (i.e., before 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 patient records should be copied or backed up periodically and kept in a secure (preferably remote), predetermined location.
- II. Laboratory 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.

EMERGENCY AND DISASTER PLANNING RESOURCES

Agency	Resource Link
The Joint Commission (1) College of American Pathologists (2) Clinical Laboratory	Emergency Management COVID-19 Resources Centers for
Improvement Amendments (3)	Disease Control CLIA Page
Federal Emergency Management Agency (4)	Emergency Preparedness
Centers for Disease Control (5)	Link to Page with Health Departments of All 50 States
American Society for Reproductive Medicine (6)	COVID-19 Risk Assessment and Mitigation Resources
ASRM. Emergency plan for IVF programs. Fertil Steril 2021.	

SUMMARY AND RECOMMENDATIONS

 The primary objective of an emergency action plan (the "Emergency Plan") should be to provide for the safety of program personnel and patients, fresh and cryopreserved human specimens, and critical equipment and records. All IVF programs and clinics should have such a plan codified and in place to protect fresh and cryopreserved human specimens (embryos, oocytes, sperm) and to provide for continuation or cessation of patient care in the event of an emergency, pandemic, or natural disaster.

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Desarrollo de un plan de emergencia para los programas de fecundación in vitro: opinión de un comité

Todos los programas y clínicas de fecundación *in vitro* deben tener un plan para proteger las muestras humanas frescas y criopreservadas (embriones, ovocitos, esperma) y proporcionar contingencias para la continuación o el cese de la atención del paciente en caso de una emergencia o desastre natural. Este documento reemplaza el documento del mismo nombre, publicado por última vez en 2016 (Comités de Práctica de la Sociedad Americana de Medicina Reproductiva; Sociedad de Tecnología de Reproducción Asistida; Sociedad de Biólogos y técnicos Reproductivos). Dirección electrónica: ASRM@asrm.org; Sociedad Biólogos y técnicos reproductivos. Recomendaciones para el desarrollo de un plan de emergencia para programas de fecundación *in vitro*: opinión de un comité.