

Guideline to prevent the misidentification of gametes and embryos

The Japanese Society of Clinical Embryologist

Introduction

It must be recognized that gametes and embryos have capability to become a human, which are completely different cells from other cells or tissues treated in the ordinary medical treatment.

Under the circumstances, handing of gametes and embryos outside the body is performed in majority of medical institutions for fertility treatment, by engineers who are in charge of culture such as a clinical embryologist. Therefore, as over 90% of this society member consisted of the clinical embryologist, it was decided that the guideline to prevent the misidentification of gametes and embryos in assisted reproduction technologies (ART) was established in this society.

Current status in Japan for the scale of medical institutions for fertility treatment and the number of clinical embryologists

According to the report about “the distribution of medical institutions from the viewpoint of the treatment cycle for in-vitro fertilization and embryo transfer” in 2006 from the ethical committee of Japan Society of Obstetrics and Gynecology (JSOG), in the aggregated data from 524 institutions with answer out of 575 registered institutions as the medical institution for ART as of December 31, 2006, only 23 institutions (4.4%) experienced over 301 cycles of annual number of oocyte retrieval. On the contrary, the number of relatively smaller institutions with less than 100 of annual number for oocyte retrieval was 401 institutions (76.5%), which was majority. Thus, it was expected that there were many institutions with only one or two clinical embryologists among the medical institutions for ART across the country. Generally, the scale of an institution becomes smaller, and the preventive measures for the misidentification tend to be insufficient. However, even in the smaller institutions, the timing of oocyte retrieval or the culture of embryos may be overlapped. Therefore, the preventive measures for the misidentification should be prepared as well as the large-/middle-class medical institutions. The Japanese Society of Clinical Embryologist (JSCE) determined the following guideline with sufficient consideration for great variation in the number of implementation.

Important points for the preventive measures for the misidentification of gametes and embryos in ART

It is easy to understand that double-check in each working process is remarkably effective to prevent the misidentification of gametes and embryos. However, it should be considered that implementing double-check may cause the time extension for germ cells to expose outside an incubator that can be close to the physiological condition. Nevertheless, it has not been identified how the time extension of exposure may affect the productivity of each individual embryo at present. Additionally, it is necessary to determine the rule in consideration for possibility to increase the frequency of occurrence of unexpected accidents such as falling or dropping a dish with gamete, embryos, or sperm due to implementation of double-check.

Specific preventive measures for the misidentification of gametes and embryos

1. Participants for prevention of the misidentification

Basically, it is necessary to incorporate the method in which double-check is implemented in each working process and the record of check is preserved. In the case that implementation of double-check for each process of treatment and examination is difficult due to an issue of personnel number, such as only one clinical embryologist in an institution, it is recommended to establish the system that either of a doctor, a nurse, or a patient oneself can participate in double-check. Regarding the participation of a patient, we recommend that the person to check will ask the patient oneself to speak and tell his/her name and either of the ID number, date of birth, or the name of husband/wife to identify the person oneself, of which information should be checked whether it is correct or not with the medical records or others. It is recommended that the system is established, in which double-check is implemented in the following working process and the record of check is preserved.

- I. Delivery and receipt of a container with sperm inside
- II. Check oocytes and sperm at the insemination/ microinsemination
- III. In case of transferring an embryo to a new dish for replacing a culture media
- IV. Check the dish with a embryo for transfer at the embryo transfer
- V. Check the container such as a straw tube at the cryopreservation or thawing of gametes and embryos

2. Description of the patient information on a container such as a dish in which there is gamete or an embryo

Regarding the description of the patient information on a container such as a dish with gamete or an embryo, name of the patient must be written both on a cap and a body of the container. Furthermore, it is advisable to write another information additionally to identify the patient oneself such as the ID number, date of birth, or name of the partner in marriage. It may also be better to identify by color as setting variation of colors in addition to the numeric or the print information.

3. Principles for handling gametes or embryos in the ART laboratory

- I. Regarding the handling of gamete or an embryo in the laboratory, only a container of one patient should be placed on the same working table at the same time.
- II. After the working process, check if there is no gamete or an embryo, or the equipment to be used for those handlings on the working table.
- III. Considering the possibility that a part of gametes or embryos are attached on the working table, clean the working table using medicinal solution such as ethanol for disinfection once the working process finished.
- IV. It is recommended to preserve the record (for example, a checklist) for the evidence to show correct implementation.
- V. For use of a centrifuge, it is recommended to use a centrifuge for one patient at the same time. In case of using a centrifuge for multiple patients, double-check must be implemented for every time to eject in order to confirm if gamete or an embryo is correctly sorted on each working table.

4. Management for the storage place of containers such as dishes with gametes and embryos inside in the incubator

- I. Although it is recommended not to culture with containers such as dishes with gametes or embryos inside for multiple patients in the same incubator at the same time, if a space in a laboratory is limited, device appropriate ways.
- II. If it is not avoidable to culture with containers such as dishes with gametes or embryos inside for multiple patients in the same incubator at the same time, avoid to culture placing containers of multiple patients on the same tray in the incubator.
- III. Describe or enter the information on the record of paper media or electronic media managed in the laboratory such as the ART record in order to understand where each germ cell is stored in the incubator.
- IV. It is recommended to label on outside such a door of the incubator to show the stored place.

5. Delivery and reception of containers with sperm inside and outside of the laboratory

It is recommended to describe the name of the patient and another information to identify the patient oneself both on the cap and the body of containers with sperm. If possible, it is better that the information is described by the patient oneself. It is recommended to clearly check the information by reading out for both parties at the delivery and reception of the container. It is required to device something to make a record of handwriting signs or seals on the examination form by both the deliver side and the received side of the container.

6. Oocyte retrieval and embryo transfer

- I. Before oocyte retrieval or embryo transfer, always confirm the patient by speaking out between staff in charge of the oocyte retrieval room (doctors, nurses, assistance nurses, or clinical laboratory technologist) and a clinical embryologist of the laboratory. Additionally, it is recommended to prevent misidentification of patients by double-check to confirm the patient with the records (paper media or electric media).
- II. At the embryo transfer, it is recommended that the clinical embryologist in charge will directly confirm with the patient oneself just before the transfer.
- III. The information of all handling process, such as the number of oocytes and embryos; i.e. the number of collected oocytes, embryos, unfertilized oocytes, abnormal fertilized oocytes, denatured oocytes, transplant embryos, cryopreserved embryos, or discarded embryos, must be managed by stating in the laboratory records or the medical records.

7. Handling cryopreservation and thawing of gametes or embryos

It is recommended that handling cryopreservation and thawing of gametes or embryos is also implemented after double-check by two types of check such as the medical record of the patient and the ART records.

In closing

For providing the safe and high quality of ART, incorrect culture methods and operation should be avoided. Especially, the misidentification of gametes or oocytes will be an enormous influence, not for the patient oneself alone but for the public. It is crucial to improve communication to build the reliable relationship between healthcare staff and patients, and also to incorporate the double-check system for each working process. For providing the safe medical service, we, this society, will hope

that variety of innovative approaches will be uniquely implemented by each medical institution based on their each reason, as well as wishing to sufficiently secure the sufficient number of staff for the laboratory.

Prepared by: the subcommittee for preparation of Guideline to prevent the misidentification of gametes and embryos

Ikuo Tachibana, Osamu Okitsu, and Takuji Nishihara