

Mishaps: How and Why Mistakes Occur in the Assisted Reproductive Technologies Laboratory, and How to Prevent Them

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Why Mishaps Occur

- **Personnel**
 - **Patients**
 - **Clinical staff**
 - **Laboratory staff**

Why Mishaps Occur

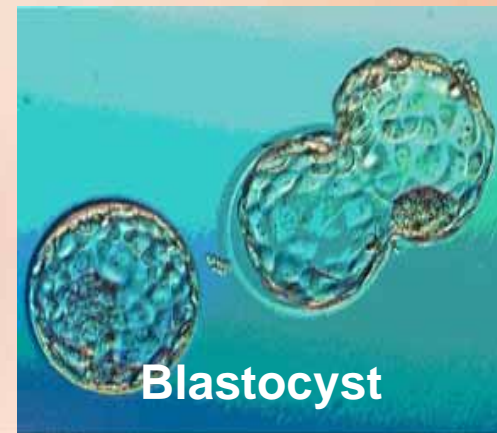
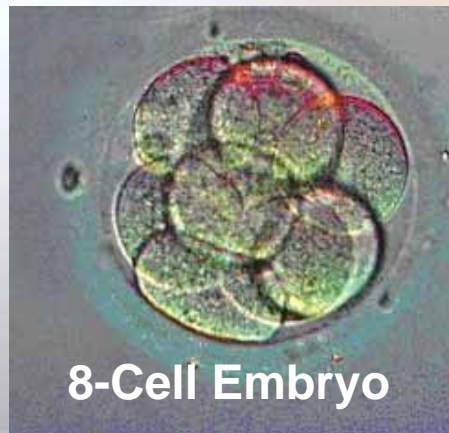
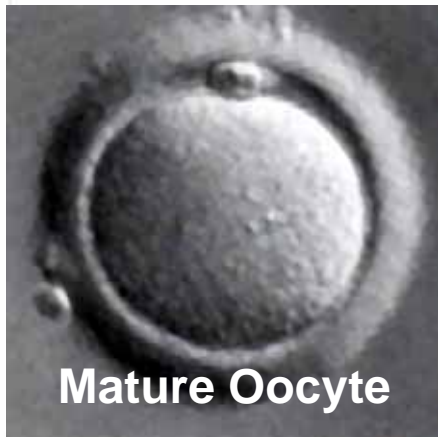
•Tissues

–Microscopic size of gametes/embryos

- Oocytes – 100 μm ~ 0.004 in
- Spermatozoa – 5 x 3 μm ~ 0.0002 x 0.0001 in
- Blastocyst – 200 μm ~ 0.008 in

–Patient's reproductive tract

- Unexpected pathology
- Cervical mucus



Why Mishaps Occur

- **Complexity of procedures**
 1. **Oocyte processing**
 2. **Sperm processing**
 3. **Insemination, fertilization, embryo culture**
 4. **Embryo transfer**
 5. **Cryopreservation, storage and use of gametes and embryos**

1. Oocyte Processing

- Misidentification of patient
- Container/medium toxicity
- Misclassification of oocyte
- Incubator malfunction
- Atmosphere toxicity
- Mislabeling of oocytes
- Damage/destruction of oocytes



2. Sperm Processing

- Misidentification of patient
- Container/medium toxicity
- Incorrect liquefaction time/temperature
- Atmosphere toxicity
- Mislabeling of sperm
- Damage/destruction of sperm



Intracytoplasmic Sperm Injection

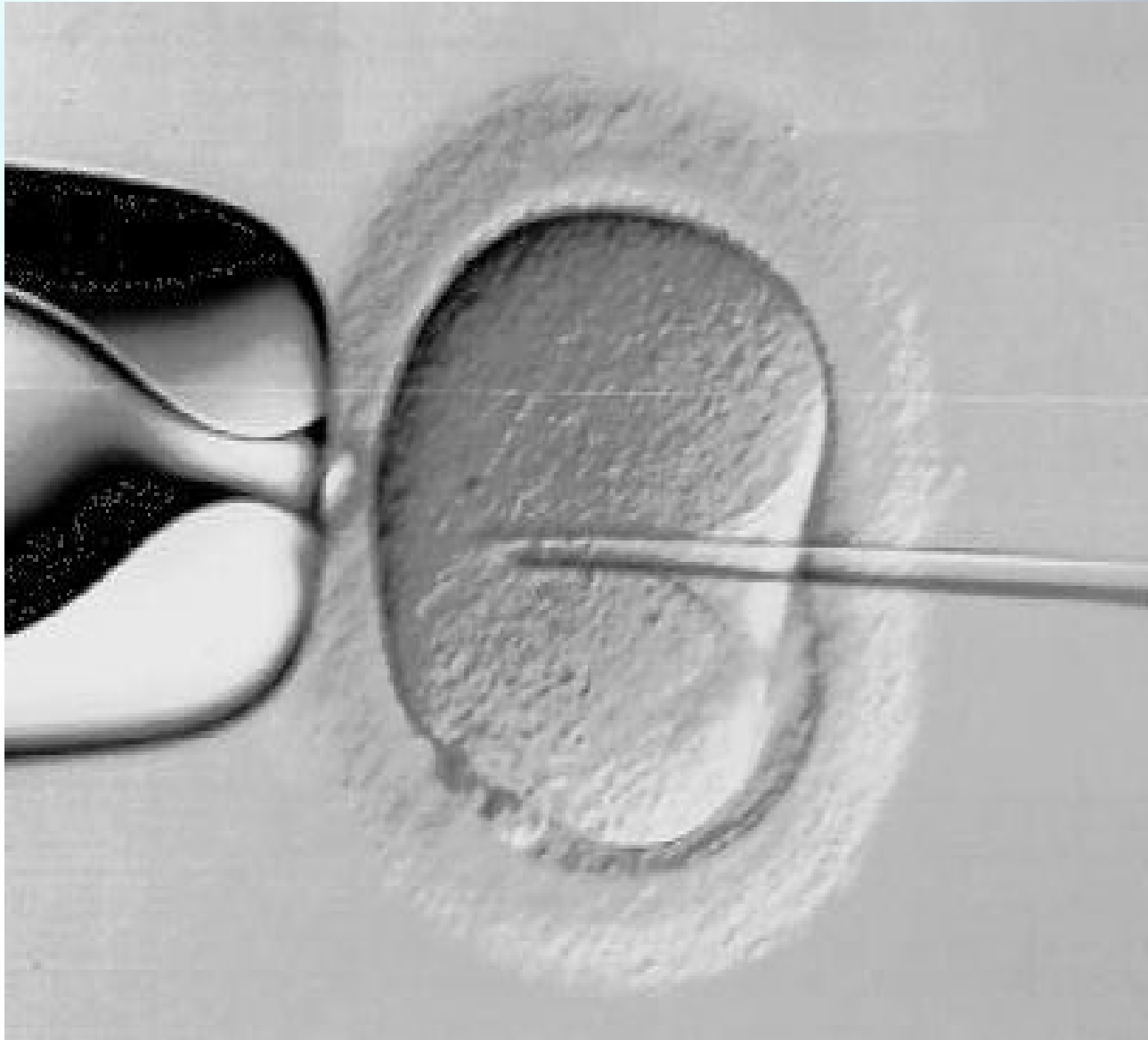


Photo courtesy of C. Sinoway, University of Cincinnati/Christ Hospital Center for Reproductive Health

3. Insemination, Fertilization, Embryo Culture and PGD*

- Insemination with incorrect sperm
- Mislabeling of oocytes
- Container/medium/instrument toxicity
- Incorrect quantity of sperm
- Misclassification of oocyte
- Incubator malfunction
- Atmosphere toxicity
- Damage/destruction of oocytes or embryos

* PGD = Preimplantation Genetic Diagnosis



4. Embryo Transfer

- **Incorrect assessment of embryo development**
- **Catheter/medium toxicity**
- **Wrong embryos transferred to patient**
- **Damage to embryos**
- **Loss of embryos**
- **Embryos retained in catheter**

5. Cryopreservation, Storage and Use of Embryos

- Cryopreservation damage
- Loss of gametes or embryos
- Contamination
- Equipment failure
- Loss of identification
- Loss of viability
- Patient-tissue mismatch



Mishaps in a Large IVF Center

(1997-2007; 12,495 Oocyte Retrievals)

- No effect on patient care (33)

– Oocyte retrieval.....	1
– Equipment malfunction...	4
– Labeling.....	4
– Clinical procedure.....	9
– Technical procedure.....	14
– Embryo transfer.....	1

- Possible effect on patient care (41)

– Oocyte retrieval.....	2
– Equipment malfunction...	5
– Labeling.....	0
– Clinical procedure.....	7
– Technical procedure.....	20
– Embryo transfer.....	7

Measures to Minimize Mishaps

- **Personnel training (technical proficiency, honesty, ethical behavior)**
- **Documented maintenance procedures (equipment, facilities)**
- **Quality assurance program**
- **Quality control procedures**
- **Documentation of all procedures and deviations from standard procedure**
- **Documentation of chain of custody for all cells and tissues**

Disclosure of Medical Errors Involving Gametes or Embryos

- 1. Clinics have an ethical obligation to disclose errors out of respect for patient autonomy and in fairness to patients.**
- 2. Errors that affect the number or quality of gametes or embryos should be disclosed unless they clearly have a minimal effect on patient interests.**
- 3. It is obligatory to disclose immediately errors in which the wrong sperm are used for insemination or gametes or embryos are mistakenly switched and the result is embryo transfer, conception, or the birth of a child with a different genetic parentage than intended.**
- 4. Clinics should promote a culture of truth-telling and should establish written policies and procedures regarding disclosure of errors to patients.**
- 5. 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.**