



KARNATAKA STATE OBSTETRICS AND GYNECOLOGY ASSOCIATION ETHICS AND MEDICOLEGAL COMMITTEE

MEDICOLEGAL BULLETIN

Week 22: Infertility Treatment & IVF – Managing Expectations, Failed Cycles, Consent, and Medicolegal Liability

1. REAL LIFE CASE SCENARIO

A 36-year-old woman with diminished ovarian reserve underwent IVF treatment. Before treatment, the couple was verbally informed that success could not be guaranteed. After two unsuccessful cycles, the couple alleged that they had been told pregnancy was “almost certain.” They demanded reimbursement of treatment expenses and alleged unnecessary investigations, excessive medication, inadequate counseling, and lack of transparency regarding success rates.

The records contained consent for procedures but very little documentation regarding the couple's prognosis, realistic chances of success, possibility of cycle cancellation, or need for repeated cycles. The major medicolegal issue was therefore not simply that IVF failed — it was:

“Were realistic expectations established and properly documented before treatment started?”

2. MEDICOLEGAL RISKS IN INFERTILITY PRACTICE

Infertility treatment is particularly vulnerable to disputes because it combines:

- High financial expenditure
- Emotional vulnerability of couples
- Uncertain treatment outcomes
- Multiple procedures over time
- Expectations of pregnancy
- Embryo and gamete handling
- Sensitive personal information

Common allegations: “Doctor guaranteed pregnancy,” inadequate disclosure of success rates, unnecessary IVF, inadequate consent, gamete or embryo identification errors, confidentiality breaches.

3. WHAT THE LAW EXPECTS

Infertility and ART practice in India must be considered within the framework of the Assisted Reproductive Technology (Regulation) Act, 2021 and applicable Rules.

The treating team should ensure:

- Appropriate indication for treatment
- Valid informed consent
- Realistic counseling regarding prognosis
- Transparency regarding procedures and costs
- Proper handling and identification of gametes and embryos
- Confidentiality and proper record maintenance
- Compliance with applicable ART regulations

Never guarantee pregnancy or a live birth. Medicine can offer treatment. It cannot guarantee biological outcomes.

4. DOCUMENTATION – THE DOCTOR'S STRONGEST DEFENSE

- Diagnosis causing infertility
- Ovarian reserve where relevant
- Semen parameters
- Treatment options discussed
- Why IUI / IVF / ICSI was advised
- Expected limitations of treatment
- Possibility of treatment failure & cycle cancellation
- Risks of ovarian stimulation
- Number of embryos transferred.
- Financial counseling where appropriate.

Cryopreservation details where applicable
Follow-up plan

Avoid vague statements such as “Good chance of pregnancy.” Prefer documented individualized counseling:

“Success cannot be guaranteed. Prognosis and possibility of unsuccessful cycle explained to couple.”



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5. PRACTICAL SAFE PRACTICE – WHAT TO DO

- Give realistic success expectations
 - Individualize counseling according to age and ovarian reserve
 - Explain that more than one cycle may be required
 - Discuss alternatives to IVF
 - Use procedure-specific consent forms
 - Maintain strict embryo/gamete identification protocols
 - Document embryo transfer details meticulously
 - Maintain confidentiality and follow ART statutory requirements
- Never allow marketing language to become a medical promise.

6. COMMON MISTAKES TO AVOID

Advertising “guaranteed pregnancy”

- Quoting unrealistic success rates
 - Poor documentation of counseling sessions
 - Taking only generic blanket consent
 - Failure to explain cycle cancellation
 - Inadequate embryo/gamete traceability
 - Poor communication after an unsuccessful cycle
 - Allowing commercial pressure to influence clinical indication
- The more expensive and emotionally demanding the treatment, the more important transparent counseling becomes.

7. CLINICAL–LEGAL PEARL

IVF failure is not negligence.

An unrealistic promise followed by poor documentation can become a medicolegal problem.

8. REAL COURT CASE INSIGHTS (FOR UNDERSTANDING)

In infertility disputes, the legal question is generally not simply “Did the patient become pregnant?” The more relevant questions are:

- Was treatment medically appropriate?
- Was informed consent obtained?
- Were realistic expectations communicated?
- Were accepted protocols followed?
- Were gametes and embryos handled appropriately?
- Were records properly maintained?
- Was the patient misled regarding outcome or success?

ART practice requires both clinical competence and strong systems of consent, traceability, confidentiality, and documentation.

9. TAKE-HOME MESSAGE

Infertility treatment is not a contractual promise to produce a baby. It is medical treatment with an inherently uncertain biological outcome.

Counsel realistically → Consent specifically → Treat appropriately → Maintain traceability → Document meticulously.

Never sell certainty where medicine can offer only probability.

Next Week's Topic; Retained Surgical Sponge/Instrument After Cesarean or Gynecological Surgery – The Medicolegal Consequences of a Preventable "Never Event"



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