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Manual of

Protect Yourself: Medicolegal Safety

Understanding the Law

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CHAPTER 3

Counseling in ART

Leena Patankar

INTRODUCTION

We all agree that medicine which we practice today is no longer the same as it used to be. It has a legal angle to it which none of us can escape and so it is important for all of us to be not only skillful but safe as well. After knowing the history, conducting the examination and investigations, we come to certain diagnosis and decide the treatment accordingly and advice the patient the same. In today's practice only advice is not enough. Counseling plays a major role where it helps the couples understand not only their condition but also the treatment. Counseling is endorsed by taking the consent whereby the couple agrees that they have understood the every aspect of the treatment. Thus, counseling and consents are the integral part of our practices but are often ignored and neglected. We all are aware that there are guidelines for "Assisted Reproductive Technology (ART)" practice set in 2010. Till it becomes a law these guidelines form the basis of our ART practices. Let us see how counseling and consents help in making our practice better.

COUNSELING

It is the professional advice and support given to the individual, couples in the present context (prospective parents as well as those involved in the treatment, e.g., donors and surrogates) to help them deal with their problems, making them understand the processes involved in the treatment, various options available, results as well as the risks involved so as to make important decisions.

Is Detail Counseling Enough?

No, because being only verbal it is not proof that you have discussed every detail with the couple and that is why consents are must!

Consent

It is the documentation of counseling. A written voluntary permission given by the couple by agreeing to something to allow something to happen. This makes your counseling full proof.

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Types of Counseling

1. *Procedural:* In this the couple is told in details about the procedure including the risks and the failures.
2. *Psychological:* This is important as the couples undergoing ART are under lot of stress, apprehension and doubts. Psychological counseling relaxes them and preparing them better for the prolonged treatment. Psychological counseling is also required in cases of ART failures for the couples to cope up with the negative results and making them hopeful for the subsequent cycles.
3. *Financial:* This is also equally important as ART treatment include huge costs. Also, being an elective procedure the couples must be made aware of the maximum cost involved so that they prepare for the same well in advance.

Types of Consents

1. Procedural
2. Financial
3. *ICMR (Special legal purpose):* ICMR has made specific consents for each and every procedure of ART. It is the contract between the treating doctor and the commissioning couple. By this, the commissioning couple agrees that through artificial means, the child born belongs legally to them. Likewise, the couple involved in the gamete donation or surrogacy agrees that although their gametes or uterus is being used they do not have any right to the child.

Tips for Taking Consents

1. The content should be lawful, real, and valid.
2. It should be free from coercion, fraud, misrepresentation, undue influence, or bias.
3. It should be agreed and signed by both the partners involved, voluntarily and in full awareness.
4. It should not be common but procedure specific containing adequate information about the treatment, i.e., purpose, nature and procedure of the treatment, benefits as well as risks, results, consequences even after refusal of the treatment and alternatives.
5. It must be taken before the procedure.
6. The sources of the gametes (including self-gametes), number of embryos transferred or frozen must be mentioned.
7. Take the consent even if the couple denies any treatment, e.g., surgical extraction of the sperm or embryo freezing. It is important to note that the treatment was offered but it was the couple's decision to deny it.

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8. Never alter the case records or add anything after the signature of the patient in case of a lawsuit or on request of the patient or to favor anyone. This is forgery and unethical practice.

HOW TO KEEP RECORDS AND FOR HOW LONG?

- Records are confidential. Privacy should be maintained.
- Documentation can be typed, computerized or handwritten.
- It should be preserved for a minimum of 10 years or till the time the case continues in case of a lawsuit.
- ICMR has set various consent forms for the ART clinic as well as ART Bank.

CONSENT FORMS FOR THE ART CLINIC

- *Form D:* For IVF/ICSI
- *Form E:* IUI using husband's semen
- *Form F:* IUI using donor's semen
- *Form G:* For freezing embryos
- *Form H:* For surgical extraction of sperms
- *Form I:* Oocyte retrieval/embryo transfer
- *Form J:* Agreement for Surrogacy
- *Form K:* For the donor of oocytes
- *Form L:* For the donor of sperms

(Consent of the spouse is also mandatory in case of donor gametes)

Type

ICMR form
Procedural Consent
Self-cycle
D, I (OPU), I (ET), G
OPU, Anesthesia, ET
OD cycle
D, I(ET), G
Anesthesia, ET
ED Cycle
D, I (ET), G
ET
Donor
K, Affidavit consent
OPU, Anesthesia
IUI-H
E
Stimulation Consent
IUI-D

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E
Stimulation Consent

CONSENT FORMS FOR THE ART BANK

- *Form S:* For the commissioning couple
- *Form R, R1, R2:* For the donors and surrogates for offering their services
- *Form T, U:* Contract between ART clinic and ART Bank for the donors and surrogates.

In the end, I would say, safety is as important as success. A good record keeping not only makes you legally safe but it also reflects your ethical and transparent patient care. It also ensures the couple's understanding, involvement as well as the responsibility during the course of the treatment. So make documentation a habit and you do not have to lose your sleep over it anytime.

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