

## ICMR spurs public debate on infertility clinics

The Indian Council of Medical Research (ICMR), New Delhi in collaboration with the Indian National Academy of Medical Sciences has put up for public debate the 'National Guidelines for Accreditation, Supervision and Regulation of Assisted Reproductive Technologies (ART) Clinics in India'. Several countries, including Egypt, Brazil, Saudi Arabia, Korea and Mexico have guidelines and legislation in place. According to Nirmal Kumar Ganguly, Director General, ICMR, 'India has neither guidelines nor legislation for the ethical practice of ART'. People now have an opportunity to read the draft guidelines available both from the ICMR and on their website as 'obviously, for such a major step, this document needs to be widely debated and discussed by as many interested parties concerned as possible', stated Ganguly.

In several societies of the world, infertile couples face an uphill challenge in terms of social and family pressures, and are treated as outcasts in many social events. This burden they carry almost always leads them to a sense of desperation, and they knock on the doors of infertility clinics. Gullible infertile couples in their intense desire for parenting are prey to rampant undesirable practices in ART, provided by practitioners of this thriving, money-spinning business that keeps money registers clanging. According to the World Health Organization, 80 million couples worldwide are infertile, with 15% of them in India. On a conservative basis, the market for infertility treatment could be plugged at over Rs 25,000 crores per year. With a success rate of less than 30% for the ART procedures, the whole exercise can be both expensive and emotionally draining, given the societal pressures.

The first ART baby was born in July 1978, by a combination of *in vitro* fertilization (IVF) and embryo transfer (ET), an IVF-ET method. Simplified, this method involves mixing sperms and eggs in a dish in a laboratory and then transferring the embryo into an appropriately readied uterus of the lady. In the same year, the first Indian and the world's second successful baby was born due to IVF efforts of a team from Kolkata. In 1986, India's first test-tube baby, Harsha, was born through IVF procedure in Mumbai fol-

lowed close on heels by other successes from various parts of the country.

India needs to monitor IVF activities. The ICMR has, in its preface to the guidelines spoken of the 'repulsive tales' in the short history of IVF in the country. 'Eggs and embryos have been stolen from women and given to others or to researchers. Fertility drugs have been sold illegally and medical records have gone amiss. Women recruited as surrogate mothers have refused to part with the newborn baby. India has been known to play host to visiting foreign IVF infertility experts to carry out those procedures that have been banned in the home country of the visiting experts. Sale of eggs and embryos is subtly advertized over the Internet by some IVF clinics in India.'

In view of the above undesirable activities, the draft ART guidelines are of significant value. At this juncture, India has neither guidelines nor legislation for the ethical practice of ART. An expert committee set up for the purpose of drawing up guidelines had extensive consultations with a wide range of people. These draft guidelines are now accessible for people to read and comment on while providing their valuable suggestions, if any, on this important matter.

ART implies any technology that helps in obtaining a pregnant state by manipulating sperm and eggs outside the body, and the resultant embryo is then subsequently transferred into the uterus. Technologies such as artificial insemination (AI), IVF-ET and gamete intra-fallopian transfer (GIFT) are part of ART procedures. Such techniques offer no treatment for the condition of infertility, but instead provide a technical solution to the problem.

ART clinics have mushroomed all over India to cater to the growing demand. The draft ART guidelines describe the requirements of ART clinics in detail under three headings. These are as follows: (1) Minimum physical requirements of ART clinics; (2) Essential qualifications of the ART team; (3) ART procedures and their respective indications.

The standard criteria necessary for screening of patients and selecting a suitable procedure with information to be given for possible complications, are a salient feature of these guidelines. Clinics engaged in the following activities are to

be regulated by an Accreditation Authority.

- Any fertility treatment that involves the use of gametes which have been donated or collected, and *in vitro* processes;
- Any fertility treatment that involves use and creation of embryos outside the human body;
- Storage of gametes or embryos;
- Research on human embryos.

Public comment is invited on the following issues pertaining to 'Code of Practice' described in detail in the draft guidelines. Some points as given in the summary note issued to the press are as follows:

- The ART clinic must not be a party to any commercial element in donor programmes or in gestational surrogacy.
- No ART procedure shall be done without the consent of the spouse.
- Sex selection at any stage of embryos of any particular sex should not be permitted, except to avoid the risk of transmission of a genetic abnormality.
- Use of sperm donated by a relative or a known friend of either the wife or the husband should not be permitted. It will be the responsibility of the ART clinic to obtain sperm from appropriate banks.
- The committee has recommended to accept semen only from the Semen Bank and not from any individual. Hence it has also been recommended that the Semen Bank should be an independent organization. If set up by an ART clinic, it must operate as a separate identity.
- No relative or a person known to the couple may act as surrogate.
- Surrogacy by assisted conception should normally be considered only for patients for whom it would be physically or medically impossible/undesirable to carry a baby to term.
- The genetic (biological) parents must adopt a child born through surrogacy.
- After a specific consent, the embryos may be stored for five years and stored embryos may be used either for another couple or for research after taking the consent of the couple to whom the embryos belong.
- The sale or transfer of human embryos or any part thereof, or of gametes in