COMMENT

ICMR guidelines on Assisted Reproductive Technology: lacking in vision, wrapped in red tape

LAXMI MURTHY[1], VANI SUBRAMANIAN[1]

[1]Saheli Women's Resource Centre, Unit Above Shop 105-108, Defence Colony Flyover Market, New Delhi 110 024 INDIA e-mail: saheliwomen@hotmail.com

According to estimates of the WHO, 13-19 million couples in India are infertile. Infertility due to reproductive tract infections and genital tuberculosis is preventable and amenable to treatment, and an estimated 8 per cent of infertile couples opt for medical intervention involving the use of advanced Assisted Reproductive Technologies (ART). It is in this context that the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, by the Indian Council of Medical Research (ICMR) and the National Academy of Medical Sciences, India, 2005, are significant.

The world's second and India's first IVF baby, Kanupriya alias Durga, was born in Calcutta on October 3, 1978, about two months after the world's first IVF baby, Louise Brown. Since then, the field of assisted reproduction has developed rapidly. Newer techniques, modifications of existing ones, and new approaches characterise this specialisation. In this context, particular care needs to be taken to protect the rights of women subjects of research as well as the consumers of these techniques. Infertile women, given the social pressure to reproduce as well as their own intense desire to conceive, are particularly vulnerable to commercial interests and experimentation in the medical field, since desperation might lead them to consent to hazardous techniques in the hope of conceiving.

Addressing some concerns

The 2005 guidelines (1) do take on board some of the potential hazards of these new technologies, including:

Potential for misuse: The guidelines rightly address the possible misuse of ART, such as sale of embryos and stem cells [1.6.11.3], particularly in the context of the ban in several countries on research on embryos (including the US and Germany). Since ART clinics are the only source of embryonic stem cells, which have a possible potential for use in therapeutic situations, the guidelines caution that the stand taken by foreign governments on embryo research opens up the possibility of embryos from developing countries (that do not have appropriate national guidelines in this area) being commercially exploited and sold to foreign countries. Therefore, the guidelines recommend that sale or transfer of human embryos or gametes to any party outside the country must be prohibited. Within the country, such embryos or gametes could be made available to bona fide researchers, with both parties (the donor and the receiver) having no commercial transaction, interest, or intent.

Research in public interest: Similarly, the guidelines on research [3.2.9] make it mandatory for the accreditation authority to approve all research that involves embryos created in vitro, within the framework of whether the research is in public interest. However, "public interest" has not been defined.

National database: Taking note of the risks of ARTs for future generations and the societal gene pool, the guidelines propose the establishment of a National Database for Human Infertility in order to track the trends of transmitting abnormal genes that might otherwise have been rejected through natural selection in an infertile couple.

Redefining "legitimacy": The guidelines recommend going beyond the outdated Indian Evidence Act, 1872, that limits legitimacy of a child born to only within 280 days after dissolution of marriage (by death or divorce): "The law needs to take note of the scientific advancements since that time. Thus a child born to a woman artificially inseminated with the stored sperms of her deceased husband must be considered to be a legitimate child notwithstanding the existing law of presumptions under our Evidence Act. The law needs to move along with medical advancements and suitably amended so that it does not give rise to dilemma or unwarranted harsh situations."

However, in the main, as a document that should ideally lay down guiding principles for research and practice related to ARTs, the guidelines fall short.

Looking through a narrow lens

In 2002, Saheli had submitted detailed recommendations to the ICMR's Draft Guidelines for Assisted Reproduction. While some of these were incorporated in the final document, several areas of concern remain.

First, for the ART guidelines to stand on their own, there is a need to reiterate safeguards for research subjects. This is particularly necessary in the commercial context where the manufacturer in the guise of researchers themselves stands to gain from the results of the trials. It becomes incumbent upon neutral bodies to ensure that ethical guidelines are adhered to and also to bring to light any violations. For this, well-formulated guidelines drafted with foresight and long-term perspective are essential. The ICMR guidelines fail to articulate such a vision.

Reinforcing social prejudice: For instance, ethical guidelines

should not accept the social stigma attached to infertility as a norm. Societies have evolved social ways for childless couples to deal with infertility-with, for instance, adoption, foster-parenthood, etc. The guidelines should ideally encourage adoption and foster parenthood, and avoid loaded statements such as: "Infertility, though not life threatening, causes intense mental agony and trauma that can only be best described by infertile couples themselves" [in the 'Introduction']. It would have been more appropriate to stress the need for prevention of infertility as a public health measure, which is guaranteed to enhance the quality of life without ART.

Lack of flexibility: Scientific developments such as stem cell research have a direct impact on ART. The ethical dilemmas involved in the commercial transfer of embryonic material, stem cells, etc. are complex, and have yet to be played out in the arena of individual lives, the medical establishment, and the market. It is still too early to visualise all the knotty and delicate situations that could emerge. Ethical guidelines for ART need to be broad and flexible in order to accommodate these future scenarios, but stringent enough to prevent violation of individual rights. The guidelines leave the approval (as well as updating) of newer techniques entirely to the National Advisory Committee (NAC), without any guiding framework for the granting of such approval. While Chapter 9 lists the composition of the NAC, there is little detail about its functioning, mandate, and scope.

Technocratic approach: The guidelines have detailed descriptions of technical procedures and lists of indications for the same, as well as discussion on the diagnosis of infertility and complications associated with the procedures, all of which are redundant. The discussion on technical procedures is relevant only in so far as they pose foreseeable ethical dilemmas.

Informed consent not ensured: The crucial issue of informed consent is dealt with rather summarily and in vague terms: "More particularly, the clinic must make sure that patients are well informed about the treatment being offered to them, the reasons of suggesting a particular form of treatment, and alternative therapies available if any." Chapter 3, dealing with ethical and legal considerations, talks only about written consent [3.2.5], but fails to make informed consent mandatory. In fact, the nine sample consent forms in Chapter 4 seem designed more to insure the clinic and medical personnel from legal action, rather than to protect the rights of the individuals accessing ARTs. While conducting clinical trials or offering newer and experimental procedures, it should be ensured that the person is provided adequate and comprehensible information. Information about the potential risks and benefits should be provided verbally as well as in written form in simple, easily understandable language with minimum use of technical jargon. Written information should be provided in the regional language whenever necessary, even for newer, potentially complicated procedures.

In the chapter on research, the guidelines blithely state that ART offers a "unique situation" to study the biology of reproduction in human subjects without compromising ethical issues: "For example, it is perfectly legitimate and ethical to take tissue and body fluid samples from an infertile couple to study the cause of infertility. This is an area that has not been exploited in India. Another line of research that is extremely important is to study early embryonic development -- a subject that has remained in darkness for quite a long time." Any document of this kind is not expected to provide suggestions on what needs to be researched; it should restrict itself to the ethical issues involved.

Rigid notions of family: In what at first reading might appear to be a progressive move, the guidelines recommend that there be no bar to the use of ART by a single woman who wishes to have a child, and no ART clinic may refuse to offer its services to her. Interestingly, the entire section [3.16.4] has been deleted in the corrigendum. What pressures or re-thinking led to this last minute deletion?

In general, ARTs should be made available to any consenting adults who desire to have a child using these technological innovations. Neither the marital status of the persons (married, unmarried, single, divorced) nor their sexual orientation (heterosexual, homosexual or bisexual) should be used as a decision-making criterion. Changing social trends the world over should be kept in mind while setting up ethical guidelines, and accordingly the words "husband" and "wife" must be substituted by "male partner" and "female partner".

The guidelines state that the clinic and the couple shall have the right to have the fullest possible information from the semen bank about the donor, such as height, weight, skin colour, educational qualification, profession, and family background. This reinforces the regressive notion that intelligence is strictly associated with these criteria.

Conclusion

While the guidelines attempt to incorporate some issues related to social justice and gender inequality, they still fall short on many fronts. The ethical guidelines should go beyond technicalities and build effective safeguards so that the unequal power relationship between the providers and users of new technology is minimised. The guidelines should also keep in mind the unequal gender balance and ensure that the rights of women users of these technologies are not compromised in any manner.

The very title 'National guidelines for accreditation, supervision and regulation of ART clinics in India' makes it clear that the ICMR, the apex body in India for the formulation, coordination, and promotion of biomedical research, has limited itself to creating red tape on the running of clinics. It is critical to envision future trends and lay down an ethical framework for biomedical research, especially in the new frontier of human reproduction that could change the very face of humanity. This role, it seems, is not one that the ICMR is ready to play.

Reference

1. Indian Council of Medical Research, National Academy of Medical Sciences (India). National guidelines for accreditation, supervision and regulation of ART clinics in India. New Delhi: Ministry of health and family welfare, government of India; 2005.