Journal of Assisted Reproduction and Genetics, Vol. 20, No. 7, July 2003 (© 2003)

ART Regulations Around the World

Accreditation, Supervision, and Regulation of ART Clinics in India—A Distant Dream?

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Submitted March 4, 2003; accepted March 28, 2003

You cannot escape the responsibility of tomorrow by evading it today.

Abraham Lincoln

INTRODUCTION

The development of assisted reproductive technologies (ARTs) in India began with efforts to create "test tube babies" with in vitro fertilization in the 1980s. But rather than commit public funding to advance such research, the Indian government withheld the use of government funds for research on human embryos, largely as a byproduct of the debate over population control. Without government funding, research on human embryos was outside of government regulation and oversight, and continues to take place in private settings with private investment, beyond governmental rules and public scrutiny. In addition to the absence of government oversight, scrutiny from health insurance companies was also absent, since till last year the only insurers were government owned monolithic companies and they do not cover assisted reproductive technologies. Whatever we might think about health insurers, they perform the valuable function of determining the appropriate use of new and expensive technologies, by refusing to pay for services that do not meet certain standards. Since assisted reproduction is not usually covered, there is very limited third-party oversight. ARTs have slipped through the cracks in the oversight system that covers nearly every other area of clinical research and medical care. There is no good reason why assisted reproduction ought to be treated differently than other area of medicine, except for its unique history. Without insurance to pay for it, assisted reproduction became market-driven. New technology introduced by one clinic is quickly offered by others as a matter of survival. But unlike other areas of medicine, in which new therapies are developed after controlled research in humans, ARTs often are introduced directly from the lab as clinical services for patients. Data are collected as patients are treated with untested new approaches, creating the only area of medicine where patients come for treatment but in reality pay for the privilege of being research subjects. The irony is hard to ignore: The research protection policies applied elsewhere in medical research were driven by efforts to prevent exploitation of the vulnerable—yet patients confronting infertility are often the most vulnerable.There are a few straightforward ways to bring assisted reproduction into the fold. Research in assisted reproduction should receive the same sort of approval and oversight as government funded research. Such policies are long overdue. Bringing ARTs into the open will better serve patients and improve research oversight. In the process, it will go a long way toward convincing the public that this is a technology we can manage. Each society has approached the ethical and legislative aspects of IVF in its own particular way. This

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1058-0468/03/0700-0276/0

situation has now emerged in India, where increasing numbers of couples now utilize this approach to the alleviation of their infertility. As IVF expands worldwide, its ethical aspects enter into increasingly diverse societies. The demand for some sort of ethical control is also widened as new technologies are invented and applied, and as the number of IVF clinics continue their large-scale increase. At current count, there are 396 "IVF clinics" in India and mushrooming weekly! A foreign visitor recently described his visit to India thus: "In India anytime is tea-time, any place is a urinal, and everyone is a doctor." This is definitely an exaggeration, but we certainly produce "IVF doctors" in the most remote corners of the subcontinent! The subcontinent has unfortunately witnessed unregulated and unsupervised growth of ART centers often serviced by untrained or poorly trained staff. A National weekly newsmagazine did an undercover investigation of IVF clinics (many run by quacks) and got into the "Laboratories" of some shady IVF centers which were booming with sex-preselection advertisements in National newspapers—They photographed bare rooms with pigeons flying in and out through ventilator ducts! On a scientific basis, there is no University-based ART teaching program and there is an obvious lack of training even in well-equipped centers. Most practitioners of inferility treatment are self-taught. Embryology and its attendant subjects, including gametogenesis, genetics, reproductive endocrinology, and other such similar related subjects, is hardly taught as a distinct discipline in any of the Indian colleges nowdays. The new term, "Clinical Embryologist," has been coined to include all those biologists (zoologists, microbiologists, biochemists, veterinarians, etc.) who assist the gynecologist in processing semen, screening follicular aspirates for selecting oocytes, inseminating them in vitro or by intracytoplasmic injection of spermatozoa(ICSI) and handing over the developing embryo to the attendant gynecologist. In some instances the gynecologist doubles up as the embryologist for want of trained staff.

There are no guidelines as yet; Mr Prasada Rao, Secretary to the Government of India, Ministry of Health and Family Welfare, released *Draft Guidelines for the Accreditation, Regulation, and Supervision of Assisted Reproductive Technologies Clinics* in India on September 4, 2002 at a public function held in New Delhi in the presence of the Director General of the Indian Council of Medical Research (ICMR)and the President of the National Academy of Medical Sciences (NAMS) (1). The *Guidelines* were prepared on the basis of several consultations and public debates held during the past 2 years. Professor R. G. Edwards participated in one of the early meetings where the need for national guidelines was discussed in Bangalore on November 4, 2000. Much more remains to be done in India with its pluralistic society. A national common law, acceptable to people belonging to different cultural and religious backgrounds,is yet to be established despite the long debates; personal laws still govern most Indians. The legal profession will have to be pressed to develop legal guidelines for the practice of ART to suit every Indian. All said and done, the altruism of Indian politics is that Indians want their politicians and regulators to stay out of the bedroom, but there may be at least one good reason to legislate and regulate ARTs—it could prevent the issue from being turned over completely to the lawyers.

IS THERE REALLY ANY NEED FOR REGULATION OF ASSISTED REPRODUCTIVE TECHNOLOGIES IN INDIA?

There has been much debate in the Indian medical community in the last 10 years about whether there is any need for legislation in relation to the provision of ARTs. Undoubtedly, the law already has some influence in the way ART treatments are provided, to whom and on what terms. However, because of the relatively recent development of these technologies, the common law has had little opportunity to develop in this area. Accordingly, there is a great deal of uncertainty as to how the law may respond to disputes which arise in relation to ART, such as those involving the ownership and use of gametes and embryos.

ART has been developed by the medical and scientific community primarily as a treatment for infertility. Thus, it is generally provided and, to some degree regulated, in the same manner as other medical treatments. However, like some other areas of recent scientific and medical technology, it has been argued that ART is in some way qualitatively different from other medical treatments. Rather than simply alleviating the medical condition of an individual through treatment which has consequences only to that individual, ART alleviates infertility by allowing for the birth of another person.Thus, the interests of a third person (the child born as a result of the technology) are affected by the treatment. In some cases, ART is not used as a medical treatment for infertility at all, but as an alternative means of obtaining a pregnancy

for fertile persons who cannot, or do not wish to, for a variety of reasons, engage in coitus. The question arises as to whether ART is so qualitatively different from any other kind of medical practice that medical practitioners require a license from the State merely to carry out these treatments.

The benefits of licensing could be said to be as follows:

- It ensures that only persons who hold appropriate qualifications are able to gain a license and hence practice ART;
- It allows for the imposition of sanctions, such as the cancellation or suspension of a license, in cases of misconduct;
- It allows for the imposition of conditions upon the practice of ART(such as the keeping of records, the approval of research);
- It allows the Government to raise revenue for the purposes of regulating ART through the imposition of license fees.

How a society regulates ART depends on cultural context. The challenge for the regulatory regime is to balance protection for patients and society with freedom for medicoscientific creativity.Neither an exclusively market-regulated nor a peer- regulated approach is realistic politically, or desirable socially, ethically, and legally. Legitimate social issues that go beyond the exclusive expertise of doctors and scientists or market choice by patients need to be accommodated within the regulatory regime. Within this context, four key issues need to be thought of: the lack of a shared social ethic that helps the needs of the community to be balanced against those of its individual members; the negative impact of intrusive external regulation on scientists and doctors; the requirement for doctors and scientists to review their professional structures reflectively and critically if they are to be entrusted with peer-regulation; and the desirability of constructive dialogue between regulators and regulated rather than the use of coercion and criminal sanctions.

The *Guidelines* released by the Government of India address the following issues (2,3):

(i) Ensuring the ethical practice of assisted reproductive technology;
(ii) Maintain a national registry of all assisted reproductive technology clinics;
(iii) Accredit and license assisted reproductive technology clinics;
(iv) Supervise performance of assisted reproductive technology clinics regularly;
(v) Regulate functioning of assisted reproductive technology clinics and take punitive action against erring clinics;
(vi) Make assisted reproductive technology affordable to the economically weak;
(vii) Draw up guidelines for the use of spare embryos;
(viii) Support training and research in assisted reproductive technology.

After the "British-Raj"(Raj = dominion or rule) which existed for over a 100 years preindependence, India passed through a 50-year phase of the "license-Raj"which was passed on to us courtesy our socialist leaders and the USSR! What actually happens is the spawning of licensing for just about everything gives rise to a parallel economy sustained on bribes. The Prenatal Diagnostic Act(PNDT Act) made antenatal sex determinations a crime punishable with imprisonment and hefty fines. But, you could get away by paying a fraction of the amount to the certifying Inspector as a bribe. This is common knowledge in India that everything is run on greased palms. As responsible ART specialists, we are scared that with licensing, quacks might be able to buy licenses and even renew them. That scenario might be more dangerous than the present day unregulated ART practices.

But then, we are not extending or preserving life by using these medical technologies but we are creating life, and that creating some unique responsibilities to the child that is being created, and to the parents or the donors or the third party involved in bringing this child to life. There is a unique responsibility on the part of the physicians and scientists working in this area and even important considerations for society. Accreditaion, regulation, and supervision of assisted reproductive technology clinics is not unique to the Indian situation; other countries have already trodden this path. However, there are two main alternative approaches to the problem. Some countries have taken legislative steps, such as the Human Fertilization and Embryology Act in the United Kingdom (4). In other countries professional societies such as the American Society for Reproductive Medicine have drawn up guidelines that are followed to a great extent by assisted reproductive technology practitioners (5). The proposed ICMR guidelines have generated some interest among practitioners who express both support for efforts to improve safety and concern about the limitations such restrictions might introduce. While being in favor of guidelines that will protect patients, medical associations also have some concerns about

the new ICMR guidelines must not be so cumbersome or expensive that they inhibit research or increase the cost of treatment—an especially important consideration because these treatments are still not covered by insurance.

WHAT ARE THE LESSONS LEARNT FROM THE WEST?

Assisted reproductive technologies are rapidly changing the concepts of reproduction. Reproduction is no longer a matter of chance encounter between an egg and spermatozoa. An egg can now be forced to fertilize outside the body by ICSI, develop into an incipient embryo and lead to a pregnancy and a live birth following the transfer of the early embryo from the Petri dish into the mother's womb. It has been stressed by the Indian Council for Medical Research that clinics handling such important events in the procreation of our species need to be accredited, to be provided with guidelines and their work to be supervised by an independent body established by the State. Britain, the European Union and United States, among other developed countries of the World, have established mechanisms to achieve such goals (6). India, like most of the developing countries, still lacks these essential services. Nevertheless, there is growing awareness for such needs and steps are being taken to achieve such objectives. For example, the National Board of Examinations, Ministry of Health and Family Welfare, Government of India has taken steps to offer postgraduate degrees in Reproductive Medicine. The National Academy of Medical Science has initiated a discussion on what needs to be done to draw up guidelines for the ethical practice of medically assisted reproductive techniques and to offer suggestions for establishing a national Accreditation and Supervisory Body for Infertility Clinics.

Fertility treatment in the United Kingdom takes place within a strict regulatory framework outlined by the HFEA that represents the outcome of legislative decisions aimed at protecting the interests of both patients and the public, while maximizing the acceptable reproductive options available to them (7). The constitution of the HFEA—its multidisciplinary membership, internal committee structure, and the function of its officers—is characterized as a mechanism that ensures that relevant perspectives inform its decision-making while guarding against the charge of partiality. Through the Code of Practice it produces and the licensing system it operators, the HFEA both protects and supports good clinical decision-making within the ART community (7).

Regulatory guidelines in place at the local, state, and national levels affect medical practices in reproductive medicine and assisted reproductive technology in the United States. These guidelines are in addition to many standards and practices currently in use and endorsed by individual hospitals and organizations such as the American Society for Reproductive Medicine (ASRM)and the Society for Assisted Reproductive Technology(SART) (8).

While regulatory compliance in assisted reproduction is generally quite good in the United States, it appears that Americans are now entering an era of even more intense regulatory control of IVF-related procedures (8). Newly mandated federal oversight is likely to create a significant and long-term impact on all areas involving the practice of reproductive medicine. Most U.S.-based assisted reproduction practice, even those accustomed to setting their own standards with minimal governmental involvement, should be preparing for greater oversight and requirements for additional licensing. It is as yet unclear how these new regulations will affect day-to-day operations, but it seems likely that personnel at all levels of the IVF practice will need to be familiar with and incorporate these changes into their practices and protocols.

The U.S. Food and Drug Administration (FDA) has published proposed regulations related to reproductive tissue since 1998. The original recommendations, called "Good Tissue Practices," were developed in an effort to standardize assisted reproduction procedures related to handling spermatozoa, oocytes, and preembryos (8). Newer regulations were entered into the Federal Register in January 2001, and are scheduled to come into effect nationally by 2003 (8). All facilities that handle spermatozoa, oocytes, or preembryos will be required to register with the FDA and will be audited to ascertain compliance. A list of registered centers will be published on the FDA web site and available for reference and use by the general public.

According to the FDA, these new regulations have been introduced in an effort to guarantee a minimum standardized level of treatment for all patients receiving assisted reproduction treatment where the use of donor spermatozoa, oocytes, or preembryos is involved. One major goal of the new regualations according to the FDA is to reduce the risk of transmission of infection or disease that can be associated with the use of human tissue in assisted reproduction

treatment. Many of the new regulations may not have as great an impact on assisted reproduction centers that are currently registered as tissue banks because these new national regulations closely resemble guidelines already in place in New York State and Florida. The FDA regulations will primarily focus on procedures surrounding the recovery, screening, processing, storage, and distribution of reproductive tissues. All programs processing or cryopreserving donated spermatozoa or oocytes will fall under these new national regulations. Currently, assisted reproduction centers licensed as state tissue banks are audited on everything from the calibration of instruments, record-keeping, and the required charting in both the clinical and laboratory setting, to the type and frequency of screening for donors. Now the FDA will add its oversight in these areas.

As these regulations have been developed and refined, it is interesting to note that there has been little national debate or protracted involvement from a large contingent of the assisted reproduction technology community. When the FDA first asked for comment on regulations back in 1997, there was flurry of correspondence from reproductive endocrinologists across the country. However, since the proposed rules were printed in January 2001, there has not been significant additional input from practitioners in the field. I think, the Indian ART fraternity is behaving predictably similarly—when the ART draft guidelines were first proposed, there was a sea of opposition which has now ebbed almost completely. The few points in the draft guidelines that are being opposed tooth and nail by the ART fraternity in India are (i) Disclosure of sperm donor's identity to children conceived from donor insemination once they are adults. (ii) Banning of egg donors from family and friends while encouraging commercial egg donation. Indian society is relatively more conservative and third party reproduction is a taboo subject; cutting across all strata of society. Most of the donor egg IVF done today in India is with the help of family or friends or egg-sharers and we would not like to have the North American commercialization to creep into traditional Indian society which would result in ART becoming even more expensive and out of reach of even the 10% populace in India that can afford it today.

CONCLUSION

The doctor–patient relationship has changed dramatically over the years. The recent advances in reproduction and genetics in particular have reshaped this important relationship. Arguably, the move from medicine as an art to medicine as a science has colored expectations, raising hope on the one hand and promising despair on the other. In addition, it has raised enormous and weighty ethical problems, which also pose challenges for the law. Many of the dilemmas confronting law and ethics are matters of human rights rather than clinical judgment (9). This requires an informed and thoughtful response, not just from the scientists and clinicians who control the techniques and technologies but also from society and the law. Only when the necessary debate has occurred can we harness medicine appropriately, so as to minimize any potential for harm while at the same time reaping the undoubted benefits on offer (10,11).

Society has always seemed to demand a little more from human beings than it will get in practice.

George Orwell, A collection of Essays

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