Marketing Assisted Reproductive Technologies: A Global Growth Industry

Tarrytown Meetings, July 28, 2010 Reproductive and genetic tourism working session

Shree Mulay, Associate Dean and professor, Community Health and Humanities Division, Memorial University, St. John's Newfoundland

Phenomenal growth of medical tourism

- Although medical tourism began as early as the 1980's it is only since 2000 the private sector involved in health care delivery has launched a multi-pronged approach to woo the medical tourism trade;
- In India, Confederation of Indian Industry (CII) and McKinsey studies claim current growth of 30% per annum will be sustained to yield up to 1-2 billion USD to the private hospitals.

Factors responsible for this growth in India

- As wait times increased for medical services in the west, Non-resident Indians (NRIs) sought treatment in India and claimed money from the NHS in England, who in turn offered it to other patients because of low costs;
- Big hospital conglomerates are wooing the European and American Market, whereas the smaller hospitals are targeting neighboring countries like Bangladesh, Sri Lanka and Pakistan.
- Joint ventures with foreign partners like Insurance companies is important; 51% ownership is permitted as an incentive for investing in private hospital infrastructure. International accreditation is being sought to allay fears about quality of care.

Cross border reproductive services

- Assisted human reproductive services differ from other medical services provided to overseas patients because the patients are healthy but unable to have a biologically related child or a child of a desired sex;
- The prime driver for the services is that procedures which would not be permitted in the home country can be obtained in another country that either have no regulations or the providers flaunt them without impunity;
- Many moral, legal and ethical dilemmas have arisen as the numbers of children born with the aid of ART have increased dramatically e.g. in 2000 about 200,000 children were born in 49 countries through IVF. By now these number must have doubled.

Types of services offered

People assume only IVF services are offered, this is not so;

- A large number of clinics advertise a full range of ART services; these include :

  - artificial insemination (AI),

  - in vitro fertilization (IVF),

  - intra cytoplasmic sperm insertion (ICSI),

  - laser assisted hatching (LAH),

  - semen banking,

  - embryo cryopreservation,

  - cumulus aided transfer (CAT), - diagnostic laboratory services to monitor the infertility work-up and monitoring of IVF cycles.

  Some also offer chromosome analysis and fluorescence *in situ* hybridization (FISH) and polymerase chain reaction (PCR) for Prenatal, Postnatal and Pre-implantation Genetic Diagnosis (PGD). **However, most clinics appear to focus on IVF and ICSI and vaginal or uterine insemination.**

Sex-selection

- Although not always explicit in their advertising, some clinics offer sex-selection of embryos in several countries including India and Ukraine to provide what they euphemistically say is for family balancing purposes;
- According to MNBC report in 2006 over 42% of the clinics in USA offered sex selection either through PGD or micro-sorting of sperms.

Surrogacy

- Surrogacy services are advertised by some clinics, Surrogacy arrangements, commercial or altruistic, were made quite early on in the history of IVF.
- In natural surrogacy, the **surrogate mother** provides the egg and the sperm is provided by the putative father.
- In full surrogacy, the **egg and the sperm is provided by the couple** commissioning the child. Surrogacy is advertised on websites, especially in those countries that do not prohibit commercial surrogacy arrangements;
- Few countries, notably, India, Ukraine and Russia, permit commercial surrogacy; they have no specific legislation regulating surrogacy at this time;

Surrogacy……

- Altruistic surrogacy is permitted in many countries as in Canada but not in Israel where close relatives cannot become surrogates.
- In some countries surrogacy is banned altogether as in Germany.
- While surrogacy may provide the only possibility for some people to become genetic parents, as is the case with gay men, it is fraught with legal and ethical problems because parents commissioning the surrogacy may refuse to take delivery of an infant or the surrogate mother may refuse to give up custody of the infant or the country may refuse to recognize the citizenship of the child.

Added Value?

Test-tube baby website

"We can transfer more embryos in difficult patients (unlike clinics in UK and Australia, where the number of embryos which can be transferred is limited by law).

While transferring more embryos does increase the risk of high-order multiple pregnancies, this risk is negligible in difficult patients (for example, the older women or women with previous failed IVF cycles).

In our clinic, we customize the number of embryos we transfer for each patient we treat, rather than just blindly following a guideline (which has been laid down for the general population, without considering each individual's specific problem)."

Adverse Effects of CBRS

- The range of adverse effects associated with ART are similar whether ART services are availed of in the home country or a foreign country but their consequences for the couple and the infant may be very different depending on where the procedure is carried out,
- it may pose a significant burden on the domestic healthcare system.
- Most adverse effects of ART relate to multiple births and the ensuing high risk pregnancy and prematurity of the neonate. Prematurity is associated developmental problems such as retinopathy of prematurity, cerebral palsy or higher incidence of birth defects.
- Increasingly ICSI is being offered by a large number of clinics both at home and abroad to treat male factor infertility. However, several studies show that incidence of birth defects is higher and infertility is transmitted to the male progeny.

Adverse effects….

- Users of CBRS may encounter problems that relate directly or indirectly to inadequate or no regulations concerning ART in the country where services are offered.
- These include but are not limited to the large number of embryos transferred in a given cycle under the misconception that the more embryos implanted, better the chances of pregnancy without any concern for the consequences of multiple births.
- Evidence-based guidelines for good clinical practice in the international arena are urgently needed not only with respect to assisted human reproduction but for all procedures currently offered by the medical tourist industry world wide.

Adverse effects……

- Medical emergencies overseas, such as the hyper-stimulation of the ovaries during fertility treatment;
- Financial problems because of unexpected costs related to numerous unsuccessful treatment cycles. In this context, one must take into account success rates of IVF with live births. Some clinics select the patient pool to "improve" their success rates.
- While others do not provide an accurate picture of their success rates because they use **chemical pregnancy** statistics in their ads in which HCG levels had been detected and not a live birth.
- Finally, the emotional and physical stress experienced by a woman undergoing fertility treatment would likely be exacerbated in foreign and unfamiliar surroundings and may impact on the success of such treatments. Thus the average number of cycles per pregnancy may be greater for people using IVF services in a foreign country. The blogs on websites provide an insight into the suffering experienced by women undergoing fertility treatment.

Cost to the Domestic Healthcare system when people use CBRS

- Even when IVF treatments are done in net exporter of CBRS country, pregnancy and child birth occurs in home country, therefore multiple births involve care for high risk pregnancy.
- In most instances the couple using CBRS return home after a successful implantation and establishment of the pregnancy for prenatal care and delivery in their home country. Thus any complications related to the IVF pregnancy become the responsibility of the domestic healthcare system.
- Multiple pregnancy costs are similar whether IVF was performed in the home country or a foreign country. However, most countries of Europe and North America limit embryo implantation to one or two embryos to avoid the morbidity and mortality of multiple pregnancies.

Cost to Domestic Healthcare ……

- Premature infants have to be kept in a neo-natal intensive care units for a long time; these facilities are already stretched to the limit making adequate care very difficult.
- In countries with a state-financed health insurance program, the costs are borne by the publicly-funded healthcare system.
- If there is no publicly funded healthcare or a comprehensive private insurance, the cost of taking care of several infants in the NICU can be financially crippling to the couple.
- When couples return home after IVF treatment, they may not have complete information on the treatments; this will likely impact on the domestic healthcare system because they will need more prenatal care.
- The psycho social impact of treatment failure and medical costs are difficult to estimate but it need to be considered.

Recommendations

1. The widespread marketing of very costly reproductive technologies, the burning desire to be birth parents drives couples to take risks which they would hesitate to take in other matters. However, "caveat emptor" - buyer beware underscores the need for reliable information about services overseas; the information needs to be independent, transparent, accessible and authoritative;
2. Consumer protection laws for CBRS and other health-related services are needed at the international level. In this context, international agreements on CBRS are needed and an overhaul of General Agreement on Trade in Services (GATS) are worth exploring;

Recommendations….

3. A matter of considerable concern is the trafficking in oocytes and embryos for IVF and research purposes. An international legal framework is needed to regulate and ensure that women are not exploited as a source of oocytes and embryos.
4. Some countries have moved forward on storage and disposal of frozen of embryos and the circumstances under which they may be used for stem-cell research but a large majority of countries - the net exporters of CBRS - do not have clear guidelines on these matters. These need to be addressed internationally.

Recommendations ....

5. Since the reproductive services are offered across national borders, it is not sufficient to have strong national regulatory framework but there is a need to harmonize and regulate the trade in CBRS both for the protection of the users of the services and to ensure that the domestic healthcare system is not over-stretched as a result of use of CBRS. Particular attention needs to be paid to surrogate motherhood because the possibilities of exploitation
6. A concerted effort is needed to reduce secondary infertility. This requires public health measures and implementation of sexual and reproductive health policies.

In conclusion

Participation by civil society in determining the research agenda and setting priorities is the only way to ensure a rational health policy that balances the needs for primary and secondary health care with that of tertiary health care. It is equally important that countries like India and China, which have a critical mass of scientists and there is an infrastructure for research, people develop a research program that addresses diseases of the poor. They must not let multinational corporations set the agenda. They must develop their own indigenous technology and put biotechnology to use, if and when they are needed, for the benefit of their own people.

Thank you