

## Are we exploiting the infertile couple?

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Here's a recipe to promote an IVF clinic: Buy a new piece of equipment, use it and then claim to achieve "the first pregnancy in South Asia" using this equipment. Nine months later, claim another 'first' when the baby is born - to get your name in the newspaper twice for the same procedure.

We are now seeing medicine by press release. Since doctors are not allowed to advertise in Maharashtra, they use ingenious alternative methods to market themselves and attract patients. Since most reporters are not scientifically trained or capable of critically analysing claims, they usually report verbatim whatever the doctor chooses to tell them. Once published in a "prestigious" newspaper, the report becomes gospel truth for most patients.

Some years ago, a Bombay clinic which reported the "first IVF-GIFT baby" made media headlines and won many patients, though this combination had no scientific rationale and was soon abandoned. More recently, the same clinic was one of two competing outfits which installed laser units at the same time - with both claiming a consequent pregnancy shortly afterward. When one baby "won the race" (it was born prematurely), the second clinic claimed to have produced the first baby by "combining laser-assisted hatching with blastocyst transfer".

An analysis of the medical literature shows that while assisted hatching may be helpful for older patients, it should not be offered indiscriminately to all patients undergoing IVF. One study found that it did not improve pregnancy rates in patients after IVF or ICSI (1)

Blastocyst transfer, now routine in many Indian IVF clinics, has helped in improving pregnancy rates in selected patients, usually young patients who grow a lot of eggs (2). However, the combination of assisted hatching and blastocyst transfer has no rationale, and

seems to have been devised primarily to help the doctor to claim a "first" using a "new" technique.

Claims of a technique's efficacy should be backed by scientific studies, the gold standard being the randomised controlled trial. Such a trial found no benefit to assisted hatching, even in older women (3). The Human Fertilisation and Embryology Authority in the UK has not approved the use of the laser for assisted hatching in the UK; it is untested technology of no proven benefit.

### A sacred trust, not tall claims

Infertility specialists would be happy to adopt techniques which give patients a better chance of giving birth to a baby. However, responsible doctors must not make tall claims which give patients unrealistic expectations.

Major developments in the assisted reproductive technologies (ARTs) have dramatically changed the possibilities for couples trying to have children. These advances were possible only because of the determination of desperate infertile couples.

The need to have a baby is an internal drive, and infertile patients are emotionally vulnerable and highly motivated. This provides a ground ripe for unethical practices. Patients are easily carried away by promises of "the latest technology". Many infertility doctors are disturbed by the influence of business on what they see as a sacred trust between physicians and patients.

In the US, the infertility industry generates an estimated \$2 billion annually (4). Pharmaceutical companies are investing millions of dollars in fertility-related drugs. Clinic management corporations traded on Wall Street are in the business of making a profit for investors on infertility treatment. Brokers charge fees to help couples find egg donors and surrogate mothers. Since IVF took off in the mid-1980s, there are now some 330 clinics in the US offering the procedure.

Given the stigma attached to infertility in India, and the premium

placed on childbearing to propagate the family name, the baby-making business is booming for doctors here. Since the government does not provide specialised infertility treatment, private practitioners can charge they want.

Many of the IVF clinics competing with each other in towns all over the country are poorly equipped, and the staff inadequately trained, resulting in poor pregnancy rates. Clinics start and close down in a few months, without achieving a single pregnancy — dashing many patients' hopes in the process. Given the levels of poverty and illiteracy, and the absence of a central registry for such clinics, malpractices unique to IVF clinics in India occur, but are not widely publicised.

### Inappropriate uses of reproductive technology

Technology is overused, sometimes used inappropriately, and misused by unqualified doctors. A two-day workshop on lasers or endoscopic equipment does not make a doctor competent; a number of mishaps have been reported because of operator inexperience. Such malpractices are almost inevitable, as hospitals become profit-oriented, and doctors must show their managements that they are bringing in money. The expensive micromanipulator must be 'utilised' to make it 'cost-effective'. Besides, the glamour of the latest medical gizmos can lure doctors as much as the latest model car does. Finally, the medical equipment and pharmaceutical industries spend lots of money inducing doctors to prescribe and use their newest products.

### The pregnancy rate game

Most IVF patients want to know about the clinic's pregnancy rate, though pregnancy depends on so many variables that average numbers mean little. Nevertheless, many clinics mislead patients with inflated rates. In the absence of a central registry monitoring IVF clinics, patients must believe what the doctor tells them.

To most couples, success is a baby —

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the live birth rate, or “take-home baby” rate — not a pregnancy. Some clinics quote their pregnancy rates which are considerably higher than the live birth rate, misleading patients about their chances of getting pregnant, let alone giving birth. The chances of achieving a pregnancy through IVF hover around one in three (5) but some women miscarry: The chances of actually having a baby are more like one in four (6) - but many doctors will still claim impossible pregnancy rates of over 50 per cent per cycle.

Some programmes define pregnancy when the pregnancy test is positive; others define pregnancy as a foetus seen on ultrasound. They may inflate their pregnancy rates by including “biochemical pregnancies” (pregnancies confirmed by blood and urine tests but in which the embryo does not develop beyond the earliest stage) which are fairly common after IVF.

Other ways of juggling with pregnancy rates include: accepting only patients who have a good chance of getting pregnant, or selectively reporting pregnancy rates achieved in younger women (and excluding other patients from data analysis).

### The dangers of overtreatment and undertreatment

Infertile couples also face the risk of overtreatment. Many clinics offer IVF to infertile couples as a treatment of first choice (rather than reserving it for patients who truly need it) — to keep their financial bottomlines healthy and increase their pregnancy rates. Paradoxically, rich patients may end up getting IVF unnecessarily, while poor patients who need it are deprived because of the expense involved.

Many doctors mislead patients by quoting low figures for IVF treatment, excluding “hidden” costs, such as ultrasound scans, injections or anaesthesia. Patients often end up spending much more than they had bargained for. Some doctors add new options after treatment begins — saying, for example that the patient needs ICSI because the sperm count is very poor. The couple is forced to agree to these mounting costs.

Programmes that do not offer a

complete range of services can put their patients at risk. Without embryo freezing, they may transfer too many embryos resulting in high pregnancy rates — and an increased risk of multiple births — which they count as a success.

These malpractices are not restricted to IVF clinics alone. Some gynaecologists are known to get their patients “pregnant” with an HCG injection which will produce a positive pregnancy test. The patient who believes she got pregnant and then miscarried is willing to try again and again. Others doctors will use donor sperm without the couple’s consent; and most will still not explain the risks of HIV transmission with fresh semen.

Many gynaecologists refuse to provide treatment records to their patients, to prevent them from going to another doctor. Patients who come to them on the rebound are forced to repeat all the tests: the previous doctor’s reports are not to be “trusted”. Most doctors will still not discuss all treatment options with their patients usually because they do not offer certain services. So, they may do tubal microsurgery which has poor results rather than refer their patients for IVF. Urologists ligate varicoceles for men with oligospermia, even though this does not help to improve their fertility, rather than advise them to explore IVF or ICSI. This often means that patients get fed up, and lose confidence in themselves and in doctors as well.

Many doctors are still reluctant to discuss the option of adoption, or of childfree living, even though these might be in the patient’s best interests. Many infertile patients would be quite happy to adopt a baby, or stop altogether, rather than go in for another treatment cycle, but they often need to hear this option from their doctor before they are comfortable in making such a difficult decision.

### Simplifying IVF

Few infertility specialists in India have made serious efforts to adapt IVF technology so as to bring costs within the reach of more infertile couples. Clinics could consider techniques such as intravaginal culture which does away with some of the expensive equipment and is as effective as

conventional IVF (7), and the “gentler”, natural cycle IVF which does without expensive gonadotropin injections for superovulation — it results in lower pregnancy rates but causes less stress as well. Variations of this second technique are becoming popular in the West as doctors worry about the effects of large amounts of hormones used in traditional IVF in order to produce many eggs.

At present, the government does not consider infertility treatment to be a part of comprehensive reproductive health services. One looks forward to a change in this area, providing more infertile couples access to assisted reproductive technology at affordable prices so that they will no longer be exploited by unscrupulous doctors.

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