



# IFS VISION

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Edited by: Dr Surveen Ghumman Sindhu

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## President's Message

Dear Friends,

This is the time of year when all roads lead to the mega event of our society that is Fertilvision-2013 which is approaching fast. This time, Fertilvision-2013 is unique in many ways. Most important is our society has crossed 1000 member mark & I am sure all members will be there on 6-8<sup>th</sup> Dec in Delhi. Scientific Program is having very high academic contents surpassing all previous events held till now in the country. We have introduced a 3 days certification course in Embryology 1<sup>st</sup> time in India covering whole syllabus of ESHRE Certification.

This will give much needed boost to improve overall scenario in embryology. Apart from this, 6 more workshops are there to choose from, depending on your areas of interest. Finally don't miss the gala evening banquet with Music, Dance & Humor filled program specially planned for you & it is coming free to all delegates. Last date for abstract submission is 15<sup>th</sup> Nov, so send in your research work & video & become eligible for various awards.

I appeal to all members to introduce & bring atleast one more colleague of yours for this great event of the year. So what you are waiting for, just send in your registrations & experience the difference. Be there in Delhi at Fertilvision-2013, 6<sup>th</sup> – 8<sup>th</sup> Dec. For more detailed Scientific Programme, events & registration log on to [www.fertilvision2013.com](http://www.fertilvision2013.com) or contact secretariat.

Looking forward to welcome you at Fertilvision-2013.

Dr Kuldeep Jain,  
President, IFS

## From the Desk of the Web Editors...



Dear Members,

This IFS Vision raises issues on single parents and same sex couples getting insurance coverage for ART and fertility preservation in cancer patients being covered in their treatment of cancer. We hope to get a response from our readers on their view points.

We congratulate our members on their International activities and achievements which are enlisted.

We look forward to your involvement in the annual conference.

Dr Mangala Telang

Dr Surveen Ghumman Sindhu



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### INDIAN FERTILITY SOCIETY

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READER'S PAGE

*Viewpoints on Legal, Ethical and Regulatory Issues*

Dear Readers,

The last issue discussed controversies on single parent surrogacy and whether background criminal check was required for foreigners availing ART considering the recent case of a pedophilic availing surrogacy.

This issue asks the experts the following questions

**Question:** Should egg sharing be allowed or is it exploitation?

**Question:** ICMR has given guidelines that when 7 eggs are available for each, sharing should be allowed. However, it is not just the quantity of eggs which decides the outcome but also the quality. Does it mean that it is ICSI for all in egg sharing to omit GV and MI oocytes from the count of 7?

**Question:** Do stringent ART laws give fuel to desperate and wrong measures and should ART laws be more compassionate?

*Opinion of the Experts On These Issues....*



*Dr Sudha Prasad  
Joint Secretary, IFS*

**Question:** Should egg sharing be allowed or is it exploitation?

**Question:** ICMR has given guidelines that when 7 eggs are available for each, sharing should be allowed. However, it is not just the quantity of eggs which decides the outcome but also the quality. Does it mean that it is ICSI for all in egg sharing to omit GV and MI oocytes from the count of 7?

I really feel egg sharing should not be done. The couple who has exhausted a good portion of their income and the female partner who has gone through multiple injections and monitoring should get the advantage of all her eggs. This is because each oocyte may not be mature and hence, may not fertilize. Once oocyte banks are available this system is not required.

**Do stringent ART laws give fuel to desperate and wrong measures and should ART laws be more compassionate?**

Stringent laws are required with certain issues. For example, I am not in favor of surrogacy for international couples. We submit our female population, who are not affluent, at risk to our high maternal mortality rate. Here, regulations must be stringent. WHO, UNICEF, UNFPA and The World Bank : Analysis and interpretation of the 2010 estimates that:- Developing countries account for 99% (284 000) of the global maternal deaths. The majority of which are in sub-Saharan Africa (162 000) and Southern Asia (83 000). These two regions accounted for 85% of global burden, with sub-Saharan Africa alone accounting for 56%. The MMR in developing regions (240) was 15 times higher than in developed regions.



*Col Pankaj Talwar VSM  
Executive member, IFS*

**Question:** Should egg sharing be allowed or is it exploitation?

The assisted reproductive technologies (regulation) Bill – 2010, chapter – IV, ,Para 20, sub Para (5) state that Assisted reproductive technology clinics shall obtain donor gametes from ART banks that have ensured that the donor has been medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child. This implies that ART banks will have repository of the donated eggs which can be further sold /distributed to the ART clinics like it is being done for the frozen semen. Fresh gametes from the donors would not be used by the clinicians as per the law after the egg banks are established in the country. Sub Para (16) further state that only a registered ART bank (and no other organization) shall be authorized to advertise for, procure or provide semen, oocyte donor or surrogate mother. Sub Para (3) also states that When an ART bank receives a request from an assisted reproductive technology clinic for a donor oocyte, a responsible member of the staff of the ART bank will accompany the particular donor to the assisted reproductive technology clinic, and obtain a written agreement from the authority designated for this purpose by the clinic, that the clinic shall, under no circumstances (except when asked by a court of law), reveal the identity of the donor to the recipient couple or individual or to anyone else; the clinic shall also ensure that all its staff is made aware of the fact that any step leading to disclosure of the identify (i.e., name and address) to the recipient couple or individual or to anyone else, shall amount to an offence punishable under this Act. This implies that ART banks may send the donors to the ART centre for egg retrieval when requested by them. Further referring to chapter – V, Para 26 subpara (6) An ART bank may advertise for gamete donors and surrogates, who may be compensated financially by the bank. **With this background we understand that legally the ART clinics have no right to enter into any agreement with the donors unknown or IVF stimulated patients directly. Thus the question of the IVF discount does not arise at all in the IVF clinics.**

Such issues occur in Europe due to non-availability of complete ART treatment through NHS thus forcing few IVF cases from poor strata to donate illegally their oocytes to recipients to save few thousand pounds. To finance this treatment, many couples are using up their savings or are getting into debt through family or bank loans or even re-mortgaging or selling their homes. Such a scenario is very common in Indian setup for the financial lure wherein all the three parties-namely IVF stimulated cases (donors), recipients and the clinicians benefit financially. In a poor country like our with no legal documents in place this is a win- win situation for all. Moreover such illegal IVF cycles are carried out without proper counseling of the couples. Here the main loser is the Donor who may require further stimulation if such cycle fails and does not realize that she may have to be stimulated again putting her at financial disadvantage in future. Patients from upper socio economic strata freeze spare oocytes and embryos for future use. Thus keeping the legal and medical aspects as recommended by the ICMR in mind I feel that such egg sharing cycles are illegal should not be carried out and are a form of exploitation of poor patients who are lured into this to save money. The government should cover ART treatment under the insurance thus discouraging such unethical practices.

**Question: ICMR has given guidelines that when 7 eggs are available for each, sharing should be allowed. However, it is not just the quantity of eggs which decides the outcome but also the quality. Does it mean that it is ICSI for all in egg sharing to omit GV and MI oocytes from the count of 7?**

As we can foresee ,in the future we would be having registered ART egg banks functioning independently as per the ethical clauses applicable to the society and dictated by law. Only denuded, metaphase 2 oocytes would be frozen/vitrified, banked and latter distributed to ART clinics. ICSI is mandatory for frozen thaw oocyte cycles. In case fresh oocyte donation cycles are carried out, the maturity of the oocyte may be checked by the morphological scoring of the OCC but I still feel that due to limited number of oocytes available to the clinics ICSI should be performed.

Since the IVM is more of a research issue presently and wont be clinically applicable to or setups before next 10 years ,GV and MI oocytes are to be rightfully discarded .

**Question: Do stringent ART laws give fuel to desperate and wrong measures and should ART laws be more compassionate?**

In Canada, laws and policies consistently reject the commodification of human organs and tissues, and Canadian practice is consistent with international standards in this regard. Until the Assisted Human Reproduction (AHR) Act of 2004, gamete donation in Canada was an exception: Canadians could pay and be paid open market rates for gametes (sperm and egg) for use in in vitro fertilization (IVF). As sections of the AHR Act forbidding payment for gametes (Section 6) and permitting only reimbursement of receipted expenses (Section 12) gradually came into effect in 2005, Canada did away with this anomaly. Medical practice and legal prohibitions in assisted human reproduction are now consistent with other areas of medicine where tissues and organs are taken from one person to benefit others: Altruistic donation, rather than selling and buying, will be the norm. The prohibition of payments for gametes introduced with the AHR Act places medical donation for IVF on a par with all other organ and tissue donation for a wide range of medical conditions. Because of the previous anomaly, however, the change has interrupted expectations: Patients who were able to pay to secure egg donations prior to 2004 are no longer able to do so, and the supply of donor sperm also is expected to fall dramatically over a period of time. As per ICMR guidelines chapter – V, sourcing, storage, handling and record keeping for gametes, embryos and surrogates, Para 26, subpara (6) An ART bank may advertise for gamete donors and surrogates, who may be compensated financially by the bank. This is an ideal recommendation and I feel that the gamete donation should be permitted but monitored by legal bodies. This will ensure regular availability of gametes for the needy and bring end to unscrupulous practices bringing smile in life of large number of patients.

## RECENT RESEARCH

### *Gene microsurgery – A scope to edit human DNA in IVF for genetic defects*

A molecular technique that enables any part of the human genome to be altered with extreme precision has been hailed by scientists as a breakthrough in genetics at the University of Massachusetts Medical School. It is the first time researchers have been able to engineer any part of the genome without introducing mutations. Crispr uses an RNA guide molecule that can be programmed to match any unique DNA sequence. This guide is attached to a special enzyme that finds the target sequence of DNA and cuts both DNA strands in the double helix. This then allows copied DNA to be inserted into the genome and defective DNA to be deleted. Previous gene therapy techniques have made use of less accurate methods that often require the use of a modified virus that inserts DNA at random in the genome, leading to safety concerns. Crispr may soon be used in human gene therapy trials to treat incurable viruses such as HIV or untreatable genetic disorders such as Huntington's disease. This could also be used to potentially correct gene defects in human embryos in IVF. Safety of this genetic microsurgery is yet to be assessed.

### *IVA Breakthrough - An alternative to donor oocytes ?*

In Vitro Activation (IVA), whereby scientists take an ovary or a piece of ovarian tissue and treat it with drugs to stimulate the ovaries, which is grafted back into the ovaries. Proteins and other factors which help the immature follicles to produce mature oocytes are used to treat it. IVA addresses two cell signalling pathways discovered in mouse ovaries, one that prevents follicle maturation and one that promotes it. In the small study of 27 volunteers, which was published by researchers at Stanford University, five women were able to produce viable eggs. One is pregnant, one has given birth to a healthy baby and two women are waiting for an embryo transfer. This would evolve as an option for women with premature ovarian failure who do not want to use donor oocytes. A 30 year-old Japanese woman, is the first in the world to give birth through IVA.

### *Research Reveals New Measure to Predict Embryo Implantation Potential*

Using a technique known as Real-Time Polymerase Chain Reaction, the team from the University of Oxford and Reprogenetics measured the amount of mitochondrial DNA in embryos at the final stage of development prior to implantation (the blastocyst). Results revealed increased levels of mitochondrial DNA in the cells of embryos generated by women of advanced reproductive age (older than 38), as well as in embryos which were chromosomally abnormal. The scientists undertaking the research offered the theory that high levels of mitochondrial DNA could be indicative of embryos under stress, and therefore unlikely to successfully implant. Moreover they found that blastocysts with excessive quantities of mitochondrial DNA were incapable of establishing a viable pregnancy, even if they had been shown to be chromosomally normal. This finding may help to explain why a significant number of chromosomally normal embryos fail to establish a viable pregnancy. Additionally, it could potentially lead to improvements in IVF by helping to reveal which of the embryos is most likely to produce a baby.

### *Sperm test for infertile men may reduce need for surgery*

The study, led by a team from Toronto's Mount Sinai Hospital identifies two proteins ECM1 and TEX101 in semen that can be used as biological markers to predict the likelihood of finding sperm through surgical investigation. Currently, testicular biopsy is the only diagnostic method to determine the specific cause of the infertility. The researchers were able to distinguish obstructive from non-obstructive infertility and predict whether men with zero sperm counts might have testicular sperm thus helping to take better decisions avoiding unnecessary surgery

### *Is the Y chromosome no longer needed? – Only 2 genes required*

Male mice are able to reproduce healthy offspring with only two Y-chromosome genes, researchers at the University of Hawaii have discovered. They produced transgenic mice that only had the Sry gene, critical in testes development, and the Eif2s3y gene, which is involved in the initial stages of sperm production, on their Y chromosomes. These infertile mice then underwent an advanced form of IVF, called spermatid injection, where immature sperm cells are injected directly into the egg. They fathered pups that went on to have a normal lifespan and were capable of producing a second generation on their own without further assistance. Most of the mouse Y-chromosome genes are necessary for normal fertilisation. However, when it comes to assisted reproduction, the mouse study proves that the Y-chromosome contribution can be brought to a bare minimum.

LEGAL & ETHICAL ISSUES IN ART

### *Multiple birth quotas enforcement on IVF Clinics unjustified – HFEA loses legal battle*

In 2011, as part of an effort to reinforce the policy to reduce multiple births, the HFEA made it a condition of a fertility clinic's treatment and storage licence not to exceed the multiple birth rate target – currently set at ten percent. The UK's High Court has ruled against the Human Fertilisation and Embryology Authority saying its actions towards two clinics over a licence condition to impose a maximum multiple birth rate were unlawful. The HFEA has now decided to withdraw the condition from all UK fertility clinics' licences. The decision on the number of embryos to be transferred to the patient should be a medical one, taking into account the patient's age, medical history and chances of conceiving. If the clinics had reached the multiple birth quota midway through the year, they would then be forced to offer all remaining patients only one embryo if they wished to comply with the condition. This may have an adverse impact on pregnancy rates and interferes with clinical judgement. It was stated that this license condition does not reflect the complexity of the scientific data, the professional debate, the financial considerations, the legal implications nor the voice of the patients.

**Question:** To what extent should a regulatory body be allowed to interfere with clinical decisions of an ART clinic?

**Question:** How can multiple births in an ART clinic be regulated

### *Bill allows gays insurance coverage on fertility treatment, denies it to cancer patients– Was the decision right?*

The 2013 California legislative year ended mid-September The Governor signed into law AB 460, a bill to protect infertility insurance coverage decisions from discrimination based on sexual orientation. Insurance coverage for infertility is based on a definition of infertility that requires the inability to conceive a pregnancy or carry a pregnancy to a live birth after a year or more of regular sexual relations without contraception. Failure to have an opposite sex partner renders this definition impractical, hence the need for legislation.

Unfortunately, the Governor vetoed AB 912, a bill mandating fertility preservation services for patients with cancer and other diseases. ASRM and its cosponsor Fertile Action, along with several cancer groups, worked diligently to educate state policymakers on the merits of the legislation and the low cost to insurers of fertility preservation coverage. A reference to this bill has been made in the previous issue of IFS Vision.

**Question:** Do same sex couples and single couples come under the definition of infertility and is insurance coverage justified for ART in these situations?

**Question:** Should fertility preservation be insurance covered in treatment of cancer patients?

STATISTICS

### *IVF touches the Five million count*

Since the birth of Louise Brown in July 1978, five million babies have been born with the help of IVF and other assisted reproductive technologies (ART). At least one-third of these children were conceived in the last six years, according to a report compiled by the International Committee for the Monitoring of Assisted Reproductive Technology (ICMART). The number of children conceived using IVF, surrogacy and egg donation and freezing climbed from around 90,000 in the 1990s to an estimated 2.5 million in 2007. Since then, an additional 1.5 million births have resulted from ART. The figure was calculated using data on ART from 74 countries. However, the researchers had to account for missing years and make approximations for other countries who had not published any data. This includes China, where an estimated 900,000 babies have been born using assisted conception. The increase is thought to be based on a range of factors, including reduction in stigma, improvements in success rates, better access to technologies in developing countries, and improved reimbursement or insurance coverage.

### *IVF sex selection allowed in Western Australia to reduce autism risk*

Sex selection in IVF through application of preimplantation genetic diagnosis as a method of avoiding autism has been approved for the first time by health authorities in Western Australia. The use of this technique could be particularly relevant for families who have more than one boy with autism, since males are about four times more likely to have autism spectrum disorder (ASD). Western Australia's health authorities will consider applications on a case-by-case basis, looking at the specific circumstances such as the number of family members already affected by the disorder. In the UK, the Human Fertilisation and Embryology Act 1990 bans sex selection in IVF except for medical reasons, such as those related to sex-linked inherited disorders. According to The West Australian, the UK's HFEA is considering the possibility of including ASD under its list of conditions to allow clinics to test for using PGD.

### *Donor eggs gaining acceptability in USA*

More and more IVF patients are using donor eggs, according to a study carried out in the USA. The study also found that the percentage of single embryos used rose from less than one percent in 2000 to 14.5 percent in 2010. Professor Schlaff said that 'many patients are willing to take the risk of having twins to raise their chances of having at least one baby and to decrease costs'. The average age of women using donor eggs remained at 41 years old, for whom a decline in egg quality is reported as a reason for using donor eggs. The average age of egg donors was 28. Nevertheless, figures show that traditional IVF remains the most used method. For most people, the desire to have a child that is genetically from both parents is very strong.

## Conferences and Events

### *FERTIVISION 2013*

9<sup>th</sup> Annual Conference of Indian Fertility Society from 6<sup>th</sup> to 8<sup>th</sup> Dec 2013 at India Habitat centre, Delhi. Please log on to <http://www.fertivision2013.com/> for details

#### *National*

1. Fertilvision 2013, Annual Conference of Indian Fertility Society to be held on 6<sup>th</sup> 7<sup>th</sup> 8<sup>th</sup> December 2013 at India Habitat Centre, New Delhi
2. 57<sup>th</sup> All India Congress of Obstetrics and Gynecology at Patna 1-5<sup>th</sup> February 2013
3. 19<sup>th</sup> National Conference of Indian Society of Assisted Reproduction (ISAR) to be held from 14<sup>th</sup> to 16<sup>th</sup> Feb 2014 at Gujrat University Convention and Exhibition Centre, Ahmedabad

#### *International*

1. 5<sup>th</sup> conference on asia pacific initiative on reproduction at Brisbane, Australia on 4-6<sup>th</sup> April 2014
2. ESHRE 2014 at Munich Germany 29<sup>th</sup> June – 2<sup>nd</sup> July 2014.

*IFS Congratulates Dr Bindhu Mehta*



**Dr. Bindu Mehta wins International Research Award**

Dr. Bindu Mehta, Clinical Embryologist and IVF Scientist at Vaunshdhara Clinic and Assisted Conception Centre was invited by the American Society for Reproductive Medicine (ASRM) to present her original research paper at the annual conference held at Boston (USA) from 12<sup>th</sup> to 16<sup>th</sup> October 2013. She received the Best Paper Award for her innovative research paper on ‘Periodicity in the levels of serum Plasminogen Activator Inhibitor-1 (PAI-1) is a robust prognostic factor for embryo implantation and pregnancy outcome in conventional IVF cycles’. This research holds immense significance as there is currently no way to study the implantation process and endometrial receptivity in human subjects. The study on the molecule PAI-1, which is a stringent regulator of invasive proteolysis necessary for successful implantation, not only throws some light on the process but also helps predict the pregnancy outcome, whether clinical, biochemical or non-conception. The levels in serum serve as a good prognostic factor for either transferring embryos in same cycle or cryopreserving them

*IFS Congratulates all Indian Delegates who participated in ASRM, Boston and gave scientific presentations with Indian data*

**PAPERS PRESENTED BY INDIAN DELIGATES IN ASRM 2013 BOSTON**

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