

Ownership, decision making, recovery & check on switching mix up of reproductive materials embryos, gametes in ART procedures, Surrogacy under proposed Surrogacy ART legislations in India¹ –

World over infertility is affecting millions of individuals, couples who are resorting to assisted reproductive technology (ART), IVF , surrogacy as a means to procreation, family formation. But in the course of availing such health care services, the concerned couples, individuals are exposed to many hardships/ limitations which impairs on their reproductive health and rights.

As the discourse and deliberations on ART, surrogacy are only confined to surrogate mother and surrogate child alone at the cost of exclusion of the plight of infertile couples, individuals and their concerns. the quality of medical treatment, health care services, right to reproductive health , right to consent, procreative decision making, right to quality effective health care, right to ownership, disposal over handling, storing ,using of gametes, embryos in the course of medical procedures which are either very minimally dealt with or left largely unaddressed.

One of such grave unaddressed issue is the switching or mix up of gametes, embryos following clinical errors, right to ownership, recovery, decision making on gametes or embryos on its use and disposal during the medical procedure and its subsequent use.

These issues are significant considering the Government of India is proposing for a novel Assisted Reproductive Technologies (Regulations) ART Bill seeking to specifically regulate issues concerning embryos, gametes and other biomedical concerns related to same². This proposed ART Bill marks distinction from the recently proposed Surrogacy Regulation Bill 2016 which seeks to address mainly surrogacy, this has been approved by the Cabinet in August 2016³. However both the Bills are undergoing necessary revisions and deliberations among the Government authorities, not yet made available in public domain in entirety, both these Bill are expected to be tabled before the parliament in the upcoming winter session of around the end of this year.

During this long drawn pendency awaiting a statutory legislation on surrogacy, ART practices in India, there is large scale malpractice, abuse of this technology by ART Clinics, Banks. These clinics, Banks are functioning outside the purview of legal supervision as unregulated, unmonitored, lacking infrastructure, expertise and function for vested or commercial gains flouting the Indian council of medical research (ICMR) guidelines as these are have no legally binding effect. While some clinics have top-class facilities, others are really bad in terms of infrastructure and technical expertise leaving scope for such clinical errors mishandling. To make matters worse, there is no accurate record on the number of ART clinics functioning in the country with the concerned Indian government authorities, the

¹ Sonali Kusum, Ph.D Research Scholar National Law School of India University Bangalore, India.

² Sushmi Dey, After surrogacy, govt to regulate IVF, sperm banks, TNN | Aug 27, 2016 available at <http://timesofindia.indiatimes.com/india/After-surrogacy-govt-to-regulate-IVF-sperm-banks/articleshow/53881298.cms>(Last visited September 1, 2016).

³ Surrogacy bill gets the Cabinet nod, NEW DELHI, August 24, 2016, available at <http://www.thehindu.com/news/national/cabinet-clears-surrogacy-bill/article9025848.ece> (Last visited September 1, 2016).

record keeping in these clinics are nil. Under these circumstances, the onus of establishing accountability, to control or check such malpractices on the part such clinics is challenging.

In the light of this, it is pertinent to suggest that such proposed Bill may address these concerns. This assumes greater significance in the light of previous ART Bills which failed short to address the same causing abridgment, privation of their reproductive rights in the absence of law to address the same.

Some of these issues in Indian context with case studies, legal implications are addressed here as follows:

I.Right of individuals, couples to be consulted in decision making on handling, usage of embryo, gametes in course of ART, medical procedure-

The ART Bill 2010⁴, 2014⁵ provides for obtaining consent in writing of all parties seeking ART to all possible stages of such treatment or procedures including the use of human reproductive materials as gametes, embryos including “freezing, storing embryos” for subsequent use and also in case of using of such embryo for “research purposes”. This provision may be read with another provision of ART Bill which directs the ART Clinic for “informing, appropriate counselling” of couples before carrying out foetal reduction following multiple pregnancy. But this provision lacks the right of couple for expressing consent in writing of the concerned individual on “decision making on foetal reduction or termination of embryo” during the course of surrogate pregnancy. Following a perusal of these provisions, it may be noted that the Bill enumerates a host of rights of couples over their human reproductive materials as gametes, embryos but the Bill falls short of expressly stating right of individuals concerned to claim ownership over the human reproductive materials as gametes, embryos.

In the guise of such provisions the ART Clinics may take decisions on termination of embryos in the course of such ART procedures, surrogate pregnancy without the consent of couples, this is evident in one such case reiterated here,

An Irish couple who had twins a boy and a girl using a commercial surrogacy clinic in India following three successive embryo implantation in the surrogate mother But one of the embryos was subjected to "foetal reduction", or termination, by the clinic because the clinic does not allow surrogates to carry triplets”. In the process of fetal reduction, the surrogate or the couple were not consulted. The couple expressed regret for the abortion or foetal reduction of third surrogate embryo as they were neither informed consulted in the decision making on the third embryo, viability of pregnancy⁶.

⁴ The Assisted Reproductive Technologies (Regulation) Bill - 2010 (Draft), Ministry of Health & Family Welfare Govt. Of India, New Delhi & Indian Council of Medical Research New Delhi, available at <http://icmr.nic.in/guide/ART%20REGULATION%20Draft%20Bill1.pdf> (Last visited September 1, 2016).

⁵ Government of India, Ministry of Health and Family Welfare, (Department of Health Research) ART Bill 2014 , 30th September 2015, available at [http://www.prsindia.org/uploads/media/draft/Draft%20Assisted%20Reproductive%20Technology%20\(Regulation\)%20Bill,%202014.pdf](http://www.prsindia.org/uploads/media/draft/Draft%20Assisted%20Reproductive%20Technology%20(Regulation)%20Bill,%202014.pdf) (Last visited September 1, 2016).

⁶ News Irish news, Couple who had twins tell of regret after embryo aborted in surrogacy , 13/01/2014 , available at <http://www.independent.ie/irish-news/couple-who-had-twins-tell-of-regret-after-embryo-aborted-in-surrogacy-29910046.html>(Last visited September 1, 2016).

II.Right of couple to be free from medical clinical errors as switching or mixing up of gametes embryos at ART clinics, Banks-

One of the lacuna under the ART Bill 2010, 2014 is the absence of provisions to address cases of “mix up or switching of gametes or embryos”. Though Bill imposes statutory duties on ART Banks “to follow highest possible standards for storage and handling of gametes and human embryos”. But there is no legal recourse or remedial measure under Bill in order to address such case of failure to perform such duty by ART clinics, banks. There have been series of such case of mix up or switching of gametes, embryos both nationally, internationally while gametes are stored with the ART Bank for usually deferred use.

These occurrences impair cardinal human rights established under constitution as well as human rights conventions including right to privacy, family formation , right to procreative or reproductive health there by constituting breach of right to life which are couples and leave the couples legally vulnerable without any legal remedy under such circumstances. Some of these case may be reiterated as below:

i. Canadian Intending couple mix up of gametes at ART Bank in India, 2005 yr.⁷-

A Toronto based couple commissioned surrogacy in India in 2005 by availing the gestational services of an Indian surrogate mother who was carrying a foetus conceived of eggs from anonymous egg donor and intending father’s sperm resulting in birth of surrogate twins boy and surrogate girl in March 2006. the couple applied for citizenship to the Canadian High Commission in New Delhi by adducing proof of genetic connection between the couple and the surrogate child using DNA Test that showed the boy was not genetically related, only girl child was genetically connected , this indicated an error or mix up or switch or swapping of gametes in the Indian fertility lab. The Canadian government permitted citizenship only for the genetically related twins but refused to issue citizenship to the other twin, leaving the couple stranded in India. The couple made an application on humanitarian and compassionate grounds for their non-biological child to be granted citizenship, the Canadian Government issued a citizenship card and travel papers to the other twin only in the year 2012 almost six years after the couple commissioned surrogacy in India.

ii. *Dr.K.K.Gopinathan vs Anitha Jayadevan*⁸ -A Kerala couple with mix up of gametes at ART Clinic in Kerala, 2012 yr.-

A Kerala based couple named Mr.& Mrs Anita Jayadevan underwent intra cytoplasmic sperm injection (ICSI) treatment using their own gametes, the sperm of her husband, her own ovum respectively. Following a DNA test, it was found that there was no genetic connection with the intending mother and the foetus. The hospital authorities admitted a donor ovum was used for artificial insemination. The couple has filed a law suit in the high court of Kerala against the Hospital authorities for Rs 20, 01,000 as damages. Ms Anitha has written a book titled as “Malicious medicine my experience with fraud and falsehood in infertility clinics”

⁷ Raveena Aulakh, Couple fights federal surrogacy policy to bring their boy back to Canada The satr, , Aug 20 2011 available at http://www.thestar.com/news/gta/2011/08/20/couple_fights_federal_surrogacy_policy_to_bring_their_boy_back_to_canada.html (Last visited September 1, 2016).

⁸ OP(C).No. 2084 of 2012 (O), OS.12/2004 of SUB COURT, TIRUR, available at <http://indiankanoon.org/doc/57268181/> (Last visited September 1, 2016). See also, Tehelka, The invisible baby makers, tehelka Issue 50 volume 11, 2014- 12 -13, available at <http://www.tehelka.com/2014/12/the-invisible-baby-makers/> (Last visited September 1, 2016).

(Malayalam language) on her testimony and recounting similar cases of mix up and switching of gametes by infertility clinics among other misuse and malpractice of technology by clinics.

It is important to note that the ART Bill 2010, 2014 has no provision to address such cases of switching or mix up of gametes or embryos therefore it is incumbent to take into consideration these international regulations to address such cases. The UK Human fertilisation and embryology authority (HFEA)⁹ Guidance Note to clinics, The European Society of Human Reproduction and Embryology (ESHRE) on Handling & Identification of patients and their gametes and embryos¹⁰ provides for code of practice for effective monitoring system of to ensure security, storing, handling of gametes and embryos. There is scheme for license for all clinics handling, using of stored or donated gametes or biological materials, Periodic inspection by the Clinical and scientific inspectors of gametes, embryos or biological materials kept at the clinic. Procedures as 'cross-identification' or double-check the identification of gametes embryos at three crucial stages namely the individuals undergoing treatment, the sperm and eggs at the time of insemination, the embryos and the patient at the time of embryo transfer. Labelling with unique identification of an individual's all biological material including gametes, embryos at all stages of treatment. Writing the names of the patients on both the lid and the bottom of the dish. Restricted Permissible access to such gametes, embryos only to such concerned or named Person in the centre, for whom it is essential to their work. No Permission for any other person to access to gametes and embryos. Maintenance of records on the location of gametes and embryos along with each occasion of handling of gametes or embryos, source of gametes and embryos, the various procedures or recourse on embryo, egg or sperm sample collected kept from the date of collection, Training of all the laboratory staff on handling of gametes, embryos is made mandatory.

It is also significant to consider American Society for Reproductive Medicine (ASRM)¹¹ which provides for redressal recourse to be followed in such cases of mix up by imposing stringent ethical obligation on the Clinics to disclose errors at the earliest as soon as discovered without any further delay. To respect patient autonomy and practice fairness in treatment, delivery of services to patients. To uphold and recognise that the patient's right to know is compelling in case of such misdirection or medical error of mix up or switching of gametes or embryos physicians are obligated to disclose to patients any error as soon as discovered that could lead to a child being born with an unintended paternity or maternity.

⁹ UK .Gov, Human Fertilization Embryology Authority, available at <http://www.hfea.gov.uk/25.html> (Last visited September 1, 2016).

¹⁰ Luca Gianaroli et al and Committee of the Special Interest Group on Embryology, ESHRE guidelines for good practice in IVF laboratories, Oxford Journals Medicine & Health Human Reproduction Volume 15, Issue , 10Pp. 2241-2246. June 26, 2000, available at <http://humrep.oxfordjournals.org/content/15/10/2241.full> (Last visited September 1, 2016).

¹¹ American Society for Reproductive Medicine, American Society for Reproductive Medicine (ASRM) , Disclosure of medical errors involving gametes and embryos: an Ethics Committee opinion, Elsevier Inc., 2015 , available at https://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Ethics_Committee_Reports_and_Statements/disclose_errors.pdf(Last visited September 1, 2016).

There may be other preventive safeguards which may be suggested for the couples to detect genetic connection of the child with the intended parents with the child during pregnancy through conduct of Preimplantation Genetics Diagnosis (PGD) as This genetic test carried out before implantation ensures a couple that the embryo shares the genetic match with the intended couples. Conduct of Amniocentesis during pregnancy which identifies genetic match with the intended couples.¹²

There ought to be specific provisions to address cases of mix up or switching of gametes under the Bill including legal recourse or remedial measure along with identification of legal accountability in case of failure on ART clinics Banks as may be the case. A list of select provisions both preventive , suggested course of action taken after the regulations, best practices of international medical regulatory bodies for safe, desirable practice of ART Technology is suggested to be incorporated under the ART Bill as there is omission to address the same in the face of rising number of such irregularities and legal complexities.

III.Right of individuals, couple to recovery of frozen embryo, gametes in the ART clinics, Banks -

Following decade long unregulated practice of overseas surrogacy in India since the year 2002 allowing foreigners to commission surrogacy in India despite the absence of legislation on surrogacy in India. Subsequently in the year 2014 the Government, Ministry of Health & family welfare through its nodal agency ICMR imposed a strict moratorium through its notification in November 2015 to all the clinics offering of surrogacy services to foreigners to stop with the immediate effect¹³, subsequently in the year 2016 the Government of India proposed for a new legislation namely Surrogacy (Regulation) Bill 2016 which imposed blanket ban on foreigners to commission surrogacy in India¹⁴.

But one of the significant issue that remains unaddressed is the right of foreign couple to recovery, retrieval of their frozen gametes, embryos in Indian surrogacy clinics. There is no legal recourse or remedy provided for the same. Many couples individuals are facing this issues. One of such couple Bassett & Smith from Seattle had initiated the surrogacy back in the year 2014 in Mumbai in pursuance of same they had frozen their embryos and they were awaiting to use the same in the year 2016. But with the drastic change in law , these couple

¹² Katherine, IVF Mistakes: Making Sure the Baby Is Yours March 26, 2007, FoxNews.com, available at <http://www.foxnews.com/story/2007/03/26/ivf-mistakes-making-sure-baby-is-yours.html>(Last visited September 1, 2016).

¹³ PT JYOTHI DATTA, Surrogacy ban: No baby boom for foreign couples thehindubusinessline November 13, 2015, available at <http://www.thehindubusinessline.com/specials/pulse/surrogacy-ban-no-baby-boom-for-foreign-couples/article7873829.ece>, sensiblesurrogacy ICMR Officially Ends Surrogacy in India... effective immediately November 2, 2015 BILLinBCN, <http://www.sensiblesurrogacy.com/icmr-officially-ends-surrogacy-in-indi/>(Last visited September 1, 2016).

¹⁴ Surrogacy bill gets the Cabinet nod, NEW DELHI, August 24, 2016, available at <http://www.thehindu.com/news/national/cabinet-clears-surrogacy-bill/article9025848.ece>(Last visited September 1, 2016).

are left in limbo left helpless in recovering the same¹⁵. There is another Chicago couples Hahne & Melich who were in the process of attempting to get their embryos transferred into surrogates in India but they are hit by the change in the Indian Government regulations¹⁶. The legal instruments or directives of government circular ought to provide requisite direction for the same. On the other side there are many fertility clinics where in there are large number of foreign couples are registered with the clinic being in the process of having their gametes fertilized in the lab , or in the process of their fertilized embryo being implanted in surrogates, the conditions or the plight of such foreign couples , individuals ought to be addressed along with the changing laws.

Closing Remarks –

It may be significant to consider some of the national, international biomedical ethical instruments touching upon human reproductive materials as gametes, embryos among others. The Ethical Guidelines for Biomedical Research on Human Participants of Indian council of Medical Research 2006¹⁷ stipulate that “the concerned couples have right to ownership of embryos and the right to decision making or consultation on embryos”. This Guidelines 2006 further states that “in case of handling or usage including storage, donation unused surplus or spare embryos, consent should be obtained from the concerned couples as the ownership rights of such embryos rest with the couple concerned¹⁸.” Similarly, the Royal Commission on New Reproductive Technologies, 1993¹⁹ provide for “right to decision making about stored gametes to the gamete providers and about embryos to the persons for whose reproduction they are created”. Likewise, The Ethics Committee of the American Society for Reproductive Medicine, 1994²⁰ provide for right of concerned individuals “to consent through written instructions concerning the disposition of the gametes or embryos”.

Taking after these instruments it may be inferred that it is the fundamental right of such individuals from whom such gametes, embryos are obtained to claim ownership, to take decisions on such human reproductive material provided by them. It is also established that the human reproductive materials including gametes, embryos are constitutive of their

¹⁵ JOANNA SUGDEN AND ADITI MALHOTRA, Foreign Couples in Limbo After India Restricts Surrogacy Services Nov. 16, 2015 available at <http://www.wsj.com/articles/foreign-couples-in-limbo-after-india-restricts-surrogacy-services-1447698601>(Last visited September 1, 2016).

¹⁶ JOANNA SUGDEN AND ADITI MALHOTRA , Foreign Couples in Limbo After India Restricts Surrogacy Services, Nov. 16, 2015 available at <http://www.wsj.com/articles/foreign-couples-in-limbo-after-india-restricts-surrogacy-services-1447698601>(Last visited September 1, 2016).

¹⁷ Director-General, Indian Council of Medical Research, New Delhi ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH ON HUMAN PARTICIPANTS INDIAN COUNCIL OF MEDICAL RESEARCH NEW DELHI 2006, available at www.icmr.nic.in/ethical_guidelines.pdf(Last visited September 1, 2016).

¹⁸ Director-General, Indian Council of Medical Research, New Delhi ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH ON HUMAN PARTICIPANTS INDIAN COUNCIL OF MEDICAL RESEARCH NEW DELHI 2006, available at www.icmr.nic.in/ethical_guidelines.pdf(Last visited September 1, 2016).

¹⁹ Royal Commission on New Reproductive Technologies (1993) Proceed with Care. Ottawa, Minister of Government Services Canada.

²⁰ Ruiz, A., Perez, I. and Pellicer, A. (1996) Cryostorage of human embryos: time to decide. Hum. Reprod., 11, 703–705., Ethics Committee of the American Society for Reproductive Medicine, Defining embryo donation: an Ethics Committee opinion, available at https://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Ethics_Committee_Reports_and_Statements/Defining%20embryo%20donation2013.pdf(Last visited September 1, 2016).

reproductive capacities, being a core facet of individual's personhood, dignity, integrity hence any such handling or manner of using or disposing the same without the person's informed consent is considered to be a serious violation of that person's autonomy²¹.

Thus any handling, using, recovery of such reproductive materials including gametes, embryos of concerned individuals and couples without obtaining their consent in writing , without due consultation of the concerned individuals and couples are constitute violation of biomedical ethical tents as dignity , integrity personhood , reproductive autonomy of an individual which has a direct bearing on the right to life, dignity, integrity , personhood of an individual, and amount to breach of reproductive or procreative rights of an individual. On the other side, the Bill needs to include both preventive safeguards for checking such switching or mix up of gametes, embryos as well as incorporate adequate legal remedies recourse to address the same.

Hence necessary measures, need to be provided under the Bill for the same in compliance with the existing international bio medical conventions, Indian bio medical ethical guidelines.

²¹ Guido Pennings What are the ownership rights for gametes and embryos?
Oxford JournalsMedicine & Health Human Reproduction Volume 15, Issue 5Pp. 979-986. available at <http://humrep.oxfordjournals.org/content/15/5/979.full>(Last visited September 1, 2016).