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Case Reference: INT/KOL/2024/139

Present: Justice Ashim Kumar Banerjee (Retired), Chairman

Dr. Sukumar Mukherjee,

Dr. Maitrayee Banerjee,

Smt. Madhabi Das.

Mr. Rahul Kothari Complainant

- Versus-

Institute of Human Reproduction (IHR)

.....Respondent

Heard on: November 29, 2024

Judgment on: January 22, 2025.

FACTS

The complainant Mr. Rahul Kothari was married to Ms. Gunjan Kothari. Since they did not have any issue out of the wedlock they approached Institute of Human Reproduction (IHR) for IVF procedure. First two procedures failed. However, the third one succeeded and the lady conceived a girl child Ms. Esha Kothari. The entire procedure was done by Dr. M. L Goenka who is no more. Esha was born on January 21, 2019. Soon after her birth, Esha had severe illness and after a prolonged illness Esha was diagnosed with BCP-ALL, a form of blood cancer. Despite prolonged treatment in carcinoma the doctors could not cure the disease and the treating team ultimately decided to undergo HLA typing which revealed no genetic match between Esha and the couple, indicating a mix-up during IVF transfer. Unfortunately, despite immense efforts of the treating team Esha breathed her last at a tender age of 4 years on March 09, 2023.

The couple then started their fight for "*justice for Esha*".

According to them, due to mix-up of the embryo at the IVF centre the child got infected that resulted in ultimate tragic death of the young girl at the tender age of 4 years.

Series of litigations were had as we find from the records. Initially, the couple lodged a complaint with all authorities concerned as against the IVF centre.

The IVF centre came up with the records that would include consent of Ms. Gunjan Kothari duly signed by her during third IVF procedure which ultimately succeeded and resulted in the birth of Esha. The couple alleged that her signature had been forged. Criminal case was initiated. Hand writing expert was engaged, however, the hand writing expert could not come to a definite conclusion to support the allegation of the couple about the forgery.

A writ petition was filed before the Hon'ble High Court at Calcutta being WPA 24738 of 2024 (Gunjan Kothari vs State of West Bengal & Ors) alleging irregularity in the investigating process of the investigating agency that ultimately resulted in final report resulting discharge of the accused persons.

The Hon'ble High Court at Calcutta passed an order to the following effect :-

" Having considered the submissions and the fact that the learned CJM, Alipore is in seisin of the application for further investigation, I direct that if it is not possible for the learned CJM, Alipore to conclude the hearing on 23rd November, 2024, then he would take efforts by fixing as many number of dates but pronounce his finding on or before 15th January, 2025.

With the aforesaid observation, WPA 24738 of 2024 is disposed of.

Report submitted be kept with the record.

This court has not entered into the merits of the case in view of the petitioner having approached the learned CJM, Alipore.

The petitioner would be at liberty to approach this court after the final outcome is arrived at by the CJM, Alipore.

The petitioner would communicate this order within a week from date to the learned Chief Judicial Magistrate, Alipore."

From the order quoted supra, it appears that the Hon'ble High Court declined to interfere as the issue had been pending before the Chief Judicial Magistrate, Alipore.

During pendency of the said proceeding, Mr. Rahul Kothari, the husband, filed a complaint before us on November 12, 2024 against the Institute that would include Dr. M.L Goenka who died in the mean time and his team of doctors and the executives involved in the process of IVF. Mr. Kothari prayed before us for a direction to initiate an investigation against IVF centre about "unethical and criminal practice."

The IVF centre submitted their response through their Advocate Ms. Sritama Bhattacharyya, vide an undated letter. According to the response, on the self same issue a criminal complaint was lodged with the Karaya Police Station being Case No 268 dated October 12, 2023, under section 120B/420/474/406 of the Indian Penal Code, later amended to include Sections 468 and 471. The case was closed by filing a closure report by the Investigating Agency. In view of such closure report the case was dropped. On the self same subject complaint before WBCERC would not be maintainable.

HEARING

We have heard the complaint on November 29, 2024. Mr. Rahul Kothari as well as Ms. Gunjan Kothari submitted in support of their complaint whereas the CE represented by the authorized representatives defended the complaint.

The hearing was concluded and judgment was reserved.

EXPERT OPINION

On our request Dr. Runa Bal, HOD Department of Obstetrics and Gynecology, NRS Medical College and Hospital, Kolkata was present at the hearing as expert. Dr. Bal, evaluated the entire medical records and submitted her opinion that is quoted below:-

DR. RUNA BAL

"The unfortunate incidence of the death of Daughter of Mr. Rahul Kothari and his wife Mrs. Gunjan Kothari due to some hematological malignancies, for which the HLA matched Bone marrow could not be obtained, brought forward a disputed Frozen Embryo transfer by the IHR. The frozen embryo was transferred on 23.5.2018. There were certain controversies in the Consent form, where only signature of Mrs. Gunjan was present (Mr. and Mrs Kothari were claiming that signature as a false one). There is a strict law in India regarding the ART procedure and a stipulation is there regarding consent of Both partners, particularly in case of Donor embryo transfer.

It is the Judiciary system who would decide and give verdict about violation of Law and Ethics.

It is also unethical to transfer a donor embryo without the consent of the spouse.

Proper counselling and informed written consent of both partners should have been taken beforehand in this sensitive issue."

DR. MAITRAYEE BANERJEE

Our esteemed member Dr. Maitrayee Banerjee has also given her opinion that is quoted below:

"This seems to be a case of institutional mal practice where embryo donation was done using gametes that did not generate from the parents. Gunjan and Rahul Kothari were being treated for infertility at IHR. They had two unsuccessful IVF attempts in 2017. The third attempt in May 2018 was successful and baby Esha was born. The baby tragically developed B- cell precursor acutelymphoblastic leukemiaand required Bone Marrow transplant as a last recourse of medical management. Her High Resolution HLA typing did not match her parents. The couple approached IHR for clarification and crucial genetic information of the biological parents for Esha's medical management. The biological father's genetic information was not revealed by IHR. Bone Marrow transplant from biological mother was done but was

unsuccessful and baby Esha sadly succumbed. The key questions that arise are as follows:-

There are clear National Guidelines for Accreditation, Supervision & Regulation of ART clinics in India set up by ICMR in 2005.

- 1) Clause 3.2.5 states no treatment should be given without the written consent of the couple. There is no husband's signature in the consent form of IHR.
- 2) Clause 3.2.7 states no women should be treated with gametes or with embryo derive from the gametes of more than one man or women during any one treatment cycle. This has clearly been violated by IHR as all boxes in the consent form including anonymous sperm, anonymous oocyte, self sperm, self oocyte are ticked.
- 3) In clause 3.5.15 which states that when DNA finger printing technology becomes commercially available, the ART clinics may offer the couple a DNA finger print of the donor without revealing his or her identity - this was refused despite urgent medical requirement.
- 4) In clause 3.5.18 semen from two individuals must never be mixed before use, under any circumstances - was clearly not followed.
- 5) Clause 3.5.22 required that the consent on the consent form must be a true informed consent witnessed by a person who is in no way associated with the clinic. There is no signature of a witness or a councillor.

6) Clause 3.12.2 states children born through the use of donor gametes and their adopted parents shall have a right to available medical or genetic information about the genetic parents that may be relevant to a child health. This was clearly required in this particular instance but was not revealed by IHR.

In conclusion, it is obvious that certain key clauses of the National guidelines were disregarded during the treatment of the couple Rahul and Gunjan Kothari. These intentional lapses were unlawful and may have contributed to the unfortunate death of baby Esha."

OUR VIEW

On evaluation of the entire medical records, and the factual scenario it is clear, that Bone Marrow could not be obtained due to mismatch of the DNA that would automatically lead to the conclusion that there had been some irregularity in the process of transfer of Frozen Embryo on May 23, 2018. Due to such mismatch Bone Marrow procedure could not be done that may have resulted in ultimate death of the child. From the records it would also appear that a donor embryo was transferred.

At the hearing, the couple strenuously contended, despite repeated requests they did not divulge the details of the donor whose embryo got transferred.

We have considered the legal issue. The Assisted Reproductive Technology (Regulation) Act, 2021 has come into effect after the birth of the child. The

said Act 2021 has no retrospective effect that could make the instant case come within mischief of the said Act, 2021.

As per under Section 22 of the said Act, 2021 the legislature made it a mandate that the clinic shall not perform any treatment or procedure without the **written informed consent** of all the parties seeking assisted reproductive technology. Appropriate guideline has come in 2005. However, the Law has come in 2021, much after the birth of the child.

National Guidelines for Accreditation, Supervision & Regulation of ART Clinics would, inter-alia, provide caution with regard to Embryo transfer. Clause 3.2.5 would deal with consent. The same is extracted below:-

" No treatment should be given without the written consent of the couple to all the possible stages of that treatment, including the possible freezing of supernumerary embryos. A standard consent form recommended by the accreditation authority should be used by all ART clinics. Specific consent must be obtained from couples who have their gametes or embryos frozen, in regard to what should be done with them if he/ she dies, or becomes incapable of varying or revoking his or her consent "

We have considered the opinion of the expert. We have also considered the views of our esteemed member Dr. Maitrayee Banerjee extracted above.

The couple had gone for IVF twice. They failed. Third time they succeeded and a girl child was born in 2019 when the said Act of 2021 was not there.

According to the couple, they did not know, the embryo resulting positively, would belong to a donor and not the husband.

The centre would strenuously contend, they implanted donor embryo after obtaining due consent from Gunjan, the wife. Gunjan disputed her signature that ultimately resulted in a criminal proceedings where the hand writing expert did not go with the complaint of Gunjan and police filed a closure report. At that juncture, the couple approached us for appropriate relief.

We have considered the issue. The applicability of the Act of 2021 is an arguable issue as whether that would have any retrospective application or not. Even, if we go by the closure report yet, there had been gross irregularity in absence of the husband's signature. It is an admitted fact, husband's signature was not obtained during third embryo implant.

The records would reveal, when the child got rare disease and the treating team decided to go for Bone Marrow transplant they came to know, about the mismatch. They approached the centre for getting particulars of the donor that was not given, possibly due to the secrecy that the centre would have to maintain.

It is a peculiar situation, the centre obtained wife's signature before implant that issue stood concluded before the court of law. Hence, the irregularity in not obtaining the husband's signature, would mere be a procedural irregularity. However, the consequence is very very serious to that we do not find any

plausible explanation. In any event, no amount of explanation could cure the defect as mandated of the statute.

Even, if it is contended, the Act of 2021 would not have any retrospective application we cannot over look the ART guide lines framed by the Central Government that was prevalent at the time of embryo which mandated the couple signature before donor embryo implant. It was not done.

We hold the centre liable for the irregularity and direct them to pay a sum of Rs. 5,00,000/- to the complainant.

The complaint is disposed of accordingly.

Sd/-

(ASHIM KUMAR BANERJEE)

We agree,

Sd/-

Dr. Sukumar Mukherjee,

Sd/-

Dr. Maitrayee Banerjee,

Sd/-

Smt. Madhabi Das.

Authenticated
M. J.
Secretary
West Bengal Clinical Establishment
Regulatory Commission