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Case Reference:INT/PAB/2023/179

Present: Justice Ashim Kumar Banerjee (Retired), Chairman

Dr. Sukumar Mukherjee,

Prof. (Dr.) Makhan Lal Saha

Sri. Sutirtha Bhattacharya, IAS (Retd)

Smt Madhabi Das

Mr. Subhasis Dutta ……..…Complainant

- Versus-

Institute of Neuroscience Kolkata……Respondents

Heard on: October 5, 2023.

Judgment on: December 5, 2023.

BACKDROP

Sreeparna Dutta, 20 years old girl was complaining of uneasiness. According to the complainant, she had no other earlier serious health issue. She got an appointment of Dr. Jacky Ganguly of INK. Dr. Ganguly advised blood test and MRI. Accordingly, MRI was scheduled on April 29, 2023. She came on fasting. Blood sample was taken. Thereafter, on the advice of the hospitalstaff Sreeparna took her lunch. The MRI was scheduled at 1 PM, when she was called. A form was given for signature. It later on transpired to be consent form for MRI. There had been some financial issue that could be resolved. The patient was taken to the MRI room however, her mother or any other relative was not allowed to go in. Even after one hour, Sreeparna was not coming back. A junior staff who came out of the MRI room, was approached when the parents came to know, the patient became serious. They went to the MRI room where they could see that Sreeparna was laying on a stretcher. She was in complete unconscious state. There was no senior doctor or technician nearby. There was bleeding from the IV channel made in the hand. There was no emergency recovery system at the MRI room. Sreeparna was lying there for about 15 minutes. She could not betaken to the main hospital premises for admission in absence of any emergency ambulance. Portable oxygen cylinder was not available. Ultimately she was taken to the other building and she was admitted in the emergency at about 4 pm. The hospital informed that Sreeparna had died due to cardiac arrest.

Being aggrieved, ill-fated father of Sreeparna, Sri. Subhasis Dutta made the complaint. We immediately asked for response from INK. INK submitted their response. According to them, the MRI was uneventful. However, the patient suddenly collapsed . According to them, the patient was taken to the critical care unit. Despite treatment, she died. The relevant explanation given by the CE is extracted below:-

"The procedure was completely uneventful. After the procedure was over the patient was observed suddenly to be deteriorating. Efforts were immediately undertaken to revive and resuscitate the patient, initially by the healthcare workers (Nurses and Technician) on the spot and a CODE BLUE was announced for additional help. Two consultants. (Dr. Sucheta Saha &Dr. Shyamashis Das) immediately came and started Cardio Pulmonary Resuscitation (CPR). CPR continued on our ambulance which transported her to the Main Hospital emergency for Advanced Cardiac Life Support facilities. During her transport via ambulance the CPR was continued by one of the consultants. All the efforts of the specialist consultant in the Emergency room was in vain as the patient could not be revived- (Annex-V)."

We heard this complaint on October 5, 2023. On our request, Dr. Sukharanjan Hawlader, HOD, Radiology, IPGMER was also present in the hearing as an expert.

Dr. Anupam Chattaraj, representing the CE, would reiterate what had stated in the response. However, esteemed members on the panel, were not at all satisfied

in absence of appropriate documentary evidence to support the contentions of the CE that they did their best. Chronological event record, post incidental analysis, CCTV footage were not produced before us. We closed the hearing and reserved our judgment giving an opportunity to INK to share those document with copy to the complainant. Accordingly, INK submitted further detailed response, almost in the same line of the earlier response, in addition, they have given the sequence of event that is quoted below:-

"SEQUENCE OF EVENTS ON 29TH APRIL 2023

1:12 PM	*Intravenous channel was placed as routine before MRI scan.*
1:55 PM	*The MRI scan of Ms. Sreeparna Dutta began.*
2:40 PM	*The scan was completed successfully and uneventfully.*
2:47 PM	*The patient complained of severe uneasiness and had one episode of vomiting in the MRI room. Although she was conscious and obeying commands. Suddenly she had a convulsion and passed urine. It was decided to take her to the CT scan room for observation and care where more facilities were available. The patient was brought out on a stretcher from the MRI room for transporting her to the CT scan room.*
2:49 PM	*Her parents were informed. Mother entered the Scans area.*

2:56 PM	*Senior Sister Dipali arrived and attended to the patient. She started Cardio-pulmonary resuscitation (CPR).*
2:57 PM	*CODE BLUE was announced.*
2:58 PM	*Dr. Sucheta Saha, Consultant arrived. She examined the patient. According to her the patient was unresponsive. Extremities were cold. There was no palpable carotid pulse.*
2:59 PM	*Dr. Shyamasis Das, another Consultant arrived. Inj. Adrenalin, Inj. Atropine & Inj. Hydrocortisone were administered from the crash cart stationed at CT Scan room. He also attempted to intubate the unconscious patient without success due to excessive secretion and decided to transfer the patient to the Emergency.*
3:07 PM	*The patient was transferred to the Emergency of main hospital via critical care ambulance. The CPR was continued during transport by Dr. Sucheta and nursing staff accompanying the patient in the ambulance. The mother of the patient also accompanied in the ambulance.*
3:17 PM	*The patient reached the Emergency. All necessary ACLS measures were undertaken by Emergency Medicine Consultant.*
4:00 PM	*The patient was declared dead."*

There had been a post incidental analysis by the Death Review Committee and the report of the Committee is also extracted below:-

"***CLOSING REMARKS BY THE CHAIRMAN***

The chairman was very saddened for the unfortunate death of a bright young student. There has been no such precedence in the past ever at the Institute of Neurosciences Kolkata. This is a great loss to the family and no words can suffice this inadvertent event. He was satisfied that the entire team of I-NK, had tried its best to save the life of a young lady but expressed that sometimes even the best of efforts do not yield the desired result. However, the reason of death can only be ascertained after autopsy, which is still pending with the police."

During pendency of the judgment, we could procure a copy of the post mortem report from the police administration. The relevant extract is reproduced below:-

<table>
<tr><td rowspan="2">II CRA-NIUM AND SPINAL CANAL</td><td colspan="3">1. Scalp- Skull and Vertebrae</td><td colspan="2">2. Membrane</td><td colspan="3">3. Brain and Spinal Cord- (The spinal canal need not be examined unless any indication of disease of injury exists)</td></tr>
<tr><td colspan="3">Sclp- healthy skull- intact
Vertebra- intact</td><td colspan="2">congested</td><td colspan="3">Wt-1220gm
Congested</td></tr>
<tr><td rowspan="2">III-THORAX</td><td>1.Walls, ribs and Cartilage</td><td>2.Pleurae</td><td>3.Larynx and Trachea</td><td>Right Lung</td><td>Left Lung</td><td>Pericardium</td><td>Heart</td><td>Vessels</td></tr>
<tr><td>Wall-healthy
Ribs – intact
Cartilage - intact</td><td>Congested</td><td>mm-congested
Hyoid & Thyroid cartilage-intact
Contains blackish fluid as found in stomach content</td><td colspan="2">Rt-330 gm
Lt-310 gm
O/d- evidence of petechial Hemorrhagic spots over visceral surface of pleura and inter lober fissure of both lungs</td><td>congested</td><td>Wt248 gm
Healthy</td><td>Healthy</td></tr>
<tr><td></td><td>1.Walls</td><td>2.Peritoneum</td><td>3.Mouth, Pharynx and Escophagus</td><td colspan="2">4. Stomach and its contents</td><td>5.small intestine and its contents</td><td colspan="2">6. Large intestine and its contents.</td></tr>
</table>

	Healthy	congested	mm-congested	Whole wt 310 gm content-60 gm of blackish fluid without any untoward smell mm. congested	mm congested content fecal matter & gas
IV-abdomen	7. Liver	8. Spleen	9. Kidneys	10. Bladder	11. Organs of generation, external and internal.
	Wt- 1170 gm congested	Wt- 105 gm congested	Rt- 110 gm Lt- 105 gm Both congested	mm- congested	External- Healthy Uterus- empty
Muscles Bones	1. Injury	2.Disease or deformity	3.Fracture	4. Dislocation	
	As noted	Nil	Nil	Nil	

On perusal of the post mortem report it would appear that the autopsy surgeon kept his decision awaiting receipt of the reports of the "preserved materials"

DR. SUKUMAR MUKHERJEE

" It is a matter of grave concern that Ms. Sreeparna Dutta aged 20 years (since diseased) has an untimely, unfortunate death on 29.04.2023 at 4 pm following pre-scheduled MRI brain and angiogram in the above institution from anaphylactic shock due to contrast (gadolinium) used which is extremely rare, unpredictable event leading to disastrous cardiac arrest. However, it raises some factual comments and questions as outlined below:

1. *As per consultation and advice of Dr. Jacky Ganguly, consultant Neurologist the patient reached the MRI room of the INK for prescheduled MRI bran and angiogram on 29.04.2023 and procedure started at 1.55 pm and scan was completed successfully and uneventfully at 2.40 pm the contrast used was gadolinium as per protocol.*

2. *AT 2.47 pm the patient felt unwell with vomiting but conscious. But after few moments she had convulsion followed by involuntary urination. She was attended by sister Dipali who initiated emergency measures with CPR. Code Blue was announced at 2.57 pm.*

3. *At 2.58 pm Dr. Sucheta Saha, Neurorehabilitation physician arrived to find the patient was unresponsive with cold extremities without palpable carotid pulse. Dr. Shyamashis Das MD, DM Rheumatologist reached at 2.59 pm to start emergency medications from crash cart inj; Adrenaline, Inj. Atropine and Inj. Hydrocortisone. He also attempted to intubate the unconscious patient without success due to excessive froth in the mouth and decided to transfer the patient to the emergency- which is stationed away from MRI room at 2.59 pm. More so no anaesthetist or ICU expert was available for urgent intubation in time.*

4. *The CPR without intubation was continued during transfer to emergency via critical care ambulance with the active support of Dr. Sucheta Saha and nursing staff to reach ER at around 3.07 pm. The mother of the patient accompanied in the ambulance at around 3.07pm .*

5. *It was extremely unfortunate that no expert anaesthetist was available on the spot for effective CPR during 'golden hour' of hypoxia following cardiac arrest. This amounts to major deficiency in service of any CE.*

6. *At 3.17 pm the patient reached Emergency Room almost 30 minutes after cardiac arrest without intubation resulting in unpredictable correction of*

hypoxia at right time. At around 4 pm the patient was declared dead in little more than one hour from the onset of event.

Comments:-

1. *On 29.04.2029 at 2.57 pm as per 'Code Blue" announcement the patient had cardiac arrest. Resuscitation was attempted with emergency pharmaceuticals available from crash cart. But it was futile without effective ventilation. The 'Golden hour' concept of CPR was incomplete without successful mechanical ventilation in an unconscious patient without intubation and more so no anaesthetist was available at right time and right place.*
2. *Anaphylactive reaction to gadolinium used during MRI is often rare and unpredictable to cause fatal outcome. However, super clinical establishment like INK should have all out precautionary measures in any eventualities which can happen to any patient specially for a planned procedure. The unfortunate death of young girl is unpardonable.*
3. *'Time is important for successful CPR which was missed unfortunately in this case and more so, effort on the part of CE is far from acceptable as per scientific protocol.*
4. *It is shocking to learn that the young girl at 20 years age could not be saved because of lack of complete supportive care in time in a super CE like INK.*

5. *Post mortem report says "death must likely due to anaphylaxis to IV contrast."*

DR. HAWLADER

Our expert Dr.Hawladerhas also given his opinion that is quoted below:-

1. *"Death rate due to gadolinium contrast induced anaphylaxis is very rare (approximate rate is 0.0010% and of the total death reported by FDA is 0.00008%).*
2. *Death due to claustrophobia (fear of being in closed spaces) is unusual and patient is unlikely to remain quiet during MRI study and almost impossible to complete the investigation."*

DR. M. L. SAHA

Our esteemed member Dr. M. L. Saha has opined as below:-

"Ms Sreeparna Dutta a 20 years College student presented to INK Neurology OPD on 20th April, 2023 with complaints of tremulousness in hands and episodic dizziness and presyncopal attack. She was seen by Dr Jacky Ganguly at OPD and he prescribed Tab Inderal (40mg) ½ tab twice daily and Zevert MD 16 1 tab twice daily, Patient was also advised to undergo a MRI and MRA brain

and neck and asked for review with the reports. One attached sheet revealed her hand movement for drawing with both dominant and non dominant hands.

Patient attended INK diagnostic center at West Range on 29.4.2-23. For the MRI study. Blood creatinine and eGFR report done at INK on 29.4.23. was within normal range. Patient data was entered by Mr Abhisek and the consent was signed by her father Mr Subhasis Dutta.

She was taken in the MRI room and gantry. There is no paper from diagnostic center about what time patient was taken to MRI gantry. There is also no record at what time the contrast was given.

After the MRI study patient condition deteriorated and was having loss of consciousness and convulsion. There is no medical records as to what happened at MRI center and what treatment was offered to the patient.

After hearing was over CE submitted a detailed document of the Institutional death review meeting and post incidence analysis held at CMD's office on 2nd May 2023.Which mentioned the chronology of events.

The MRI scan began at 155pm and MRI study was completed at 2.40pm.At 2.47pm while in MRI room patient complained of severe uneasiness and on episode of vomiting and she was conscious then. Suddenly she had convulsion and passed urine involuntarily. Patient was shifted to CT scan where some facilities are there for observation and care. At 2.49pm her parents were informed and her mother entered the scan area. At 2.56pm sister Dipali arrived

and started CPR and code blue was announced. At 2.58pm Dr Sucheta Saha a neurorehabilitation physician arrived and she observed patient was unresponsive , extremities were cold and carotid pulse was not palpable suggesting that patient has cardiac arrest. Dr Sucheta Saha did not attempt to intubate her. At 2.59pm another physician Dr Shyamasis Das a rheumatologist arrived and administered Inj Adrenaline, Inj Atropine and Inj Hydrocortisone. He attempted to intubate this patient but failed due to excessive secretion and he decided to send the patient to emergency of main hospital. At 3.07 patient was transferred in a critical care ambulance to emergency of Main Hospital and reached main hospital emergency at 3.17pm. Dr Sucheta Saha and nursing staff accompanied the patient and continued CPR at ambulance.

The records at emergency at 3.15pm revealed asystole, Bilateral carotid absent ,Pupil dilated and fixed and deeply cyanosed. Then patient was intubated at 3.25pm , 10 minutes after arrival at ER. The emergency team continued CPR for next 45 minutes after intubation on arrival but patient could not be revived and patient was declared dead at 4.01pm on 29.4.23. at emergency of INK main Hospital.

MRI report of the patient revealed minor petechial hemorrhage in right parietal lobe. The MRA report was normal.

Mr Subhasis Dutta lodged a complain with WBCERC regarding negligence in treatment of her late daughter at INK MRI center. The patient was taken into MRI room around 1pm and they were not allowed to remain by the side of the

patient. After about one hour one staff of MRI informed that their daughter has became serious. When they entered the MRI room they found her lying unconscious and there was bleeding form the IV channel, They did not find any senior technician or doctors when the patient was critical. She was not provided any emergency recovery system. They were informed that patient needs to be transferred to emergency of INK main hospital and she was shifted in an ambulance where there was no arrangement for oxygen supply in the ambulance. After admission at emergency at INK they were not updated about the status of the patient for one hour. At 4 pm they were informed that their daughter died due to cardiac arrest.

The reply submitted by INK addressed issues regarding charges for MRI and reason for not allowing her mother inside the MRI room.

As per policy of INK they perform MRI of critical patient at Main hospital campus. Only stable and walking patients are taken up for MRI at their diagnostic center at West Range. Patient was given a bell to press in case of any discomfort. The MRI procedure was completely uneventful. After the procedure the condition of the patient suddenly deteriorated and efforts were taken immediately by nurse and technician for CPR and code BLUE was announced. Two consultants Dr Sucheta Saha and Dr Shyamasis Das arrived immediately and started CPR. Patient was shifted to main Hospital emergency and CPR continued at ambulance. Patient was shifted to emergency of main

hospital. All the efforts of the consultants in the emergency room was in vain and the patient could not be revived.

Observation and Comments:-

- ***This 20 years College student was not seriously ill and attended OPD at INK with some complaints of tremulousness and dizziness and presyncopal attack. And she was advised to undergo a MRI scan.***
- ***It appears form the chronology of events that the deterioration of the patient happened in the MRI room, although study was completed , patient likely developed some reaction to the contrast given during the MRI study.***
- ***When the patient condition was critical she was undergoing CPR by the nurse on duty Mrs Dipali. Subsequently when Dr Sucheta Saha came and noted her observation , it revealed that the patient was in cardiac arrest. After arrival of Dr Shyamsis Das patient was given some medicines for resuscitation.***
- ***In this critical state the foremost requirement was intubation and ventilatory support. Dr Shymasis Das is a rheumatologist and Dr Sucheta Saha was a Neurorehabilitation physician. None of them was conversant with management of such a critical patient and the most essential component of such resuscitation like intubation that could not be done.***

- *The medical records at emergency at INK at 3.15 pm revealed that patient was in cardiac arrest and there no evidence of cardiac activities , that means the patient was virtually dead at INK diagnostic center at West Range. Then efforts at emergency could not revive the patient.*
- *This is an extremely unfortunate death. This is true that the IV contrast administered during MRI may have serious reaction. The consent form mentioned that aspect and the consent form also mentions about possible death following this reaction.*
- *This is clear that there is no arrangement at INK diagnostic center for management of such reaction to IV contrast. The patient was managed by persons not trained in critical care. Timely management could have averted this death.*
- *This is a fit case for award of compensation for this unfortunate death.*
- *Few months back there has been such incidence at two more CE at Kolkata resulting in death following IV contrast injection. This is an extremely rare situation. But it must be mentioned that every diagnostic center carrying out these investigations involving administration of IV contrast must make an arrangement for proper management of these victims so that such deaths may be averted . Provision for intubation, ventilation and proper CPR team should be made available in all diagnostic centers."*

Upon perusal of the post mortem report Dr. Saha has commented as below:-

"Not much of findings in PM. Death most likely due anaphylaxis to IV contrast."

OUR VIEW

We have considered the rival contentions. We have also considered the experts opinion extracted above. The sequence of event as well as closing remark of the Chairman of the Death AuditCommittee are also on record. We fully agree with the closing remark of the Death AuditCommittee that the post mortem report could only through some light on the issue.Sudden anaphylaxis is a rarest of rare incident as observed by Dr. Hawlader. Yet, the same happened. At 2.40PM MRI scan was completed successfully and uneventfullywhereas at 2.47 PM, after about seven minutes, the patient complained of severe uneasiness and had one episode of vomiting. She had convulsion and passed urine. It was decided to take her to the CT scan room for observation and care.

Dr. Sucheta Saha, the consultant arrived at 2.58 pm almost after 11 minutes. Dr. Das came after Dr. Sucheta Saha. The patient was transferred to the emergency main hospital at 3.07 pm. Patient reached emergency at 3.17 Pm almost after half an hour of the incident and she passed away at 4 Pm.

The incident is really shocking. However, the establishment must take it seriously. Earlier also, complain came before us as to the harassment that caused to the patient because of scattered facility of the CE.

MRI was done at a different building that was quite far off from the main building as would be evident from the sequence of event. From the place of occurrence to Emergency it took 10 minutes to reach. In golden hour, every minute counts.

Our experts are in doubt whether Dr. Saha or Dr. Das could successfully do any positive procedure to save the situation.

The consent form did mention about death as a complication. In reality, it is a rarest of rare event. The CE, claiming to be specialised uni-speciality hospital of repute, must have back up system to manage the unforeseenemergent situation. From the sequence of events, we find, they miserably failed so.

Our esteemed Member, Dr. M.L Saha categorically observed, neither Dr. Sucheta Saha nor Dr. Samasis Das was conversant with management of such critical patient and most essential component of such resuscitation like intubation that could not be done. He also opined that timely management could have averted this death.

It is really an eye opener for INK particularly, when their in patient service is situated at a different building which would at least take 10 minutes to approach by ambulance. They should either shift their MRI and / or CT scan which would have such kind threat of criticality, to their main complex or make back system ready like CODE BLUE to tackle any emergent situation.

Our Members are ad-idem on the issue, this case would deserve compensation to the bereaved family.

We direct INK to pay Rs. 10,00,000/- (Rs. 10 lakhs) to the parent of the bereaved patient as compensation. We are akin to the fact, a young girl of 20 years while studying higher education, died in such unfortunate incident. Such loss to the parents cannot be compensated by any amount of money. Our direction to pay Rs. 10,00,000/- is nothing but to acknowledge the sufferings of the parents and the members of the family and at the same time to caution the CE so that they must take serious effort to avoid such recurrence in the near future.

In case the parents would be reluctant to accept such compensation such amount be paid to the college where she was studying and such college would invest the said sum in a suitable interest fixed deposit and utilise the proceeds for benevolent activity like sponsoringof any poor meritorious student in the memory of the departed soul.

The complaint is disposed of.

Sd/-

(ASHIM KUMAR BANERJEE)

We agree,

Sd/-

Dr. Sukumar Mukherjee,

Sd/-

Prof. (Dr.) Makhan Lal Saha

Sd/-

Sri. Sutirtha Bhattacharya, IAS (Retd)

Sd/-

Smt Madhabi Das

Authenticated

Secretary
West Bengal Clinical Establishment
Regulatory Commission