Office of the West Bengal Clinical Establishment Regulatory Commission

1st Floor, 32 B.B.D Bag, West Bengal, Kolkata – 700001.

Phone:- (033) 2262-8447 , Email: wbcerc@wb.gov.in Website: www.wbcerc.gov.in

Case Reference: ID-NPG/2018/000341

Present: Justice Ashim Kumar Banerjee (Retired), Chairman

Dr. Sukumar Mukherjee,

Dr. Gopal Krishna Dhali,

Dr. Makhanlal Saha,

Dr. Madhusudan Banerjee,

Dr. Maitrayee Banerjee,

Dr. Debashis Bhattacharya and

Smt. Madhabi Das.

Pulak Majumder.....Complainant

- Versus-

RENAISSANCE HOSPITAL PVT LTD. .....Respondent

Heard on: July 11, 2018, May 16, 2019, July 4, 2019 and August 20, 2019.

Judgment on: January 9, 2020.

FACTS

The complainant got his sister Smt. Pampa Majumder aged about 47 years admitted in the Clinical Establishment with a complaint of sudden onset of drowsiness with altered sensorium

along with frothing from mouth with deviation of angle of mouth. She was admitted under the care of Dr. Ranjan Srivastava. The Doctor diagnosed acute brain stem hemorrhage having co morbid condition like hypertension & diabetes mellitus with a history of mental retardation and deaf and mute. She was admitted on January14, 2018 and unfortunately passed away on February 10, 2018. Soon after her death there had been unpleasant situation at the Clinical Establishment. The complainant would have a grievance, despite repeated request he was not favoured with copies of the medical records pertaining to the patient. In fact, the door was closed for him and he was physically resisted from entering into the premises. The police intervened. The Hospital Authority would submit, the entire medical records were seized by the police that the complainant would emphatically deny. However, in course of hearing and in terms of the order dated July11, 2018 the Hospital Authority gave copies of the medical records to the complainant. According to them, they gave it in terms of the direction of the Commission, although it had already been served upon him.

COMPLAINT

Initially, the complainant approached the Commission for non furnishing of the medical report. After receipt of the medical reports he submitted a detailed complaint alleging medical negligence and ill treatment by the Hospital Authority.

INTERVENTION BY COMMISSION

The matter came up for consideration of the Commission on July11, 2018 when the Commission directed the Clinical Establishment to provide all treatment documents to the complainant. The complainant was asked to file affidavit giving details of his complaint with corresponding liberty to the Clinical Establishment to file counter affidavit. Accordingly, affidavits were filed.

DETAILED COMPLAINT

The complainant Pulak Majumder filed affidavit on July 30, 2018. According to him, the documents submitted by the Hospital Authority were incomplete and crucial evidence were withheld. Paragraph 3 of the said affidavit being relevant here in is quoted below :

That Moreover, on dated 11/7/2018 before the Commission during HEARING, Madam SONALI CHAKRABORTY, GRIEVANCE CELL, RENAISSANCE HOSPITAL said that the Copy which was submitted to CLINICAL COMMISSION, the same copy was submitted to POLICE also

on dated 10th Feb, 2018 after DEATH of my ELDER SISTER and after the order of Hon'ble COMMISSION on dated 10/7/2018 the same copy had given to me also which was EXTREMLY FALSE COMMITMENT before the COMMISSION as POLICE of BAGUIATI THANA neither LODGED any FIR nor any GD on 10th FEBRUARY 2018 and thereafter till date so how could RENAISSANCE HOSPITAL give the INCOMPLETE DOCUMENTS without having a GD COPY or an FIR COPY to POLICE and it was obvious that the SIEZER LIST was FABRICATED or MANIPULATED by RENAISSANCE HOSPITAL or no SEIZER LIST was there which told by Madam SONALI CHAKRABORTY before the CLINICAL COMMISSION which is an EXREAM OFFENCE made by Madam SONALI CHAKRABORTY.

The Hospital authority filed counter affidavit on September 28, 2019 denying each and every allegation of Mr. Majumder. The relevant extract is quoted below:

SL NO.	*Summery of the Complain/queries*	*Source*	*Reply against the complaint*
i)	*"Renaissance Hospital had given me a Documents on dated 11/7/2018 which was submitted to Hon'ble Commission and Police also, was INCOMPLETE (ANNEX A1) and there was no EVIDENCE LEFT but consciously the papers/documents was MISSING which contain the VITAL and CRUCIAL EVIDENCE against the TREATMENT of my ELDER SISTER Miss PAMPA MAJUMDER who was admitted to Renaissance Hospital Pvt.*	*"Page 1 of 4 of the Notarized complaint lodged by Mr. Pulak Majumder dated 30/07/2018*	*i) firstly, with reference to the point, this is to mention that as per the demand of local police station we had handed over the documents i.e. BHT including all medical report, chart, vital chart, medicine card to the police officer on the same day on spot instantaneously(Receiving copy attached for ready reference **ANNEXURE-i)** and later as per the requirement as per the direction via E-mail dated: 23/03/2018 we had submitted the documents to the office of WBCERC, Kolkata on 28/03/2018, Moreover, as per the directives of WBCERC on the date of hearing we had submitted the same copy to Mr. Pulak Majumder (Receiving copy attached for ready reference **ANNEXURE – ii).** Moreover, on the basis of further direction from the commission the table*

	Ltd on dated 14th January 2018 and died on 10th February 2018 in the said Hospital.		*containing all the dises of NORAD,Insulin, KCL and along with other vitals have been submitted to the Hon'ble Commission.* *ii) Secondly , as the documents were already given on the very day of death of Late Ms. Pampa Majumder to the Police Officer Baguiati P.S (i.e. 10/02/2018) on spot on their demand instantaneously. So the question of tampering of the documents is impossible, therefore, the question of fabrication and word "no evidence left"doesn''t even arise as we have performed the general procedure foro maintaining the clinical findings of the patient Late Ms. Pampa Majumder.*
ii)	*"That Moreover, on dated 11/07/2018 before the Commission during the HEARING , MADAM SONAALI CHAKRABORTY, GRIEVANCE CELL, RENAISSANCE HOSPITAL said that the Copy which was submitted to CLINICAL COMMISSION, THE SAME COPY WAS SUBMITTED TO police ALSO ON DATED 10TH Feb, 2018 after DEATH of my ELDER SISTER and after the order of Hon'ble COMMISSION on dated 10/7/2018 the same copy had given to me*	*Page 2 of 4 of the Notarized complaint lodged by Mr. Pulak Majumder*	*i) As already mentioned above, all the documents Were given on the very day of death of Late Ms. Pampa Majumder to the Police Officer Baguiati P.S.(i.e. 10/02/2018) on spot on their demand instantaneously. Therefore, the question of fabrication and word "'no evidence left""doesn't even arise as we have performed the general procedure for maintaining the clinical findings of the patient Late Ms. Pampa Majumder.* *ii) Being Law abiding organization/responsible citizen we had instantaneously handed over the documents to the Police Office of Baguiati P.S. on the very day of the death of Late Ms. Pampa Majumder i.e. 10/02/2018. Decisioin of the Police Officer of Baguiati P.S. is not within my organization's (i.e. Renaissance*

	which was EXTREMELY FALSE COMMITMENT before the COMMISSION as POLICE of BAGUIATI THANA neither LODGED any FIR nor any GD on 10th FEBRUARY 2018 ANDTHEREAFTER TILL DATE SO HOW COULD RENAISSANCE HOSPITAL give the INCOMPLETE DOCUMENTS without having a GD COPY or and FIR COPY to POLICE and it was obvious the SEIZER LIST was FABRICATED or MANIPULATED by RENAISSANCE HOSPITAL or no RECEIVING COPY OF LOCAL POLICE STATION OF THE DOCUMENTS AS DESIRED BY THE POLICE, WHICH IS SELF EXPLAINATORY LIST was there which tole by Madam SONALI CHAKRABORTY before the CLINICAL COMMISSION which is an EXTREME OFFENCE made by Madam SONALI CHAKRABORTY."		*Hospital Pvt Ltd.) jurisdiction irrespective of FIR/GD lodged by theComplainant to police and questioning the decision of Police by us is tantamount of showing aspersion.*
	"That but utter surprise is	*Page 3 of 4 of*	*The advice of all the medicines/drugs has*

	that those vital MEDICINE which was given to my Elder Sister was MISSING i.e. INSULIN, KCL, NORAD IN THE DOCUMENTS WHICH WAS SUPPLIED TO ME, Clinical COMMISSION and POLICE."	*the Notorized complaint lodged by Mr. Pulak Majumder dated 30/07/2018*	*been documented/noted in the case sheet/BHT and based on that the KCL, Insulin, NORAD were administered which were maintained in a table from time to time for monitoring, which was also submitted to your esteemed office*
iv)	*"... so please furnish these details which was missing in the · DOCUMENTS which was supplied to me on dated 11/7/2018 as below:* *a) From which date and specific HOUR, NORAD(INJECTION or INFUSION) was given to my ELDER SISTER and what was the dose i.e. NORAD(ml/hr) for the FIRST time?* *b) What were the DOSES i.e. NORAD (ml/hr) given to the PATIENT then after in every hour till DEATH?* *c) From which date and specific KCL & INSULIN was given for the first time till DEATH in every hour."*	*Page 4 of 4 of the Notarized complaint lodged by Mr. Pulak Majumder dated 30/07/2018*	*The table containing all the dose of NORAD , Insulin, KCL and along with other vitrals have been submitted to the Honorable Commission, by the Clinical Establishment which is self explanatory. The Clinical Establishment have also submitted the receipt copy of the clinical summaries (received by Mr. Pulak Majumder) containing Clinical Conditions along other parameters of patients including vitals & treatment advice which includes Clinical/investigational information from time to time to update the patient relatives and we had e-mailed the same to all the respective competent authorities in this regard viz. CMOH, WBMC and MCI on date- 05/02/2018. In this regard, this pertaining to mention that the date of start of Injection NORAD is already noted in the respective clinical summaries*
v)	*"These are the most CRITICAL and VITAL*	*Point 7 of Page 4 of 4 of*	*As all the documents were given on the very day of death of Late Ms. Pampa Majumder*

	information which was suppressed by RENAISSANCE HOSPITAL, SO NEED THIS INFORMATION....."	*the Notorized complaint lodged by Mr. Pulak Majumder dated 30/07/2018*	*to the Police Officer Baguiati P.S. (i.e. 10/02/2018) on spot on their demand instantaneously. Immediately on the day of death of Late Ms. Pampa Majumder it was not possible/feasible for anybody to manipulate the documents.*

The matter came up for hearing on May16, 2019 when Dr. Dubey, the treating Doctor was asked to clarify the use of Norad and Atropin administered on the patient. The Commission also recorded the serious grievance of the complainant as against Dr. Ranjan Srivastava alleging "***pre-planned murder***". The matter was kept for hearing on a subsequent date. The complainant filed another detailed complaint dated April 22, 2019 and raised various issues pertaining to the treatment as surfaced from the medical records.

Considering the counter affidavit Mr. Majumder made a further written submission dated April 22,2019 wherein he raised various medical issues. The Clinical Establishment dealt with such issues in its letter dated May18, 2019 wherein they reproduced the allegation and their explanation side by side. The Extract is quoted below:

Allegation – 1- "Annex A page A36, A37 which was submitted to Clinical Commission by Renaissance Hospital indicate that Treatment sheet was manipulated as on the same date i.e. on dated 4/2/18 at 5 pm one prescriptions was made for my elder sister Pampa Majumder (ICU6) and another different prescription was made by the same Doctors at the same date and same time i.e. 5pm for the same patient.

On page A36 of annex A time was written as 05 pm and page A37 of Annex A time was written 5.00 pm.

In one page Doctors name was written as Dr. R Srivastava in a same line and in another page doctors name was written as Dr. R in one line and Srivastava in another line.

How was it possible to made two different prescription for the same patient in the same date and same time by the two same doctors?"

Explanation of Allegation-1- After detailed examination of the above allegations, this is to mention that the above two prescriptions were written. Actually during & after the examination of the patient at 5 PM on that date (i.e. 04/02/18) Dr. A. K. Dubey (Primary Physician) & Dr R. Srivastava were discussing at bed side of the patient. As per the initial discussion the advice was noted on the 1st page but as per the subsequent ongoing discussion at the same time, considering the electrolytes & other parameters, the same advice was modified and noted on the next page by the RMO. It was a continuous process of discussion between Dr. A. K. Dubey (Primary Physician) & Dr R. Srivastava for the betterment of the patient & the advice on the next page was followed. The advice on the 1st page was not followed but we neither deleted nor removed the page & kept it in the file itself to have a reference of our discussion. There is no intention to manipulate the file as alleged which is totally false & baseless. It is to be noted both the writings are on the same sheet of paper.

Allegation-2 – "Page A20 of Annex A, Neurologist Dr. G. P. Mondal was visited on dated 29/1/18 and written "CARDIAC ARREST Yesterday" "on Noradrenalin" i.e. yesterday means Cardiac arrest happened on dated 28/1/18 when Noradrenalin (used for low BP) was given to the patient but page A24 of Annex A clearly stated that on dated 29/1/18 at 11:30 and onset of Bradycardia (42/min Heart Rate) happened and Atropine was given to the patient.

But, A23 didn't show anything in the TREATMENT sheet about that CARDIAC ARREST"

Explanation of Allegation-2-The cardiac event occurred in the morning at 11:30am of 29/01/2018 and Dr. G. P. Mondal saw the patient at night when the patient was on Noradrenalin. Instead of writing 'morning' Dr. G. P. Mondal had written 'yesterday' The above writing (these above noting 'yesterday' and the 'cardiac event) of Dr. G. P. Mondal was unintentional and neither it is the cause of death nor it affected the effect of the treatment. With all due humbleness this is to highlight that the level of care provided to the patient, Ms Pampa Majumder, was so high that even after a prolonged stay in the supine position under ventilation in the ICU there was no development of pressure sore.

Allegation-3- "Moreover page C26 Annex C clearly stated that NORAD started from 29th January 2018, so no question of starting NORAD on 28/1/18, it only reflected that the TREATMENT Sheet was manipulated So, it only reflected that the TREATMENT Sheet was manipulated."

Explanation of Allegation-3- As per the document/vital chart the Inj. NORAD infusion was started on 29th January 2018. There is no question of starting the NORAD on 28th. We are unable to understand this allegation.

Allegation-4- "Annex B7 showed that ATROPIN was administered in the MEDICINE CHART at 1 pm and 3:33 pm on dated 14/1/2018 and 7.20 pm and 12.30 pm on dated 15/1/2018 but there were no information anything in the TREATMENT SHEET that BRADYCARDIA happened and ATROPINE was charged."

Explanation of Allegation-4- Inj. Atropin was administered as claimed in the allegation as STAT dose already noted in Annexure - B7 which has been signed by the R.M.O. The advice for the injection Atropin is already present on the case sheet dated 14h January 2018 by Dr. A. K. Dubey" Inj Atropin (0.6 mg)IV SOS if Pulse Rate is 'less than or equal to 60 beats/ min" as standing order. (The copy of Dr. A. K. Dubey's mentioning the same. Enclosure-A)

Allegation-5- " Annex F2 showed that a REFERRAL letter was submitted to MSVP, SUPER, SSKM on dated 29/1/2018 and I visited CM office on dated 2/2/2018 and 5/2/2018 Annex F4 and F3 and got a call from CCU SSKM on dated 6h February at about 5.29 pm and 5.32 pm and immediately informed to the official of RENAISSANCE Hospital.

Surprisingly after the information about the call from CCU SSKM, RENAISSANCE AUTHORITY formed a MEDICAL BOARD at 6.50 without taking my CONSENT and had given me a SUMMARY of the BOARD, Annex D8 and how they forgot to give the NAMES of the DOCTORS and took 3 hours to give the Names of the DOCTORS Annex D9 at about 10 p.m.

I surprised once again that Dr. A K Dubey was not there in the MEDICAL BOARD under whom my elder sister was admitted and visited 41 times.

There was no REFERRAL SHEET about the medical board so that this was unknown who called the MEDICIAL BOARD?

Annex A13, A15, A17, A19, A31 showed that Dr G P MONDAL visited my sister 5 times and paid for 5 times Annex M3. So how could it be possible that Dr G P MONDAL was there I the medical board where RENAISSANCE AUTHORITY made GD to Baguiati Thana on dated 7/2/2018 for MONEY Annex D5, they didn't take a single paisa for the MEDICAL BOARD Neither Dr G P Mondal nor Renaissance Hospital was doing charity."

Explanation of Allegation-5-Since the patient's family members were very much in a state of disbelief out of their disproportionate hope& confusion, the medical board was organized by the hospital authority and was essential to establish neurological status and prognosis and management. Hence no question of payment/ consent was required. However, Mr. Pulak Majumder was informed but he was reluctant to come/ participate in the matter. After repeated request he came at about 10:00 pm. To receive the summary. Moreover the medical board was formed in the evening of 6th February 2018 and opinion of the medical board was submitted on 6th February 2018 at 6:50 pm which has got no relationship with the referral letter to M.S.V.P. of S.S.K.M. and opinion of Medical Board was conveyed to Mr. Pulak Majumder on the same day through clinical summary dated 06/02/2018. Since Dr. A. K. Dubey was busy with patient outside he could not attend medical board was formed in the evening of 6h February 2018 and opinion of the medical board was submitted on 6th February 2018 at 6:50 pm which has got no relationship with the referral letter to M.S.V.P. of S.S.K.M. and opinion of Medical Board was conveyed to Mr. Pulak Majumder on the same day through clinical summary dated 06/02/2018. Since Dr. A. K. Dubey was busy with patient outside he could not attend the medical board.

Allegation-6-" From the above URL, Annex K page K2 column 2 states that " Qualitative and Quantitative composition" it is said that 1 ample of 2ml contain 4 mg Noradrenalin tartrate and column 6.6 Annex K page K8 clearly indicate that how to made the infusion i.e dilution instruction and showed that add 2ml concentrate to 48 ml glucose 5% solution for administration by syringe pump

But ANNEX C26 showed that they started NORAD on dated 29th of JANUARY 2018 and used ***16mg i.e*** *8 ml (4 amp) in 5% DEXTROSE solution i.e 475% STRONGER MEDICINE which CAUSED the* ***DEATH of my ELDER SISTER.***

Was there any problem of LOW BP of my ELDER SISTER?

No, there was no problem of LOW BP of my elder sister. It was a PREPLANNED.

NORAD didn't started on 29the of JANUARY 2018 as ANNEX C26, and 17 indicated from the MEDICINE bill that no Medicine had been ordered on 29the JANUARY so it was IMPOSSIBLE to start NORAD on 29th January 2018.

It may start from 30th JANUARY 2018.

But then how could the CLINICAL SUMMARY of 28th JANUARY where NORAD started from 30th JANUARY 2018?

The plan was if I Submitted the REFERRAL LETTER Annex F2, to the SUPER OF SSKM on 29th January they would start the NORAD from 30 JANUARY and no matter the PATIENT had a problem of LOW BP or not."

Explanation of Allegation-6- Regarding the qualitative and quantitative composition of injection NORADRENALIN administered as per the titrated doses which had been already noted in the vital chart from time to time, as per the advice of the treating doctors which is as per the standard protocol/doses schedule. Moreover, it was given as per the recommended mcg/kg/min (The standard schedule for the NORAD doses which is followed by the hospital is enclosed herewith- Enclosure-B)

- *Initially in emergency cases, the emergency drugs are used from the emergency cart trolley in ICU.*
- *The NORAD was started on 29/01/18 which is noted in the clinical summary handed over on 29/01/18 evening to Mr. Pulak Majumder.*

Allegation-7-" Annex E clearly showed from CMOH report that you didn't have any ICCU Unit in your nursing home but had ICU unit then how could it be possible to made HALLA, Broken Glass DOOR, Beaten Dr RK Srivastava and your staff in the ICCU as per Annex H2 and H3 and what time?"

Explanation of Allegation-7- Regarding the allegations noted above, this is to mention that it is under police investigation of Baguiati Police Station. So in this regard, we don't want to comment any more. It is pertinent to mention that Mr. Pulak Majumder and his associates were caught red handed while police was present in Renaissance Hospital.

Allegation-8-" Annex F page F6 as per the RMO Doctor SAHID, Monitor was giving false reading which may caused extreme fatal for an ICU patient and told me to immediately inform to the Authority and I informed Dr S R Srivastava, wife of Managing Director of the Nursing Home Dr. R. K. Srivastava on 3rd February 2018 but they didn't take any action.

On dated 5th February, Annex F page F12 showed that RMO Dr. Rakhi Basu wanted to give ATROPIN for low Heart Rate (Bradycardia) but not given (there was nothing in the treatement sheet) as one of the ICU technician informed the RMO that monitor had problems and by knowing these facts at about 3 pm I informed Madam Sonali Chakraborty, Grievance Cell, Renaissance Hospital when Dr. R.K. Srivastava was visiting the ICU and knowing my complain he outbursed by roaring and shouting and took challenge that the patient i.e my sister would die that day or the next day in front of us within the ICU Annex F page F12."

Explanation of Allegation-8- In context of the above mentioned allegations about the cardiac monitor this is to mention that it is totally false and baseless. Moreover, as per the medical record no bradycardia was detected/noted. The actual fact is that variation in the heart rate was reported by the patient family members and as usual (this was a frequent trait of the patient relatives of Ms. Pampa Majumder to confuse all the ICU staff during the visiting hours) during the time of visiting hours in any pretext or context they were trying to create confusion among the ICU staff, so immediately RMO examined the patient and after verifying the display in the monitor it was found that the condition didn't required administration of Atropin at that point of time. Hence, injection ATROPIN was not indicated and not administered. It would be pertinent to mention that the fluctuations and variations in the heart rate is a common feature of all such patients.

Rest of the allegations are meaningless in view of the treatment and management of the patient and these don't justify his allegations regarding the conspiracy/manipulation and killing of the patient which is totally against the ethics of medical science.

N.B.

1. This is also to mention that even in the process of hearing at commission, he has been raising all new sets of questions every time deviating from his initial agenda/allegations.

2. With all due humbleness this is to mention that the level of care provided to the patient, Ms Pampa Majumder was so high, that even after a prolonged stay in the supine position under ventilation in the ICU, no pressure sore had developed.

3. This is also to mention that as per the demand of local police station, we had handed over the documents i.e. BHT including all medical reports, vital charts, Medicine card of Ms Pampa Majumder to the police officer on the same day(10/02/2018) on spot instantaneously (Receipt

copy enclosed – Enclosure - C), so there was no question of manipulation as alleged by Mr Pulak Majumder.

The matter came up for hearing on May16, 2019 when Mr. Majumder made elaborate submission dealing with medical issues as also the ill treatment that was made to him after the unfortunate death of the patient. We heard the matter at length. We also heard the Hospital Authority and kept our judgment reserved. By our order of the said date we also asked Dr. Dubey the treating Doctor to clarify the use of Norad and Atropin administered on the patient. We also recorded the fact that the complainant had a serious allegation as against the Dr. Ranjan Srivastav alleging "***pre-planned murder***". The judgment was kept reserved.

UNFORTUNATE MAIL

While the matter was kept under consideration of the Commission Members for final decision an unfortunate mail came from the complainant making serious allegation as against one of the members of the Commission. Hence we withheld the decision and placed the matter again in the list on July4, 2019 when the complainant withdrew his allegation and requested us to keep it for further hearing. We accordingly accepted his apology and placed the matter for further hearing. We finally heard the matter on August 20,2019. Dr. Srivastava was present and he offered his explanation on the complaint made by the complainant. Hearing was concluded. We kept our judgment reserved.

OPINION

After the complaint was finally heard and judgment was kept reserved we placed the matter before our medical experts present in the panel for their respective opinion. We had also requested Dr. Santanu Tripathi, the Head of the Department Forensic Medicine, Kolkata Medical College for his expert opinion on the dose of Norad . We also considered the postmortem report that came before us in the meantime. So was the report of the committee set up by CMOH after the unfortunate death of the patient.

The autopsy surgeon opined "death was due to the effects of sequelae of diseased conditions of organs as noted". We received opinion from Dr. Sukumar Mukherjee, Dr. Madhusudan Banerjee, Dr. Santanu Tripathi and the expert committee set up by CMOH 24 Parganas North. The opinions are set out as under.

Opinion of Dr. Sukumar Mukherjee

The patient (47 Yrs.) was admitted in Renaissance Hospital Pvt. Ltd. On 14-01- 2018 in the morning with sudden onset of drowsiness and altered sensorium and frothing from mouth with deviation of ankle of mouth, primarily under Dr. A K Dubey. Her comorbid illness include T2 DM, Hypertension, Hypothyroidism, mental retardation with deafness and UTI. The provisional diagnosis was acute Brain stem haemorrhage with Hypertension and diabetes. Her vitals were BP 160/90, Pulse 60/min, RR 20/min,SPO2 98% with 2 litres O2, CBG 208 mg%, GCS E2 VIMS.

plantar extensor on right side and equivocal on left side. Pupils mildly constricted.

In the hospital she was examined by several specialists time and again as per records in the BHT. The patient had series of emergencies which were managed by various experts. The patient was on mechanical ventilation from 14.01.2018 all through and finally had to go for elective tracheostomy on 29-01-2018. Ultimately she died on 10-02- 2018 following acute brain stem haemorrhage with Hypertension , diabetes, Hypothyroidism and post tracheostomy status.

In general prognosis of acute brain stem haemorrhage is unfavourable with fatal outcome in majority of patients.

Patient had a stormy course in clinical state and this has been explained to the patient party from time to time in their own understandable language. The prognosis was always guarded. Medical Board was also done and outcome of which has been explained.

The main contentious issues were dose and frequency of NORAD (Noradrenaline) to support hypotension , besides police investigation , media publicity and manipulation of hospital BHT .

Her BP was very unstable as it happens in brain stem haemorrhage and she had transient cardiac arrest on 29 Jan 2018. Soon after she recovered and her haemodynamic instability is restored. IV infusion of NORAD was administered as per protocol. However Sri Pulak Majumdar , brother of the patient claims that strength of NORAD was 5 times higher than permissible limit which was given that caused death of the patient . Doctors dispute the allegation strongly with available literature which was submitted in Annexure 7, 11(a).

NORAD- Noradrenaline bitartrate IP is available as 2 mg equivalent to Noradrenaline base 1 mg per ml.

For the purpose of administration IV infusion 8 ml NORAD Solution (4 Ampoules) i.e. 8 mg Noradrenaline base was mixed with 42 ml 5% dextrose solution. This makes the fluid strength of Noradrenaline solution as 160 mcg/ml. The standard recommended dosage of Noradrenaline (size, mode and rate of administration) in hypotensive shock when fluid therapy fails is 0.1-0.5 mcg/Kg/mm IV with Titration as and when necessary under supervision with monitoring every hour.

The dose is calculated as per body weight .

BW	*Recommended dose*
40 Kg	*4-20 mcg/min*
50 Kg	*5-25 mcg/min*
60 Kg	*6-30 mcg/min*

If the patient is 50 Kg then it will be 5-25 mcg/min or 0.3 – 1.5 mg/hour.

This dose is equivalent to approximately 2-10 ml/hour of the reconstituted Noradrenaline solution (160 mcg/ ml).

From the available record , the patient was mostly administered in a dose of 5-25 mcg/min i.e. 300- 1500 mcg/hour or 2-10 ml/ hour by intravenous route with continuous monitoring of BP and pulse rate every hour .

Adequate fluid supplementation prior to Noradrenaline is a priority; However, it is insufficiently documented at times.

Continuous monitoring of pulse , BP and renal function every hour is mandatory during prolonged course of Noradrenaline therapy which is inadequately documented.

Desperate attempts have been made to maintain haemodynamic stability with increasing dose of Noradrenaline as on 8th – 10th Feb 2018 that did not benefit the patient much with possible adverse side effects.

The brain stem haemorrhage with possible vasomotor failure leading to refractory hypotension is a difficult situation to handle with fluid and IV Noradrenaline support. Bradycardia noticed in the patient indicates brain stem failure and IV atropine will not give sustained benefit.

The patient was put in mechanical ventilator after revival from transient cardiac arrest and continued till death on 10-02-2018 . The patient party claims that the patient died of cardiac arrest and her dead body was kept in ventilation for all those days before declaring her dead. This can be verified by ECG recordings on monitor.

The case should be primarily referred to West Bengal Medical Council.

Opinion of Dr. Madhusudan Banerjee

Pampa Majumdar 47 years, single. The case was one of brain stem haemorrhage with umpaired consciousness and paralysis she was hypertensive and was a case mental retardation with speech and hearing defect from childhood and was admitted at Renaissance Hospital, Kolkata on 14/01/2018.

Her pulse and BP was fluctuating as happens in a brain stem haemorrhage and she had transient cardiac arrest on 29th, January, 2018. The Heart started functioning soon after and Pulse BP were restored to some extent and brady cardia followed (the same are shown in notes and records of the patient's files).

Inj of non-adrenaline was administered Intra venously by bolus does followed by infusion for the transient cardiac arrest and for the Bradycardia that followed. The strength of the adrenaline is the sole bone of contention. The party claims the Strength of the Inj of adrenaline used was five times more than is permissible and it is the adrenaline Infusion that caused the death of the patient on 19th, January, 2018.

The treating doctor disputes that allegation strongly and holds that the dose used was within the safety schedule for IV Inj of Noradrenalin. He submitted medical references in support of the same claim- Annexure 7, 11(a).

The patient was put in ventilator after the revival from the transient cardiac arrest and was in ventilator for 13 days till death, on 10/02/2018 (from 30/01/2018 to 10/02/2018) as shown in page 11307189 of patients file.

The patient party claims that the patient died of the cardiac arrest and her dead body was kept in ventilator for all those day before declaring her death. The contentions issue would be

decided on the PM and ECG and the findings recorded in patient file – which are not found in the files of the patient provided.

Death certificate issued by the RENAISSANCE Hospital states that the following

Patient Name : PAMPA MAJUMDAR, 47 years, Female, Hindu.

Patient Reg. No. 29351, date 19/02/2018.

Immediate cause of death – Brain stem Acute Haemorrhage.

Antecedent cause of death – Hypertension, Diabetes, Mental retardation, UTI ,SEPSIS

Signed by Dr.Rupam Nath on behalf of Renaissance Hospital Pvt. Ltd.

Apparently there is no discrepancy or irregularity or false hood mentioned as the causes of death. The patient party was counselled of the poor progress of the patient regularly.

Ref: Noradrenaline dose in British National Formula (BNF) in case of Acute Hypotension by -

Intravenous infusion, via central venous Catheter, of a solution containing - Noradrinaline 40 microgramm (base)/ml at an initial rate of 0.16 – 0.33ml/ minute, Adjusted according to response.

No time limit for continuation of the drug is mentioned. Apparently it is up to the discretion of the treating doctor as required in individual case.

Opinion by Dr Santanu Kumar Tripathi

Noradrenalin is available as concentrate solution in ampoules. Each 2 ml NORAD ampoule (Inj Noradrenalin) contains 2 mg noradrenaline base (i.e., 1mg noradrenaline base per ml).

For the purpose of administration (intravenous infusion), 8 ml NORAD solution (4 ampoules), i.e., 8 mg noradrenalin base, was mixed with 42 ml of 5% dextrose solution. This makes the final strength of the noradrenalin solution as 160 mcg/ml.

The standard recommended dosage of noradrenalin (dose size, mode and rate of administration) in shock is 0.1-0.5 mcg/kg/min, intravenously, titrated to effect.

- *The body weight (BW) of the index patient is not available in the supplied documents. Assuming the BW be 50 kg, the recommended dose in this patient would be 5-25 mcg/min, i.e., 0.3-1.5*

mg/hour. [If the BW is 40kg or 60 kg instead, accordingly the recommended dose would be 4-20 mcg/min or 6-30 mcg/min respectively.]

To administer the recommended dose of 5-25 mcg/min (i.e., 300-1500 mcg/hour) by intravenous infusion, this translates to approximately 2-10 ml/hour of the reconstituted noradrenalin solution (160 mcg/ml).

As per the available documentation, the index patient was mostly administered the recommended dose of 5-25 mcg/min, i.e., 300-1500 mcg/hour, i.e., 2-10 ml/hour) of noradrenalin by intravenous infusion, with continuous monitoring (hourly recording of hemodynamic parameters like blood pressure and heart rate).

Therefore, broadly speaking, the dose and administration process of noradrenalin was as per standard recommendation.

However, one should take note of the following observations also.

- *Although there is an apparent lack of a precise cut-off for identifying the dose of noradrenalin associated with higher mortality, a wide range like 1-6 mg/hour has been recommended. The threshold of approximately 1.5 mg/hour of noradrenalin has often been used in some clinical trials as a definition of refractory shock, requiring rescue therapy with vasopressin. In the instant case, too much reliance is given on noradrenalin infusion. Desperate attempts to maintain hemodynamic stability with an unduly too aggressive noradrenalin infusion on 8th-9th-10th February 2018, (exceeding the highest levels of recommended doses, without resorting to additional rescue therapies with vasopressin, etc.) might have been counterproductive – at least such possibility cannot be ruled out.*
- *In general, noradrenalin infusion requires continuous monitoring of hemodynamic indices like blood pressure (more particularly the mean arterial pressure (MAP) and heart rate, and tissue perfusion of vital organs, including the kidneys. Particularly, prolonged noradrenalin infusion tends to compromise renal perfusion in shock, and therefore continuous and meticulous monitoring of renal function is necessary; and It is not clear if this was done in this case – at least there is no obvious documentation, barring one noting on 7.2.18 of creatinine 0.9 and urea 24.*
- *Any noradrenalin infusion in shock must always be accompanied by adequate and appropriate fluid supplementation and maintenance of fluid intake-output; there is*

insufficient documentary evidence (in the supplied papers) that this was properly done (barring the noting of intake-output a few times on 27th Jan, 8th and 9th Feb, 2018 that indicate positive balance and retention).

- *The rationale of such prolonged noradrenalin infusion (commencing on 29th January and continuing till the death on 10th February) seems unconvincing, while, in keeping with the background of brain stem hemorrhage, there were frequent fluctuations in blood pressure and response to noradrenalin was often erratic.*
- *There is also apparent lack of precision in the continuous dose titration of noradrenalin responding to hemodynamic changes, in the index patient.*
- *Lastly, the overall quality and comprehensiveness of documentation leaves much room for improvement.*

Report of Expert Committee set up by CMOH, North 24 Parganas

As per Baguiati P.S. Case No.U/D, Case No. 14 of 2018 & GDFNo. 630 dt. 10.02.2018 and your order no CMOH(NPG)/CE/3487 dt. 11.04.2018, we the member of the enquiry Committee have visited the Renaissance Hospital of Nazrul Islam Avenue (VIP Road) Teghoria, Kol-157. On 07.05.2018, for enquiry in to the matter of complaint lodge at Baguihati P.S. by some Pulak Majumder S/O Bimal Krishna Majumder of 14/1/A Bakshi Bagan Lane, P.S. Barasat, N-24 Pgs against Ranaissance Hospital for negligence of medical treatment.

We checked and verified all the related papers like pt. admission register, attendance register, staff register, treatment sheet, appointment letter, consent and qualification of all related staff and found as follows :-

1) *Smt. Pampa Majumder age about 47 years elder sister of Pulak Majumder admitted at Renaissance Hospital 14.01.2018, with sudden onset of drowsiness with altered sensorium along with frothing from mouth with deviation of angle of mouth.*

2) *Pampa Majumder, admitted under Dr. Anil Kumar Dubey on 14.1.2018.*

3) *Smt. Pampa Majumder shifted to ICU and referred to the doctor of different discipline according to her symptoms and dead on 10.02.2018 at the same hospital in question.*

4) *It is revealed that the Clinical condition and prognosis of the patient was brought to the notice of Mr. Pulak Majumder on regular basis through initial patient assessment report.*

5) *As per case history sheet, Bed head ticket (BHT), various diagnosis report and basis medical ethic no negligence of medical treatment is found apparently. We agree with the preliminary Post Mortem report for cause of death but unable to focus firmly about negligence treatment, application of medicine and protocol of treatment as none of us was doctor in the discipline of medicine, neuro-medicine, pulmonologist and ENT.*

6) *CE license, Trade license and other required papers as per CE Rule is updated.*

Observation:- According to case history the enquiry committee recommended to form a enquiry team consisting with specialist Doctors of Neuro Medicine, General Medicine, Pulmonologist and ENT for proper investigation whether the death occurred due to negligence of treatment or not.

MY VIEW

If we analyze the facts by taking a sum total of the complaint we would find two main grievance of the complainant. (i) Medical negligence particularly in respect of use of medicine and(ii) misbehavior and ill-treatment followed by police atrocity to suppress the grievance of the complainant. On the first issue, the complainant would specifically assert, it was a case of overdose of Norad as also misuse of Atropin. On the second issue, although the complainant did not specifically give details of the torture that he had to suffer, his oral submissions would however, give us a picture of what had happened on the fateful day. On the medical negligence, the complainant would contend, the patient was admitted on January 14, 2018. As per the Hospital Authority, she suffered a cardiac arrest on January 28, 2018 possibly, the patient died on the same day that was not recorded in the Bed Head Ticket. The incident of cardiac arrest was also not properly noted by the Doctor. The patient was dragged for days together by keeping her in ventilator although she was virtually dead by that time.

On the other issue he would contend, Ms. Sonali Chakraborty, the Administration Head not only misbehaved with him but also made a totally incorrect submission before the Commission to

the extent, the entire medical records were ceased by the police and copy of the records were handed over to him soon after the death of the patient. We understand, the complainant was arrested by the police and he was kept in police custody for a substantial period. According to him, the police personnel are influenced by the Hospital Authority and purported seizure list was nothing but an afterthought and was drawn at the instance of the Hospital Authority.

CONCLUSION

On medical negligence, we have three reports of the experts.

The committee set up by the CMOH, North 24 Pgs submitted their report on July 6, 2018, we do not get any definite assistance from the said report. According to them, there was no negligence of treatment found "apparently". They also considered the postmortem report. They were however, cautious enough to record their inability on the medical protocol as they were not the expert of the nature of treatment that was given to the concerned patient.

Dr. Sukumar Mukherjee was of the opinion, it was a case of medical negligence so we should refer it to the Medical Council as it would be within their complete domain. He would however rule out the apprehension of the complainant that the patient had died of cardiac arrest and her body was unnecessarily kept. According to him this could be verified from ECG reading on monitoring that was done at the ICU.

Dr. Madhusudan Banerjee was however, of the view, the dose that was applied, would be up to the discretion of the treating Doctor as required in individual case.

Dr. Santanu Tripathi, the Forensic Medicine Expert, would however on a different opinion. According to him, the initial dose might be correct however, the increase of dose on a later date, without maintaining precision in the continuous dose with titration, might have seriously affected the patient. We would find from his opinion and give credence to the same when he would say as follows:

- ***Any noradrenalin infusion in shock must always be accompanied by <u>adequate and appropriate fluid supplementation</u> and <u>maintenance of fluid intake-output</u>; there is insufficient documentary evidence (in the supplied papers) that this was properly done (barring the noting of intake-output a few times on 27th Jan, 8th and 9th Feb, 2018 that indicate positive balance and retention).***

- ***The rationale of such prolonged noradrenalin infusion (commencing on 29th January and continuing till the death on 10th February) seems unconvincing, while, in keeping with the background of brain stem hemorrhage, there were frequent fluctuations in blood pressure and response to noradrenaline was often erratic.***
- ***There is also apparent lack of precision in the continuous dose titration of noradrenalin responding to hemodynamic changes, in the index patient.***
- ***Lastly, the overall quality and comprehensiveness of documentation leaves much room for improvement.***

However, his opinion must get statutory support from the appropriate forum before we make the Doctor responsible and Medical Council is the appropriate forum for the said purpose.

We are unanimous of the view, it is a fit and proper case to refer the issue to West Bengal Medical Council. We feel so in view of our prima facie findings being fortified by the opinion of Dr. Tripathy.

Thus leaves us with the other question of ill-treatment and police atrocities. The police complaint is awaiting decision as we find on a query made by us. We would request the Commissioner of Police, Bidhannagar to make a detailed inquiry as to the incident coupled with allegation of police atrocities and take adequate measure in this regard. He would also see to it that the criminal complaint pending before the concerned police station is disposed of at an early date with a logical conclusion. The Commissioner of Police would also kindly inform the Commission the result of inquiry and the steps taken by him as a consequence thereof.

RESULT

The office is directed to send the medical records to the West Bengal Medical Council with a request to deal with the issue on the basis of the medical records as well as the opinions from the expert that have been received by us and referred to above, upon notice to the complainant. We also direct our office to send copy of the order to Commissioner of Police, Bidhannagar for appropriate action in terms of the foregoing judgment.

The complaint is disposed of accordingly with a liberty to the complaint to approach us again after disposal of the Medical Council proceeding if occasion so arises.

Sd/-

(ASHIM KUMAR BANERJEE)

We agree,

Sd/-

Dr. Sukumar Mukherjee,

Sd/-

Dr. Gopal Krishna Dhali,

Sd/-

Dr. Makhanlal Saha,

Sd/-

Dr. Madhusudan Banerjee,

Sd/-

Dr. Maitrayee Banerjee

Sd/-

Dr. Debashis Bhattacharya and

Sd/-

Smt. Madhabi Das.

Authenticated

ARSHAD HASAN WARSI
WBCS (Ex)
Secretary
West Bengal Clinical Establishment
Regulatory Commission
&
Joint Secretary
Health & F.W. Department