

KARNATAKA LOKAYUKTA

Bangalore

No. Compt /LOK/BCD/621/2010/ARE-1

Date: 20th May, 2011

One Major Pankaj Rai has filed a complaint regarding the death of his wife Smt Seema, Rai as a consequence of transplantation surgery conducted at Fortis Hospital, Bannerghatta Road, Bangalore. He had at first filed a complaint with the Appropriate Authority of Government of Karnataka chaired by Sri D.N. Nayak. As he was not satisfied with the enquiry conducted by the authority, he has approached Hon'ble Lokayukta.

Maj Pankaj Rai has alleged that the findings of the enquiry report with regard to the death of his wife Smt Seema Roy given by Sri D.N. Nayak, the Chairman of the Appropriate Authority is perverted. He has prayed to set aside these findings and to direct the Government to initiate appropriate action as provided in Human Organs Transplantation Act.

The enquiry had been conducted by a committee headed by Sri D.N. Nayak on 22-12-2010 at his office.

Salient features of the complaints filed with Hon'ble Lokayuktha are:

- 1) His wife Smt Seema Rai who was admitted for kidney transplantation at FORTIS Hospital on 1-5-2010 operated on 2-6-2010 at 6 AM, died as a result of pancreatic transplantation done without taking the consent of the patient or her attendants violating sec 9 of human transplantation act.
- 2) She was on regular dialysis in this hospital and doctors of the hospital had advised for kidney transplantation. The patient has registered for cadaver kidney transplantation with ZCKK on the advise of the doctors.
- 3) Though she was on regular dialysis in this Hospital, the doctors had not informed about the need of pancreatic transplantation till 10 PM of 1-5-2010. The time was very short to take a decision about the pancreatic transplantation. He states that if it were to be informed earlier he would have registered for pancreatic transplantation also with ZCKK. The very fact that he has not registered for pancreatic transplantation with

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indicates that the doctors had not informed about the need of pancreatic transplantation well in advance.

4) Patient died on 6-5-10 as a consequence of pancreatic transplantation.

5) The doctors have violated Sec. 9, 12 and 13 of Human Transplantation Act 1994.

FACTS OF THE CASE:

1) The Committee headed by Sri D.N. Nayak after conducting the enquiry has opined that

- a) FORTIS HOSPITAL has permission to conduct pancreatic surgery
- b) Have not violated section 9 and 12 of Human Transplantation Act
- c) However to avoid such complaints in future has advised the concerned authorities to take suitable measures. (ANNEXURE 1)

2) To perform transplantation surgery, the hospital should register with the Appropriate authority for transplantation of human organs set up by the Government, and get a certificate in form No. 12 and get it renewed in form No. 13 once in five years. . (ANNEXURE 2)

3) Before issuing authorization to perform transplantation surgeries, the appropriate authority should ensure that the hospital has all the infrastructure to perform transplantation surgeries including a doctor qualified in doing such surgeries.

4) As per the conditions prescribed in the authorization certificate the Hospital should print both in English and Kannada a booklet explaining the procedure, the complications and after effects of surgery and the postoperative management of both the donor and the recipient and give to both of them. In the case concerned this booklet should have been distributed to the recipient as the organs were taken from a cadaver. but Major Rai was asked to go through the web site which is not a correct procedure. The Hospital authorities have produced certain work up papers which they say, have been given to the patient. (ANNEXURE 3)

5) A written informed consent signed by the patient or by the authorized person must be taken before undertaking any procedure on a patient including surgery. (ANNEXURE 4)

6) A pre-operative evaluation of the basic parameters should be done.

7) A preoperative evaluation by a Physician as to the fitness of the patient for surgery should be taken, a Cardiologist opinion in cases of patients suffering from cardiac diseases.

8) As far as transplantation surgery is concerned, special care as prescribed for a particular transplantation should also be undertaken.

9). The patient or patient's attendants have all the right to know the condition of the patient from time to time.

10). Any action taken by doctors without an informed consent cannot be taken as an action done in good faith except during an emergency treatment given to save the life of the patient..

11). In any transplantation surgery Basiliximab (Simulect) Drug should be given to prevent certain complications.

12) Sec. 9 deals with conditions under which the transplantation can be taken up. " It specifies that the hospital should register for transplantation surgeries with the Appropriate Authority. . (ANNEXURE 5)"

13) Sec. 12 explains the procedure as to how to proceed with the operation. It states that a written consent should be taken either by the patient or by the authorized persons. .

"No registered medical practitioner shall undertake the removal or transplant any human organ unless he had explained in such a manner as may be prescribed, all possible effects, complications and hazards connected with the removal and transplantation to the donor and the recipient respectively." (ANNEXURE 6)

14). Sec.13 prescribes the functions of the Appropriate Authority. (ANNEXURE 7) as follows

a) The Central Government shall appoint by Notification one or more officers as appropriate authorities for each of the Union Territories for the purpose of this Act.

b) The State Government shall appoint by notification one ore more officers as appropriate authorities for the purposes of this Act.

c) The appropriate authority shall perform the following functions, namely:-

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i) to grant registration under sub-section (10)m of Sec. 15 or renew registration under sub-section (3) of that section.

ii) to suspend or cancel registration under sub-section (2) of section 16.

iii) to enforce such standards as may be prescribed for hospitals engaged in the removal, storage or transplantation of any human organ.

iv) to investigate any complaint of breach of any of the provisions of this Act or any of the Rules made thereunder and take appropriate action.

v) to inspect hospitals periodically for examination of the quality of transplantation and the follow up medical care to persons who have undergone transplantation and persons from whom organs are removed, and

vi) to undertake such other measures as may be prescribed.

FINDINGS:

1. The authorities have not conducted periodic inspections of the Fortis Hospital as required. (ANNEXURE 9)

2. Act clearly mentions that the permission to perform particular transplantation has to be given only after confirming that the facilities to do such transplantation are available.

3. The Appropriate Authority has given permission to various hospitals specifically mentioning the organ of transplantation.

a) Fortis hospital	Kidney and liver and homo graft.
b) Saint John Medical College Hospital	Kidney
c) Coloumbia Asia hospital	Liver, pancreas and kidney
d) Narayana Hrudayalaya	Kidney and liver
f) BGS Global Hospital	Kidney liver and pancreas

Even the Appropriate Authority appointed by Government of Tamil Nadu has given permission specifically mentioning the organ of transplantation.

The Appropriate authority has given permission to Fortis hospital to do transplantation of kidney, liver and homograft usage only.

Thus the Fortis hospital has registered with the Appropriate Authority to undertake only for kidney, homograft and liver transplantation surgeries only and not for pancreas ..(ANNEXURE 8)

3. The certificate also prescribes certain conditions to do such transplants
The hospital authorities have not printed and distributed a brochure as prescribed in the certificate. (ANNEXURE 10)

The Hospital authorities have not updated the web site as prescribed in the certificate.

4. The signature of the patient in the informed consent form appears to be not that of the patient on comparison with those of the patient in passport and consent given for blood transfusion . (Annexure 11)

5. Though the hospital authorities have explained the need for a kidney transplant and persuaded the patient to register with ZCCK for a cadaver kidney transplantation have failed to convince the need and urgency of a pancreatic transplantation. If this was done the patient would have registered for pancreatic transplantation with ZCCK.

6. Even before the Cardiologist / Physician could certify the fitness of surgery, the Surgeons have performed surgery.

7. A pancreatic transplantation has been performed on the patient without obtaining consent as prescribed.

8. In any transplantation surgery an immunosuppressant (in this case Basiliximab (Simulect) Drug should be given to prevent certain complications. This particular drug has not been given before surgery as prescribed. . (ANNEXURE 12)

9. The doctors have failed to explain the condition of the patient from time to time to the patient's attendants though the patient was serious except getting 113 bottles of blood.

10. The patient was on regular dialysis in Fortis Hospital and the nature of surgery the need , the procedure, the aftereffects ,the complications and the cost of Pancreatic transplantation was not explained as per the conditions of the authorization certificate.

11. Dr Ramacharan Thiagarajan has conducted pancreatic transplantation for the first time in this hospital. The certificate of qualification of the doctor does not specifically indicate that he has expertise in conducting pancreatic surgery

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OPINION

- 1 The Enquiry Committee headed by Sri. D.N. Nayak should have gone into all the above details before giving the report.
2. The Government may take appropriate action on the lapses pointed out.
3. The appropriate authority should be more vigilant and make periodic inspection and follow up the patients as prescribed in the Act.
- 4 Major Pankaj Rai has to approach the concerned authorities for taking action against concerned doctors for the negligence on their part.


(DR. C.S. HANUMANTHAPPA.)


(DR. R. CHANDRASHEKHARA)


(DR. K.R.KAMATH)


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