

### **21 June 2008**

The patient is a 42 year old female, a homemaker, who previously worked as a teacher at an International School in Bangalore, suffered from Diabetes for more than 20 years and Hypertension for more than 15 years which resulted in Chronic kidney disease. The patient's husband was a retired Major and a Vice-President at a multi-national IT company – *Cap Gemini*. She first presented to Fortis Hospital (then Wockhardt Hospital) in June 2008 for Nephrology Consultation with Dr. Rajanna Sreedhara. Prior to June 2008 she was treated at Manipal Hospital, Airport Road, Bangalore for several years. The patient and family indicated that although it was closer their home, they left Manipal Hospital as they did not like the treatment received there.

### **June 2008 – Apr 2009**

Between June 2008 and Apr 2009, the patient was seen in OPD 13 times by the Nephrologist for medical management. The patient was treated conservatively with medical therapy (diuretics, anti-hypertensives, erythropoietin, iron, etc.). On August 16, 2008, her estimated GFR was 21 cc/min placing her condition at the time as CKD-Stage IV. During these OPD visits, as part of long-term management of CKD, the Nephrologist discussed in detail with the patient, husband and daughter about various treatment options for renal replacement therapy including dialysis and transplantation. Outcomes of these treatment modalities were discussed – 1-year mortality of a patient on dialysis is about 20 – 25% and 1-year mortality with transplantation is about 10 – 15%. The Nephrologist also provided additional sources of information such as [www.kidney.org](http://www.kidney.org) (website of National Kidney Foundation) and [www.aakp.org](http://www.aakp.org) (website of American Association of kidney patients) for patient and family to review.

The patient was seen by Dr. Murali Manohar for AV fistula creation in Jan 2009 and AV fistula was created on 12 Feb 2009 in preparation for hemodialysis.

After reviewing all the information provided by the Nephrologist and after further discussions with the Nephrologist, the patient and family decided to proceed with kidney transplantation because of better long term survival and improved quality of life compared to dialysis. After understanding all the pros and cons and after discussing with her family members, on 29/04/2009 the patient voluntarily registered herself with Zonal Coordination Committee of Karnataka (ZCCK) for cadaver kidney transplantation. Because of large number of patients who register with ZCCK, the patient was aware that it would take a long time for her to get a cadaver organ allocation by ZCCK.

### **May 2009 – Nov 2009**

The patient was seen in OPD 6 times by the Nephrologist for medical management. Her renal function gradually worsened. As she was becoming uremic and fluid overloaded, hemodialysis was begun on 18 Nov 2009.

After dialysis was begun the patient and her family also discussed with the Nephrologist regarding living donor kidney transplantation since waiting period for cadaver organ allocation from ZCCK could last several years. Her husband and daughter evinced interest to be kidney donors. However, the patient herself was hesitant in this regard and was not in favor of undergoing renal transplantation from a live person at that point.

### **Nov 2009 – April 2010**

With the initiation of hemodialysis, the patient's uremic symptoms and fluid overload status improved. In Dec 2009, first cadaver kidney transplantation was done at Fortis Hospital, Bannerghatta Road after ZCCK allocated cadaver organ to another dialysis patient who was on the waiting list for more than 3 years. Since the reference patient had also registered with ZCCK, she was eagerly looking forward to her turn for cadaver transplantation.

The patient and her family continued to discuss with the Nephrologist about cadaver transplantation as well as living donor transplantation. Risks and benefits of transplant were discussed several times with patient and family. Because of the possibility of an **elective living related donor transplantation surgery** (from husband or daughter), the Nephrologist advised the patient undergo a complete cardiac evaluation on 26-12-2009 (*Annexure: Hemodialysis Record 26/12/2009*). Following this advice, an ECHO Cardiogram was done on 29-12-2009. The ECHO did not show any regional wall motion abnormalities. Ejection fraction was 47%. Subsequently, the patient was seen by Senior Cardiology Consultant Dr. Subhash Chandra on 11-1-2010. He recommended the patient to proceed with coronary angiogram as part of complete cardiac workup in preparation for an elective living donor transplant surgery. However, the patient refused to undergo coronary angiogram at that time as she was still not in favor of receiving a kidney transplant from her husband or daughter. The Nephrologist continued to remind the patient to proceed with CAG whenever he saw the patient during dialysis rounds. However, she kept on postponing angiogram scheduling on one pretext or other.

In March 2010, the patient decided to proceed with coronary angiogram. On 1-3-2010, a pre-authorization form for Cashless Access was submitted by the patient's husband (the complainant) to his Medical Insurance Company (United Healthcare India) for pre-approval of Coronary angiogram to be performed by Dr. Subhash Chandra on 5-3-2010. However, the Insurance Company rejected Cashless Access for the proposed procedure in their letter dated 3-3-2010. Then the patient and her family requested the Nephrologist to give a letter to the Insurance Company to appeal against the rejection of their pre-authorization request. Dr. Sreedhara gave hand written letter dated 10-March-2010 on

Wockhardt Hospital Letter head requesting the Insurance Company to “*kindly approve the procedure so that patient can get prepared for transplantation*”. As noted above, this letter was given keeping in mind the possibility of elective living related donor transplantation.

It must be noted that the patient did not have angina or other active cardiac symptoms and was hemodynamically stable during her dialysis sessions. All dialysis parameters were stable. In Feb/March 2010, she had slight elevation of transaminases. Routine Viral markers (Hep B, Hep C and HIV) were all negative. Nucleic acid testing for viral antigens was also negative. Thus, the patient was stable on maintenance hemodialysis treatments.

**Saturday, 1 May 2010:**                      5 PM – 9 PM

The Nephrologist received a call from ZCKK that a cadaver donor had been identified and the patient might be **potentially** one of the recipients. The Nephrologist called the patient to inquire if she was interested and if she had fever or any other symptoms that would preclude this emergency surgery. The patient informed the doctor that she was doing well without any problems and was eager to proceed with cadaver transplantation surgery. She was advised to go to TTK Blood Bank where tissue Cross-match testing would be done. Then, the patient along with her family (husband and daughter) came to Fortis Hospital for admission for Cadaver Transplantation. The husband himself signed the Admission Profile/Consent at 8.40 PM on 1-May-2010. She was admitted to Room No. 751.

Given the emergency nature of cadaver transplant surgery, the Nephrologist **faxed** “Cadaver Kidney Transplantation – Pre-Op Recipient Orders” at 7:55 PM itself to the Hospital (i.e., even before the patient reached the Hospital) so that all pre-operative evaluations could begin soon after patient’s arrival in the Hospital to evaluate her suitability for the **emergency cadaver transplant surgery**.

**1 May 2010:**                      9 PM – 11:30 PM

The Nephrologist also rushed to the Hospital and evaluated the patient on this Saturday night. She had no active complaints. All vital parameters were stable. The Nephrologist again discussed with patient, husband and daughter regarding medical aspects of kidney transplantation including immunosuppressive medications – risks, benefits, duration of therapy, etc. [It is pertinent to note that the Nephrologist had discussed with the patient and her family about transplantation during her OPD visits over the previous two years. The patient and her family had several queries which were all answered by the Nephrologist and several rounds of discussions with the Nephrologist.] After a thorough discussion again on the night of 1-5-2010, the patient did not have further queries and was ready to proceed with cadaver transplantation surgery.

Dr. Ramcharan Thiagarajan (RCT), multi-organ transplant surgeon, also rushed to the Hospital to evaluate the patient on the night of 1-5-2010. After evaluating the patient, he specifically discussed with patient and family regarding surgical aspects of kidney transplantation surgery including risks and benefits. The surgical risks of this EMERGENCY CADAVER TRANSPLANT SURGERY including bleeding (due to underlying kidney disease and medications) and infection risk (due to underlying kidney disease, diabetes and immunosuppressive therapy) were discussed in detail with the patient and family.

Dr. Ramcharan Thiagarajan further informed the patient and family that the cadaver pancreas was also available and that there were no other registrants for pancreas. Because the patient also had insulin requiring diabetes, she could consider simultaneous pancreas transplant as well. He discussed in detail risks and benefits of simultaneous pancreas-kidney (SPK) transplantation. He informed them that in the long term combined SPK transplant was more beneficial than kidney alone. He also informed them that surgical risk of the combined SPK surgery was more than kidney transplantation alone since the organs had to be placed intra-peritoneally.

Mr. & Mrs. Rai and Ms. Abha Rai in the presence of Ward Nurse and ward resident doctor (Dr. Bhagya) were informed that they could turn down the pancreas option and instead go ahead with kidney transplant alone as they had registered with ZCCK for kidney alone in April 2009.

After above discussions, patient and family informed all the doctors in the presence of ward nurse that they would like to proceed with combined SPK transplantation. At this time, the patient also indicated that she wanted to discuss with her sister in New York about the combined SPK transplant surgery. Dr. Sreedhara encouraged her to discuss about the surgery with her sister or anybody else she wished to and came out of the patient's room to write his notes in the file. About 10 – 15 minutes later, while Dr. Sreedhara was writing his notes in patient's file at the desk, Mr. Rai came out of the patient's room and personally informed the doctors, Dr. Sreedhara, Dr. RCT, and Dr. Bhagya, in the presence of the ward nurses that the patient and her family wanted to proceed with combined SPK transplant surgery.

[The ward resident doctor in the Hospital, Dr. Bhagya, was also present when Dr Sreedhara and Dr. Ramcharan discussed about the risks of surgery with the patient and her family. Dr. Bhagya has also noted that the patient wanted to discuss with her relative in United States. Dr. Bhagya was present when Mr. Rai came out of the patient's room to inform all the doctors that they wanted to proceed with the combined SPK surgery.]

At this point, Dr. Sreedhara again informed Mr. Rai that they could revise their decision and go for kidney transplant alone until the time the patient was taken to the Operation Theater.

The above noted doctors discussions with the patient and her family explaining risks has also been documented by the Nurse in her progress notes written at 11 PM on 1-5-2010. The nurse also has documented that “High Risk Consent” taken. After High Risk Consent was taken, the nurse informed the Anaesthesia doctors to review the patient for pre-anaesthesia evaluation which is mandatory before a patient undergoes any surgery.

The signed “*Informed Consent for High Risk Procedure for cadaver Renal + Pancreas transplantation*” witnessed by patient’s daughter was handed over to the ward resident doctor (Dr. Bhagya K). The nurse has recorded this event in Nursing Progress Notes. When the signed Informed Consent form was handed over to Dr. Bhagya, she (Dr. Bhagya) again went back to the patient’s room and re-confirmed the patient’s decision regarding the Informed Consent for combined SPK surgery.

After discussions with the patient and family, Dr. Ramcharan Thiagarajan left for BGS Global Hospital to retrieve organs from the cadaver donor at about 11:30 PM.

**[Important Note:** If the patient had not consented for the surgery on the night of 1-5-2010, the Dr. Ramcharan would have gone back to his home and not to BGS Global Hospital since the cadaver organs would have been allocated to the subsequent patients on the waiting. In this particular case, two other patients were also admitted on the night of 1-5-2010 for possible kidney transplantation at – 1) Mallige Hospital and 2) Columbia Asia Hospital. ZCK always calls more number of patients than the number of available organs so as to have back up in case one or more patients have adverse cross-match results or do not undergo surgery for any other reason (See *Annexure: ZCK data pertaining to cadaver transplant surgery on 02.05.2010*). Therefore, if Mrs. Rai and her family had not given consent on the night of 1-5-2010, the surgeon from either Mallige Hospital or Columbia Asia Hospital) would have gone to BGS Global to retrieve the cadaver kidney. By calling more patients than the number of organs available ZCK tries to ensure that the precious cadaver organ does not go waste. In this particular case, apart from our patient, the patient at Mallige was allocated the other kidney whereas the patient from Columbia Asia Hospital was not allocated any organ.]

**1 May 2010:**                    11:30 PM – 6 AM (2nd May)

Pre-operative Anesthesia Evaluation was done by the Anesthesia team doctors around mid-night on 1-5-2010. All laboratory parameters including electrolytes and PT, aPTT and ECG were found to be normal. Patient was accepted for surgery under ASA Grade III.

The patient was started on broad-spectrum antibiotics as a prophylactic measure to prevent infections. Immunosuppressive medication orders were also written to prevent rejection of the transplanted organs.

Patient remained stable while awaiting surgery. As a special medicine – Simulect (IL-2 Receptor antibody used to prevent rejection) – was not available in the Hospital Pharmacy, Mr. Rai went out to procure the medicine (Simulect) directly from the pharmaceutical company. In this regard, he called Dr. Sreedhara several times to speak to the pharmaceutical company on his behalf since he (Mr. Rai) did not have enough cash on hand to purchase the medicine.

[In fact, Mr. Rai collected the medicine from the pharmaceutical company representative at about 7.30 AM on 2-5-2010 and immediately handed over the medicine to the Operating Theater staff to be administered to the patient. The medicine was given to the patient at about 8:15 AM which is about 2 hours before clamp release time of transplantation.

**Important Note:** If the husband did consent for the surgery, he would never have purchased the medicine and handed over the same to the OT staff. If the husband had not handed over the medicine, then the surgery would have been cancelled.]

ZCCK informed Dr. Sreedhara at about 4:30 AM that the tissue cross-match was negative and that Mrs. Rai indeed would get the cadaver organs as she was on top of the waiting list. Dr. Ramcharan was already in the process of retrieving the cadaver organs from BGS Global Hospital and bringing the organs to Fortis Hospital via Ambulance. He reached Fortis Hospital at about 6 AM.

**2 May 2010:**            6 AM – 10.30 AM

As the patient and family had given Informed Consent to proceed with combined SPK transplantation and the tissue cross match test was good, the patient was shifted to the OT at about 5:45 AM. A second pre-anaesthetic evaluation was conducted in the OT. All investigation reports and ECG were reviewed again. Patient was found to be stable for surgery under ASA Grade III.

Surgical incision was made at 7.35 AM. Immunosuppressive medicines were given - Simulect and high dose steroids (Solumedrol). Kidney transplant surgery completed by 10.30 AM. Kidney began making urine, about 330 ml urine was produced on the operating table.

The surgeon noted slight increase in blood oozing and attributed this to anti-platelet medicine (Deplatt-A) that the patient was taking. The patient remained hemodynamically stable. Dr. Ramcharan decided to proceed with pancreas transplant.

**Important Note:** Since this was an emergency surgery, there was no time to stop Deplatt-A. In an elective surgery situation, Deplatt-A would have been stopped for about a week before surgery.]

**2 May 2010:** 10.30 AM – 7 PM

Pancreas transplant was completed by about 5 PM. The organ looked healthy with good tissue turgor. There was no evidence of ischemia or rejection of the transplanted organs. Because of further increase in oozing, the surgeon observed the surgical site for additional 2 hours to ensure no bleeders were left behind. As no bleeders seen, the surgical incision was closed and the patient shifted to Surgical ICU at 7 PM.

Blood sample was sent for tests (CBC, PT and aPTT).

**2 May 2010:** 7 PM – 10.30 PM

In Surgical ICU, the patient was on ventilator and vasopressor medicines to maintain her BP. Antibiotics were continued. Dr. Sreedhara and Dr. Ramcharan discussed in detail the course in the OT with patient's husband.

The patient was also evaluated by Medical Intensive Care team (Dr. Madhusudhan). The amount of blood in the surgical drain was low for 2 hours, then suddenly increased at about 9 PM. Post-op laboratory tests also revealed increased PT, PTT and decreased platelets consistent with a diagnosis of Disseminated Intravascular Coagulation (DIC) which leads to excessive bleeding. Dr. Ramcharan evaluated the patient and decided to conduct exploration of surgical site to look for any bleeding vessels.

The laboratory values of interest are given in the following table.

Date Time	1-May- 2010 11:02 PM	2-May-2010 7:27 PM	2-May- 2010 10:52 PM	3-May- 2010 6:10 PM	4-May- 2010	4-May- 2010	5-May- 2010
<b>TEST NAME</b>	<b>Pre-OP</b>	<b>Immediate Post-OP Surg #1</b>	<b>Pre-OP Surg #2</b>				
PT	12.6	37	23.4	28	38.3	29	25.4
Control	12	12	12	12	12	12	12
<b>PT- INR</b>	<b>1.05</b>	<b>3.37</b>	<b>2.06</b>	<b>2.50</b>	<b>3.50</b>	<b>2.59</b>	<b>2.25</b>
aPTT	32	126	80	71.6	59.6	79.6	76.2
Control	31	31	31	31	31	31	31
Hgb	9.6	6.8	6.6	6.2	8	9.4	7.4
Platelet	177,000	112,000	91,000		30,000	96,000	45,000

TC	8,700		12,600		9,700		5,800
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**2 May 2010:** 10.30 PM – 12.20 AM (3 May 2010)

First re-exploration surgery was done. There were no bleeding vessels. Only generalized oozing was noted from the peritoneal surfaces further confirming diagnosis of DIC. The surgeon decided to do only pack the abdomen so that he could re-examine the site again later if bleeding persisted.

**3 May 2010:** 12.20 AM – 5 AM

Patient remained on ventilator and vasopressors because of low BP. She continued to ooze blood into the surgical drain.

**3 May 2010:** (POD # 1) 5 AM – 10.30 AM

The patient was shifted to OT for second re-exploration surgery. While inside the OT, she had a brief period of bradycardia and cardiac arrest which was immediately reversed with resuscitation. Second re-exploration was done. Again, no bleeding vessels were found. Another senior surgeon (Dr. Aashish Shah) also explored the surgical site and confirmed that there were no blood leaks. Right internal iliac artery was ligated to decrease bleeding. Only diffuse oozing noted at the surgical site consistent with DIC.

The patient was shifted back to SICU.

**3 May 2010:** (POD # 1) 10.30 AM onwards

Coagulation parameters still remained abnormal consistent with DIC. Measures taken to control bleeding due to DIC included transfusions with blood, plasma, platelets, cryoprecipitate, vitamin K, etc.

The patient was evaluated by Nephrologist (Dr. RS), Critical Care specialist (Dr. Rajani Bhat), Critical Care Anesthesia (Dr. Murali Chakravarthy), Urologist (Dr. Mahendra Jain) and transplant surgical team (Dr. RCT and Dr. Anand).

Patient also underwent hemodialysis without any hemodynamic deterioration.

Dr. RS, Dr. RCT and other doctors of the transplant team discussed with patient's husband several times regarding the patient's critical condition. Patient's condition including the brief episode of bradycardia/cardiac arrest was informed to the patient's

family. The husband urged the doctors to do whatever was necessary to save the patient. He appreciated and thanked the doctors for all their efforts.

**4 May 2010** (POD # 2)

Patient remained in SICU on vasopressors and ventilator. She was still oozing blood through the surgical drain but hemodynamic parameters were gradually improving. Treatment for DIC as noted above continued to stabilize the patient. Broad spectrum antibiotics were continued.

During the entire hospitalization, the patient received multiple units of blood and blood products as detailed below:

- Packed red blood cells (33 units)
- Fresh Frozen Plasma (52 units)
- Platelets (15 units)
- Pheresis platelets (5 units)
- Cryoprecipitate (14 units)

To control the coagulation abnormality and bleeding, the patient also received aprotinin, Vit K and desmopressin.

Low BP was due to extensive bleeding. However, once the coagulation parameters improved and the rate of oozing decreased, her BP got better and the vasopressor agent doses were decreased.

Post-operatively she was also evaluated by the cardiologist. The Cardiologist evaluated the patient including a screening ECHO and did not find any evidence of ischemia.

The patient was evaluated by Dr. RS, Dr. Rajani Bhat, Dr. Mahendra Jain, and Surgical Intensive care and Medical Intensive Care and Dr. RCT and transplant surgery team of doctors.

Dr. RS, Dr. RCT and other doctors of the transplant team again discussed with patient's husband several times regarding the patient's critical condition. The husband again urged the doctors to do whatever was necessary to save the patient. He appreciated and thanked the doctors for all their efforts.

**5 May 2010** (POD # 3)

The patient's condition further improved with decrease in requirement for vasopressors. BP was also much better. Patient was awake and responsive and communicated with the

medical staff and the family. Rate of blood oozing through the surgical drain had decreased. Coagulation parameters were improving. The patient underwent hemodialysis without any hemodynamic deterioration.

She was evaluated by Dr. RS, Dr. Rajani Bhat, Dr. Mahendra Jain, and Surgical Intensive care and Medical Intensive Care and Dr. RCT and transplant surgery team of doctors. The doctors discussed the possibility of extubation.

Dr. RS, Dr. RCT and other doctors of the transplant team again discussed with patient's husband several times regarding the patient's critical condition. The husband again urged the doctors to do whatever was necessary to save the patient. He appreciated and thanked the doctors for all their efforts.

Later in the day, the patient developed fever. Broad spectrum antibiotics (Pipracillin + tazobactam, Linezolid and Fluconazole) were given.

**6 May 2010:** (POD # 4)

Fever was worsening touching as high as 104°F. Her BP again decreased along with decreased glucose. Her white cell count (TLC) also decreased to 2,800 and platelets decreased. All these parameters were indicative of severe sepsis. Higher broad spectrum and anti-fungal agents – Meropenem, Vancomycin, Amikacin and Caspofungin – were administered.

She was evaluated by Dr. RS, Dr. Rajani Bhat, and Surgical Intensive care and Medical Intensive Care and Dr. RCT and transplant surgery team of doctors.

Dr. RS and Dr. RCT again discussed with patient's husband several times regarding the patient's critical condition. They informed the extreme grave condition of the patient and poor prognosis. He understood her critical condition and again appreciated our efforts and thanked all the doctors involved in the care. He requested us to do whatever that is required to save the patient.

**6 May 2010:** (POD # 4) 8 PM – 9 PM

Patient's overall condition deteriorated. Heart rate was fluctuating. At 8:40 PM she went into asystole. CPR and ACLS protocols were performed. But, she did not survive and declared dead at 9 PM by Dr Haridarshan (Surgical Registrar).

The SICU Nurses note is given below:

At 8:55 PM on 6/5/2010 the nurse has recorded the following:

“Patient condition explain to pt husband. Attenders came & see the patient. CPR on going. Pt is not responding. No pulse. No Blood pressure. ET & oral suction done.”

At 9:00 PM on 6/5/2010 the nurse has recorded the following:

“Pt declared at 9 PM by Dr. Darshan. Informed Dr. Ramcharan by Dr. Darshan. Informed Dr. Rajanna Sreedhar. Informed Dr. Mahendra Jain. Informed night supervisor & Informed MOD. Informed to Dr. Selwine by nursing supervisor Sr. Puspa.”

Dr. Darshan informed the family of the death.

**The cause of death was post-operative bleeding due to Disseminated Intravascular Coagulation and Septic Shock in a patient with End-Stage Renal Disease due to Diabetes and Hypertension treated with Hemodialysis.**

**6 May 2010:** (POD # 4) 9 PM – 11 PM

The Nephrologist also informed the patient’s husband about the death. The husband requested Dr. RS to contact the Emergency Room doctor to help take care of his agitated daughter. Dr. RS called the Emergency Room doctor to request him to evaluate and treat the daughter. Dr. RS called the Emergency Room doctor again to make sure the daughter got proper attention and care.

The patient’s family members were constantly updated about her critical condition throughout hospitalization. The patient’s husband profoundly thanked the doctors and other medical staff for their excellent service in connection with the treatment given to his wife during the entire hospitalization.

**30 May 2010**

Three weeks later, to the shock and disbelief of the doctors and the Hospital, the husband lodged a police complaint alleging negligence at J.P. Nagar Police Station and followed it up with another complaint of medical negligence before the Karnataka Medical Council. The husband made the Police to register a case under section 304 (which is meant for murder cases) instead of 304-A (to be used in allegations of medical negligence). The police referred the matter to the Karnataka Medical Council for their opinion.

\* \* \* DISCUSSION \* \* \*

Patients with diabetes and kidney failure are very sick to begin with and are highly susceptible to infection. When transplantation surgery is performed, these patients are given very high doses of immunosuppressive medicines (to decrease immunity) that further increase the risk of infection. Consequently infection is always a major risk for any patient who undergoes transplantation. All these facts were clearly explained to the patient and her family during counselling at OPD visits for nearly 2 years before the surgery. These issues were again discussed with the patient and her family on the night of 1-5-2010.

Although dialysis is a life-saving procedure, overall prognosis is very poor for dialysis patients. In fact, cancer patients live longer than dialysis patients. Even in advanced countries such as the United States, annual mortality of dialysis patients is about 25% and the mortality is even worse among diabetic patients. The mortality after kidney transplant is about 10% in the first year, and better thereafter. Consequently, transplant patients fare better than dialysis patients although they still have lot of risks such as infections, cancer, etc. and have much higher risk of morbidity and mortality compared to general population or diabetics without kidney failure.

The surgery of transplantation is very complex and undertaken by highly trained transplant surgeons supported by a comprehensive transplant team including various specialist doctors in well equipped hospitals. Even in transplant centres in the United States, the peri-operative mortality for kidney transplant surgery is about 0.6% and that for simultaneous kidney-pancreas transplant surgery is about 1%.

Compared to western countries, cadaver transplantation is a rare surgery in India. Even most major Hospitals in Bangalore may conduct one or two such surgeries in a year due to the paucity of cadaver organ donation. Consequently the Hospitals and doctors perform this procedure as a service to patients and not with a profit motive. In fact, patients who register with ZCCK have to wait for several years before they are allotted a cadaver kidney because of a very long waiting list. That being the case, there is no question of conducting cadaver transplant surgery if the patient is not willing. If one patient does not want to get the cadaver kidney, several more are always waiting and eager to get the same kidney.

Infection is a major post-operative complication in any solid organ transplantation causing significant morbidity and mortality. As noted above, diabetic kidney failure patients are always at high risk for infection, the risk further increases when they receive very powerful immunosuppressive medications. This apart, even after all appropriate prophylactic measures, infection can arise from the transplanted cadaver organ itself or from the recipient patient since the patient's intestine is cut open to anastomose the pancreatic duct. The intestinal fluid is always full of bacteria and may lead to the spread of infection. Multiple surgeries and massive bleeding as occurred in the reference case further increase the risk of infection as the blood clot in the surgical sites act as a good culture medium for bacteria to grow. Thus, despite state-of-the-art infection control policy and procedure, one cannot completely eradicate infection in

100% of cases. There will always be some transplant surgeries complicated by post-operative sepsis. In fact, post-operative sepsis occurs even in most advanced countries such as the United States.

Several experts in the field of transplantation from India and the USA have reviewed the reference patient's medical case history and concluded that all the treatment was given as per standard protocol and that the doctors did everything possible to save the patient. They all concluded that although the outcome is unfortunate, it was not due to any negligence on the part of the doctors.

The Karnataka Medical Council (KMC) conducted a careful and thorough enquiry of the medical negligence complaint filed by the patient's husband. They reviewed the medical records, affidavits, cross-examination, expert evidence and evidence from Department of Health and Family Welfare and ZCKK. It is pertinent to note that the complainant did not produce any expert evidence or expert opinion in support of his medical negligence complaint. After this detailed enquiry that lasted a year, the **KMC came to a unanimous conclusion that there was "No negligence or Violation of Code of Medical Ethics" by the Doctors and consequently exonerated the doctors.**

In conclusion, it is evident that

1. The patient received the best possible treatment at Fortis Hospital over a period of 23 months from June 2008 till May 2010 both as out-patient and in-patient.
2. Cadaver kidney + pancreas transplantation was done with the consent of the patient and her family.
3. The patient developed extensive bleeding after surgery due a blood disorder called Disseminated Intravascular Coagulation (DIC). All appropriate treatment was given for DIC and over the next 3 days, the bleeding rate did decrease and she was improving. In fact, she was alert and responsive and communicating with doctors, nurses and her family members.
4. On post-operative day 3, the patient developed fever which worsened on the next day (post-operative day 4) and she died because of infection and septic shock.

Thus, it is very clear that the patient has received the best possible care before, during and after surgery. All the doctors involved the care of this patient tried their level best to save the patient. Unfortunately, patient succumbed due to her medical condition namely diabetes and kidney failure.