15 -ാം കേരള നിയമസഭ

6 -ാം സമ്മേളനം

നക്ഷത്ര ചിഹ്നം ഇല്ലാത്ത ചോദ്യം നം. 2128 **01-09-2022 - ൽ മറുപടിയ്ക്ക്**

വൃക്ക മാറ്റിവച്ച രോഗി മരിച്ച സംഭവത്തിന്മേലുള്ള അന്വേഷണം

ചോദ്യം		ഉത്തരം	
ശ്രീ എം വിൻസെന്റ്		**ശ്രീമതി വീണാ ജോർജ്ജ്** **(ആരോഗ്യ- വനിത-ശിശുവികസന വകുപ്പ് മന്ത്രി)**	
(എ)	തിരുവനന്തപുരം മെഡിക്കൽ കോളജിൽ വൃക്ക മാറ്റിവച്ച രോഗി മരിച്ച സംഭവത്തിൽ ആരോഗ്യ വകുപ്പ് അഡീഷണൽ ചീഫ് സെക്രട്ടറിയുടെ അന്വേഷണം പൂർത്തിയായോ; അന്വേഷണ റിപ്പോർട്ട് ലഭ്യമാക്കുമോ;	(എ)	അന്വേഷണം പൂർത്തിയായിട്ടുണ്ട്. അന്വേഷണ റിപ്പോർട്ടിന്റെ പകർപ്പ് അനുബന്ധമായി ചേർക്കുന്നു.
(ബി)	അഡീഷനൽ ചീഫ് സെക്രട്ടറിയുടെ അന്വേഷണത്തിന്റെ ഭാഗമായി മരണമടഞ്ഞ രോഗിയുടെ ബന്ധുക്കളിൽ നിന്ന് വിവരങ്ങൾ ശേഖരിച്ചിരുന്നോ; എങ്കിൽ എന്തൊക്കെ വിവരങ്ങളാണ് ലഭിച്ചതെന്ന് വിശദമാക്കുമോ; പ്രസ്തുത വിവരങ്ങൾ ശേഖരിച്ചിട്ടില്ലെങ്കിൽ അതിനുള്ള കാരണം വിശദമാക്കുമോ;	(ബി)	ഇല്ല. ഈ വിഷയത്തിൽ വകുപ്പുതല അന്വേഷണമാണ് അഡീഷണൽ ചീഫ് സെക്രട്ടറി നടത്തിയിട്ടുള്ളത്. ട്രാൻസ്പ്ലാൻറുമായി ബന്ധപ്പെട്ട പ്രവർത്തനങ്ങളുടെ ഏകോപനത്തിലും മാനേജ്മെന്റിലും കോർഡിനേഷനിലും എന്തെങ്കിലും വീഴ്ചയുണ്ടായിട്ടുണ്ടോ എന്നും ഒഴിവാക്കാവുന്ന കാലതാമസം ഉണ്ടായിട്ടുണ്ടോ എന്നുമുള്ള വിഷയങ്ങളാണ് അന്വേഷണത്തിന്റെ പരിധിയിൽ ഉൾപ്പെട്ടിരുന്നത്. ആയതിനാലാണ് രോഗിയുടെ ബന്ധുക്കളിൽ നിന്ന് വിവരങ്ങൾ ശേഖരിക്കാതിരുന്നത്.
(സി)	വിഷയം സംബന്ധിച്ച കേസന്വേഷണത്തിന്റെ ഭാഗമായി മെഡിക്കൽ ബോർഡ് രൂപീകരിക്കണമെന്നാവശ്യപ്പെട്ട് പൊലീസ് അന്വേഷണ ഉദ്യോഗസ്ഥൻ കത്ത് നൽകിയിരുന്നോ; എങ്കിൽ പ്രസ്തുത കത്തിന്മേൽ സ്വീകരിച്ച നടപടിയെന്താണന്ന് വ്യക്തമാക്കുമോ?	(സി)	കേസന്വേഷണത്തിന്റെ ഭാഗമായി മെഡിക്കൽ ബോർഡ് രൂപീകരിക്കണമെന്നാവശ്യപ്പെട്ട് അന്വേഷണ ഉദ്യോഗസ്ഥനായ കഴക്കൂട്ടം സൈബർ സിറ്റി സബ് ഡിവിഷൻ അസിസ്റ്റന്റ് കമ്മീഷണർ തിരുവനതപുരം ജില്ലാ മെഡിക്കൽ ഓഫീസർക്ക് കത്ത് നൽകിയിട്ടുണ്ട്. ആയതിനൊപ്പം ലഭിച്ച പോസ്റ്റ്മോർട്ടം റിപ്പോർട്ടിൽ opinion as to cause of death ലബോറട്ടറി ഇൻവെസ്റ്റിഗേഷൻ പെന്റിംഗ് ആയതിനാൽ റിസർവ്വ് ചെയ്തിട്ടുള്ളതായി രേഖപ്പെടുത്തിയിരിക്കുന്നു. രോഗി മരണപ്പെടുന്ന കേസുകളിൽ ഫൈനൽ പോസ്റ്റ്മോർട്ടം റിപ്പോർട്ടും കെമിക്കൽ അനാലിസിസ് റിപ്പോർട്ടും ജില്ലാ മെഡിക്കൽ എക്സ്പർട്ട് കമ്മിറ്റിയിൽ കേസ് പരിഗണിക്കുന്നതിന് അത്യാവശ്യമാണ്. ആയതിനാൽ, പ്രസ്തുത കേസിൽ മേൽപ്പറഞ്ഞ റിപ്പോർട്ടുകൾ കൂടി ബന്ധപ്പെട്ട അന്വേഷണ

			ഉദ്യോഗസ്ഥനായ കഴക്കൂട്ടം അസിസ്റ്റന്റ് പോലീസ് കമ്മീഷണർ സമർപ്പിക്കുന്നതിന് ജില്ലാ മെഡിക്കൽ ഓഫീസിൽ നിന്നും കത്ത് നൽകിയിട്ടുണ്ട്. കഴക്കൂട്ടം അസിസ്റ്റന്റ് പോലീസ് കമ്മീഷണറിൽ നിന്നും മേൽപറഞ്ഞ റിപ്പോർട്ടുകൾ കൂടി ലഭ്യമാകുന്ന മുറയ്ക്ക് ടി രോഗിയുടെ ചികിത്സയുമായി ബന്ധപ്പെട്ടുള്ള വിവരങ്ങൾ പരിശോധിക്കുന്നതിന് ടി മേഖലയിൽ നിന്നുമുള്ള വിദ്ഗ്ധ ഡോക്ടർമാരെ ഉൾപ്പെടുത്തി ജില്ലാ മെഡിക്കൽ എക്സ്പർട്ട് കമ്മിറ്റി രൂപീകരിച്ച് ഈ കേസ് പരിഗണിക്കുന്നതും അഭിപ്രായ റിപ്പോർട്ട് അന്വേഷണ ഉദ്യോഗസ്ഥൻ കൈമാറുന്നതുമാണ്.

സെക്ഷൻ ഓഫീസർ

REPORT ON THE ENQUIRY VIDE GO (Rt) 1484/2022/H&FW dated 22-06-2022

Subject: Alleged delay in kidney transplant at Government Medical College Trivandrum on 19th June 2022, and its possible connection to the death of the recipient.

Scope of the enquiry:

1. Was there any unjustified and avoidable delay or lapse in any step of the procedure of the organ retrieval and transport process, transplant surgery or post care?
2. If so, did this have any impact on the outcome of the transplant operation?

Methodology

The persons who were directly involved in the matter, and a few persons who could witness to the incidents of Sunday the 19th June, were interviewed. Statements were also taken from them. The records of the case were examined, including the preliminary inquest report. The guidelines GOI and GOK regarding organ transplant and the duties and responsibilities of the personnel of K-SOTTO were also perused.

To assist in answering the second question, which involves specialized medical expertise, a team of medical experts was set up vide GO (Rt) 1631/2022/H&FWD dated 05-07-2022. That part of the inquiry is progressing.

Findings:

1. **What were the potential sources of delay and was there any delay?**
    a. Sending samples for cross-matching (no delay noted, as the potential candidates needed to arrive at the hospital)
    b. Sending potential recipients for tests and dialysis (possible savings of at least half an hour)
    c. From arrival of organ to receipt at theatre (10 to 15 minutes, but since the recipient's dialysis and incident management took more time than expected, there was no consequence in this case)
    d. Time taken to prep the recipient patient after dialysis (no delay noted)
    e. Wait time for surgeon to arrive (no unusual delay noted.)

2. **Could the dialysis of the persons preliminarily selected have been scheduled earlier?**
    - There are nine dialysis beds in the Nephrology department. It is stated by the SOTTO Nodal Officer that the first dialysis started at 12 noon. It appears that the dialysis started before the crossmatching results were in. As the nine dialysis beds were not all occupied between 8 a.m. and 4 p.m., all the potential transplant recipients (and the deceased patient Mr. Sureshkumar) could have been taken up for dialysis earlier.
    - Mr. Sureshkumar's evaluation was completed by 10 a.m. according to messages sent to Dr Vasudevan. It is not clear why he was not taken up for dialysis right away.
    - The preferential scheduling of potential recipients to dialysis beds could have been done by the Nephrology HOD, but he was not in station and he had not given charge to his next in command, and he had also not followed up with anyone in his department to ensure that the activities were happening in time.
    - The reason why the operation happened over 2 hours after the organ arrived, is stated to be because the recipient patient was not ready for surgery till then. However, there is no indication that this could have changed the time of the surgery by anything more than an hour.

3. **Could the assessment of the possible recipients have been more detailed and would it have improved recipient selection or subsequent treatment?**
    - There is a system by which an updating of the records of the waiting list is supposed to be done by the Nephrology department/ K-SOTTO every three months. This was last done on April 2022, but may not have included the actual details of the patient's current work up records. It is not clear whether the list of 44 persons used to call candidates on Sunday 19th June, was the updated list as of April 2022.
    - In the absence of pre-existing medical work up as of April 2022 (the date of last updating), reliance was placed on the records of 2021 in the case of the Recipient Mr Suresh Kumar.
    - The entire job of assessing and working up the potential recipients appears to fall on the Nephrology department and hence the HOD Nephrology is

responsible for ensuring that this is being done properly. The HOD Nephrology has not even contacted his department team to find out whether the activities are on schedule.

- The HOD Urology appears to have made all necessary inquiries and kept himself informed about the status of activities throughout Sunday.
- The medical expert team assisting this enquiry should assess whether the work up and assessment done by the PGs on Sunday 19th June was adequate to estimate the current condition of the Recipient Mr. Suresh Kumar

4. **Could the choice of recipient been done differently and if yes, would it have made a difference to the choice of recipient?**
    - Although seniority in the waiting list is the primary criterion for selecting a recipient out of the otherwise matched and fit-for-operation candidates, it is understood that some institutions have committees consisting of doctors from the relevant departments that consult and discuss to decide on the most appropriate recipient out of the potentials from the waiting list.
    - There is no clear evidence as to when the decision that Sureshkumar would be the recipient was taken, and whether the inputs of all departments concerned was taken, and who exactly took the decision. The HOD Urology has given some indication in this regard, that the decision was taken only after 2 p.m.
    - The messages sent to the Urology HOD show that some information was available regarding the current findings in Echo and Doppler etc, including the calcification and some diastolic dysfunction. Given the assessment of risk in the records of the previous Urology consultations, the expert team advising this enquiry, should also assess whether the available (and testable) information about the Recipient Sureshkumar could have eliminated him as a potential recipient or raised him to High Risk rather than Moderate Risk.

5. **Could the transport and receipt of the kidney have been done any faster or any better?**
    - The Transplant Coordinators failed to even come to the hospital or even coordinate or assist by phone. All the work that they were supposed to do was done by the PGs of Nephrology or Urology. Note that in the (private) donor hospital, their Transplant Coordinator was available and involved right from

receiving the doctors from Amrita and MCT and seeing off the organ transport ambulances.

- The task of arranging for the ambulance and the receipt of the organ was entirely that of the Transplant Coordinators. This is clearly listed in their duties and responsibilities. Other than giving the Nephrology PG a phone number of Ranjit Ambulance Services (which is the only service they appear to have used over the last 6 or 7 years), the Transplant Coordinator Mr Aneesh admits that he has done nothing else.
- The claim of one Transplant Coordinator Mr Vinod is that he was on leave on Saturday, and that the leave had been applied for earlier. This does not excuse his complete refusal to even find out what is being done in the hospital on Sunday, and whether any substitute is carrying out his duties.
- The Transplant Coordinator Mr Aneesh has given no reason for his absence from duty. Although the 19th (the day when all the work of the Transplant Coordinators was to be carried out) was a Sunday, it does not excuse the Transplant Coordinators from coming to work. The work of organizing organ transplants is not something that can be scheduled for workdays and daytime hours. *The work of the Transplant Coordinators is something that has to be done on whichever day the organ becomes available and that will include Sundays.* It must be noted that doctors and other staff - even those who were not posted on duty - were working round the clock.
- The Transplant Manager (who has anyway no authority over the Transplant Coordinators) lives away from Trivandrum, and did not come to the hospital, but did a fair amount of her duties over phone.
- The K-SOTTO Executive Director has been inexplicably lenient in this matter, not even insisting that the SOTTO staff should be on duty on-site to carry out their responsibilities. He should explain his non-action in the matter
- The organ box was to be received by the Transplant Coordinator when it arrived. But the Transplant Coordinators defaulted in their duties. They were not there, and they had not arranged for someone else to be there in their stead. This is the main reason for the absence of the designated person to receive the ambulance and the organ box at arrival at MCT.

- This also explains why the lift was not kept ready for the arrival, why the wrong theater door was used, and why there was no doctor in scrubs ready to receive the box (all these should have been coordinated and managed by the Transplant Coordinators).
- Again, the SOTTO Executive Director, knowing that these Transplant Coordinators were absent and were not doing their job, should have made alternate arrangements to cover for their absence.
- The administrative issues surrounding the employment of these Transplant Coordinators may have been known to the Ambulance Service, leading to the arrangements made by the Ambulance Service or by outsiders for receipt of the organ.

The final question that remains to be answered is whether the operation that started at 9 p.m. on the 19th could have been started any earlier and whether it would have made any difference to the outcome of the operation. As the first potential candidate was taken in for dialysis after noon, based on the possible timing of dialysis, theoretically there could have been an hour's savings. As the kidney is considered viable for at least 18 hours (some studies say it is viable for up to 24 hours), there is no indication that starting the operation 60 minutes earlier would have made any difference to the outcome of the operation.

However, a team of medical experts have been asked to opine whether the processes involved in assessing the candidates, deciding the recipient, preparing the recipient, and conducting the operation and the post-op care, could have been done more efficiently and whether any act of commission or omission could have impacted the outcome of the operation. Most significantly, whether there were any red flags in recipient selection and care that were missed by the team. Their report is awaited.

Conclusions/ Recommendations:

i. Any transplant from a deceased donor is by its very nature, not something that can be scheduled in advance. There are government orders that specify the actions to be taken in any transplant case, but these are not in the form of a checklist of activities with points of responsibility specified. Based on the experience of

previous cadaveric transplants done in Trivandrum Medical College, and other medical colleges of the state, the K-SOTTO Executive Director and Nephrology department could have created a process flow and checklist to ensure a seamless procedure for the transplant – from off-site donor to recipient. Such a checklist could also have ensured that in emergency situations, the jobs or activities involved can be easily understood and transferred to available personnel.

ii. The suspension of the HODs of Nephrology and Urology departments may be revoked.

iii. Disciplinary action may be taken against the HOD of Nephrology for dereliction of duty, unauthorized absence, supervisory lapse and failure of coordination. It is clear that the HOD Nephrology had not taken permission to leave station on Sunday the 19th (and had not informed the Principal/DME) and left the state without giving charge of the department to anyone. In spite of knowing from Saturday 18th that the donor kidney was to be received the next day, he did not make necessary arrangements to ensure that the role of the Nephrology department was carried out well. He also did not even call to find out status updates of the situation in the hospital.

iv. The contracts of the two Transplant Coordinators of SOTTO (Mr Vinod and Mr Aneesh) should be terminated immediately. The role of the Transplant Manager Ms Sharanya should be clarified by the K-SOTTO Executive Director, including a clear indication of how her duties can be done without coming to the hospital (as she lives far away from the medical college). There are at least two other staff of K-SOTTO whose duties and actual output are not clear. The chain of command in K-SOTTO should be clearly articulated.

v. The K-SOTTO Executive Director should give a report to the DME regarding the actions taken to improve the process flow and the functioning of the K-SOTTO staff, including hiring and training new staff. As the number of actual transplants in Trivandrum (about 40/year), Kozhikode (about 35/year) and Kottayam (about 5/year) is not high, the coordinators should be used to ensure more detailed and more frequent updating of waiting lists and other ancillary activities.

vi. A Committee should be set up for the selection of organ recipients using the criteria accepted and laid down in the guidelines of GOI, GOK etc. The decisions taken by the Committee should be well documented, with proper justifications.

vii. Based on my inquiries, it is clear that *the outcome of the transplant surgery was not affected by the 10 to 15 minutes delay in the receipt of the organ at the Medical College hospital*. In addition, my inquiries could not prove that the outcome of the surgery would have been any different if the dialysis and surgery had been done an hour earlier, but the report of the team of experts may be awaited to establish this aspect.

Dr Asha Thomas, ACS Health (Med Edn)
15-07-2022