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5th NATIONAL CONVENTION ON MEDICINE & LAW 2020

| WHITE PAPER |

5th JULY, 2020

WHITE PAPER ON LEGAL ISSUES IN HEALTH CARE - 2020

Recommendations of the '5th National Convention on Medicine & Law 2020'

THIS WHITE PAPER documents the recommendations of the 5th National Convention on Medicine & Law 2020 organized by the Institute of Medicine & Law on the 5th July 2020. In view of the current pandemic, for the first time, this Convention was organized online. Two sessions were organized on 'Organ Transplant in India – Legal Issues and Solutions' and 'Legal & Regulatory Framework for Tele-Health – The Way Forward'. Thought leaders amongst doctors, lawyers, editors of medical and law journals, academicians, and representatives from medical associations, hospitals, regulators and policy makers were part of the deliberations.

Healthcare in India is at crossroads and newer challenges are emerging with every passing day. This makes it imperative for doctors, medical associations, and hospitals to come together to identify and discuss the legal issues relating to medicine and to find practical and legally appropriate solutions. Policy makers need to be updated about these contentious issues and the changes required in the legal and regulatory framework.

The Convention is a platform to identify the legal issues relating to medicine, discuss them threadbare, and suggest remedial measures. The suggestions and actions recommended by the Convention will be conveyed appropriately to the regulators and policy makers.

5th National Convention on Medicine & Law 2020
Session on ''Organ Transplant in India - Legal Issues and Solutions'

CHAIRPERSON:

Justice (Retd.) Sunil Ambwani
Former Chief Justice Rajasthan High Court
Chairman - e-Committee, Supreme Court

Moderator:

Dr. Parag Rindani
CEO - Wockhardt Hospital, Mumbai

Convenor:

Dr. T. N. Ravisankar
Faculty in Medical Law - Anna Institute of Management
Founder-member - 'Professional Protection Scheme', IMA, Tamil Nadu

Speakers (Indian)

Dr. Bharat Shah
Secretary - ZTCC Mumbai
Managing Trustee - Narmada Kidney Foundation

Dr. Dhruva Chaudhary
President – Indian Society of Critical Care Medicine

Dr. Harish Pathak
HOD - Forensic Medicine, KEM Hospital, Mumbai

Dr. Lalit Shah
Convenor, Legal Cell - Urological Society of India

Mr. Mahendrakumar Bajpai
Advocate - Supreme Court
Hon. Director - Institute of Medicine & Law

Dr. Noble Gracious
KNOS - Kerala Network for Organ Support

Dr. Rahul Pandit
Indian Society of Critical Care Medicine

Dr. Ratna Devi
Chair - International Alliance of Patient Organisations
Founder - Indian Alliance of Patient Groups
Founder Board Member - NCD Alliance in India

Dr. Roop Gursahani
Neurology Society of India

Dr. S. K. Mathur
President – ZTCC Mumbai

Dr. Sunil Shroff
Mohan Foundation

Dr. Swarnalatha
Jeevandan, Telangana

Dr. Vasanthi Ramesh
Director – National Organ & Tissue Transplant Organisation (NOTTO)

Speakers (International)

Dr. Ajith Tennakoon
Chief Judicial Medical Officer - Department of Forensic Medicine, Institute of Forensic Medicine and Toxicology, Sri Lanka

Dr. Joseph Palmero
Superintendent / Chief Medico-legal - Philippine National Police Crime Laboratory

Dr. Maria Paula Gomez
Executive Director - DTI Foundation, Parc Científic de Barcelona, Barcelona, Spain

Special Thanks for the invaluable contribution

Ms. Olga Joos
CDC Foundation, US

Dr. Luc Noël
Former “Coordinator Clinical Procedures", WHO, Geneva

Mr. C.E Karunakaran
Managing Trustee, NNOS Foundation

TOC

01. Simpler Laws

India has a robust statutory framework on organ donation and transplant which was enacted in 1994, the Transplantation of Human Organs Act and the rules thereunder were laid down in 1995. The Act was amended in 2011 and the rules were further amended in 2008 and 2014. The purpose of the said Act is to regulate retrieval, storage and transportation of human organs for therapeutic purpose and prevent commercial dealings in human organs. The statutory framework has appropriate mechanism to protect the underprivileged and prevent exploitation.

Unfortunately, the current statutory framework instead of making the process simpler seems to have made it more tedious especially for cadaver transplant. The problem gets further compounded in cadaver transplants as the issues such as religion, emotions, social norms, and so on. Hospitals, both transplant centers as well as retrieval centers are the ones that are the most affected.

Recommendations

- *The statutory processes and procedures should be made simpler and easily implementable.*
- *Processes and procedural formalities related to Brain-stem Deaths should be made easier and convenient for both the patients and the healthcare providers.*
- *The procedural responsibilities should be more on the statutory and hospital authorities instead of the doctors involved with the patient. Doctors should be made less accountable; but monitoring must be robust.*
- *A single authority for reporting, compliance and directions should be contemplated.*

02. Uniform Determination of Death

The absence of a uniform definition of death in India is posing a big problem today, especially in organ donation. The legal definition of death is found in three statutes, namely:

- **Registration of Births and Death Act, 1969 - Section 2b.**

  "Death" means the permanent disappearance of all evidence of life at any time after live-birth has taken place

- **Indian Penal Code - Section 46**

  "Death" — The word "death" denotes the death of a human being, unless the contrary appears from the context

- **Transplantation of Human Organs Act, 1994 - Section 2d & 2e**

(d) "brain-stem death" means the stage at which all functions of the brain stem have permanently and irreversibly ceased and is so certified under sub-section (6) of section 3.

(e) "deceased person" means a person in whom permanent disappearance of all evidence of life occurs, by reason of brain-stem death or in a cardio-pulmonary sense, at any time after live birth has taken place;

Brain-stem Death is included in the definition of death only in the Transplantation of Human Organs Act and therefore its application is limited only in cases where the said Act is applicable, that is only when organ donation is contemplated and not otherwise. This is in accordance with the universally acceptable laws of interpretation of statutes.

In fact, the Registration of Births and Death Act defines death as permanent disappearance of all evidence of life whereas in case of Brain-stem Death the heart, lungs and other parts of the body are still functioning as a unit. This statutory incompatibility is causing confusion and hindrance in declaring Brain-stem Deaths.

Brain-stem Death is applicable only in case of organ donation and is not otherwise accepted as death in India. Diagnosis and declaration of Brain-stem Death is done only when the patient's relatives agree for organ donation. It is fairly common that after agreeing to donate organs and completion of all procedures relating to Brain-stem Death, the family changes its mind and thereafter the patient is not declared as dead.

This legal problem has been one of the reasons for low donations in a few States. This is also straining healthcare resources, especially in public healthcare facilities as a person who is Brain-stem dead keeps occupying the intensive care set-up till cardio-respiratory death occurs. India therefore needs a central law on uniform determination of death.

Furthermore, even after a patient is declared Brain-stem dead the medical team and the hospital administrator are reluctant to switch off the ventilator. The need of the hour is to have clear provisions in the current Act or the rules made thereunder making it mandatory to remove ventilator from such a patient.

Some States in India have recognized this problem and have come up with appropriate solutions. Kerala and Gujarat have notified statutory guidelines whereby a mandatory duty is cast on healthcare providers to declare Brain-stem Death without waiting for consent for organ donation and thereafter the ventilators can also be switched off.

Recommendations

- *The issue of organ donation and definition of Brain-stem Death should be decoupled.*
- *Parliament should pass a central law on the lines of 'Uniform Determination of Death Act (UDDA)', a model legislation from United States on the subject. Alternatively, the definition of death in The Registration of Birth and Death Act, which is currently in the process of getting amended, should include Brain-stem Death as a form of death.*
- *Another option is to simply amend the Act and to append the current definition of 'Brain-stem Death' with the following - "and shall also be deemed to be death under the relevant provisions of the registration of Births and Deaths Act 1969 irrespective of removal of human organs or tissues."*
- *The current statutory framework should include a very specific provision, an enabling but mandatory one, for removing the ventilator from a Brain-stem dead patient.*

03. Surrogate Decision-making Hierarchy

Surrogate decision making is a big problem in healthcare. It causes huge chaos especially in times of crisis. Close relatives of an incompetent patient are often found to be disagreeing amongst themselves on the treatment preferences for the patient. The problem is not limited to organ donation but extends to other areas such as end-of-life decisions and is experienced across the world.

Most of the jurisdictions in the world have legislated on this aspect very specifically. Uniform Anatomical Gift Act (UAGA) in United States and Human Tissues Act (HTA) in United Kingdom are the prominent ones that clearly define who can give consent for donation.

A typical surrogate decision-making hierarchy is as follows:

- A court appointed protector / guardian who supersedes everyone
- Spouse or partner, including civil partner
- Parent / child
- Brother / sister
- Grandparents / grandchild
- Niece / nephew
- Stepfather / stepmother
- Friends

In India, the term "near-relative" was defined in the original Transplantation of Human Organs Act (1994) to include only the first-degree relatives, that is, "spouse, son, daughter, father, mother, brother or sister". This definition was substituted by the 2011 amendment, and the current definition is as follows:

Transplantation of Human Organs Act, 1994 - Section 2 (i)

"near-relative" means spouse, son, daughter, father, mother, brother, sister, grandfather, grandmother, grandson or granddaughter"

The current law merely provides a list of near relatives but neither prescribes the hierarchy nor the procedure for surrogate decision-making. Furthermore, a uniformly

applicable surrogate hierarchy is not found in any other statutory instrument in India.

In June 2020, All India Institute of Medical Sciences (AIIMS) published an end-of-life care guidance document which has a surrogate hierarchy. It not only recognizes the spouse but also the live-in partner. Unfortunately, this document does not dwell on how the relationship should be verified and the process of involving surrogates in decision-making. Furthermore, legally speaking this will merely be a guidance document without any force of law. Healthcare providers are therefore bound to shy away from using this hierarchy in real life situations.

India has one more problem, a unique one. It is the absence of a uniform civil code. Every religion has its own hierarchy of relatives statutorily defined in their personal laws. This issue is also politically contentious. But a uniform hierarchy can certainly be prescribed only for healthcare purposes especially for organ donation.

One alternative that can be explored is that whenever there is a dilemma on the surrogate hierarchy, the issue can be referred to the District Government Counsel, Civil (DGC Civil) for opinion who in turn can refer it to the court. But this process would obviously be time-consuming and grossly unworkable for organ donation.

Recommendations

- ***Surrogate decision-making hierarchy should be statutorily defined at least for organ donation. This definition could be extended to end-of-life care and such other purposes in healthcare. The socio-cultural preferences of the Indian society should be taken into account in defining the order of decision makers. The list should be comprehensive and the order of preference should be clearly laid down.***
- ***Procedures and processes relating to surrogate decision-making should also be statutorily prescribed so that there is no confusion at the point of delivering health care. If the member on the top of the list is not present at that point in time, the next in the list should be given the authority to take decision.***

04. Medico Legal Cases (MLC)

The legal necessity to perform post mortem in medico legal cases causes delays or even results in refusal to donate. It is quiet common that even after initially agreeing to donate, the family later refuses for the same as they apprehend further delay in getting the dead body. The State of Tamil Nadu recently reported steep decrease of 76% in organ donation and one of the biggest reasons for the same was medico legal cases requiring inquest.

Most medico legal cases, especially accident victims, have head injuries and the cause of death is absolutely clear yet the body is sent for post mortem. The involvement of the police ought to be minimal in case of accident victims where the doctors are sure about the cause of death but this does not happen and the usual procedure followed in other medico legal cases is followed.

In US, autopsies are not performed in such cases. The relatives are informed about the nature of death and the organs are retrieved.

In India, the Transplantation of Human Organs Act 1994 and Transplantation of Human Organs and Tissues Rules 2014 provide
The legal framework governing organ donation in medico legal cases is as follows:

Transplantation of Human Organs Act, 1994 - Section 6.
Authority for removal of human organs from bodies sent for post-mortem examination for medico-legal or pathological purposes.
Where the body of a person has been sent for post-mortem examination-

(a) for medico-legal purposes by reason of the death of such person having been caused by accident or any other unnatural cause; OR

(b) for pathological purposes,

the person competent under this Act to give authority for the removal of any human organ from such dead body may, if he has reason to believe that such human organ will not be required for the purpose for which such body has been sent for post-mortem examination, authorize the removal, for therapeutic purposes, of that human organ of the deceased person provided that he is satisfied that the deceased person had not expressed, before his death, any objection to any of his human organs being used, for therapeutic purposes after his death or, where he had granted an authority for the use of any of his human organs for therapeutic purposes after his death, such authority had not been revoked by him before his death.

Transplantation of Human Organs and Tissues Rules, 2014 - Rule 6.

Procedure for donation of organ or tissue in medicolegal cases.

(1) After the authority for removal of organs or tissues, as also the consent to donate organs from a brain-stem dead donor are obtained, the registered medical practitioner of the hospital shall make a request to the Station House Officer or Superintendent of Police or Deputy Inspector General of the area either directly or through the police post located in the hospital to facilitate timely retrieval of organs or tissue from the donor and a copy of such a request should also be sent to the designated post mortem doctor of area simultaneously.

(2) It shall be ensured that, by retrieving organs, the determination of the cause of death is not jeopardised.

(3) The medical report in respect of the organs or tissues being retrieved shall be prepared at the time of retrieval by retrieving doctor (s) and shall be taken on record in post-mortem notes by the registered medical practitioner doing post-mortem.

(4) Wherever it is possible, attempt should be made to request the designated post-mortem registered medical practitioner, even beyond office timing, to be present at the time of organ or tissue retrieval.

(5) In case a private retrieval hospital is not doing post mortem, they shall arrange transportation of body along with medical records, after organ or tissue retrieval, to the designated post-mortem center and the post mortem center shall undertake the post-mortem of such cases on priority, even beyond office timing, so that the body is handed over to the relatives with least inconvenience.

There are two distinct issues in medico legal cases.

The first issue pertains to the confusion on whether the retrieving hospital has to merely 'inform' the police about organ retrieval or a 'permission' is required. The relevant provision (Rule 6.[1]) simply states that "the registered medical practitioner of the hospital shall make a request to the Station House Officer or Superintendent of Police or Deputy Inspector General of the area either directly or through the police post located in the hospital to facilitate timely retrieval of organs or tissue from the donor". The term 'request' could be interpreted both the ways, that is 'to inform' or 'to take permission'.

But the hospital authorities across the country are interpreting it to mean that permission of the police is required before proceeding further, probably out of abundant precaution and fear of legal problems in future. In a widely reported case from Navi Mumbai, when the hospital sought permission for organ retrieval from the police, the police officer informed the relatives of the prospective donor that the doctors make money out of organ donations. The relatives ultimately refused to donate.

Furthermore, even NOTTO on its official website clearly states that "The police department has to be 'informed' that a patient is brain dead if it is a medico- legal case, but the declaration of Brain-stem Death is only done by a panel of doctors." (https://www.notto.gov.in/faqs.htm).

Efforts have been made repeatedly to get this confusion cleared but there is no authoritatively clarification on the correct procedure that should be followed in such cases. The need for an official clarification is therefore acute.

The second issue is that most of the retrieval centres are private hospitals and are not the designated autopsy centres. Generally, government hospitals are authorized as autopsy centres. After retrieving organs, the police performs 'Panchanama' and thereafter the dead body is shifted to the autopsy centre. At times, it takes upto 24 hours for performing post mortem and handing over of the dead body to the relatives. The relatives apprehend that this waiting period may further extend in case of organ donation.

Dr. Ajit from Sri Lanka pointed out that in their country all institutions have transplant coordinators who inform the police and get suitable approval. The judicial medical officer and the pathologist who will be performing autopsy later are also informed and they can attend the harvesting procedure to observe injuries and condition of the organs. Autopsy is done in the morgue and report is submitted to the respective authorities. This procedure has helped in improving transplants.

Dr. Joseph Pamero from Philippine pointed out that in their country they have an Eye Bank Foundation, a non-profit organization, that has MOU with the Philippine National Police

for retrieval of cornea from cadavers. Forensic autopsies are conducted by the medicolegal officers from Philippine National Police. The Eye Bank officials go with the on-duty forensic pathologist and after consent from the relatives, the eye bank official removes cornea prior to autopsy. If the next of kin is not available, law permits the hospital director and the forensic pathologist to give consent for retrieval of cornea. Furthermore, autopsy in case of accident is not mandatory. The law in general does not require autopsy unless the attending physician resist signing the death certificate.

Appropriate permission could be given to the retrieving hospitals in case of organ donation to conduct post mortem in the same hospital. A side room next to the Operation Theatre could very well be provided by the retrieving hospital for this purpose. The autopsy team can look at the dead and 'only' if required open the three cavities. This will reduce the time for handing over the dead body and the consequent trouble caused to the relatives. The retrieving hospital could pay for the expenses incurred in bringing the autopsy team to the retrieving hospital.

Recommendations

- *The statutory authorities should come out with a clarification about the need to only 'inform' the police about organ retrieval and not wait for their permission. Alternatively, hospitals associations and the police can jointly seek clarification from the authorities in this regard.*
- *Permission should be granted to perform post mortem of medico legal cases who have donated organs at the retrieval centers. The forensic team from the nearby authorized autopsy center should be directed to reach the retrieval center during harvesting or thereafter. All efforts should be made to ensure that the dead body is handed over to the relatives at the earliest.*

05. Unclaimed Bodies

The legislature in all its wisdom had contemplated and taken into account unclaimed bodies in hospital and prisons in the Act. The relevant provision is as follows:

Transplantation of Human Organs Act, 1994 - Section 5.

Authority for removal of human organs in case of unclaimed bodies in hospital or prison.

(1). In the case of a dead body lying in a hospital or prison and not claimed by any of the near relatives of the deceased person within forty-eight hours from the time of the death of the concerned person, the authority for the removal of any human organ from the dead body which so remains unclaimed may be given, in the prescribed form, by the person in charge, for the time being, of the management or control of the hospital or prison, or by an employee of such hospital or prison authorised in this behalf by the person in charge of the management or control thereof.

(2). No authority shall be given under sub-section (1) if the person empowered to give such authority has reason to believe that any near relative of the deceased person is likely to claim the dead body even through such near relative has not come forward to claim the body of the deceased person within the time specified in such subsection (1).

But inspite of the aforesaid express provision in the Act since 1994, not a single organ donation from an unclaimed body has happened in the last 25 years. One reason for this state of affairs happens to be the absence of appropriate rules and regulations on this specific aspect.

Recommendations

- ***Secondary legislation is required as the primary statute, Transplantation of Human Organs Act, 1994, has express provisions on this subject. Rules and regulations should be framed clearly specifying the criteria, procedures, roles, and responsibilities for organ donation in case of an unclaimed body.***

06. Fear-psychosis of Doctors

Fear among doctors about legal issues perhaps restrains them from getting involved in organ donation.

The non-implementation of a recent government order issued in Kerala in January 2020 is an excellent illustration of the aforesaid. The order clearly directs that in case of a patient who is certified as Brain-stem dead, doctors are free to remove ventilator even if the relative's object. But despite the order, none of the doctors have implemented this order to put off the ventilator due to the prevailing fear psychosis.

Recommendations

- *All stakeholders including the authorities should take clear, convincing and cogent steps to remove the fear psychosis of doctors and to instill confidence.*
- *An overarching law should be enacted to protect doctors for actions taken in good faith, similar to the protection provided to judicial officers. Any advice given by doctor should be presumed to be in good faith.*

07. Environmental Changes

Apart from legal changes, environmental changes are also required. Everyone has to be made aware of organ donation and its importance; the healthcare challenge before the country with the largest number of people suffering from non-communicable diseases; the resultant exponential rise in the number of people requiring organs; and the impossibility of meeting demand for organs unless the ordinary citizens of the country realize importance of organ donation and commit themselves to this cause.

Recommendations

- *Awareness and sensitization at every level using every possible means is required to motivate common people towards organ donation.*
- *A positive environment for organ donation needs to be created.*

07A. Hospital's Attitude

Cadaver organ donation is essentially a hospital centric process. Hence the focus inside the hospital must be greater. But the marked disinterest of the medical fraternity especially doctors in ICU happens to be a cause of concern.

Dr. Maria Paula Gomez, Executive Director - DTI Foundation, Spain, stressed the importance of recognizing organ donation as a distinct and important hospital service. She pointed out from global statistics that only the hospitals attitude towards organ donation has a direct correlation with the number of organ donation. A positive attitude and good knowledge especially of ICU staff is therefore very important. If doctors at hospitals are not following the legally correct steps, it is only due to lack of training and lack of knowledge of law.

Recommendations

- *Efforts should be made to change the attitude of the doctors working in hospitals, especially the ones in ICU's, by providing them appropriate training and information, especially about legal aspects of organ donation.*
- *Hospitals should have more transplant coordinator who should lead the donation process.*

07B. Public Awareness

There is a lot of mistrust and miscommunication about organ donation among the general public. There is a need to create mass awareness about organ donation.

Dr. Maria Paula Gomez, Executive Director - DTI Foundation, Spain, pointed out that the community must be informed periodically about the importance of organ donation rather than informing them about filling the organ donation forms or getting an endorsement on driving license.

Recommendations

- *There is need to drive mass awareness among general public about the importance and relevance of organ donation.*
- *Information about organ donation should be easily available at a number of public places, easily accessible to the masses, and that too from authoritative sources.*
- *Social media should be optimally used to promote the cause.*

07C. Media Sensitizing

Organ donation is today perceived as a 'racket' and to some extent media is also responsible for this sorry state of affairs. The headlines that are splashed about a few cases is causing irreparable harm to the ones who are waiting to get organs. There is a bad name attached with organ donation and this is one of the reasons for doctors and hospitals trying to play safe and donors are shying away. There is a need to educate and sensitize the media about organ donation. They must be made aware of the legal processes that are in place to protect donors and recipients from unscrupulous elements.

Recommendations

- *Media should be sensitized on organ donation, especially the law and the legal processes.*
- *Statutory bodies like NOTTO / ROTTO / SOTTO should take the lead in creating this awareness.*
- *Media should also be involved in evolving and implementing a comprehensive communication strategy to promote organ donation.*

08. Formal Patients Organization

The donors as well as recipients and their family members have apprehensions and misconceptions about organ donation. They need an answer and that too from an organization or authority that has the requisite information, is neutral and can be trusted. A formal patient's body for organ donation could fill this gap. Such a patient's body could not only dispel misconceptions about organ donation but also help new people navigate the system by providing them the right kind of information, counselling and sharing positive donor stories. Such a body can play an important role in channelizing non-monetary rewards and recognition programs in partnership with the authorities and the hospitals

Recommendations

- *A formal body having representatives of patients and the various patient's organization should be contemplated by amending the current legal framework. Alternatively, the authorities can recognize and involve a few of the existing patient's organization working in this domain with clearly defined*

09. Board of Medical Experts

Board of medical experts comprising of a team of doctors has to certify Brain-stem Death before retrieval of human organs. The relevant statutory provisions are:

Transplantation of Human Organs and Tissues Act 1994 - Section 3.(6).

Authority for removal of human organs

Where any human organ is to be removed from the body of a person in the event of his brain-stem death, no such removal shall be undertaken unless such death is certified, in such form and in such manner and on satisfaction of such conditions and requirements as may be prescribed, by a Board of medical experts consisting of the following namely:

(I) the registered medical practitioner in charge of the hospital in which brain-stem death has occurred;

(ii) an independent registered medical practitioner, being a specialist, to be nominated by the registered medical practitioner specified in cause (i), from the panel of names approved by the Appropriate authority;

(iii) a neurologist or a neurosurgeon to be nominated by the registered medical practitioner specified in clause (i), from the panel of names approved by the Appropriate Authority; and

(iv) the registered medical practitioner treating the person whose brain-stem death has occurred.

The number of experts in this Board could very well be reduced. The purpose can be served even by two doctors - the treating doctor and another specialist, who could be a neurologist or neurosurgeon. The inclusion of the doctor 'in-charge of the hospital' in the Board seems to be without any real purpose except for adding up the numbers of doctors in the Board. The doctor in-charge of the hospital is generally a non-clinician or even if clinician, he/she does not practice and is involved only in administrative functions. In practice, they sign the certificate only after the other three members of the Board have signed. Their inclusion therefore is a futile procedural requirement that should be removed.

The statutory provisions in Europe and UK mandate that such a certification is done by two doctors only.

Recommendations

- *The number of members constituting the Board of medical experts certifying Brain-stem Death should be reduced.*
- *The 'registered medical practitioner in charge of the hospital' should be removed from the Board of medical experts certifying Brain-stem Death.*
- *The registered medical practitioner treating the person and another specialist, neurologist or neurosurgeon should be sufficient to certify Brain-stem Death.*

10. Brain-stem Death Certificate

The Certificate issued by the Board of Medical Experts certifying Brain-stem Death is in Form 10 (For certification of Brain-stem Death) of the Transplantation of Human Organs and Tissues Rules, 2014. This certificate is issued under the following statutory provisions:

Transplantation of Human Organs and Tissues Rules, 2014 - Rule 5.(4).

A registered medical practitioner, before removing any organ or tissue from the body of a person after his or her death (deceased donor), in consultation with transplant coordinator, shall satisfy himself the following, namely:-

(a) ...

(b) ...

(c) that in the case of brain-stem death of the potential donor, a certificate as specified in Form 10 has been signed by all the members of the Board of Medical Experts referred to in sub-section (6) of section 3 of the Act:

Provided that where a neurologist or a neurosurgeon is not available, an anesthetist or intensivist who is not part of the transplant team nominated by the head of the hospital duly empanelled by Appropriate Authority may certify the brain stem death as a member of the said Board;

(d) that in the case of brain-stem death of a person of less than eighteen years of age, a certificate specified in Form 10 has been signed by all the members of the Board of Medical Experts referred to in sub-section (6) of section 3 of the Act and an authority as specified in Form 8 has been signed by either of the parents of such person or any near relative authorised by the parent.

This certificate (Form 10) is not the Death Certificate that is acceptable to the authorities for any purpose such as insurance claims. It is not even accepted by the Registrar of Births & Deaths. Hence another certificate has to be prepared by the hospital, the usual one. Thus two certificates are prepared in case of Brain-stem Death. It will be expedient if the Certificate issued by the Board of experts certifying Brain-stem Death is treated as the Death Certificate for all purposes and intent.

Recommendations

- ***Requisite changes should be made in Form 10 (For certification of Brain-stem Death) and the same should be accepted as the 'Death Certificate' of the Brain-stem dead person.***

11. Diagnosing / Declaring Brain-stem Deaths

One of the biggest hinderances in organ donation happens to be the abysmally low rate of Brain-stem Death certification in ICU. The fear psychosis and lack of knowledge, confidence and motivation among doctors and hospital management happens to be the crucial reason behind this marked disinterest resulting in low rate of organ donation.

The statutory provisions mandate that doctors after identifying Brain-stem Death patients have to approach the family for organ donation, but no procedure is prescribed for doing so or verifying whether the same has been done or not. Appropriate changes in laws are therefore required.

Both public and private sector hospitals should take appropriate steps in this direction. More doctors must be given the responsibility of diagnosing Brain-stem Deaths in hospitals. Hospitals having ICU should optimally use the services of skilled counsellors for the said purpose.

An independent committee of eminent doctors who are neither connected with the government or the hospitals doing transplant can audit deaths in ICU to find out the number of Brain-stem Deaths that were certified and if not, the reasons for not doing so.

Recommendations

- *Appropriate changes should be made in the law clearly specifying the procedure to be followed by doctors to identify and diagnose patients who are Brain-stem dead.*
- *Audits of ICU deaths can be taken up voluntarily or could be statutorily prescribed.*

12. Role of NOTTO / ROTTO / SOTTO

NOTTO, ROTTO and SOTTO (National / Regional / State Organ and Tissue Transplant Organization) are statutory bodies envisioned under the Act. They are responsible for laying down guidelines and protocols and for ensuing better connectivity between the donors and the recipients in different parts of the country. Unfortunately, SOTTO is still in the process of being formed in most of the States although the need to have regional connectivity is acute.

Furthermore, more transparency is required with respect to data uploaded by the transplant or retrieval centers to the national registry. This process has to be real-time and the allocation of organs should be digitized and transparent.

The list of transplant or retrieval hospitals available on the website of NOTTO should be user friendly keeping in mind the social and educational conditions of the common man. These statutory bodies should also provide information and knowledge, dispel misinformation and create awareness about organ donation amongst public.

Dr. Maria Paula Gomez, Executive Director - DTI Foundation, Spain, commented that organ donation cannot happen in isolation. Connectivity, networking and transparency about data as well as the legal and regulatory framework is required.

Recommendations

- *NOTTO should take the lead in making the requisite information and guidance available to the common man easily and also in creating awareness.*
- *Ensuring greater transparency and making real-time information available should be taken up by NOTTO on high priority.*

13. Public Hospitals

A very large number of patients come to public hospitals. Unfortunately, in most of the States in India public hospitals exhibit an apathetic attitude towards organ donation. Infrastructure bottlenecks and shortage of resources seems to be the primary reasons for this sorry state of affairs. The State as well as the hospital authorities need to address these issues and motivate the doctors and hospital administrators in this direction. Public-private partnership especially collaboration in multi-organ transplants is one way of promoting organ donation.

Recommendations

- *Organ donation should be promoted in public hospitals.*
- *Newer avenues such as public-private partnership should be seriously explored with the clear objective of increasing organ donation and ensuring equitable access as well as safety, quality and efficacy.*

14. Increasing NTORC's

There is a need to recognize more hospitals as Non-Transplant Organ Retrieval Centers (NTORC). This can be done without diluting the criteria for getting recognized but the processes and procedures for getting recognition must be made simpler. More and more hospitals must be identified and motivated to become NTORC.

Recommendations

- *The authorities should contemplate and ensure that the process for getting recognition as NTORC simpler.*

15. Alternatives / Ancillary Tests to Apnea Test

The current law recognizes only apnea test as the tool to confirm Brain-stem Death. But there are various instances when this test cannot be performed such as patients having high cervical spine fracture or bilateral orbital fractures. Medical science approves of other tests by which Brain-stem Death can be confirmed.

Recommendations

- *Other ancillary tests for determining Brain-stem Death when apnea test is not possible should be made legally permissible.*

16. Donation after Cardiocirculatory / Cardiopulmonary Death (DCD)

There is nothing in the current law that expressly or even impliedly prohibits or in any way restrains Donation after Cardiocirculatory / Cardiopulmonary Death (DCD). But the statutory framework fails to prescribe specific procedures and processes for the same resulting in indifference amongst healthcare providers towards DCD.

Recommendations

- *Appropriate rules, regulations and/or guidelines on Donation after Cardiocirculatory / Cardiopulmonary Death (DCD) should be framed and notified.*

17. Medical Curriculum

The definition of death in the current medical curriculum is only cardio-pulmonary death. Students of medicine must be made aware of the changes that have happened in law and the concept of Brain-stem Death must be introduced. The Medical Council of India had already taken a decision to include the topic of organ donation and transplant in the curriculum for under-graduates and post-graduates.

Recommendations

- *Brain-stem Death should be introduced in the undergraduate and postgraduate curriculum in medical colleges at the earliest. Educating on the process and imparting training in organ donation should be introduced in certain postgraduate specialities such as anesthesia, emergency, neurosurgery and neurology.*

18. Tier-2 / Tier-3 Cities

Awareness and activities about organ donation are largely a big-city phenomenon in India today. There is an urgent need to give more attention to Tier-2 and Tier-3 cities. There are good hospitals that can be designated and recognized as Non-Transplant Organ Retrieval Centers (NTORC). Efforts must be made to ensure that proper awareness and information about organ donations percolates down to these cities also.

Recommendations

- *There should be concerted efforts to create awareness about organ donation in Tier-2 and Tier-3 cities.*
- *Hospitals in these cities should be facilitated and recognized as NTORC.*

19. Incentivizing Family

For cadaver transplants, the family of the donor can be incentivized in some way, not necessarily monetarily. One such suggestion is to ensure that the immediate family members get preference in organ allotment should they need it in future. A specific provision could be added in the current statutory framework.

Recommendations

- *Donor family should be incentivized by giving immediate family members preference in getting organs in future.*
- *Donor family should be accorded, honor, recognition, respect, acknowledgment and attention from the State as well as the society.*

20. Opt-in System vis-a-vis Opt-out System

The efficacy of opt-in as compared to the opt-out system happens to be one of the most debatable issue in organ donation all over the world.

Dr. Maria Paula Gomez, Executive Director - DTI Foundation, Spain, pointed out from statistics that there is no correlation between the countries who have opt-in or opt-out systems and the number of donations. Countries with opt-in legislation also have good number of organ donation and there is no marked increase if one shifts to opt-out.

The current Indian system of opt-in seems to be appropriate. But the system for registration for organ donation must be made more robust and easier for the donor.

Recommendations

- *No change in the current opt-in system is required.*
- *The current systems and processes should be made more robust and easier for the donor.*

21. COVID Period

The number of organ donations and transplants have reduced drastically during the current pandemic. COVID test is mandatory for both the recipient as well as the donor. Moreover, the patients and/or attendants are very apprehensive and even enquire whether the doctors and the hospital staff have tested negative or not. On the other hand, the medical team is not sure whether they can proceed with retrieving or transplanting without COVID test in accordance with law. Getting the confirmatory test done takes time and this may not be possible at all times.

Recommendations

- *The authorities should formulate a policy for situations such as epidemics and other disasters.*
- *Clear directives, advisories and guidelines should be issued for the current pandemic.*

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