**‘Dead Enough to be an Organ Donor but Not Dead Enough to Switch off the Ventilator’ - Dilemmas in Indian ICUs when it comes to Organ Donation’**

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**Abstract**

The Transplant law in India recognises brain death for organ donation and it was passed in 1994. In Intensive care units (ICU) when relatives say no to organ donation in a brain death situation, clinicians are often struggling to switch off the ventilator and hand over the body. Ventilating a dead patient creates ethical dilemmas and also occupies valuable ICU bed. Delinking brain dearth from organ donation is essential and this requires inclusion of brain death in the law that governs the ‘birth and death act’ so that a uniform policy is framed in the country. The rules in the current law also needs to define ‘the no touch time’ after asystole so that donation after circulatory death is made possible to increase the potential organ pool.

**Introduction**

Organ donation after brain death in India has gone up almost five times in five years. In the year 2016, there were about 830 deceased donors from brain death criteria of death in India compared to 196 donors in the year 2012(1).This increase in the donors gave the gift of life to approximately 2,300 patients with the transplantation of critical organs such as kidney, liver, heart, lung, intestine and pancreas. The pool of potential organ donors in India with brain death is high due to the increase in the rate of fatal road traffic accidents.

In India over 400 people die daily due to road traffic accidents and most are between the age groups of 15-29 years (3). Head injury is an important cause of mortality worldwide especially when there is a two wheeler involved in an accident and in over 30% such instances, it is the associated cause of such deaths (4). Fatal traumatic brain injuries were seen in 68.73% cases of head injury in a study from All India Institute ( 2)

Currently not even 1% of brain deaths are converted into organ donation due to various reasons (5). One among the various reasons is linking brain death to organ donation. Other reasons include lack of awareness of concept of brain death among the public, religious reservations against organ donation and lack of trust in the healthcare system.   In India when brain death is linked to organ donation, most clinician will declare brain death only if relatives first say yes to organ donation (6).

**Concept of Brain Death**

Brain death was first recognized in Paris in the intensive care units, where they found that some patients with head injury or intracranial bleed never recovered and the condition was called *Coma de Passé* (meaning beyond coma) in 1959 (7,8). In 1968, a special committee from Harvard Medical School gave it recognition and since then brain death became an accepted form of death (9). As the blood circulation remained intact with a beating heart and breathing being supported by ventilators, it was realised that the rest of the body organs and tissues could be kept functional. In this situation organ donation was an option to save multiple lives and since that time this form of death has been an important source for scarce organs and tissues such as heart, lung, liver, pancreas, kidney, intestines, corneas, bone, heart valves and skin to name a few. More importantly the confirmation of brain death also allowed the withdrawal of treatment that no longer benefitted an individual who had died. In 1976, UK criteria for diagnosing death using the neurological criteria was published (10) and it was subsequently clarified in Codes of Practice in 1979, 1983, 1998, and 2008. In the latest Code of Practice (2008) there is no mention of organ donation. It is a Code of Practice for all deaths. There is no mention of brain death or brainstem death – just death. Criteria for confirming death after cardio-respiratory death have been laid down. The ‘UK Organ Donation Taskforce’ was set up in 2008 to identify barriers to donation and transplantation within existing operational and legal frameworks. It came out with 14 recommendations that were accepted in full by all four health departments. The Taskforce said that donation should be considered to be a fundamental component of end of life care and that an independent UK-wide Donation Ethics Group should be established. As a result of implementing the Taskforce’s recommendations, there was a 50% increase in deceased donation by 2013 with one-third of overall donations originating from donations after circulatory or cardiac death (11). In the USA in 1981, Uniform Determination of Death Act (UDDA) gave equivalence to death determined by neurological and cardiovascular criteria (12)\_These developments have lead to the scientific belief that human death ultimately involves the irreversible loss of the capacity for consciousness, combined with the irreversible loss of the capacity to breathe and this can only happen when there is brain death after the circulation comes to a stop.

Along with these advances there was also simultaneous development of powerful immuno-suppressants to overcome organ rejection that resulted in improved graft outcomes. Both these important developments meant that organ transplants became an accepted surgical procedure for the replacement of failing organs. However over the years the success with organ transplantation has also meant longer waiting lists, as the demand for organs has far exceeded the supply. To overcome this shortage many countries set up legislation such as ‘presumed consent’ (13),where the state presumes that a person is an organ donor unless they have expressed otherwise and ‘mandated choice’ on the driving license to ensure that organs in brain death situation can be procured to save lives of organ failure patients. Among the countries where presumed consent or the opt out option is in force includes - Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Denmark, Singapore, Greece, Hungary, Israel, Italy, Latvia, Luxemburg, Norway, Turkey, Poland, Portugal, Slovak Republic, Slovenia, Spain and Sweden(14). Presumed consent is ethically challenging concept and hence not universally acceptable. Besides normal adults, it also includes donation of organs from vulnerable groups such as minors, mentally challenged and from religious groups that do not favour organ donation. It also deprives individual who may not wish to donate certain organs or tissues due to their own personal reasons. More importantly a society allows for any action or decision taken to be reversed but in presumed consent such reversal is not possible and this leads to coercion and violation of autonomy of that individual. (15). Presuming automatic consent for organ donation also raises legal questions such as who owns the body and its organs and tissues in the first place after a person is dead be it in a hospital or at home.

**When family SAYS NO to donation in brain death situation**

The standard definition of death in India like many other countries is well accepted and defines death as an ‘irreversible cessation of circulatory and respiratory functions.’ However, as highlighted previously all deaths eventually reside in the brain as it is only the nerve cells where death is irreversible, as they cannot be revived or regrown once they are dead. This happens after an average interval of 5 minutes after the heart comes to a stop due to loss of blood circulation to the brain.

Brain death as form of death was legislated in 1994 through the Transplantation of Human Organs Act for the purpose of organ donation in India (16)

#### Unlike standard definition of death where only one doctor is required to certify death, in brain death four doctors are required for certification and this certification is required to be done twice at six hours apart ( 5). In 2011, further amendment in transplant law in India requires the doctors and coordinators in the ICU to ask for organ donation in the event of brain death . This is popularly known as ‘required request’ and is legislative requirement in many states in the USA where it mandates hospital personnel to discuss the possibility of an anatomical gift with the relatives of a deceased. This clause was included to increase the rate of organ donation so as to overcome the critical shortage of transplantable organs (17).

Twenty three years after its acceptance as a cause of death, brain death as a concept has still not been fully accepted by both the medical fraternity and the public in India. Often a peculiar situation crops up in the intensive care units (ICU) where intensivists will often not switch off the ventilators if the family says no to donation and this creates an unforeseen ethical dilemma. There is still another caveat that needs to be highlighted. Normally the diagnosis of brain death is first suspected in a road traffic accident, when an MRI or CT of the brain shows extensive brain injury and there are clinical signs such as lack of pupillary response, corneal reflex or cough reflex to substantiate this diagnosis. However the gold standard test for establishing brain death is to establish the lack of spontaneous breathing through an apnea test. Currently in certain units clinicians will only perform an apnea test if the relatives will say yes to donation. This creates another situation as the law does not permit that organ donation should be discussed or requested for before brain death diagnosis is fully verified. This means many such patients will continue to be ventilated despite being brain dead as an apnea test may not have been done to confirm it.

In brain death if a family says yes to organ donation, multiple organs are retrieved to save lives but if they say so to donation there is no standard of care laid out due to confusion about what constiutues death in India. Brain death is not mentioned on the death certificate as there is no provision for this and death is always mentioned as cardio-pulmonary death as is universally acceptable for cremation, burial or for insurance claims.

Many doctors also are of the opinion that consent is required to withdraw ventilation in brain death situation. Occasional stories in the media of ‘miraculous recoveries’ from coma or a ‘dead person coming alive’ that have been widely circulated (18, 19) may have led to the defensive stance among these doctors. The public perception in understanding and accepting brain death as death when the heart is still beating and the body is warm to touch with occasional spinal reflexes also leads to confusion in their mind. All this can make it difficult to withdraw ventilation. Continuing ventilation of a brain- dead patient also prevents care of another critical patient when the intensive care beds are full and leads to ethical dilemmas among the clinicians (20)

There have also been situations where the family themselves have desired the continuation of ventilation in the hope of a ‘miracle’ and have become belligerent if doctors have advised against it (15). Due to the general lack of trust in the healthcare system, hospitals in such situations have often yielded to the wishes of the relatives and continued unnecessary ventilation of the brain dead. As ventilation gets prolonged the issues related to care of such a deceased gets more complicated. The ethical and financial challenges of ventilating someone who is declared brain dead, but is not an organ donor, requires delinking brain death from organ donation ( 21). Many hospitals which have faced such problems have had to write off the costs of hospitalisation or intensive care or otherwise faced the wrath from the family and media.

**Laws determining death in India**

There are essentially three components when we start to define death. The concept of the soul leaving the body when we die, universal clinical criteria for determining that death has occurred and lastly specific medical tests to show if the criteria for death has been fulfilled or not. The first component is chiefly philosophical while the second and third components are medical. The common universal law standard for determining death is the generally accepted, as cessation of all vital functions, traditionally demonstrated by an “absence of spontaneous respiratory and cardiac functions”.

At present death is an important component of three different Laws in India -

1. The Registration of Births and Deaths Act, 1969

2. Section 46 of Indian Penal Code

3. Transplantation of Human Organ Act of 1994

Under Section 2(e) of [The Transplantation of Human Organs Act, 1994](http://health.bih.nic.in/Rules/THOA-1994.pdf), a deceased person means a person in whom there is a permanent disappearance of all evidence of life, by reason of brain stem death or in a cardio-pulmonary sense. However the legal inconsistency occurs in light of other two Indian legislation on death which were framed prior to the Transplantation of Human Organs Act (22 ). The section 46 of Indian Penal Code states - “the word death denotes death of a human being unless the contrary appears from the context”(23) whereas Section 2 (b) of the [Registration of Birth and Death Act](https://indiankanoon.org/doc/1636244/), 1969, defines death as "death" means the permanent disappearance of all evidence of life at any time after live-birth has taken place24. Both these do not make brain stem death as a criterion for death. As a result, a person whose brain stem is dead and whose breathing is supported by a ventilator could be considered to be alive under this Act as in ‘brain stem dead ’not all evidence of life has been lost with a beating heart and other functioning systems.’ It becomes even more complicated when there is a pregnant woman with viable foetus who is declared brain dead. Life as a term of definition can mean life of a cell, tissue, an organ or of a person as a whole. Oxford dictionary defines life as, ‘The condition that distinguishes animals and plants from inorganic matter, including the capacity for growth, reproduction, functional activity, and continual change preceding death.’

The other technical question that arises is, if the family says no to donation and the doctors withdraw the ventilation, would it be necessary to certify brain death as laid down by the Transplant law that requires four different doctors to declare brain death twice at 6 hours apart. Will the same rigorous method need to be applied in such certification if there was no organ donation? Can this be reduced to one certification or if second certification after six hours is required could it be reduced to one or two doctors instead of getting all four.

**Requirement of Uniform Declaration of Death**

The advances in medical frontiers have meant that with the use of ‘Extra Corporeal Membrane Oxygenation’ (ECMO) and ‘Left ventricular Assist Devices’ (LVAD) one does not require heart or lungs to be kept alive. The definition of death currently is not only important for brain death and organ donation but also for resuscitation and donation after circulatory death.

To tackle these issues, it becomes mandatory for the Government of India to look at how death is defined and to have a policy for ‘uniform definition of death’ and include both the circulatory and neurological criteria of death. Delinking brain-death from organ donation will help avoid any ambiguity in interpretation of the law and help free ventilator beds in difficult situations.  A uniform legislation on death has been incorporated in many other countries including the USA that have faced similar problems in the past (25).

Uniform legislation on death will require mentioning brain death as a form of death in the ‘Registration of Births and Deaths Act’ and this will need to be included in the certificate too. The act can define death as ‘death of an individual who has sustained either -

(a) irreversible cessation of circulatory and respiratory functions, or (b) irreversible cessation of all functions of the brain stem’. The rules can define that determination of death must be made in accordance with accepted medical standards.

The current stress on donation after circulatory death to increase the organ pool too requires that we in India define how long doctors should wait after asystole has occurred, before they can safely proceed to organ donation. In the UK, this ‘no touch time’ is defined as 5 minutes while in some other countries it is 10 and even 20 minutes in case of Italy (26). When making any rules, a consensus would be required from the medical professionals about the ‘no touch time’ for organ donation and this aspect needs to be included in the law or its regulations for safely proceeding to organ donation.

**Conclusion**

Advances in medical frontiers have blurred the boundary between life and death and laws written in the past need to be revised to avoid ambiguity and overcome ethical dilemmas. An unconscious person can now survive for decades without regaining consciousness, and life that is totally meaningless can be prolonged for indefinite periods. Death no longer can be looked as an event but rather as a process since a brain-dead person’s life can be extended so that they can become organ donors.

Let not the medical faculty is burdened with decisions that have societal implications and let not medical establishments resort to roundabout methods to declare death in the ICUs raising countless ethical questions. Thus, the journey for India has begun towards clarity in terms of death and addressing a pressing need to make death more dignified, ensure that medical care is more objective and applicable to everyone irrespective of whether organ donation takes place or not.

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