

COMMENTS**“Brain death” and “circulatory death”: Need for a uniform definition of death in India****SUNIL SHROFF, SUMANA NAVIN****Abstract**

In India, the definition of brain death is contained only in the Transplantation of Human Organs Act (THOA) of 1994. Doctors of ICU patients who are brain dead are unsure of what to do when the relatives refuse organ donation. However, ventilating a dead patient goes against correct medical practice and also blocks a valuable ICU bed. Delinking brain death from organ donation is essential, and this requires inclusion of “brain death” in the definition of death in The Registration of Births and Deaths Act, 1969, so that a uniform policy can be framed in the country.

Introduction

In India the concept of brain death has been intimately linked with organ donation, as it is defined only in the Transplantation of Human Organs Act (THOA), 1994 (1) which governs organ transplantation and has enabled the development of the current cadaver-based organ transplant programme.

However, given that this definition exists only in THOA (2), there is lack of clarity in the minds of medical professionals on the appropriate steps to take when a person is suspected to be brain dead and the relatives have not consented to organ donation (2). It is believed that clinicians are reluctant to declare brain death in such cases (3). Additionally, it is believed that, because of the public’s mistrust of the healthcare system, some relatives fear that the patient has been declared brain dead for the purpose of organ donation.

Concept of brain death

The traditional definition of death in India, as in many other countries, is an “irreversible cessation of circulatory and respiratory functions.” However, death eventually resides in the brain as the nerve cells cannot be revived or regrown

once they are dead. This happens due to cessation of blood circulation to the brain, which occurs about five minutes after the heart comes to a stop.

Brain death was first recognised in intensive care units in Paris, where it was found that some patients with head injury or intracranial bleed never recovered. The condition was named *coma de passé* [beyond coma] (4). In 1968, a special committee from the Harvard Medical School in the United States (US) arrived at a consensus on the definition of brain death and since then the concept of brain death has been accepted by the medical community (5). In 1981, the Uniform Determination of Death Act was enacted in the US. It said that “An individual who has sustained either (i) irreversible cessation of circulatory and respiratory functions, or (ii) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made with accepted medical standards” (6). According to the 2010 guidelines of the American Academy of Neurology, to determine “cessation of all functions of the entire brain, including the brain stem,” physicians must determine the presence of irreversible coma (the cause of coma should be known), the absence of brainstem reflexes, and the absence of a breathing drive after a CO₂ challenge (apnoea test). Usually one neurological examination is sufficient to pronounce brain death. However, some US state statutes require two examinations. Legally, all physicians are allowed to determine brain death in most US states, though neurologists, neurosurgeons, and intensive care specialists may have specialised expertise (7). The confirmation of brain death allowed the withdrawal of treatment that no longer benefitted an individual who had died. In 1976, the UK criteria for diagnosing death using neurological criteria were published (8) and subsequently clarified in Codes of Practice. The latest Code of Practice (2008) (9) also lays down criteria for confirming death after cardiorespiratory failure. In 1977, the Australian Law Reform Commission addressed the absence of a definition of death in Australian law, recommending that a statutory definition of death should be introduced. The Commission recommended that death be defined as: a) irreversible cessation of all functions of the brain of the person; or b) irreversible cessation of circulation of blood in the body of the person (10). Brain death testing is carried out by two medical practitioners with specific experience and qualifications according to State and Territory laws. Two separate sets of tests are performed, with each doctor being

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responsible for performing one set of tests. The tests may be done consecutively but not simultaneously (11). These developments are based on 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 blood circulation to the brain ceases, leading to brain death.

As the blood circulation to the rest of the body is maintained with a beating heart, and breathing is supported with the use of a ventilator, the organs (other than the brain) and tissues of a brain-dead person can be kept functional for a period and used to save multiple lives. For this reason, a brain-dead cadaver is an important source of scarce organs and tissues such as heart, lungs, liver, pancreas, kidneys, intestines, corneas, bones, heart valves and skin, to name a few. The acceptance of the Harvard criteria in 1968 led to organs being transplanted from brain dead donors subsequently. Prior to that, some organ transplants were performed from donors after circulatory death.

Brain death was defined in Indian law in 1994, through the Transplantation of Human Organs Act (and its 2011 amendment) for the purpose of organ donation and transplantation in India, as evidenced by the insertion of clauses pertaining to this in the brain stem death certificate – Form 8/Form 10 (12,13). In 2011, a further amendment to the transplant law in India required the registered medical practitioner of the hospital having an Intensive Care Unit facility, in consultation with the transplant coordinator, to make the family aware of the option to authorise or decline organ and tissue donation (14). This is popularly known as “required request”.

While only one doctor is required to certify death according to the traditional definition of death, four doctors are required for certification of brain death, and this certification is to be done twice, six hours apart, as per the THOA (15).

When the patient is brain dead and the family says no to donation

Twenty-three years after it was described in the Indian law, brain death as a concept has still not been fully accepted by the medical fraternity and the public in India.

If the family of a person declared brain dead agrees to donation of any of the person’s organs, the steps outlined in THOA for declaration of brain death are followed (1), organs are retrieved, after which the ventilator is turned off. But if they say “No” to donation, there is no standard of care.

Often a peculiar situation crops up in ICUs, where intensivists will not switch off the ventilator if the family says “No” to donation. Furthermore, while the diagnosis of brain death is first suspected 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, the gold standard test for certifying brain death is to establish the lack of spontaneous breathing through an apnoea test. The apnoea test is done twice and if there is no

spontaneous breathing, the patient is certified brain dead by the panel of four doctors as required by the THOA. Currently, it is known that in some units, clinicians will perform the second apnoea test only when the relatives agree to donation, since the understanding is that brain death certification is for the purpose of organ donation only. This is because there have been situations where after the second apnoea test has been done and brain death has been certified (this is the official time of death), the family has said “No” to organ donation and asked the doctors to keep the patient on the ventilator till circulatory death occurs. The doctors comply because they do not want to escalate the grief of the family, and they also say that there are no guidelines about disconnecting the ventilator in a situation when organ donation is not authorised by the family. This means many such patients will continue to be ventilated despite being brain dead. The second apnoea test and certification of brain death is not taken into account, and the time of death is when circulatory arrest occurs. For this reason and because of the resource intensive protocol in brain death certification, ICU doctors do not want to venture into testing for the second time if the family does not verbally consent to organ donation after the first apnoea test is done.

Brain death is not mentioned on the death certificate as there is no provision for it, and death is always mentioned as cardiopulmonary death, which is universally acceptable for cremation, burial or for insurance claims.

Many doctors are also of the opinion that consent is required to withdraw ventilation from a person certified brain dead. False and misleading stories in the media of a person making a “miraculous recovery” from coma or a “dead person coming alive” (16,17) may have led to these doctors taking a defensive stand. The public has difficulty in understanding and accepting that brain death is, in fact, death, since the heart is still beating and the body is warm to the touch with occasional spinal reflexes. This can make a doctor reluctant to withdraw ventilation. There are situations in which the family of a brain-dead person demands continuation of the ventilator, hoping for a “miracle,” and becomes belligerent if doctors advise turning it off. Hospitals, in such situations, have often yielded to the wishes of relatives (18). Continuing the ventilation of a brain-dead patient also prevents care of another critical patient when ICU beds are full, and leads to ethical dilemmas among clinicians (18).

In this context, there is an urgent need to delink brain death from organ donation (19).

Laws determining death in India

The common universal legal definition of death is 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: The Registration of Births and Deaths Act, 1969 (RBDA); The Indian Penal Code, 1862 (IPC) (Section 46); and The Transplantation of Human Organs Act of 1994 (THOA).

Under Section 2(e) of The Transplantation of Human Organs

Act, 1994, a deceased person is 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 at any time after live birth has taken place”(1). However, the other two Indian laws which were framed prior to THOA do not mention brain death in their definition of death and hence the universal acceptance of brain death has been absent in India. According to Section 46 of the IPC, the word death “denotes death of a human being unless the contrary appears from the context” (20), whereas Section 2 (b) of the Registration of Births and Deaths Act (RBDA), 1969, defines death as “the permanent disappearance of all evidence of life at any time after live-birth has taken place” (21). Neither definition makes brain stem death a criterion for death (both definitions should also mention death as irreversible cessation of circulatory function). As a result, a person whose brain stem is dead and whose breathing is supported by a ventilator and heart is beating, could be considered to be alive under the RBDA, as not all “evidence of life has been lost”.

Requirement of uniform definition of death

To tackle these issues, it is essential that the Government of India state a policy for a “uniform definition of death” that includes both the circulatory and neurological criteria of death. Delinking brain death from organ donation by removing the offending clause in the brain stem death certificate form given in the THOA Rules would be a good start to help avoid ambiguities in interpretation of the law. It would also help to free ventilator beds in difficult situations and prevent ethical challenges as described earlier. Uniform legislation on death has been incorporated in many other countries including the USA, UK and Australia, as mentioned above, that have faced similar problems in the past (6,9,10).

Uniform legislation on death will require inclusion of brain death as a form of death in the The Registration of Births and Deaths Act, and it will need to be included in the death certificate as well. 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”.

Conclusion

The journey towards clarity in defining death has begun for India. Such a definition will address a pressing need to make death more dignified, and ensure that medical care is objective and applicable to everyone, irrespective of whether or not organ donation takes place.

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