
Executive summary

Health Council of the Netherlands. Determining death in postmortal organ donation. Protocols and criteria, including an updated Brain Death Protocol. The Hague: Health Council of the Netherlands, 2015; publication no. 2015/13.

This advisory report aims to provide a binding national guideline for determining death in postmortal organ donation. This guideline describes how death must be determined in three distinct situations in which organ donation after death may occur. One part of the guideline is an updated version of the Brain Death Protocol. This advisory report does not pertain to donation by a living donor.

Background and goal of this advisory report

In 1998 the Organ Donation Act (WOD) was introduced to provide legal safeguards for a careful approach to organ donation and to safeguard the rights of the donor. Among other things, the act dictates that it must be determined whether a potential donor is brain dead. This determination must occur according to the Brain Death Protocol, drafted by the Health Council based on the current state of the art regarding methods and criteria for determining brain death. Periodic adjustment of the protocol is part of this process.

When the WOD was drafted, organ donation after death primarily involved donors who were on mechanical ventilation with irreversible damage to brain function. In such ‘brain dead’ donors, death is determined according to the Brain Death Protocol. Since that time, however, there has been a significant rise in the proportion of donors in whom death is ascertained based on circulatory criteria: irreversible cardiac and circulatory arrest. Although such donors currently

encompass half of all donors after death, there are no specific legal rules for determining death based on circulatory criteria.

In response to a previous Health Council advisory report, the minister of Health, Welfare and Sport stated that he was of the opinion that a general standard should exist in the Netherlands for determining death – within the context of organ donation – based on circulatory criteria, and asked the Health Council to draft a protocol to this end.

During the course of the advisory process, the definition of the problem was broadened, as various parties in the field expressed a need for an all-encompassing protocol covering all forms of donation after death. Such an integrated protocol would provide guidance both for determining death based on circulatory criteria and based on brain death. Another question that arose was whether the Brain Death Protocol was still current after the last update from 2006.

The Committee that prepared this advisory report examined the rules for determining death based on circulatory criteria by collecting the protocols used in daily practice and testing them against the current state of scientific knowledge. In updating the Brain Death protocol, the Committee sought to find a solution for the grey areas that existed in daily practice.

Two roads to donation after death: expected or unexpected death

There are two essentially different paths that may lead to donation after death. The first situation involves a patient admitted to hospital in whom death is expected; the second a person who dies suddenly and unexpectedly.

The first path that can lead to donation after death (death is expected) begins when a patient's prognosis worsens dramatically despite intensive treatment on an intensive care unit (ICU), or if a catastrophic clinical situation fails to show any improvement and there is no hope of recovery. Usually this involves patients who have suffered severe brain injury, for example due to an accident or cerebral haemorrhage, who require intensive care and mechanical ventilation. If it is determined that further treatment does not provide any hope of recovery, and there is an intention to donate, two situations may arise. If there are clinical indications that the patient is brain dead, this is assessed based on the Brain Death Protocol. This situation leads to *donation after brain death* (DBD). In a proportion of patients in whom death is expected due to the severity of the injury and poor prognosis, however, brain death will not occur (swiftly), or cannot be determined. In such patients, it may be decided to withhold further treatment focused on recovery, and subsequently suspend vital function support (including

ventilation), at which point full circulatory arrest is awaited and death may be determined (based on circulatory criteria). This situation leads to *donation after circulatory death* (DCD), and because death is expected, this is termed the ‘*expected*’ DCD scenario (eDCD).

Expected death due to euthanasia that occurs in the hospital also offers a path towards organ donation, and may be considered a distinct form of eDCD. This situation is not part of the protocols presented in this advisory report.

The second path that may lead to donation (unexpected death) begins when a person experiences circulatory arrest, often outside of the hospital, after which resuscitation is initiated. If attempts to resuscitate fail, the decision will be made to suspend further treatment. If donation is an option, death – unexpected in this situation – is determined on circulatory grounds. Donation now follows the unexpected DCD scenario (uDCD).

Decision moments during the donation process

There are a number of distinct decision moments that may be identified along the paths that lead to donation, which form the basis for the guideline that is provided in this advisory report. The significant deterioration in prognosis in a patient receiving intensive treatment, marking the beginning of the path towards expected death, is reason for multidisciplinary consultation between members of the medical team. If the decision is made that treatment focused on recovery is no longer of benefit, and thus no longer in the patient’s best interests, a preliminary assessment of (medical) donor suitability is performed. If the patient is suitable, the Donor Registry is consulted. This may reveal that the patient consents to donation, or objects, leaves the decision to family or another specific person, or that the patient has not recorded any wishes in this regard. If the patient has registered consent, there is nothing standing in the way of a donation procedure. If the decision on donation is left to family, if no objection is registered or if the patient has not recorded any wishes, the family is consulted and options for donation are discussed. From this moment forward, preparatory measures may be taken in the interest of implantation of organs in the future recipient, which are intended to improve the chances of successful donation in the subsequent organ transplantation. This can include procedures intended to determine medical suitability for organ donation, or measures taken in order to improve the physical condition and stability of the donor, or measures intended to maintain the viability of the organs. Which measures are acceptable is in part codified in law, and further specified in this advisory report. The measures described above may also be taken while contact is sought with family members

who are not immediately available in situations where there are concerns about preserving the quality of the organs, in order to keep donation a viable option.

If there is a suspicion that the patient is brain dead at this stage, the Brain Death Protocol is followed to determine whether this is the case. This is the usual DBD procedure. However, if there is no suspicion of brain death, or brain death cannot be determined, the eDCD protocol comes into play.

If one of the above decision moments reveals that organ donation is no longer an option, regular end-of-life care is continued in accordance with the relevant guidelines. Tissue donation (e.g. skin, cornea, heart valves and bone/tendon tissue) remains a good possibility in such cases.

In the uDCD path to donation, time is of the essence. This path begins with the determination that the resuscitation attempts following circulatory arrest have been unsuccessful, and the subsequent decision to suspend them. This is followed by assessment of medical suitability as a donor and consultation of the Donor Registry. If the Donor Registry does not contain an objection to donation, organ preserving measures will be taken as swiftly as possible. The uDCD protocol applies from this moment forward.

Determining death: the Brain Death Protocol and revision of the protocol

The WOD states that determination of death in the DBD scenario follows the Brain Death Protocol (BDP), drafted and revised by the Health Council. Since the previous revision of the BDP in 2006, however, a number of problems have been reported regarding its implementation. They pertain primarily to the performance and order of (supplemental) tests. These issues made revision necessary. The underlying principle in the BDP is the whole brain death concept, as codified in the law: death as the complete and irreversible loss of brain function, including brain stem and spinal cord function. Brain death is determined in three steps: 1) determining whether the so-called preconditions have been met; 2) clinical neurological examination; 3) supplemental testing, encompassing the following tests: electro encephalography (EEG), transcranial Doppler study (TCD), or CT angiography of the brain vessels (CTA), and the apnoea test. One of the changes currently proposed by the Committee is that patients who receive medication to suppress brain function (pharmacological neurodepression) may not be assessed for brain death, in case the neurodepression interferes with an accurate evaluation of test results. The procedure may only be initiated once it can be assumed that the effects of the medication have worn off sufficiently. Furthermore, the Committee states that loss of higher brain function must be determined using one of the following

investigations: EEG, TCD or CTA. For this purpose, these tests may be considered to be equivalent. However, an exemption is a situation in which circulatory arrest is imminent while pharmacological neurodepression is still present. In such a circumstance, a test of brain perfusion, with either TCD or CTA, must be performed. If the supplemental test used indicates a lack of brain function or perfusion, the subsequent apnoea test must confirm brain death.

Determination of expected circulatory death (eDCD)

The eDCD protocol begins with the decision to withdraw life support and determination of the moment when the patient will be disconnected from the ventilation equipment (the so-called switch-off procedure). Timing and location must be scheduled with care. When circulatory arrest occurs, the organs are no longer perfused, and the longer this situation persists, the greater the damage to the organs. After an overly long ischemic time, organs are no longer viable for transplantation.

Determining death in eDCD has two crucial components: 1) determination of circulatory arrest ('mechanical asystole'); 2) respecting an observation period after circulatory arrest without intervention: the no-touch time. Circulatory death is ascertained by recording the absence of an intra-arterial pressure wave or based on another current method of monitoring circulation. A no-touch period of five minutes is then observed. This time is required to rule out spontaneous recovery of circulation and breathing. After this time has elapsed, irreversible circulatory and respiratory arrest exists and death may be declared.

Determination of unexpected circulatory death (uDCD)

Failure of a correctly performed resuscitation attempt is in itself proof that circulation cannot be restored, and that loss of function is permanent and irreversible. Because there have been case reports of 'autoresuscitation' (spontaneous but temporary recovery of heart activity and circulation), in particular immediately after ceasing resuscitation attempts, a no-touch period is also observed in uDCD after stopping resuscitation before death may be declared. In the opinion of the Committee, a five minute waiting period is reliable and sufficient based on available data from the literature.

In the event of uDCD, in addition to organ preservation measures available for other forms of donation, Regional Perfusion (RP) with hypothermic or normothermic fluid may also be performed via cannulas inserted into the large

blood vessels in the groin. This method is intended to protect the organs, reducing the amount of damage. RP may also be performed with the body's own blood and at normal temperature. In this case, the blood is routed via an extracorporeal circuit by a pump and supplied with oxygen by an artificial lung. The Committee notes this is still an experimental technique that may only be performed within the context of research.

A guideline for determining death in donation after death

The Committee's considerations have resulted in a guideline for donation after death and determination of death in three distinct situations that is intended to be binding.

Legal aspects

Finally, the Committee proposes a number of changes be made to the WOD. This pertains in particular to section 14 of the law, where brain death and the Brain Death Protocol are mentioned. In the opinion of the Committee, procedural requirements for determining death in DCD should be included in the law, and the asymmetry with respect to determination of brain death should be ended. Furthermore, the Committee notes section 22 is unclear; paragraph 3 could be interpreted as stating an additional five minutes must be waited after the no-touch period of five minutes and determination of death, which was clearly not the legislator's intent.

Conclusions and recommendations

This advisory report provides a comprehensive guideline for the three distinct forms of donation after death. Used together with the detailed protocols for daily practice by the Netherlands Transplantation Foundation, that cover all aspects of transplantation and handling of donated organs, and that are referred to repeatedly throughout this advisory report, it provides a standard for determination of death in postmortal donation. The principles and procedures proposed in this advisory report should therefore serve as a binding guideline.

Finally, this treatment standard should be mentioned in the WOD. The lack of an explicit reference to donation after circulatory death in the law is deemed to be a gap. The law also contains other points that deserve clarification.

The Committee recommends:

- Determination of death in all forms of donation after death as currently occurs in practice be regulated by an overarching guideline as described in this advisory report. This guideline encompasses both the Brain Death Protocol and procedures for determining death in DCD, and should be given the same status as the current Brain Death Protocol. This accurately reflects the growing practical importance of donation after determination of death based on circulatory criteria, and ends the asymmetry in the protocols for determining death as enshrined in law for various different forms of donation after death.
- To update the Organ Donation Act so that determination of death based on neurological and circulatory criteria is mentioned and treated equally under the law.
- To periodically revise the proposed guideline to reflect the state of the art, as is currently the case for the Brain Death Protocol.
- To adopt and publicise the updated Brain Death Protocol.