

DETERMINATION OF DEATH. NEW GUIDELINES IN SWITZERLAND*

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The introduction of mechanical ventilators in medicine made it feasible to maintain vital functions in severely brain damaged individuals for a prolonged period. Ventilators interrupted the natural process of dying and lead to situations where the brain was irreversibly damaged while circulation and blood oxygenation were still maintained. Mollaret and Goulon called this 'coma dépassé' in their 1959 landmark report of 23 patients. The coma dépassé patients had lost all brainstem reflexes, their electroencephalograms were flat, and the coma was irreversible in all of them. In 1968 an ad hoc committee at Harvard Medical School in Boston defined the criteria of 'brain death': Unresponsiveness, absence of movements and breathing and absence of brainstem reflexes in a patient whose cause of coma was known. These criteria became widely known as the 'Harvard Criteria'. In Switzerland guidelines to define death were introduced by the Swiss Academy of Medical Sciences (SAMS) in 1969 and revised in 1983, 1996 and 2005. Organ transplantation made the diagnosis of death of potential organ donors a delicate matter, and this was the main reason that such guidelines were needed.

According to the Swiss guidelines death is defined as 'complete and irreversible cessation of all brain functions, including brain stem function'. Unlike in some other countries, irreversible loss of brain stem function is not considered as death. Dying is a natural process in the transitional zone from life to death. Death is a condition. It can result from primary injury or disease of the brain that causes irreversible loss of brain function, or from persistent failure of blood circulation or oxygenation long enough to cause irreversible damage to the brain and cessation of all brain function.

* The views expressed with absolute freedom in this paper should be understood as representing the views of the author and not necessarily those of the Pontifical Academy of Sciences. The views expressed in the discussion are those of the participants and not necessarily those of the Academy.

The diagnosis of death by physicians relies on four points:

- the history
- results of ancillary investigations
- clinical findings
- and the proof that cessation of brain function is irreversible

Death is present when history and ancillary findings indicate a severe organic brain damage, clinical findings show absence of pupillary light reflexes, brainstem reflexes, and apnea in a deeply comatose patient, and when the physicians involved to determine death have proved that absence of brain function is irreversible. For this, the patient can be observed for a defined period, or ancillary tests can be used to show absence of cerebral blood flow.

Additional requirements to make the diagnosis of death are normothermia (body temperature $>35^{\circ}$), absence of metabolic disorders or intoxication, absence of drugs interfering with neuromuscular transmission and absence of polyradiculitis.

According to the SAMS 1996 guidelines the proof that brain function had ceased irreversibly in a patient with known cause of coma and adequate circulation and blood pressure was made by observing the patient for 6 hours. In a child younger than 5 years this observation period had to be prolonged to 24 hours and in patients with unknown or uncertain cause of coma or suspected intoxication to 48 hours. Absence of respiration had to be documented by an apnea test and a doctor qualified as a neurologist, neurosurgeon or a pediatric neurologist who was not part of a transplantation team had to participate in the determination of death. Ancillary investigations were to be used only in situations when clinical signs were equivocal or could not be tested. Examples are facial trauma where cranial nerve function cannot be examined, or polyradiculitis, where facial muscles can be paralyzed because of nerve conduction failure. After cranial trauma, arteriography can show absence of cerebral blood flow and prove death, in polyradiculitis involving the cranial nerves, electroencephalography can show cerebral activity and prove existence of life.

In patients with cardiac arrest irreversibility of cessation of brain function was considered proved when cardiac function and circulation did not recover after 30 minutes of uninterrupted resuscitation. Such patients are potential organ donors, so-called 'non heart beating donors'.

The rationale behind the SAMS 1996 guidelines, i.e. the use of an observation period instead of ancillary tests to prove the irreversibility of cessation of brain function was its easy and wide applicability. Such

guidelines could be used in all hospitals, both in hospitals with advanced technical equipment and in small, regional hospitals with limited diagnostic technology.

In 1996 the legal time of death was at the beginning of the observation period (T1). After T1 medical measures to prepare organ donation and transplantation were legally permitted while the dying patient was awaiting confirmation of the diagnosis 'death' until the end of the observation period (T2).

Probably in 2007 a new law relating to transplantation of organs, tissues and cells will become effective in Switzerland. The SAMS guidelines for determination of death will be part of it. This law says that 'medical measures that serve only the conservation of organs, tissues or cells, must not be performed before the death of the donor, except the donor has been informed and has given his or her consent'. The lawyers drawing up this new law felt and determined that the time of death will be at the end of the observation period (T2). Only then medical measures to prepare organ donation and transplantation must be started. Such a change compared to 1996 would make transplantation of organs difficult and many organs and lives would be lost. Therefore, the only way out of this impractical situation was a revision of the 1996 SAMS guidelines and the use of ancillary tests to prove irreversibility of cessation of brain function, similar to guidelines in other countries. With the use of ancillary tests T2 can be moved closer to T1 and death can be diagnosed already shortly after the first observation of absence of brain function.

According to the 2005 SAMS guidelines the proof of irreversible cessation of brain function in a patient with adequate circulation and blood pressure can be made in two ways, either by observing the patient or with the help of ancillary tests. Observation periods are equal to the 1996 guidelines. One minor change relates to the age of a child requiring a 24 hours instead of an 8 hours observation period. It was lowered from 5 to 2 years. Ancillary tests have to prove the intracranial arrest of circulation. For this purpose appropriate are transcranial Doppler sonography, spiral computed tomography, ^{99m}Tc-HMPAO-Scintigraphy, or intraarterial digital subtraction arteriography. Electrophysiological tests were considered inadequate because of potential false positive results. When cerebral blood flow falls from physiological levels of 40 to 60 ml/100 g white and grey tissue/min below 20 ml/100 g tissue/min electrical function of nerve cells may cease while there is still enough flow to preserve the structures of the brain cells. Therefore, methods demonstrating absence of cerebral blood flow are less

likely than electrophysiological tests and extremely unlikely to yield false positive results, provided that ancillary testing is performed by someone with the appropriate skills. Quality requirements are specialty certifications for the particular test for physicians performing it.

Another change from the 1996 to the 2005 SAMS guidelines concerns 'non heart beating donors'. In patients with persistent cardiac arrest irreversibility of cessation of brain function is proved when uninterrupted resuscitation during at least 20 minutes does not result in recovery of cardiac activity and circulation does not recur after an additional period of 10 minutes observation. If no resuscitation is attempted, an observation period of 10 minutes has to be respected as well.

New to the 2005 guidelines is a section on information and assistance to the patient's family and the therapeutic team. The patient's family, in particular, is faced with unusually severe stress and grief, especially if the death is unexpected. It is essential to inform the patient's family thoroughly, with empathy, in a suitable and calm environment and without time pressure. After an appropriate period of time the family can be asked about possible organ donation. Assistance must be offered to the patient's family not only before death and organ donation. Assistance is needed during and after death and organ donation even more. Special attention has to be paid to the emotional stress of the therapeutic team as well and, if needed, psychological support should be available to team members.

The Swiss guidelines and model protocols for 'The determination of death in the context of organ transplantation' are available at www.samw.ch in German, French, Italian and English.*

* This text is also printed in the Annex (see page 335).