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The Determination of Death in the Context of Organ Transplantation

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Item Type	Preprint
Authors	Swiss Academy of Medical Sciences
Publisher	Swiss Academy of Medical Sciences
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Download date	2026-09-24 21:52:27
Link to Item	http://hdl.handle.net/20.500.12424/185487

The Determination of Death in the Context of Organ Transplantation

Medical-ethical guidelines



SAMW
Schweizerische Akademie
der Medizinischen
Wissenschaften

ASSM
Académie Suisse
des Sciences Médicales

ASSM
Accademia Svizzera delle
Scienze Mediche

SAMS
Swiss Academy
of Medical Sciences

The Determination of Death in the Context of Organ Transplantation

Medical-ethical guidelines

Approved by the Senate of the SAMS on 24 May 2011

The German text is the authentic version.

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The determination of death in the context of organ transplantation

Medical-ethical guidelines

I. Preamble

Since 1 July 2007, the legal requirements for organ transplantation in Switzerland have been specified at the national level in the Federal Act on the Transplantation of Organs, Tissues and Cells (Transplantation Act)¹. As regards the criteria for death, the Act relies on the neurological definition, according to which a person is dead if all functions of his brain², including the brainstem, have ceased irreversibly. For the determination of death, the Transplantation Ordinance makes reference to the SAMS guidelines on «The Determination of Death in the Context of Organ Transplantation». Legislators have thus made, not the definition of death, but the regulations for its proper determination subject to the current state of medical science. After death has been determined, organs may be removed if consent has been previously given by the donor or surrogate consent is obtained from authorized third parties (the so-called extended consent solution).

The definition of death comprises not just biological and medical, but also legal and ethical elements. It not only involves statements about pathophysiological conditions associated with death, but also implies a specific conception of life and death. In particular, it also indicates what procedures may be performed on the deceased. Ascertaining the patient's wishes, treating an organ donor up to the time of determination of death, applying medical measures for organ preservation until organs are removed and managing relatives are all responsibilities which involve major challenges and emotional stress for the treatment team. From an ethical and legal perspective, it is essential that death should be reliably diagnosed, the wishes of the deceased taken into account, and support provided for relatives during this difficult period. These are the goals pursued by the present guidelines. Firstly,



The central committee of the SBK/ASI has approved these guidelines and recommends to their members and all nurses to apply them and to abide by them.

- 1 Federal Act of 8 October 2004 on the Transplantation of Organs, Tissues and Cells (SR 810.21).
- 2 Throughout the text, for the sake of readability, the masculine form is used in a gender-neutral manner.

they specify the clinical signs and additional tests which are to be taken into consideration in the determination of death; secondly, they define the processes leading up to organ removal and the responsibilities of the physicians and other professionals involved. They also deal with organ removal after irreversible cardiac arrest (non-heart-beating donation), addressing the specific ethical issues arising in this situation. These guidelines are based both on the Transplantation Act (TxG) and on an expert legal opinion concerning questions relating to organ removal from deceased persons and preparatory medical measures.³

II. Guidelines

1. Criteria for death⁴

A person is dead if the functions of his brain, including the brainstem, have ceased irreversibly.⁵

With the irreversible cessation of all cerebral functions, a person permanently loses the organ that controls the entire organism. Thereafter, all organs, tissues and cells inevitably die. Death may be due to the following causes:

- irreversible cessation of the functions of the brain, including the brainstem, as a result of primary brain damage or disorder;
- permanent cardiac arrest, which reduces or abolishes the cerebral circulation, until the irreversible cessation of the functions of the brain and brainstem – and thus death – ensues (death after cardiac arrest).

2. Determination of death

2.1. Death due to primary brain damage

The determination of death involves a clinical examination in which all seven of the following clinical signs must be observed:

1. coma;
2. bilaterally dilated pupils, unresponsive to light;
3. absent oculocephalic and vestibulo-ocular reflexes
4. absent corneal reflexes;
5. no cerebral response to painful stimuli;
6. absent cough and gag reflexes;
7. no spontaneous respiration (apnoea test).

The clinical examination is conducted jointly by two physicians («two pairs of eyes» principle); one of these clinicians must not be directly involved in caring for the patient.

Both of the physicians diagnosing death must be suitably qualified (see Section 2.4.).

3 Guilloid O., Mader M.: Vorbereitende medizinische Massnahmen im Hinblick auf eine Organentnahme. Rechtsgutachten zu verschiedenen Fragen im Zusammenhang mit dem Transplantationsgesetz. March 2010 (www.bag.admin.ch/transplantation/00695/01488/11830/index.html?lang=de; also available in French)

4 These criteria for death only relate to situations in which organ donation is envisaged. In all other cases, death is to be determined by a physician in accordance with the general rules of medical practice. Here, in particular, irreversible cardiopulmonary arrest, leading to death, is taken as the main criterion for death.

5 Art. 9 TxG and Art. 7 Transplantation Ordinance (TxV).

If the cause of the cessation of brain function is clearly apparent and the examination is carried out in accordance with the circumstances and methods described in the Annex⁶, the diagnosis is based exclusively on the clinical signs.⁷

If the cessation of brain function is not adequately explained by the structural damage detected by imaging, if potentially reversible factors cannot be excluded as contributory elements, or if cranial nerve function cannot be clinically assessed, then the absence of cerebral circulation must be demonstrated by means of an appropriate additional test.

For this purpose, the following methods may be used:

- transcranial Doppler ultrasonography or colour-coded duplex ultrasonography;
- computed tomography angiography (CTA);
- intra-arterial digital subtraction angiography (IA-DSA);
- magnetic resonance imaging and angiography.

The requirements for the various techniques are specified in the Appendix⁸.

2.2. Death after permanent cardiac arrest

Under the Transplantation Act, death in the case of permanent cardiac arrest is also defined as irreversible cessation of the functions of the brain and brainstem. Here, death occurs as a result of permanent cessation of the cerebral circulation due to cardiac arrest.

After cardiac arrest (absence of cardiac activity) has been diagnosed by means of transthoracic echocardiography (TTE) in four-chamber view or from the subxiphoid position and a stand-off period (without resuscitation measures) of at least 10 minutes has elapsed, the following clinical signs are assessed; all of these must be observed:

1. coma;
2. bilaterally dilated pupils, unresponsive to light;
3. absent oculocephalic and vestibulo-ocular reflexes;
4. absent corneal reflexes;
5. no cerebral response to painful stimuli;
6. absent cough and gag reflexes;
7. no spontaneous respiration.

6 III. Appendix A. Clinical signs of death.

7 The reliability of the clinical signs is widely recognized (cf. the literature listed in the Appendix). There is no evidence that better results are obtained if the examination is repeated after an interval for observation, provided that the initial examination is correctly performed.

8 III. Appendix B. Additional (instrumental) tests.

The clinical examination is conducted jointly by two suitably qualified physicians («two pairs of eyes» principle); one of these clinicians must not be directly involved in caring for the patient. Additional tests are not necessary, since the cardiac arrest documented by TTE over a period of 10 minutes excludes the possibility of adequate cerebral circulation.⁹

2.3. Death in children

For children over 1 year old, the rules given in Sections 2.1. and 2.2. are applicable.

In post-neonatal infants¹⁰, the determination of death – where the cause of cessation of cerebral function is known – involves two clinical examinations (including the apnoea test) separated by an observation period of 24 hours.¹¹ If the cessation of brain function is not adequately explained by the structural damage detected by imaging, if potentially reversible factors cannot be excluded as contributory elements, or if cranial nerve function cannot be clinically assessed, then the absence of cerebral circulation must be demonstrated by means of an appropriate additional test after the second clinical examination.

9 The determination of pulselessness by palpation has been proved to be unreliable and therefore appears to be unsuitable for precise establishment of the time of cardiac arrest with a view to subsequent organ donation. Likewise, the electrocardiogram (ECG) cannot be used to determine cardiac arrest since cardiac electrical activity in the absence of mechanical contractions can often still be detected in the ECG for some time after death.

10 I.e. children aged over 28 days (or 44 weeks postmenstrual age) but less than 1 year.

11 The reliability of the clinical signs and also of the additional tests for demonstrating irreversible cessation of brain function is less well researched for infants than for later age groups. In addition, a mandatory observation period would appear to be advisable in view of the thesis that the softness of infantile cranial structures could permit short-term reversibility of pressure-related cessation of cerebral circulation.

In neonates¹² the removal of organs for transplantation is to be avoided on ethical and medical grounds.¹³

2.4. Professional qualifications

The clinical assessment must be carried out by physicians with specialist training and experience in the field of brain death diagnosis.¹⁴

For the clinical determination of death in children, specialist training in paediatric intensive care medicine or paediatric neurology is required.

The additional test must be performed by a suitably qualified specialist.

2.5. Independence

To avoid conflicts of interest, the organ removal and transplantation processes must be strictly separated.

According to Article 11 TxG, physicians who determine the death of a potential donor must not:

- a. participate either in the removal or in the transplantation of organs, tissues or cells; or
- b. be subject to the instructions of a medical professional who is involved in such activities.

In intensive care medicine, the question of independence is especially relevant. A conflict of interest may even arise with regard to the question of whether measures are to be withdrawn or continued. It is conceivable that possible recipients may be patients in the same intensive care unit as a potential donor. This circumstance is addressed by the requirement that an independent second physician should be involved in the determination of death («two pairs of eyes» principle).

¹² I.e. children aged under 28 days (or less than 44 weeks postmenstrual age).

¹³ The statements made concerning older infants are even more applicable for neonates. In particular, the cranial structures are especially soft. The observation period required to document irreversible cessation of cerebral circulation has not been reliably defined to date.

¹⁴ For adults, this is true e.g. of specialists in neurology and intensive care medicine; for children, it applies to physicians with specialist training in paediatric intensive care medicine or paediatric neurology. In these specialist courses, brain death diagnosis is included in the curriculum.

2.6. Documentation

The clinical findings, any additional tests performed and discussions concerning consent are to be recorded in writing. The protocols included in the Appendix are available for this purpose; they may be supplemented by institution-specific documentation.

3. Ascertainment of the patient's wishes

The steps described below are applicable for organ removal both in cases of death due to primary brain damage and in cases of death after cardiac arrest (non-heart-beating donation, NHBD). However, in discussions concerning possible organ removal after cardiac arrest, additional points need to be considered (cf. Section 5.)

3.1. Discussion of organ donation and institution of organ-preserving measures

In general, patients who are considered to be potential organ donors do not have mental capacity. Therefore, if a patient is considered to be a potential donor, the possibility of organ donation should be raised with his legal representative or relatives. This calls for a high degree of empathy and consideration. If it is possible to raise the question at an early stage, it is advisable to do so, because relatives will then have more time to reflect on the matter. Discussion of the withdrawal of life-sustaining treatment (change in the treatment goal) must take place separately, prior to the provision of information on organ donation and the medical measures required for this purpose. The decision to withdraw life sustaining treatment must not be influenced by the possibility of organ donation. If death has occurred under vigorous treatment, discussions are to be adapted accordingly. If possible, communication of a death should take place separately from raising the question of organ donation.

In the case of patients with mental capacity whose prognosis is hopeless, the possibility of organ donation should be considered and the question addressed, unless this is obviously inadvisable. If a patient is willing to donate his organs, he must also be informed of the need for organ-preserving measures to be taken.

Discussions of the possibility of organ donation must convey a sense of respect for the patient and relatives. They should be conducted in a peaceful environment, if possible without any time pressure.

It is important that these discussions should be conducted by the attending physician, with continuity being assured.

In summary, discussions designed to determine the potential donor's wishes must meet the following requirements:

- as regards content: comprehensive and intelligible information on the patient's health status and prognosis (likelihood of death), withdrawal of life-sustaining treatment, the type and extent of organ-preserving measures, as well as their purpose and effects, the determination of death, the procedure for a possible organ removal and the steps taken thereafter;
- as regards the framework: peaceful atmosphere, empathy for and attention to relatives; sufficient time for explanation of the situation, space for questions and concerns, offer of additional discussions with suitable professionals, who if possible should be available throughout the process.

3.2. Consent to organ removal and the institution of medical measures for organ preservation

Ideally, the potential organ donor will have expressed his wishes concerning organ donation and organ-preserving measures in advance, e.g. via a donor card. Frequently, however, this is not the case. In this situation, the patient's wishes need to be determined. Here, it must be established whether there is any evidence that the patient has or has not (or would or would not have) consented to organ removal and the use of organ-preserving measures. In this assessment, close relatives play a key role.

Those who make decisions on behalf of the patient are required to take his presumed wishes into account; these take precedence over their own preferences.

a) Removal of organs for transplantation

If the potential donor has not personally expressed any wishes regarding organ donation, the close relatives decide on his behalf. The following persons are authorized to do so, in the following order of precedence: 1. spouse or registered partner, 2. children, parents and siblings 3. grandparents and grandchildren and 4. others close to the patient. The removal of organs is not permissible if consent is withheld by the authorized representatives. This is also applicable if a patient does not have an authorized representative, or if the latter cannot be contacted in good time.¹⁵

¹⁵ Art. 8TxG and Art. 3TxV.

b) Use of organ-preserving measures

If a legal representative¹⁶ is available or if the patient has designated a trusted person to act as his representative, these persons decide on the use of organ-preserving measures. If the patient lacks a legal representative, organ-preserving measures may be used – with the relatives' consent – if this is in accordance with the patient's presumed wishes.¹⁷ If it becomes clear that the patient would probably not have consented to the use of organ-preserving measures, or if the relatives are unable to say what the patient would have wanted, then organ-preserving measures must not be used.

3.3. Specific points relating to children

With regard to children, decision-making processes differ from those defined for adults only in the fact that, in this situation, legal representatives (generally the parents) are always available to make decisions on the patient's behalf. Otherwise the rules specified in Sections 3.1 and 3.2 are applicable. If the two parents take different views and no agreement can be reached, organ removal should not be undertaken.

4. Organ removal in cases of death due to primary brain damage

If the prognosis for a patient with primary brain damage is hopeless, the goal of treatment changes. The emphasis is no longer placed on preserving life, but on palliative care. If in this situation there are no obvious medical contraindications¹⁸ to organ donation, the patient is in principle considered to be a potential organ donor, and his wishes regarding donation need to be ascertained (cf. Sections 3.1. and 3.2.). If consent to organ donation has been granted, the treatment team is faced with the challenge of allowing the patient to die in dignity and respecting the needs of relatives, but at the same time taking specific medical measures to preserve the transplantable organs in optimal condition.

¹⁶ Until the entry into force of the new adult protection law in 2013, relatives are not authorized to act as representatives in medical decision-making prior to the death of a patient, unless they are granted such authority under cantonal law.

¹⁷ According to the expert opinion (Footnote 3, op. cit., pp. 47–48), the priority for patients with a hopeless prognosis is no longer saving life or restoring health, but serving the interest of «dying in dignity». On this view, the use of organ-preserving measures under the conditions defined in the guidelines is legally acceptable.

¹⁸ E.g. a metastatic tumour.

4.1. Medical measures before death

With regard to medical measures, a distinction is to be made between those designed for organ preservation and those designed to assess donor suitability.

*Organ-preserving measures*¹⁹ are a prerequisite for any organ donation; they are crucial to the success of transplantation. They generally involve the continuation of existing treatments (artificial respiration, administration of drugs and solutions to maintain circulatory function), laboratory analyses to guide treatment and hormone replacement to maintain the internal milieu. After the change in the treatment goal, they no longer serve the patient's therapeutic interests but are pursued for the purpose of organ preservation. In deciding whether or not a measure is to be used, consideration is be given to the patient's individual situation and the risks are to be assessed. Medical measures of this kind are not to be applied for more than 2 days.

Measures for the assessment of donor suitability primarily involve serological and immunological analyses.²⁰

4.2. Medical measures after determination of death

After the determination of death, medical measures for organ preservation and measures for the assessment of donor suitability are permitted for a maximum of 72 hours.²¹

¹⁹ No definitive list of preparatory medical measures is given, since such a list may go out of date.

5. Organ removal in cases of death after cardiac arrest

5.1. Maastricht classification

The Maastricht classification essentially distinguishes the following situations:

- a) Dead on arrival in hospital (Maastricht category 1)
- b) Unsuccessful resuscitation (Maastricht category 2)
- c) Death after withdrawal of life-sustaining treatment (Maastricht category 3)
- d) Cardiac arrest after death due to primary brain damage (Maastricht category 4)

For all these categories, organ removal or perfusion with preservation solution must be performed as rapidly as possible after the determination of death, in order to minimize the period of warm ischaemia (which causes organ damage). In the case of Maastricht categories 1 and 2, the relatives are generally not prepared for the death and have to consider the question of organ transplantation under time pressure. This is an extremely stressful situation.

a) Maastricht category 1

In category 1 donors, death has already been determined before or upon their arrival in hospital. If consent to donation is available, organ removal may be undertaken. If consent is not available, preparatory measures for organ removal (in particular, introduction of a double-balloon catheter for perfusion of organs with cold preservation solution) may be taken until the relatives can be contacted (cf. Section 5.3.).

b) Maastricht category 2

In category 2 donors, organ removal is performed after unsuccessful resuscitation. Because a reduced circulation is maintained with cardiopulmonary resuscitation (CPR), the determination of death may only be made after CPR efforts have been abandoned and persistent cardiac arrest with complete cessation of circulation has subsequently been observed for a 10-minute period (under normothermic conditions²²).

²⁰ Under Art. 30 TxG, there is a duty to verify the suitability of the donor. Article 31 Para. 1 TxG specifies a requirement to ensure that organs have been tested for pathogens or evidence thereof.

²¹ Art. 10 Para. 3 TxG in conjunction with Art. 8 TxV.

²² In patients with hypothermia, the core body temperature must have risen to 35°C.

Unsuccessful resuscitation means that, despite CPR efforts being correctly performed for at least 20 minutes, there has been no restoration of cardiac activity with spontaneous circulation, and the patient presents the clinical signs of death (listed in Appendix A). If spontaneous cardiac activity and circulation are temporarily restored during resuscitation, CPR efforts are to be pursued for another 20 minutes after the cessation of this activity.

c) Maastricht category 3

In category 3 donors, organ removal is performed after the death of a patient due to the withdrawal of life-sustaining treatment in a condition with a hopeless prognosis. Such patients have normal cardiac activity as long as they continue to receive life-sustaining measures (in particular, artificial respiration). Once these measures have been discontinued, the patient dies as a result of cardiac arrest. Here, death is determined as specified in Section 2.2. The interval between the determination of death and organ removal should be as short as possible.

d) Maastricht category 4

In category 4 donors, cardiac arrest occurs unexpectedly, during preparations for organ removal, after the determination of death due to primary brain damage. In this situation, the following options are available:

- restoration of circulatory function;
- rapid transfer to the operating theatre;
- introduction of perfusion catheters (generally Double lumen catheter for organ preservation;
- abandonment of organ donation.

The option adopted will depend on the circumstances. If cardiac arrest occurs en route to the operating theatre, rapid organ removal will be attempted in the theatre. If cardiac arrest occurs in the intensive care unit, there should be a rapid transfer to the operating theatre or perfusion catheters should be introduced.

5.2. Withdrawal of treatment (Maastricht category 3)

The procedure and setting for the withdrawal of treatment, together with the subsequent medical measures planned, must be discussed with the relatives in advance, calmly and in detail. Primarily, it needs to be established how long the relatives wish to remain at the patient's bedside. It is important to inform them that the irreversible cardiac arrest which is the cause of death frequently occurs very rapidly, but that it may possibly only occur several hours after the withdrawal of treatment. The relatives need to know that, because of the risk of damage caused by warm ischaemia, organ removal has to be performed as rapidly as possible after the occurrence of cardiac arrest and the determination of death. They must be prepared for the time pressure which exists once cardiac arrest has occurred, and they should have the opportunity to say goodbye to the dying patient beforehand.

If treatment is withdrawn in the intensive care unit, it is possible, firstly, after the determination of death, to move rapidly to the operating theatre for organ removal. This procedure is only feasible for organs which are less susceptible to ischaemia, such as the kidneys or lungs. The relatives must be prepared for the associated time pressure and rapid transfer of the deceased donor. Alternatively, it is possible, after the determination of death, to cannulate the donor's femoral vessels in the intensive care unit and to initiate organ perfusion there (cf. Section 5.3.).

The setting for the withdrawal of treatment, in particular, also needs to be discussed with the relatives. If they consent to the procedure taking place in the operating theatre (specifically in anticipation of the transplantation of organs particularly susceptible to ischaemia, such as the liver), it is in principle possible for them to accompany the dying patient into the theatre and remain with him until cardiac arrest occurs. However, this has to be discussed in advance. If the operating theatre is considered as a potential setting for the withdrawal of treatment, the following points should be noted:

- The separation of the processes of treatment withdrawal and organ removal has to be maintained under more difficult conditions.
- During the withdrawal of treatment and until the determination of death, palliative care is guided solely by the patient's well-being.
- If the occurrence of death is delayed to such an extent that the removal of organs in optimal condition appears to be at risk, there must be no pressure on the attending physician to hasten death.
- The special circumstances associated with this setting for the withdrawal of treatment must be discussed with the relatives in advance.

The relatives must be informed that it may not be possible to proceed with organ removal if cardiac arrest only occurs after a prolonged period of very low blood pressure, resulting in inadequate perfusion and oxygenation of organs.

5.3. Medical measures

Measures designed to maintain organ perfusion, such as cardiac massage or introduction of femoral cannulae for cold organ perfusion, are carried out in category 1, 2 or 4 donors after death has been determined. If the donor has not consented to organ donation himself, medical measures for organ preservation may be carried out for a maximum of 72 hours, in order to bridge the gap until consent has been given by the relatives.²³ If, by the end of this period, the relatives have not granted consent to donation, organ removal cannot take place.

The question of medical measures being taken before the determination of death only arises with potential donors in category 3. In this group of patients, the withdrawal of treatment is planned, and preparatory medical measures to maintain organ quality and reduce warm ischaemia time can be initiated, as well as serological and immunological tests, as soon as the requirements specified in Section 3.2. are met.

In particular, this applies to the following measures:

- a) *Administration of anticoagulants*: Anticoagulant drugs are administered immediately prior to cardiac arrest, i.e. at a time when death is imminent.
- b) *Introduction of perfusion catheters*: The introduction of catheters permits rapid organ perfusion after the onset of cardiac arrest, thus optimizing donor organ function. This avoids the need for a hurried transfer of the donor to the operating theatre.

²³ Art. 10 Para. 3 TtG in conjunction with Art. 8 TtV.

6. Care of relatives

Death due to primary brain damage is more difficult to comprehend than death from cardiac arrest. As long as artificial respiration is continued, a patient who has died as a result of primary brain damage does not appear to be dead – in the conventional sense – to most people: the ventilator makes the chest rise and fall, the skin feels warm, the pulse is palpable and in some cases external stimuli may even trigger movements and circulatory responses due to spinal reflexes. This frequently gives rise to uncertainties. At this time of leave-taking, requests for relatives to express their views within a short period on the presumed wishes of the deceased regarding donation are often felt to represent an additional burden.²⁴

The pressure of time is even greater in the case of non-heart-beating donation (Maastricht categories 1, 2 and 4). On the other hand, the prospect of a donor's organs possibly saving or improving the quality of other people's lives may also be a source of comfort.

Relatives have a considerable need for information, which may ease their burden to a certain extent. In this situation, the local transplant coordination centre plays a special role as a higher-level body. It is therefore also responsible for ensuring that the organ donation process and information flow proceed smoothly, and if necessary coordinating additional relative-care measures.

Relatives should be informed about all the key steps. They should be provided with a contact address which can offer expert assistance or refer relatives to the appropriate agency. In particular, they need to know when and in what circumstances they can say goodbye to their loved one. A great deal of experience and empathy is required to be able to recognize unarticulated as well as articulated needs, especially given the pressure of time. It is essential to define the allocation of roles within the organ donation process and the tasks, authority and responsibilities of the various people involved.

7. Management of the cadaver

Before, during and after organ removal, the donor's cadaver is to be treated with the respect that is due to any recently deceased person, and in accordance with the same requirements. The donor's cadaver must be returned to the relatives in a suitable state for the funeral rites. The local transplant coordination centre is responsible for ensuring that the relatives are provided with all the relevant information (in particular, concerning any delays, e.g. for medicolegal investigations). In organ removal procedures, the body, though dead, still has a largely functional spinal and autonomic nervous system (cf. Appendix A. «Clinical signs of death», paragraph 5). The body can therefore react to stimuli and exhibit motor responses. With the administration of anaesthetics, such responses can be substantially eliminated. This helps to ease the burden on the people involved in the organ removal. As the administration of anaesthetics provides a degree of ischaemic protection and prevents damage to the donor organs, it is also in the interest of the recipient. For these reasons, the use of inhalational anaesthetics is recommended.

8. Training and support for the care team

In their daily work, nursing professionals and physicians in intensive care units are exposed to emotionally stressful events. For the ICU team, caring for an organ donor represents a major challenge. How such situations are perceived, handled and coped with varies from one individual to another.

Efforts to deal with the fate of the deceased and his relatives, as well as the various interactions between attending physicians, nursing staff, consultants, relatives and the transplant coordination centre, demand a high level of professional, psychological, communicational and organizational skills, and may push members of the care team to their limits.

24 Kesselring A, Kainz M, Kiss A. Traumatic Memories of Relatives Regarding Brain Death, Request for Organ Donation and Interactions with Professionals in the ICU. American Journal of Transplantation 2006.

Accordingly, recurrent information and training events for the care team are indispensable. All members should receive regular training in the following areas:

- determination of death in accordance with the guidelines;
- pathophysiology of death;
- organizational processes before, during and after organ donation;
- ethical aspects of organ donation and the concept of brain death;
- management of relatives.

An opportunity should be provided to review difficult situations at a debriefing session involving everyone concerned. All ICUs providing care for organ donors should offer supervision and stress management programmes.

III. Appendix

A. Clinical signs of death

In the determination of death, the clinical examination to determine the signs of cessation of brain function is of central importance. The circumstances and methods of this examination are described below:

1. *Coma of known cause:* A coma of known cause is present if the condition is adequately explained by structural brain lesions detected by imaging.
This is subject to various conditions: the core body temperature must be over 35°C, the patient must not be in shock and his condition must not be (partly) caused by metabolic derangements or drug intoxication/poisoning. In all other situations, an additional (instrumental) test is required.
2. *Bilaterally dilated pupils, unresponsive to light:* Partially dilated or anisocoric pupils do not preclude the determination of death, provided that they do not respond to light stimuli.
3. *Absent cervico-ocular and vestibulo-ocular reflexes:* If no eye movements occur in response to rapid passive head turning or extension and flexion of the neck, the oculocephalic reflexes are absent. This test may only be performed if cervical spine trauma is excluded. The vestibulo-ocular reflex is assessed by performing the caloric ice water test.
4. *Absent corneal reflexes:* The corneal reflexes can be tested by touching the cornea with a cotton swab.
5. *No response of any kind to painful stimuli:* The response to painful stimuli should be tested by applying pressure to the exit point of the trigeminal nerve branch on the supraorbital ridge. (In some cases, a persistent upper or lower limb response is observed when painful stimuli are applied outside the trigeminal region.) In a brain-dead patient, spinal reflexes with complex motor responses may still be present. Thus, spontaneous and reflex movements occurring in response to stimuli do not preclude brain death (e.g. abdominal reflex, cremaster reflexes, isolated jerks of the upper extremities, unilateral extension-prona-

tion movements). In doubtful cases, an additional (instrumental) test is to be performed (preferably non-invasive transcranial Doppler ultrasonography or colour-coded duplex ultrasonography).²⁵

6. *Absent cough and gag reflexes*: The examining physician seeks to elicit the cough and gag reflexes by stimulating the posterior pharynx and trachea.
7. *No spontaneous respiration*: The absence of spontaneous respiration is to be demonstrated by the apnoea test.

Normal neuromuscular function is a prerequisite for the apnoea test. If a patient has received muscle relaxants, neuromuscular monitoring must be performed to confirm that neuromuscular function is preserved.

The apnoea test consists of the following steps:

- Arterial blood gas analysis to determine baseline values of PaCO₂ and arterial pH and to calculate the relationship between PaCO₂ and end-tidal CO₂.
- Delivery of 100% oxygen for 10 minutes.
- Continuous monitoring by transcutaneous oxygen saturation measurement.
- Hypoventilation (with end-tidal CO₂ or transcutaneous pCO₂ monitoring) at a rate of 0.5–2 L/minute until a PaCO₂ of 60–70 mmHg (8–9.35 kPa) can be expected.
- Arterial blood gas sampling to demonstrate that the PaCO₂ has risen above 60 mmHg (8 kPa) and the pH has fallen below 7.30.
- Disconnection of the ventilator. Oxygen is supplied via a catheter inserted into the endotracheal tube at a rate of 2–4 L/minute (max. 2 L/minute in children with a narrow endotracheal tube); to prevent barotrauma, the catheter must not be inserted too deeply.
- Observation for (absent) respiratory movements for 1 minute.
- Reconnection of the ventilator, with pre-test settings.

If transcutaneous oxygen saturation falls below 80%, the apnoea test is to be prematurely discontinued.

To prevent dangerous circulatory disorders in patients with severe oxygenation disturbances or significant left heart failure, the test is carried out as above, but without the disconnection step:

- After arterial blood gas sampling, the ventilator is switched to spontaneous breathing mode (CPAP mode, no breathing support), apnoea ventilation is switched off and the settings are further modified so that spontaneous respiratory movements can be detected. It should be borne in mind that cardiogenic breaths may occur if the flow trigger setting is too sensitive.
- Observation for (absent) respiratory movements.
- Resumption of ventilation, with pre-test settings.

In children under 1 year of age, observations are made with the ventilator set to CPAP; the target values are a PaCO₂ of 90 mmHg (12 kPa²⁶) and a pH below 7.25, and oxygen saturation should not fall below 80%.

If the apnoea test cannot provide conclusive results (e.g. in severe chronic hypercapnia) – as in the situation where cranial nerves cannot be evaluated – an additional (instrumental) test must be performed.

25 Saposnik G, Basile VS, Young B. Movements in Brain Death: A Systematic Review. *Can J Neurol Sci* 2009; 36:154–60.

26 Brill R, Bigos D. Apnea threshold and pediatric brain death. *Crit Care Med* 2000; 28: 1257.

In the determination of death, additional (instrumental) tests are used if the aetiology of the cessation of function is unclear. The aim of the additional test is to confirm the cessation of the cerebral circulation.

The value of such tests is dependent on the mean arterial pressure during the test. The results are only relevant if the mean arterial pressure at the time of the test is at least 60 mmHg in adults and children, and at least 45 mmHg in infants. The mean arterial pressure at the time of the test must be recorded in the test report.

The following tests are essentially suitable for detecting cessation of the cerebral circulation:

1. transcranial Doppler ultrasonography or colour-coded duplex ultrasonography ,
2. computed tomography,
3. magnetic resonance imaging,
4. digital subtraction angiography.

1. Transcranial Doppler ultrasonography or colour-coded duplex ultrasonography

The test involves extracranial Doppler ultrasonography of the internal carotid artery visualized by B-mode and colour flow imaging and transtemporal transcranial colour-coded ultrasonography of the middle cerebral artery bilaterally to a depth of 55–65 mm in pulsed-wave Doppler mode. Characteristic of cessation of the cerebral circulation is the observation, bilaterally, of pendular flow or only low-frequency spectra (max. 50 cm/s, duration < 200 ms).

2. Computed tomography (CT)

Spiral CT before and after intravenous administration of contrast medium for visualization and quantification of cerebral perfusion (perfusion CT) and for visualization of neck vessels supplying the brain and intracranial vessels (CT angiography) can demonstrate cessation of the cerebral circulation.

3. Magnetic resonance imaging (MRI)

MR angiography and perfusion MRI after intravenous administration of a gadolinium-based contrast agent can demonstrate cessation of the cerebral circulation. However, use of these techniques is significantly restricted by their limited availability, the possible incompatibility of patient utensils (tube, catheters, wires, etc.) and the fact that they are contraindicated in the presence of metallic foreign bodies.

4. Digital subtraction angiography (DSA)

To demonstrate cessation of the cerebral circulation, both common carotid arteries and at least the dominant vertebral artery have to be selectively catheterized. Injection of contrast medium into each common carotid artery should lead to filling of the external carotid artery and its branches, and to filling of the cervical and possibly the intracranial extradural portion of the internal carotid artery. If a visualized vertebral artery is suspected to be hypoplastic, then the contralateral vertebral artery must also be visualized. Cessation of the cerebral circulation – and thus death due to brain damage – is considered to have been demonstrated if the cerebral (i.e. intracranial intradural) arteries and veins are not discernible in either the supratentorial or the infratentorial compartment.

²⁷ This section is based on the recommendations of the Swiss Society of Neuroradiology on the use of additional neurological tests in the determination of death (issued in October 2010), which were developed in connection with the present guidelines. The recommendations are available online (in German) at: www.swissneuroradiology.ch/index.php/fortbildung.html

Protocol for the determination of death due to primary brain damage

For children over 1 year old and adults

This protocol must be kept at the patient's bedside. After death, as an important document, it is to be filed in the medical records.

Patient's surname and first name:

Date of birth:

Patient identification no.:

	Date/time	Physician 1 Stamp or block capitals and signature	Physician 2 Stamp or block capitals and signature	Go to no.
1. Determination of death based on clinical signs				
a) Metabolic cause of coma excluded by laboratory tests; core body temperature $\geq 35^{\circ}\text{C}$; effects of sedatives/muscle relaxants				1.b)
b) No suspicion of CNS infection or cranial polyradiculitis				1.c)
c) No evidence of pharmacological or toxic cause of coma				1.d)
d) Clinical determination of death				1.e)
e) Apnoea test positive				2.
2. Determination of death (irreversible cessation of brain function)				
a) Clear cause of cessation of brain function, namely:				4.
b) Causes of cessation of brain function not clearly identifiable or reliable diagnosis not possible				3.
3. Additional tests				
a) Transcranial Doppler ultrasonography or colour-coded duplex ultrasonography				4.
b) Computed tomography (CT)				4.
c) Magnetic resonance imaging (MRI)				4.
d) Digital subtraction angiography (DSA)				4.
4. Consent to organ removal obtained and presumed wishes regarding organ-preserving measures determined				5.
5. No contraindications to organ removal				6.
6. Preconditions for organ removal met²⁸				

²⁸ In cases where violent death is suspected, the police or public prosecutor's office must be notified prior to organ removal.

Protocol for the determination of death due to primary brain damage

For infants beyond the neonatal period up to 1 year

This protocol must be kept at the patient's bedside. After death, as an important document, it is to be filed in the medical records.

Patient's surname and first name:

Date of birth:

Patient identification no.:

	Date/time	Physician 1 1 st clinical examination Stamp or block capitals and signature	Date/time	Physician 2 2 nd clinical examination Stamp or block capitals and signature	Go to no.
1. Clinical examination					
a) Metabolic cause of coma excluded by laboratory tests; core body temperature $\geq 35^{\circ}\text{C}$; effects of sedatives/muscle relaxants excluded					1.b)
b) No suspicion of CNS infection or cranial polyradiculitis					1.c)
c) No evidence of pharmacological or toxic cause of coma					1.d)
d) Clinical determination of death					1.e)
e) Apnoea test positive					2.
2. At the end of 24 hour observation period: 2nd clinical examination					
a) Metabolic cause of coma excluded by laboratory tests; core body temperature $\geq 35^{\circ}\text{C}$; effects of sedatives/muscle excluded					2.b)
b) No suspicion of CNS infection or cranial polyradiculitis					2.c)
c) No evidence of pharmacological or toxic cause of coma					2.d)
d) Clinical determination of death					2.e)
e) Apnoea test positive					3.
3. Determination of death (irreversible cessation of brain function)					
a) Clear cause of cessation of brain function, namely:					5.
b) Causes of cessation of brain function not clearly identifiable or reliable diagnosis not possible					4.
4. Additional tests					
a) Transcranial Doppler ultrasonography or colour-coded duplex ultrasonography					5.
b) Computed tomography (CT)					5.
c) Magnetic resonance imaging (MRI)					5.
d) Digital subtraction angiography (DSA)					5.
5. Consent to organ removal obtained					6.
6. No contraindications to organ removal					7.
7. Preconditions for organ removal met ²⁹					

²⁹ In cases where violent death is suspected, the police or public prosecutor's office must be notified prior to organ removal.

Protocol for the determination of death after permanent cardiac arrest (NHBD)

For children over 1 month old and adults

This protocol must be kept at the patient's bedside.

After death, as an important document, it is to be filed in the medical records.

Patient's surname and first name:

Date of birth:

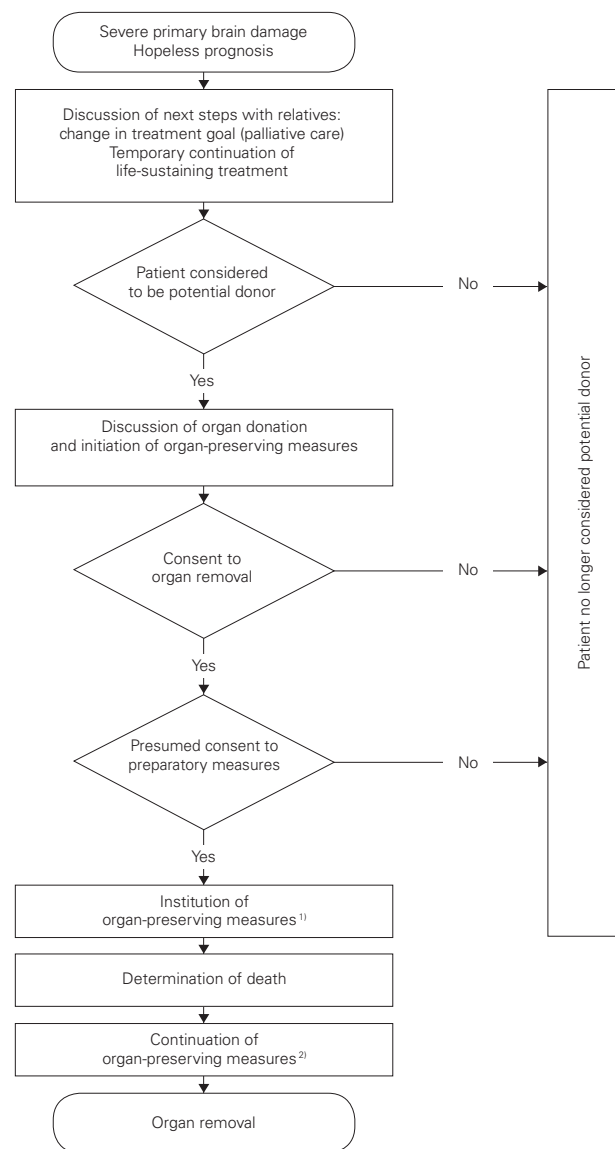
Patient identification no.:

	Date/time	Physician 1 Stamp or block capitals and signature	Physician 2 Stamp or block capitals and signature	Go to no.
1.	No spontaneous circulation for at least 20 minutes despite resuscitation measures (Maastricht category 1 or 2)			2.
2.	Reason for withholding resuscitation measures (Maastricht category 3):			3.
3.	Cardiac arrest first determined by physician by means of transthoracic echocardiography (TTE) (absence of cardiac activity in four-chamber view or from subxiphoid position)			4.
4.	Death determined by physician after cardiac arrest lasting 10 minutes without resuscitation			5.
5.	Institution of medical measures for organ preservation and assessment of donor suitability, from the diagnosis of death until a decision is taken by the close relatives, or until organ removal in cases where consent has already been granted, for a maximum period of 72 hours			6.
6.	Relatives informed about the organ removal process In the case of Maastricht category 3 donors, information about the institution of medical measures and the organ donation process must be provided prior to the withdrawal of treatment and cardiac arrest.			7.
7.	Consent to organ removal obtained and presumed wishes regarding organ-preserving measures determined			8.
8.	No contraindications to organ removal			9.
9.	Preconditions for organ removal met ³⁰			

³⁰ In cases where violent death is suspected, the police or public prosecutor's office must be notified prior to organ removal.

D.

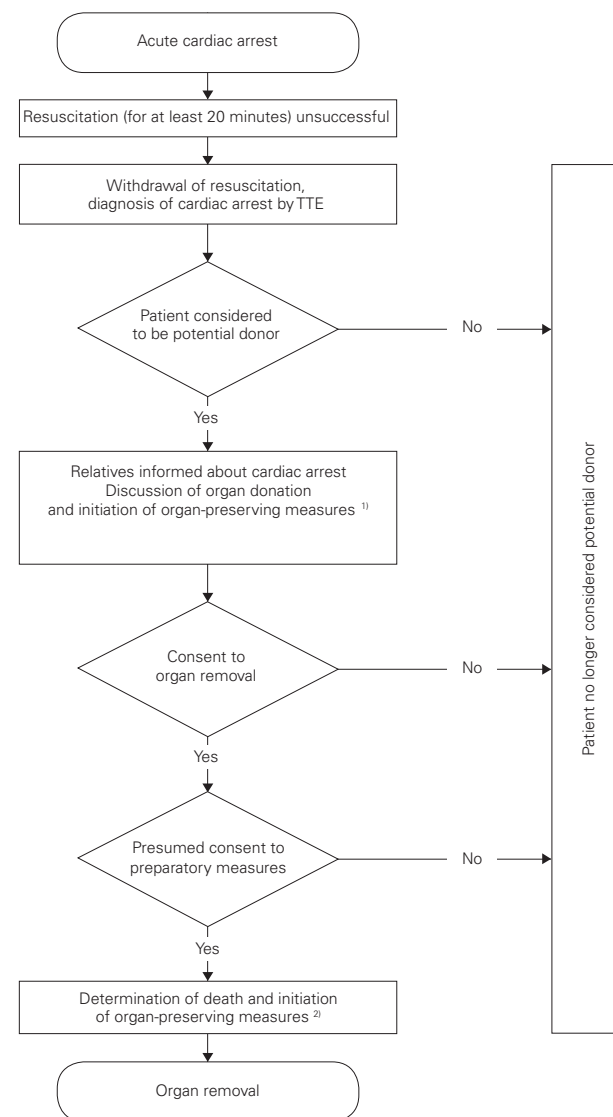
Flow chart: determination of death due to primary brain damage



- 1) Prior to the determination of death, organ-preserving measures are not to be applied for more than 2 days from the time of the decision (change in treatment goal).
- 2) After the determination of death, organ-preserving measures are not to be continued for more than 72 hours.

D.

Flow chart: determination of death after cardiac arrest Maastricht categories 1 and 2



- 1) Discussion may also take place after the determination of death.
Organ-preserving measures are not to be applied for more than 72 hours after death.
- 2) No earlier than 10 minutes after withdrawal of resuscitation measures.

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Information on the preparation of these guidelines

Mandate	On 6 February 2009 the Central Ethical Committee (CEC) of the SAMS appointed a sub-committee to revise the medical-ethical guidelines entitled «The Determination of Death in the Context of Organ Transplantation».
Sub-committee responsible	Professor Jürg Steiger, Basel (Chair) Lic. theol. Settimio Monteverde, MAE, Basel (Vice-Chair) Ursula Hager, MAE, Zurich Professor Christian Kind, CEC (Chair) St Gallen Dr Roger Lussmann, St Gallen Professor Philippe Lyrer-Gaugler, Basel Professor Stephan Marsch, Basel Dr Luca Martinolli, Bern Professor Manuel A. Pascual, Lausanne Dr Bruno Regli, Bern Dr Peter Rimensberger, Geneva Lic. iur. Michelle Salathé, MAE, Basel Dr Theodor Weber, Bern Professor Markus Weber, Zurich
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Consultation	The guidelines were submitted for broad consultation in February/March 2011.
Approval	The final version of these guidelines was approved by the Senate of the SAMS on 24 May 2011.
Entry into force	The guidelines come into force on 1 September 2011.

Publication details

Design	vista point, Basel
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www.samw.ch/en/Ethics/Guidelines/Currently-valid-guidelines.html



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