

Chapter I. Transplantation

§ 1

Organs or other biological material may be removed from any person who has given his written consent thereto for the treatment of another person's disease or bodily injury. Such an operation may only be performed when it does not involve any immediate risk to the donor's life or health.

Consent may be given by a person who has reached 18 years of age. When special circumstances so indicate, also persons under 18 years of age may give their consent with the endorsement of their guardian and the person who has parental custody and is responsible for the care of the minor. In such cases, the operation must also be approved by the Directorate of Health Services.

Before such consent is given, the donor must have been informed by a doctor of the nature of the operation and of the consequences which may ensue. The doctor is under an obligation to make sure that the person concerned has understood the content and significance of the information given.

§ 2

Organs and other biological material may be removed, for the treatment of another person's disease or bodily injury, from a dead person who in writing or verbally has taken a decision to that effect.

Even if such a decision has not been taken, the operation referred to may be performed on a person who dies during illness or who is brought dead to the hospital, unless the deceased or his next-of-kin have expressed themselves as being against it, or there is reason to assume that the operation would be contrary to the views held by the deceased or his next-of-kin, or other special grounds contraindicate the operation.

As far as possible the deceased's next-of-kin shall be notified of the death before the operation takes place.

§ 3

Operations pursuant to § 2 must not be performed in cases where there may be a question of forensic autopsy and the operation may have a bearing on the result of this.

§ 4

Before operations pursuant to § 2 may be performed, death shall be confirmed by two doctors who shall not themselves perform the operation or the transfer to the recipient. A record shall be kept of the operation. The record shall state the time of death, the cause of death, the names of the doctors who confirmed the death and in what way this was done.

The operation must not be performed by the doctor who treated the deceased during his final illness.

§ 5

Operations pursuant to §§ 1 and 2 may only be carried out at hospitals approved therefor by the King.

§ 6

The withdrawal of blood, the removal of small pieces of skin and other minor operations of a corresponding nature may be effected notwithstanding the provisions in this Act.

Chapter II. Hospital autopsies

§ 7

On medical grounds an autopsy may be performed on a person who has died in a hospital or some other health institution as stated in the Hospitals Act of 19 June 1969 no 57, § 1, first paragraph, or on a person who is brought in dead to such an institution.

Nevertheless, an autopsy may not be performed if the deceased or his next-of-kin have expressed themselves as being against it, or there is reason to assume that such an operation would be contrary to the views held by the deceased or his next-of-kin, or other special grounds contraindicate the operation.

The autopsy may not be performed before the deceased's next-of-kin have been notified of the death and a period of 8 hours has elapsed since death occurred. If the deceased or his next-of-kin

have given their consent, the autopsy may be performed earlier.

If special reasons render it necessary to ascertain the cause of death without delay, the autopsy may be performed without regard to these conditions.

§ 8

An autopsy pursuant to § 7 must not be performed if there is reason to assume that a forensic autopsy will be required.

Chapter III. Donation of bodies

§ 9

For use for teaching purposes and research in anatomy and other medical subjects at the universities and other places of learning, such institutions as the King decides may require the donation/surrender of:

- a) the body of any person who after having reached 18 years of age has made a written statement concerning the donation of his body for such purposes,
- b) a body which is in the keeping of the public authorities when the deceased's next-of-kin consent to such surrender or do not undertake to assume responsibility for the burial,

Surrender pursuant to litra b) must not take place if there is reason to assume that surrender would be contrary to the views held by the deceased or if the deceased's next-of-kin forbid such surrender.

§ 10

The expenses connected with the donation/surrender of bodies pursuant to § 9, as well as the costs of burial, shall be borne by the institution to which the body is donated/surrendered.

Chapter IV. Miscellaneous provisions

§ 11

Anyone who in pursuance of this Act obtains knowledge of confidential circumstances is subject to the pledge of secrecy regarding such circumstances unless his duty or service require otherwise.

§ 12

The Public Administration Act - with the exception of chapter VII regarding regulations - is not applicable to matters under this Act.

§ 13

The King issues regulations to implement and supplement this Act.

§ 14

Anyone who makes a decision regarding the removal of any organ(s) or other biological material, except subject to the conditions prescribed by the Act, shall be punished by fines, unless the case is punishable under stricter penal prohibitions.

§ 15

The Act shall enter into force from the date decided by the King. The King may decide that the various chapters in the Act shall enter into force at different times.

§ 16

From the date when Chapter III of the Act enters into force, Act no 1 of 20 May 1899 relating to the Donation of Bodies for Use in the University's Teaching of Medicine is repealed.

Guidance on definition of death

Cf. Regulations regarding the definition of death, laid down by Royal Decree of 10 June 1977

The death of an individual has traditionally been confirmed by the cessation of respiration and cardiac function, sometimes also by secondary changes such as rigor mortis (post mortem rigidity), livor mortis (post mortem discoloration) and algor mortis (body temperature tending to correspond with surroundings).

Since new forms of treatment have become usual in medicine, it has become clear that the cessation of respiration and heartbeat for a short period (minutes) is not a decisive indication of death, but that the diagnosis of death must be based on the cessation of brain function. Some patients are able to resume a worthwhile existence after a short cessation of respiration and/or heartbeat as a result of successful resuscitation. In cases of open heart surgery, the heart and lungs may be put out of action for a longer period (hours) by means of technical appliances such as the heart-lung machine and artificially reduced temperature. The precondition for the continuance of life after a temporary cessation of respiration and heartbeat is that the function of the brain is maintained.

On the other hand, the functions of the heart, kidneys and certain other organs may be maintained by artificial means even after the brain has been totally destroyed. It has seldom proved possible, however, to maintain the functions of these organs for more than 3-4 days after the brain has ceased to function, even with the optimum use of medical technology and skilled care. Also in these situations, which can only occur in the case of patients where treatment with artificial respiration has been put into effect, it is the cessation of brain function which decides that continued life is not possible. A universally valid definition of death must therefore be based on the fact that brain function has ceased.

The following definition shall be the basis of the diagnosis of death:

Death has taken place when there is total destruction of the brain with complete and permanent cessation of all functions in the cerebrum, the cerebellum and the brainstem (mesencephalon, pons and medulla oblongata).

This definition of death is of universal validity and covers all causes of death.

The signs of the total destruction of the brain are either permanent cessation of heartbeat and respiration or the following criteria which must be satisfied if heartbeat and respiration are artificially maintained:

1. Recognized intracranial pathological process (i.e. disease or injury inside the cavity of the skull).
2. Total unconsciousness.
3. Cessation of own respiration.
4. Cessation of all brain nerve reflexes.
5. Cessation of the electrical activity of the brain, i.e. no electrical activity demonstrable by electroencephalography (iso-electrical or 'flat' EEG).
6. Cessation of blood supply to the brain demonstrated by cerebral angiography (i.e. X-ray photography of head after injection of contrast medium into carotid arteries).

Re 1. Recognized intracranial pathological process

Total destruction of the brain occurs if the pressure inside the cavity of the skull rises to the same level as the blood pressure so that the blood supply to the brain ceases. The rise of pressure in the cavity of the skull is caused by space-consuming pathological processes and/or swelling of the brain (i.e. brain oedema or an increase of fluid content in the brain).

The destruction of the brain may be due to disease or injury inside the cavity of the skull itself, such as haemorrhages, abscesses, inflammations and head injuries (primary causes) or disease or injury outside the cavity of the skull which lead to lack of oxygen in the brain (secondary causes).

Re 2. Total unconsciousness

Here there must be failure to react to light, sound, touch and pain-producing stimuli. The spinal cord - which lies outside the cavity of the skull - may have reflex functions even if the brain in its entirety has been destroyed. Spinal cord reflexes (i.e. muscle contractions in response to tapping of the sinews) may

therefore be present, even if death has occurred.

Re 3. Cessation of own respiration

This is an absolute requirement for the diagnosis of death.

Re. 4. Cessation of all brain nerve reflexes

Reflexes which pass the brain stem - which lies in the cavity of the skull - must not be able to be obtained: the pupils must not react to light, the corneal reflex (blinking when the cornea is touched) and the vestibulo-ocular reflex (movement of the eyeball following the injection of cold water into the auditory canal) must not be able to be produced.

Re. 5. Cessation of the electrical activity of the brain

An iso-electrical or 'flat' electroencephalogram is usually an indication of the total destruction of the brain. On its own the EEG examination is not sufficient proof that the brain has been totally destroyed, because in cases of poisoning by soporific drugs and narcotics, of low body temperature (hypothermia) or of acute lack of oxygen patients may temporarily have an iso-electrical electroencephalogram. If radiological examination (cerebral angiography, see under next heading) has already shown that the blood supply to the brain has ceased, the EEG examination may be omitted.

Re. 6. Cessation of blood supply to the brain demonstrated by cerebral angiography

Confirmation by angiography that the blood supply to the brain has ceased is the decisive indication of total destruction of the brain. The injection of contrast medium must be made into all four arteries which carry blood to the brain, namely both arteries of the neck (the carotid arteries) and both arteries of the cervical vertebrae (the vertebral arteries).

If the injection of contrast medium in both the carotid arteries has shown that neither of these is carrying blood to the brain, it is sufficient to make an injection of contrast medium into one of the vertebral arteries if the contrast medium flows back in the other without the veins in the cavity of the skull being filled with contrast medium.

The blood pressure must be measured before, during and after the radiological examination, so that it is certain

that the absence of contrast medium in the veins in the brain is not due to a fall in blood pressure during the actual examination. If the blood pressure falls while the examination is being carried out, it must be repeated with a stabilized blood pressure.

CONCLUSION

If all the criteria 1-6 are satisfied, the patient shall be declared dead. The doctor shall complete the medical death certificate (normal report of death) and the special medical death certificate when the diagnosis of death is made on the basis of the total destruction of the brain. In the event, operations in accordance with § 2, cf. §§ 3-5, of the Act relating to Transplantation may be performed.

OTHER REQUIREMENTS

Act no 6 of 9 February 1973 relating to Transplantation, Hospital Autopsies and the Donation of Bodies etc, Chapter I - Transplantation, lays down no stipulated qualifications in respect of the two doctors who, pursuant to § 4, are responsible for the diagnosis of death. One of these two doctors should have a senior post and be qualified in internal medicine, surgery, neurosurgery, neurology, anaesthesiology, clinical neurophysiology or radiology. One of the two doctors should have been among those who treated the deceased during his final illness. .

Regulations regarding the definition of death, in pursuance of Act no 6 of 9 February 1973 relating to Transplantation, Hospital Autopsies and Donation of Bodies etc, Chapter I - Transplantation. Laid down by Royal Decree of 10 June 1977 pursuant to § 13 in the Act

§ 1

A person is dead when there are conclusive indications of the total destruction of the brain with complete and irreversible cessation of all functions in the cerebrum, the cerebellum and the brainstem. The permanent cessation of cardiac function and respiration are conclusive indications of the total destruction of the brain.

§ 2

All of the following criteria must be satisfied for it to be possible to make a diagnosis of death with total destruction of the brain if respiration and cardiac function are maintained by artificial means.

1. Recognized intracranial pathological process
(i.e. disease or injury inside the cavity of the skull).
2. Total unconsciousness.
3. Cessation of own respiration.
4. Cessation of all brain nerve reflexes.
5. Cessation of the electrical activity of the brain
(i.e. no electrical activity demonstrable by electroencephalography: iso-electrical or 'flat' EEG).
6. Cessation of blood supply to the brain demonstrated by cerebral angiography (i.e. X-ray photography of the head after injection of contrast medium into the carotid arteries).

§ 3

The time of death is formally the point of time when the diagnosis of total destruction of the brain is made.

§ 4

If the diagnosis of death is made in cases where respiration and cardiac function have not been maintained by artificial means, the doctor shall complete the usual medical death certificate (normal report of death).

If the diagnosis of death is made on the basis of total destruction of the brain with regard to defined criteria, while respiration and cardiac function are maintained artificially, in addition to the usual medical death certificate (report of death), a special medical death certificate shall be completed by the doctor. This latter certificate shall be written on the prescribed form in two or three (see below) identical copies, all signed by two doctors. One copy shall be included with the deceased's hospital case records. The second copy shall be filed by the medical superintendent for the hospital department where the death occurred. If any organ(s) is/are to be removed for transplantation, a third copy shall be incorporated in the record which must be kept of the operation performed, pursuant to § 4 of the Act of 9 February 1973 relating to Transplantation, Hospital Autopsies and Donation of Bodies etc.

§ 5

These regulations shall enter into force on 1 July 1977.