

### Brain Death and Decisions Regarding Organ Donation

OPINION

Deutscher Ethikrat



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### **1 INTRODUCTION AND OBJECTIVE**

The transplantation of organs removed post-mortem is considered an established treatment method in medical practice. Procurement of organs is premised on the willingness of a donor, or of persons deciding for the donor, to make organs available for transplantation following the occurrence of death.<sup>1</sup> The measures associated with this - and the criteria for removal guiding their execution - occasionally lead, nonetheless, to deeply felt uncertainties among possible donors and next-ofkin, as well as among those seriously ill individuals waiting for an organ donation. These uncertainties arise not least of all due to the fact that the hope of saving a life is linked to the death of another human being. For many people, the ambivalence implied by this is also connected to the question of how it can be possible to obtain living organs from a dead person. In fact, it has only become possible through modern intensive care to maintain bodily functions even when all brain functions have already irrecoverably expired. The "brain death" which can be diagnosed in this case is commonly equated with the death of the human being.

This concept of brain death underlies post-mortem organ donation in Germany as regulated in the *Transplantationsgesetz* (Transplantation Act, TPG). For many people, despite the fact that intensive care enables the temporal decoupling of brain death from the expiration of other organs' and tissues' functions, doubts are still associated with the idea of brain death; these doubts have accompanied transplantation medicine since the first heart transplant in 1967<sup>2</sup> and have not

No preliminary judgment is associated with this formulation concerning how death is to be understood, especially whether brain death is a sure sign of death (see additionally chapter 4). The use of the term "postmortem" also poses no such preliminary judgment, but relies rather on the regulation of the Transplantation Act, which speaks of removal from dead donors.

<sup>2</sup> See the articles in Schlich/Wiesemann 2001.

quieted in the fifteen years since the German Transplantation Act has entered into force.

Nevertheless, the controversy surrounding the legitimacy and adequacy of brain death as a criterion for human death appeared – at the beginning of this century and following three decades of discussion conducted intensively worldwide – to be essentially settled. Insofar as critics rejected the understanding of brain death as the death of the human being, their opposition had largely receded from the public legal policy debate into juridical, philosophical and medico-ethical specialist literature. Many national legal systems had expressly or tacitly accepted brain death as the death of the human being and integrated it into the relevant areas of their normative systems as a sufficient prerequisite for post-mortem organ donation. A basic public discussion on the fundamental legitimation questions no longer seemed obligatory.

That changed at the latest at the end of 2008 when the U.S. President's Council on Bioethics issued a White Paper with the title Controversies in the Determination of Death.<sup>3</sup> Previously in the U.S. in 1981, the National Conference of Commissioners on Uniform State Law suggested a model for a legal definition of death that expressly included complete cerebral death as the death of the human being along with "classical" cardiovascular death.<sup>4</sup> In the following years, this definition was incorporated into the legal systems of most American states. Nonetheless, the legal policy consensus thereby established has since become brittle - so the White Paper already notes in 2008 in its introduction. A range of traditional philosophical, medical and legal objections to the equating of human death with brain death had not been silenced despite the broad legal recognition and had indeed garnered support through the outcomes of new studies. Against this background of controversy once more inflamed in science, philosophy and clinical practice, it

<sup>3</sup> President's Council on Bioethics 2008.

<sup>4</sup> Cf. National Conference of Commissioners on Uniform State Laws 1981.

had hence become essential for legal policy to review the criterion of brain death again in regard to its ethical justifiability as a sufficient condition for human death.<sup>5</sup>

However, not only in the USA, but also in all other nations, which – like Germany – accept brain death in their legal systems and clinical praxis as the death of the human being and as the basis for post-mortem organ removal, a deepened resumption of the discussion surrounding brain death appears indispensable. In the fall of 2011, the German Ethics Council therefore conducted a public event on this topic in its series *Forum Bioethik* (Bioethics Forum). It now presents in this opinion the outcomes of its extensive engagement with questions in the context of brain death.

This occurs not only against the backdrop of the persisting debate, but also on the occasion of the latest reforms to the Transplantation Act. Among other things, the so-called decision-solution was introduced during this revision. With Section 2 TPG, comprehensive education of the population was also shifted more strongly into the foreground. Of importance in this regard is, above all, candid communication with next-of-kin and legal representatives (custodian, authorized representatives) of potential organ donors. In this context, it is especially important to the German Ethics Council to illuminate contentious issues in dealing with death and the determination of death. In the Council's point of view, such a discussion is an important prerequisite for establishing more trust in transplantation medicine. The earning of trust is, in turn, an important prerequisite for being able to effectively treat people who are ill.

The present opinion does not deal with the topic of the loss of trust resulting from the manipulations recently made known in organ allocation. Also left aside are the fundamental

<sup>5</sup> In the conclusion, the majority of the President's Council on Bioethics argues for brain death as criterion of death (President's Council on Bioethics 2008, 89).

questions of a fair and transparent allocation of organs raised in this regard, as well as numerous connected problems of organisational structures and the legitimacy of decision-makers in transplantation medicine (this pertains especially to the German Medical Association and Eurotransplant). Without doubt, these are also of significance for the social acceptance of transplantation medicine, yet they demand a separate analysis.

The opinion, which is concerned solely with post-mortem organ donation, concentrates on *two central questions*:

(1) First, the basis for post-mortem organ donation, the concept of brain death, is submitted to a thorough analysis. The German Ethics Council would like to work through this many-leveled discussion, as well as to make the various perspectives and arguments transparent. This relates centrally to the dead-donor rule – that is, the rule applicable to transplantation medicine in German law (apart from the special requirements connected to cases of living donation) – which requires that the donor must be dead during organ removal. The Dead-Donor Rule also raises questions in regard to the practice of non-heart-beating donation, somewhat prevalent in other countries; in this process, organs are removed following cardiac arrest, without requiring the determination of brain death.

(2) In addition, the concept of brain death proves to be a communicative challenge. The conditions for open and transparent processes of communication and their design form the opinion's second point of emphasis. Two levels may be differentiated in the process:

For one, information and education of the population need to be considered as a whole. In this respect the new legislation regarding the so-called decision-solution requires that education covers the entire scope of the decision and must be open in outcome (Section 2 (1) No. 2 TPG). With this legal revision, Germany has chosen a path for which, in the estimation of Axel Rahmel, the current medical Director of the German Organ Transplantation Foundation, there is "no international model<sup>°6</sup> and which therefore all the more requires a diligent analysis and evaluation.

Beside this macro-level, communication on the micro-level surrounding the potential organ donor also needs to be examined. Here, focus is required on the procedures in intensive care units in preparation for a (possible) transplantation, on the attitudes of the actors concerned, and not least of all on the discussions with next-of-kin and authorized representatives or custodians of the potential organ donor (see chapter 5).

<sup>6</sup> According to Axel Rahmel in conversation with *Deutsches Ärzteblatt* (http://www.aerzteblatt.de/nachrichten/52348 [2015-01-15]).

# 2 TAKING STOCK AND DEFINING THE PROBLEM

# 2.1 State of the art of transplantation medicine

Medical historians describe the idea of complex internal illnesses being traceable to the failure of a single organ as a development of the late 19<sup>th</sup> century. The transfer of tissue, primarily skin, was already systematically researched in the 19<sup>th</sup> century. The first transplantation of a human kidney was performed by the Ukrainian surgeon Yurii Voronoy in 1936. However, the female patient only survived a few days and the donor organ which was taken from a corpse did not function at any point. Nevertheless, transplantation of inner organs was considered to be an ideal therapy that, due to practical problems, simply was not (yet) feasible.<sup>7</sup>

After the Second World War, research took up these preliminary studies. Immunological issues shifted into the foreground. The first successful kidney transplantation to a human was performed in 1954 at Peter Bent Brigham Hospital in Boston. The medical team around surgeon Joseph Murray transferred a kidney into a patient from his identical twin brother, without any immunological defense reaction being triggered. This first clinical success showed that genetic compatibility constitutes an essential precondition for surviving a transplantation. In 1963, Wilhelm Brosig performed in Berlin for the first time ever a successful living donation between a mother and daughter.<sup>8</sup>

In 1967, Christiaan Barnard undertook the first heart transplantation in the South African Groote Schuur Hospital;

<sup>7</sup> Cf. Schlich 1998, 7 ff.

<sup>8</sup> Cf. Achilles 2004, 99.

his patient, nevertheless, died only a few days later as a result of the medical measures taken against the rejection reaction.<sup>9</sup>

At first, uncontrollable rejection reactions remained the basic problem for transplantation medicine, due to the lack of adequate methods of immunosuppression. The unsatisfactory clinical results led to stagnation in transplantation medicine at the beginning of the 1970's. Only after the introduction of immunosuppressant Cyclosporin A at the start of the '80s could rejection responses be reduced and the graft survival rate considerably increased.<sup>10</sup> Due to the improved possibilities of immunosuppression, the three-year graft survival rate for kidney transplants rose from 45% between 1966 and 1970 to 84% between 1996 and 2000.<sup>11</sup>

The transplantation of donor organs is today considered to be a standard therapy for terminal organ failure. Between 1963 and 2012 in Germany alone, 116650 organs were transplanted in total.<sup>12</sup>

The following table offers an overview of which organs were transplanted in what numbers over the previous years.

<sup>9</sup> Cf. Hamilton 2012, 347 ff.

<sup>10</sup> Cf. Pichlmayr 1987.

<sup>11</sup> Cf. Doxiadis et al. 2004.

<sup>12</sup> Deutsche Stiftung Organtransplantation 2014, 10.

Transplanted O (not including t	rgans in ransplar	Germar nts from	ıy 2003- living d	-2014 onors, n	or Dom	ino tran	splants)					
Year	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Kidney	2111	1989	2190	2253	2340	2188	2172	2272	2055	1820	1547	1508
Heart	393	398	396	412	394	382	363	393	366	345	313	304
Liver	773	810	888	971	1088	1060	1119	1187	1116	1017	884	879
Lung	212	240	262	253	284	270	272	298	337	357	371	352
Pancreas	191	187	165	141	139	137	115	163	171	161	128	120
Small intestine	$\infty$	ω	2		Ч	11	$\infty$	10	9	6	Ч	6
Organs	3688	3726	3903	4031	4250	4048	4049	4323	4054	3706	3248	3169

Figures for 2003 to 2007: Deutsche Stiftung Organtransplantation 2013, 28, 33, 36, 39, 43 (figure for small intestine transplants on consultation); Figures for 2008 to 2013: Deutsche Stiftung Organtransplantation 2014, 65;

Preliminary figures for 2014: http://www.dso.de/organspende-und-transplantation/transplantation.html [2015-01-28]

At present, there are 47 transplant centres in Germany. Most have specialized in certain organs.13

Since the beginning of transplantation medicine, there has been a considerable dearth of organ donors, and not only in Germany. In 2013, within the country alone, 965 people died who had been registered on the waiting list for an organ.<sup>14</sup> Many of these presumably could have been saved with a transplant.

Due to the rise in transplants performed, especially those for living kidney donations, the waiting list has been able to be reduced, despite the light increase in new registrations. Nonetheless, 7671 patients were waiting for a donor kidney in Germany in 2013.<sup>15</sup> Only about a third of these received a kidney in the same year.16

### 2.2 Organ donation process in Germany

#### 2.2.1 Introduction

In Germany, the donation of organs for transplantation purposes was regulated in the Transplantation Act (TPG) from 1997.<sup>17</sup> As far as removal of organs "from dead donors" is concerned, Section 3 (1) No. 2 TPG stipulates that removal is only permissible when the death of the organ donor has been certified according to norms corresponding to the current state of knowledge in medical science. Pursuant to Section 3 (2) No. 2, removal is also not permissible without prior determination

<sup>13</sup> The precise list of facilities and their specializations can be found on the websites of Eurotransplant (http://www.eurotransplant.org/cms/ index.php?page=patient\_germany\_aanv [2015-01-13]) and the German Organ Transplantation Foundation (http://www.dso.de/servicecenter/ krankenhaeuser/transplantationszentren.html [2015-01-13]).

<sup>14</sup> Cf. Eurotransplant International Foundation 2014, 55.

Cf. ibid., 65.
 Cf. Deutsche Stiftung Organtransplantation 2014, 65.

<sup>17</sup> Gesetz über die Spende, Entnahme und Übertragung von Organen und Geweben (Law concerning the Donation, Removal and Transplantation of Organs and Tissues) from 5 November 1997, last revised through Article 5d of the Law from 15 July 2013 (BGBl. I, 2423).

of the final, irremediable loss of overall function of the cerebrum, the cerebellum and the brainstem according to rules of procedure corresponding to the current state of knowledge in medical science. This condition of final loss of functions in all parts of the brain (during maintained cardiovascular function) is summarized as "brain death." Pursuant to the guidelines of the German Medical Association concerning the determination of brain death (see here, as well, Section 2.3.2), brain death is defined in transplantation medicine practice as identical to the death of the human being within the meaning of the Transplantation Act.<sup>18</sup>

#### 2.2.2 Diagnostics of brain death

Brain death, which is verified by means of neurological procedures, is established, with few exceptions, worldwide as a criterion of death.<sup>19</sup> The concept of brain death was developed against the background of medical possibilities for supporting the mechanics of breathing and replacing the respiratory drive. The manner by which brain death is determined is defined in detail in the guidelines of the German Medical Association concerning certification of brain death.<sup>20</sup> Physicians can only confirm brain death on this basis when a series of requirements are fulfilled, clinical symptoms of loss have been certified and evidence of the irreversibility of the clinical symptoms of loss has been established.<sup>21</sup> Following a protocol, these conditions are verified in a specified sequence.<sup>22</sup>

<sup>18</sup> Wissenschaftlicher Beirat der Bundesärztekammer 1998, A-1861.

<sup>19</sup> Matsuo 2003; Ida 2003; Bagheri 2007; Ishii/Hamamoto 2009; Ishihara 2012; Byung-Sun 2005; Zeiler 2009, 450 ff.

<sup>20</sup> The guidelines revised by the German Medical Association are currently at the Federal Ministry of Health for approval. The new version could, therefore, not yet be consulted for this opinion.

<sup>21</sup> Concerning brain death diagnostics, see also Hoffmann/Masuhr 2014; Deutsche Stiftung Organtransplantation 2011.

<sup>22</sup> See Wissenschaftlicher Beirat der Bundesärztekammer 1998, A-1866.

As prerequisites for the certification of brain death, the guidelines mention an acute, serious brain damage and the exclusion of certain factors – among which poisoning (intoxication), hypothermia, ingestion of certain medications, or coma, for example due to a metabolic disease – which might be considered during the period of examination as possible temporary causes of loss of brain function.

Clinical symptoms of loss include the diagnosis of loss of consciousness (coma); lack of reflexes in the brainstem (brainstem areflexia); and respiratory arrest (apnea). Coma is evidence that the cerebral cortex (*Cortex cerebri*), but also more deeply located areas are no longer capable of functioning. Note 3a of the guidelines of the German Medical Association defines, for brain death diagnosis, the requisite degree of coma as loss of consciousness without opening of the eyes and without other cerebral reactions to repeated, adequate pain stimuli. This fact is not only essential in neurobiological terms, but also differentiates the concept of brain death from other concepts, such as that of so-called neocortical death, in which only parts of the cerebral cortex cease to function (see chapter 4).

In humans, voluntary movements are controlled by the cerebral cortex. It is the neural basis for the perception and control of visual, auditory and olfactory stimuli; language and linguistic comprehension; spatial and temporal orientation; and all cognitive and emotional activities, as well as those of intellect and reason. Consciousness is tied to the integrity of the cerebral cortex and more deeply located areas of the brain, such as subcortical nuclei and the reticular formation, as well as the brainstem.

It can sometimes be difficult to differentiate various impairments to consciousness – such as coma, persistent vegetative state (apallic syndrome), or minimally conscious state – from brain death; it is, however, always achievable with correspondingly extensive diagnostics.<sup>23</sup> This is also the case for patients

<sup>23</sup> Dehaene/Changeux 2011.

with so-called locked-in syndrome, who find themselves in a condition of almost complete immobility due to damage to neural pathways, but are, nonetheless, awake and conscious.<sup>24</sup>

In differentiating various disorders of consciousness, modern imaging techniques, such as functional magnetic resonance imaging (fMRI) and positron emission tomography (PET), have contributed to a further clarification in recent years, for instance through measuring activities in the cerebral cortex during cognitive tasks or metabolic activities in comatose patients.<sup>25</sup> In contrast to other disorders of consciousness, brain death means that neural activity and metabolism are absent from the brain.<sup>26</sup>

In the further course of brain death diagnostics, more deeply located brain regions are examined, such as the brainstem. This is done by testing the reflexes, whose function depends on the integrity of the nerve cells and their connections in the brainstem. Reflexes are mediated by circuits of interconnected nerve cells and take place "automatically". Among the reflexes examined are the corneal reflex, which upon touching of the cornea leads to blinking of the eye; and the pharyngeal and tracheal reflex, which prevents the entry of food into the windpipe (trachea). Besides the nuclei of the cranial nerves associated with these various reflexes, the brainstem also contains vitally important regulatory centres for respiration and circulation. Breathing and the cough reflex are regulated by the respiratory centre, in the lower part of the brainstem (medulla oblongata). Here, regulation is effected by cranial nerves IX and X, which register the partial pressures of oxygen  $(O_2)$ and carbon dioxide  $(CO_2)$  in the carotid arteries and the aorta. On the basis of this information, the respiratory centre controls the respiratory muscles necessary for inhalation and exhalation. The test for respiratory arrest (apnoea test) examines

<sup>24</sup> Ibid. 2011, 218; Masuhr/Neumann 2007.

<sup>25</sup> Boly et al. 2012; Laureys/Schiff 2012; Laureys/Fins 2008; Eickhoff et al. 2008.

<sup>26</sup> Laureys 2005.

whether an increased carbon-dioxide pressure in the blood triggers spontaneous breathing. Respiratory arrest is considered proven when no spontaneous breathing kicks in given a partial pressure of  $CO_2$  greater than or equal to 60 mmHg. To avoid endangering or damaging the patient due to the increased partial pressure of  $CO_2$ , the apnoea test is conducted as the final clinical examination.

Evidence for the irreversibility of the loss of brain functions is gathered through a second clinical examination later in time (12/24/72 hours, depending on type of brain damage and age of the patient), potentially supplemented by instrument-based findings given the respective case history of the patient. Further findings to be considered include a flat-line EEG, certification of termination of the so-called evoked potential (EP)<sup>27</sup> or proof of cerebral circulatory arrest. According to the presently available data, it is not indicated to make any specific instrument-based additional procedure mandatory in general. On the other hand, there are instrument-based diagnostics proscribed in the guidelines above and beyond the clinical examination, depending on the situation.<sup>28</sup> The evaluation of the respective situation demands, in any case, the examining physicians' correspondingly proven professional expertise. Only suitably qualified examiners are in a position to decide whether the customary brain death diagnostics should be supplemented in the respective case by one or more instrumentbased additional procedures.<sup>29</sup>

<sup>27</sup> Potential differences in the EEG, which are triggered through stimulation of a sensory organ or peripheral nerve, for example.

<sup>28</sup> Wissenschaftlicher Beirat der Bundesärztekammer 1998, A-1862 f.

<sup>29</sup> Cf. also the opinion of Weiller et al. 2014, in which the request is made that at least one of the two physicians diagnosing brain death be a neurologist or neurosurgeon with longstanding experience in intensive care and routine practical experience in determining brain death.

## 2.2.3 Intensive care treatment previous to a possible organ removal

As a rule, brain death diagnostics is preceded by a phase in which the affected person is treated in intensive care as a critically ill patient. In what follows, such treatment is, therefore, first described independent from being conducted as part of a possible organ removal.

The gradual extinguishing of the brain's controlling functions leads to pathophysiological changes. Consequences, among others, include disruptions in regulating the circulatory system; problems with pulmonary physiology; rapid-onset hormone deficiency or, respectively, cessation of hormone production; electrolyte imbalances; coagulation disorders; and a drop in temperature. These malfunctions interact with one another in a complexly reciprocal form and can lead together to a multi-system failure.

Disruption in regulation of the circulatory system: Normally, regulation of the circulatory system occurs through autonomous control of the diameter of blood vessels. Narrowed vessels raise blood pressure; dilated vessels allow blood pressure to fall. The vegetative nervous system, especially the so-called sympathetic nervous system, is chiefly responsible for this control. This is driven centrally through the neurotransmitter adrenaline. With the incremental loss of the brain's control functions, decreased cardiac output and hypotension (low blood pressure) result. Additionally, a reduction in the volume of blood circulating (hypovolaemia) is possible. The rapid reduction in centrally controlled hormone secretion (vasopressin and cortisone; see the section on endocrine disorders) and a possible diabetes insipidus<sup>30</sup> can, for their part, be responsible for the depletion in fluids, but can also considerably reinforce this. Therapy consists primarily in increasing the fluid

<sup>30</sup> A hormone-deficiency illness, which leads to considerably increased urination, among other things.

volume. Should the supply of fluid alone not be adequate, then the blood pressure must be raised through medication, for instance by administering catecholamines, such as adrenaline, and supplying hormones.

*Ventilation:* Should spontaneous breathing fail, assisted ventilation becomes an element in the provision of intensive care. As far as possible, a low percentage of oxygen is sought (if possible, lower than 40%); the oxygen parameters in the blood are measured continuously. Anything that could damage the lungs at this point (a so-called aggressive ventilation) should be avoided. Frequently in acute events, which ultimately lead to brain death, the inhalation (aspiration) of a material occurs – for instance saliva or food.

*Endocrine disorders:* Due to disruption of the hypothalamic-pituitary axis, hormones are no longer produced in the hypothalamus and pituitary; this results relatively quickly in a state of depletion. The loss of vasopressin leads to a diabetes insipidus in more than 80% of patients. Clear indications are increased urination above 5 ml/kg/h; a urine specific gravity of less than 1005 mg/l; and colourless urine. If this is not immediately countered through medication, a chain-reaction of organ damages ensues. The sodium content in the blood rises, which damages the liver. Therapy entails administering, at an early stage, medications that inhibit the excretion of water, such as desmopressin or vasopressin, as well as volume replacement.

*Electrolyte imbalances:* These include particularly elevated concentrations of sodium (hypernatremia) and potassium deficiency (hypokalaemia), which beyond a certain limit can trigger severe cardiac side effects, such as cardiac arrhythmia. This is often caused by a diuretic, but also through diabetes insipidus. Therapy consists either in replacing the lacking/reduced electrolyte or, with elevated values, in a drug therapy for reduction of the increased excretion of fluids.

*Hyperglycemia:* There can be multiple reasons for high blood sugar (hyperglycemia). For instance as a secondary effect of a reduction in body temperature, it is possible that a

decrease in the metabolism, decline in insulin production and decrease in the metabolism of sugar may occur. The incidence of brain death itself (general reduction in metabolic rates) or volume replacement through isotonic glucose solution during hypernatremia can also cause hyperglycemia. Therapy consists in administering short-acting insulin.

*Coagulation disorders:* If the release of anticoagulatory (fibrinolytically active) agents exceeds a certain level, coagulation disorders result. The therapy of choice is the administering of antifibrinolytic agents such as FFP (fresh frozen plasma), for instance.

Problems in regulating temperature: Hypothermia can occur through the loss of the hypothalamic centre for temperature regulation and the loss of blood vessel control. Body temperature should not fall below 35 °C (due to possible cardiac arrhythmias, coagulation disorders, etc.). Sometimes covering the patient no longer suffices so that an active warming becomes necessary; as well, the use of infusion warmers may be advisable.

The pathophysiological changes described above are recognizable only through strict control of the vital signs and continuous assessment. As part of an optimal monitoring, the following elements are necessary, among others:

- >> measurement of arterial blood pressure,
- » measurement of central venous pressure,
- » measurement of peripheral oxygen saturation,
- » measurement of temperature, for both the peripheral and core temperature,
- » precise accounting of fluid levels in terms of ingress and egress,
- »» surveillance of respiratory parameters,
- » laboratory tests, such as for blood sugar, but also for arterial blood gases, for example,
- » and where applicable, the use of PiCCO (pulse contour cardiac output) for measuring cardiac output.

## **2.2.4** Transition from patient-oriented therapy to donation-centred measures

During intensive care treatment, the question may arise at a certain point for the treating physicians of whether continuation of therapy is still indicated in medical terms. If this question is answered in the negative or should a statement be in effect regarding limitations of treatment,<sup>31</sup> the consequence would be the limitation or, respectively, termination of the aforesaid intensive-care interventions. If the patient concerned is, however, identified as a possible organ donor, then the vital functions are temporarily maintained further. This occurs by continuing important intensive-care measures that, as a rule, have already been resorted to. They are now, however, no longer carried out in the therapeutic interest of the patient (the potential organ donor), but rather serve exclusively the maintenance of the organs' eligibility for transplantation and the assurance of the high quality of these organs. From this point in time, they are, therefore, designated as *donation-centred* or organ-protective measures.

The Transplantation Act contains no provision concerning the question of what medical measures necessary for a transplantation, under what conditions, ought already to be performed on a potential organ donor *after the discontinuation of therapy* and prior to the certification of brain death (and thus, consequently, on those who are dying). It is, however, of significance from an ethical and legal perspective whether these so-called organ-protective measures occur *before* the start of the brain death certification process, *during* this process or *after* its completion (see section 2.3.3.2).

<sup>31</sup> For example, in an advance directive.

Measures for organ protection entail first and foremost:

- » artificial ventilation, in order to guarantee the supply of oxygen requisite for cardiac function and blood flow to the organs;
- >> the administering of medications that serve to maintain hemodynamics – that is, the circulation of the blood (vasoactive medications, i.e., drugs acting on the blood vessels);
- » hormone treatment to compensate for the absence of important hormones;
- » laboratory tests to determine the dosage for such organprotective measures;
- » intensive-care measures, such as corneal eye care and repositioning the potential donor in bed, for example.<sup>32</sup>

The precise content and extent of organ-protective measures is the object of discussions and studies in medical circles.<sup>33</sup> As one particular problem of organ-centred measures, the possibility is discussed that in rare cases these can lead to the development of a PVS (persistent vegetative state, or "waking coma"), in which the patient can once again breathe and swallow autonomously without recovery of consciousness.<sup>34</sup> No indications can be found in the literature, however, concerning whether and how frequently such cases have occurred.

## 2.2.5 Measures following certification of brain death

Pursuant to current law and in clinical practice, brain death is viewed as coincident with the death of the human being (see section 2.3.2). For this reason, the legal regime for dealing with

<sup>32</sup> See Guillod/Mader 2010, 10 f., 19 (with reference to recommendations from the Schweizerische Gesellschaft für Intensivmedizin 2006, 16 f., 19).

<sup>33</sup> For a summary, see McKeown/Ball 2014.

<sup>34</sup> See Schöne-Seifert et al. 2011a, 6.

the organ donor also changes at the moment of certification of brain death. Patient rights are no longer relevant; instead, law concerning *Totensorgerecht* [law of custody of the deceased] comes into force for next-of-kin (see section 2.3.3).

Along with organ-protective measures, serological and immunological examinations are initiated as further preparatory measures, insofar as these were not already performed previously, in order to ascertain the donor suitability of the potential organ donor (above all for the purpose of confirming that no pathogens such as HIV, hepatitis or cytomegalovirus are transmitted during an organ transplantation)<sup>35</sup> and in order to determine the donor's blood type, as well as tissue type, for selection of an appropriate organ recipient.

In due course, the brain-dead organ donor is brought from the intensive care station to the operating room. In preparation for organ perfusion, the blood vessels of the organs to be removed are prepared by the surgeons, and heparin is administered to prevent blood coagulation. In order to avoid a reflexive, cold-induced narrowing of the vessels (vasospasm) due to the central administration of cold preservative solution (aortal perfusion), drugs to block this process are administered immediately prior to the start of the aortal perfusion. Cardiac arrest occurs as a result. Immediately afterwards, the introduction of the cold preservative solution into the aorta begins. Organ-protective measures, including ventilation, are brought to a conclusion with the perfusion of all the organs. Only in the case of a planned lung removal is ventilation continued until the lung is transplanted.

While in classic anaesthesia, consciousness and pain perception are (must be) disabled for a patient who is not braindead through blocking of central receptors, measures to protect against pain are not used following certification of brain

<sup>35</sup> The Swiss Transplantation Act from 8 October 2004 (AS 2007 1935) stipulates a test to that effect (Article 31) and, if applicable, the removal and inactivation of pathogens as well (Article 32).

death, since the perception of pain, as well as consciousness, are extinguished irreversibly once brain death has set in.<sup>36</sup> One part of brain death diagnostics is devoted precisely to verifying the failure of those structures at the basis of pain perception. Since, nevertheless, peripheral receptors and circuits may not be compromised, in contrast to the brain, and since moreover the inhibiting effect of the brainstem on the spinal cord has been lost, motor reflexes may emerge, which are conducted via the spinal cord and can appear like conscious movements of the organ donor. In addition, surgical stimuli during the explantation can induce a rise in blood pressure and heart rate. However, these are also caused exclusively by spinal reflexes and do not result from any perception of pain. As a rule, the organ donor is given muscle-relaxant drugs during the surgical procedure to prevent spinal reflexes. Rise in blood pressure and heart rate are, likewise, counteracted through corresponding medications. Even if there is no medical indication for pain therapy, an organ donor can formulate a requirement to that effect and make consent to organ removal contingent on it.

During the removal of organs, there is a pathophysiologically and organisationally determined procedure, which, however, varies if the organ-donation approval refers only to certain organs. After adequate cooling and perfusion of the blood vessels has been produced, the organs from the chest cavity are removed first. The pancreas, liver and both kidneys follow. Additionally, blood vessels and auditory ossicles, bones, skin, etc. can be removed at this point, while the cornea, for example, may still be removed several hours later.

Following removal of the organs, it is the task of the socalled abdominal team to close all wound cavities. Parallel to this, all catheters still in place are removed. Pursuant to Section 6 TPG and in compliance with the medical ethos, the organ removal and all related measures must be performed in a

<sup>36 &</sup>quot;Following brain death, there is no longer any perception of pain" (Bundesärztekammer 2001, A-1417). Cf. Wijdicks et al. 2010.

manner according to the physicians' duty of care, with respect for the dignity of the organ donor. The corpse is to be delivered to the funeral in a dignified state; prior to this, the next-of-kin are provided the opportunity to see the corpse.

# 2.3 The legal framework for post-mortem organ donation

## 2.3.1 Overview of the key regulations of the Transplantation Act

Since 1997, the Transplantation Act has defined the legal framework for the transplantation of organs and tissues in Germany. The law, which is complemented by statutory instruments, as well as by the guidelines of the German Medical Association, has been amended several times since – not least as a result of the transposition of European standards. First, in 2007, the scope of application was expanded to the transfer of human cells; and the handling of tissues was refined on the basis of the EU Tissues and Cells Directive<sup>37</sup> and harmonized with EU law. In 2012, the law was adapted to the specification of the EU Directive "on standards of quality and safety of human organs intended for transplantation"<sup>38</sup> and to the introduction of the so-called decision-solution.<sup>39</sup>

The Transplantation Act differentiates between the removal of organs and tissues from deceased donors (chapter 2) and living donors (chapter 3). Pursuant to Section 8 (1) sentence 1 No. 3, among others, a living donation is only permissible if

<sup>37</sup> Directive 2004/23/EC of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and allocation of human tissues and cells (OJ L 102 from 7 April 2004, 48).

<sup>38</sup> Directive 2010/45/EU of 7 July 2010 (OJ L 207 from 6 August 2010, 14).

<sup>39</sup> Gesetz zur Regelung der Entscheidungslösung im Transplantationsgesetz (Law on the Regulation of the Decision-Solution in the Transplantation Act) from 12 July 2012 (BGBI. I, 1503).

at the point in time of the living donation, no post-mortemdonated organ is available. The present opinion deals exclusively with post-mortem organ donation. For the allocation of the organs procured thereby, Section 12 (3) No. 1 contains the requirement that organs mandated for allocation – these are, pursuant to Section 1a No. 2 TPG, the heart, lung, liver, kidneys, pancreas, and intestine – are to be allocated according to rules that correspond to the state of knowledge of medical science, particularly depending on the prospect of success and urgency for eligible patients. In doing so, the waiting lists of the transplantation centres are to be treated as a uniform waiting list (Sentence 2).

In its provisions, the Transplantation Act resorts to a large extent to the organisational structures and actors that were already responsible for transplantation medicine care prior to the law's entering into force:

(1) The German Medical Association has been furnished through Section 16 (1) TPG with a far-reaching authority to set guidelines. It has, accordingly, to establish in guidelines the state of knowledge of medical science, *inter alia*, for the rules concerning certification of death pursuant to Section 3 (1) sentence 1 No. 2; the procedural rules for diagnosis of brain death subject to Section 3 (2) No. 2 TPG; the regulations concerning admission to the waiting list; as well as those regarding organ allocation pursuant to Section 12 (3) No. 1 TPG.

(2) Pursuant to Section 11 (1) No. 1, the removal of organs from deceased donors – including the preparation for removal, allocation and transfer – is a joint task, in regional cooperation, of the transplantation centres and hospitals performing removals. The coordinating body established subject to Section 11 (1) No. 2 TPG for the organisation of this task – the German Organ Transplantation Foundation – has to organise the cooperation in relation to organ removal from deceased donors and the execution of all measures required until transfer (with the exception of the allocation of organs) in compliance with the guidelines of the German Medical Association pursuant to Section 16 (Section 11 (1a) No. 1 TPG).

(3) The allocation of organs mandated for allocation is organised by an allocation agency, which is, meanwhile, responsible for seven additional countries<sup>40</sup>: the Dutch Eurotransplant International Foundation. Section 12 TPG assigns the allocation body (Eurotransplant) to procure organs that are subject to allocation according to the rules established in the guidelines of the German Medical Association.

(4) As of 1 August 2012, at least one professionally qualified transplantation officer is to be appointed in all hospitals performing removals.<sup>41</sup> This transplantation officer – who reports immediately to the medical management of the removal hospital, yet is independent in the discharge of duties and subject to no orders (Section 9b (1) No. 2 and 3 TPG) - is, as incisively formulated in the opinion of the *Bundesrat* (Federal Council) concerning the government's draft bill, the "'Kümmerer' [carer] for all organ-donation concerns on site within the removal hospital."42 To sketch this copious and demanding task, Section 9b (2) (not conclusive) describes that the transplantation officer is responsible for the removal hospitals complying with their obligation to report potential organ donations (No. 1); for accompanying donors' next-of-kin, defined pursuant to Sections 3 and 4, in an adequate way (No. 2); for seeing that assignments are made and courses of action established in the removal hospitals so as to comply with the duties from the Transplantation Act (No. 3); and for physicians and nursing staff in the removal hospital being regularly informed about the importance and process of organ donation (No. 4). The officer is to be released from other tasks to the extent that this

<sup>40</sup> Besides Germany, these are Belgium, Croatia, Luxembourg, the Netherlands, Austria, Slovenia and Hungary.

<sup>41</sup> Section 9b TPG, integrated in the transposition of Article 12 of Directive 2010/45/EU of the European Parliament and Council through the *Gesetz zur Änderung des Transplantationsgesetzes* (Law concerning the Amendment of the Transplantation Act) from 21 July 2012 (BGBI. I, 1601).

<sup>42</sup> Deutscher Bundestag 2011, 31.

is required for the proper performance of his or her tasks (Section 9b (1) sentence 4, 1<sup>st</sup> clause TPG).

With this federal regulation, the duty exists as a matter of principle for all removal hospitals to commission a transplantation officer, in compliance with Section 9b TPG. Any commissioning of a transplantation officer that possibly occurred earlier pursuant to state law is not valid as a commission in accordance with Section 9b (1) No. 1 TPG. In this respect there is no ordinance for continuation, which should in any case not be taken as self-evident.<sup>43</sup> However, Section 9 (3) TPG leaves to state law further specifications regarding the transplantation officer, in particular the determination of the required qualifications and any legislation on the organisational position. Given the key function for the entire process of organ donation that Section 9b TPG assigns to the transplantation officer, it is vexing that the implementation of legislative federal guidelines has only partially occurred in the states up to this point: of the federal states, only Baden-Wuerttemberg, Bavaria, Hesse, Mecklenburg-Western Pomerania, North Rhine-Westphalia, Rhineland-Palatinate, Saxony and Schleswig-Holstein have enacted regulations concerning the transplantation officer in their implementing laws or decrees. Some of these states, such as Baden-Wuerttemberg and Rhineland-Palatinate, had already issued corresponding legal provisions before the federal legislature accorded the states the task in Section 9b (3) of the Transplantation Act to regulate the further specifications.

These states would have to examine their regulations; and if applicable, to adjust and confirm them as law for the purpose of Section 9b (3) TPG. In other states (Bremen, Hamburg, Lower Saxony), a transposition has so far remained unaccomplished, or the state legislature has contented itself with issuing a delegated power to the executive for issuing statutory instruments, of which, however, no use has been made to date (Berlin, Brandenburg, Saxony-Anhalt, Thuringia). Apart from

<sup>43</sup> On this point, Rixen, in: Höfling 2013, Section 9b, para. 2.

the merely insufficient heed for federal guidelines in the states, a further circumstance needs to be emphasized, which requires a closer analysis: It concerns the variable manner of configuring the legal status and scope of duties of the transplantation officer in the states that have issued implementing regulations. These differences concern, for example, the qualifications of the person to be commissioned as transplantation officer; the nature and scope of their release from other activities; as well as their possible compensation. The state of Brandenburg explicitly declines to instigate more specific provisions before the federal government has issued regulations concerning remuneration and release of the transplantation officer. The state claims that it is not in a position to legislate the pay; that the federal government must decide what the position is worth to it.<sup>44</sup>

## 2.3.2 The certification of death and brain death as prerequisites to removal

The regulations of the Transplantation Act concerning postmortem organ donation are the outcome of a long and intensive parliamentary debate about the concept of death to be taken as a basis and the corresponding criteria for death.<sup>45</sup> In Section 3 (1) No. 2, a condition of permissibility is prescribed, according to which the organ or tissue donor's death has to be certified in line with rules corresponding to the state of knowledge of medical science. Section 3 (2) No. 2 TPG declares, furthermore, the removal of organs and tissues as inadmissible if, prior to any removal from the organ or tissue donor, final, irremediable loss of overall function of the cerebrum, cerebellum and brainstem has not been determined according

<sup>44</sup> According to Jens-Uwe Schreck, Managing Director of the *Landeskrankenhausgesellschaft Brandenburg* (State Hospital Society Brandenburg), in the *Ärzte Zeitung* (http://www.aerztezeitung.de/864503 [2015-01-21]).

<sup>45</sup> Detailed description in Rixen 1999, 382 ff.

to procedural rules corresponding to the state of knowledge of medical science. This provision is supplemented by Section 5, which concerns more detailed terms regarding the methods of providing evidence for certifications pursuant to Section 3 (1) No. 2 and (2) No. 2 TPG, and requires that physicians who certify brain death are not allowed to be involved in either the removal or transfer of organs and are also not permitted to be bound by instructions of any physician involved in like manner. Certifications are to be made by two qualified physicians, who have examined the organ donor independently of each other (Section 5 (1) No. 1). The certifications; point in time; and underlying findings are to be documented and the potential organ donor's next-of-kin and confidantes are to be provided with the opportunity for inspection.

The complicated regulatory structure of the Transplantation Act, which from a comparative legal perspective becomes particularly evident in comparison with the clear statement in Swiss law,46 was the expression of a widespread uncertainty and scepticism in the legislative process of that time: Should and can it be the task of the legislator to specify when a human being is dead?47

The consequence of the legal regulation<sup>48</sup> is a controversy regarding the appropriate interpretation of the legal provisions for transplantation.<sup>49</sup> Primarily, it has to be noted that Section 3 (2) No. 2 TPG formulates a necessary condition for organ removal. If certification of brain death is lacking, this simultaneously means that explantation is forbidden.<sup>50</sup> Therewith any organ removal is inadmissible which is based on a - however formulated - partial brain death concept. In this way, it was

<sup>46</sup> In the Swiss Transplantation Act, Article 9 (1) states: "A person is dead when the functions of his or her brain, including the brain stem, have ceased irreversibly."

<sup>47</sup> See on this discussion, Rixen 1999, 383 ff., with further references.
48 Merkel (1999, 115) speaks of the "legislative descent."

<sup>49</sup> According to Deutsch (1998, 778), the Transplantation Act works with "two concepts of death"; in contrast, Merkel 1999, 114 f.; see further Rixen 1999, 385 ff.

<sup>50</sup> See Merkel 1999, 115.

simultaneously guaranteed that independently of what is ultimately viewed as death in terms of Section 3 (1) No. 2, an organ removal is inadmissible following cardiovascular failure without certification of brain death. The Transplantation Act leaves open, however, whether diagnosis of brain death also implies a *sufficient condition* for the transplantation of vitally important organs. The text of Section 3 (1) No. 2 TPG speaks merely of death that is certified according to the rules corresponding to the state of medical knowledge. The transplantation legislators have, however, decided on this regulatory concept in cognizance of and with approval for the equation of brain death with the death of the human being that was in practice in the context of transplantation medicine at the time of the adoption of the law (not only) in Germany.<sup>51</sup> This is underscored in the relevant guidelines of the German Medical Association, which, according to Section 16 (1) sentence 1 No. 1 TPG, have to specify the state of knowledge of medical science for the rules regarding certification of death pursuant to Section 3 (1) No. 2 and the procedural rules pursuant to Section 3 (2) No. 2 TPG.

Thus far, the German Medical Association has complied with this regulatory duty only in the context of the guidelines for the Certification of Brain Death (Section 3 (2) No. 2).<sup>52</sup> At any rate, no separate guidelines exist to this point concerning the certification of death pursuant to Section 3 (1) No. 2 TPG. For now, the Scientific Advisory Council of the German Medical Association's *Dritte Fortschreibung 1997 mit Ergänzungen gemäß Transplantationsgesetz (TPG)* (Third Update 1997 with Additions according to the Transplantation Act (TPG)) of the *Richtlinien zur Feststellung des Hirntodes* (Guidelines for Certification of Brain Death) is taken as a basis for the practice

<sup>51</sup> Hence, a number of commentators speak of the legislative conception in Section 3 TPG as amounting to an implicit recognition of brain death as the death of the human being; see Höfling/Rixen, in: Höfling 2013, Section 3 para. 11.

<sup>52</sup> See also Parzeller, in: Pühler/Middel/Hübner 2008, 82.

of post-mortem organ donation.<sup>53</sup> There, along with the definition of brain death,<sup>54</sup> this sentence is found: "With brain death, the death of the human being is determined in medical scientific terms."<sup>55</sup> Only in this respect do the guidelines also address the determination of death pursuant to Section 3 (1) No. 2 TPG, apart from the diagnostics of brain death.

As a result, the provisions of Section 3 (1) No. 2 and (2) No. 2 and Section 16 (1) sentence 1 No. 1 TPG, in combination with the guidelines of the German Medical Association, lead to concordance between the certification of death pursuant to Section 3 (1) No. 2 and of brain death pursuant to (2) No. 2; and, thereby, to the concept of brain death underlying the regulation of post-mortem organ donation.

Beyond the problems outlined above, the regulatory conception of the Transplantation Act raises further questions. These concern, for example, the validity and binding force of the German Medical Association's guidelines<sup>56</sup> and the constitutional admissibility of delegating norm-setting power to an authority organised under private law, such as the German Medical Association. In order to address these concerns, an amendment has, meanwhile, entered into force whereby the guidelines of the German Medical Association require

<sup>53</sup> See Wissenschaftlicher Beirat der Bundesärztekammer 1998. The guidelines have been revised by the German Medical Association and are currently in process at the Federal Ministry of Health for approval. Hence, the amended version could not be incorporated in the context of this opinion.

<sup>54 &</sup>quot;Brain death is defined as the state of irreversibly extinguished overall function of the cerebrum, cerebellum and brainstem. In this condition, cardiovascular function is maintained artificially through controlled ventilation" (Wissenschaftlicher Beirat der Bundesärztekammer 1998, A-1861).

<sup>55</sup> Ibid., A-1861.

For more detail, Taupitz 2003. The Federal Constitutional Court (First Chamber of the First Senate) recently emphasized in a decision that the specialized courts can and must examine the guidelines of the German Medical Association for their compatibility with higher-ranking law (BVerfG, 1 BvR 2271/14, para. 4).

approval from the Federal Ministry of Health (Section 16 (3) TPG).<sup>57</sup> Still unregulated are the requirements for organ and tissue removal in embryos and fetuses (see Section 4a TPG), since the corresponding guidelines from the German Medical Association, which is to prepare these according to Section 16 (1) sentence 1 No. 1a TPG, have still not been adopted.<sup>58</sup>

# 2.3.3 Extended consent solution and so-called decision-solution

#### 2.3.3.1 Overview

The removal of organs requires, pursuant to Section 3 (1) sentence 1 No. 1 TPG, the prior consent of the organ donor. If neither a written consent nor a written objection from the possible organ donor exists, then the next-of-kin<sup>59</sup> should be consulted on whether any statement by the possible organ donor regarding an organ donation is known (any consent or objection to

<sup>57</sup> With Section 5d of the *Gesetz zur Beseitigung sozialer Überforderung in der Krankenversicherung* (Law for Remedy of Social Strain in Health Insurance) from 15 July 2013 (BGBI I, 2423), Section 16 (2) TPG was supplemented through the provision that the guidelines of the German Medical Association are to be substantiated with reference to the state of knowledge of medical science concerning transplantation medicine and, particularly, that a comprehensible review of the state of knowledge of medical science has to be provided. The newly integrated Section 16 (3) TPG stipulates that the guidelines of the German Medical Association, as well as amendments to it, are to be submitted for approval to the Federal Ministry of Health. The Federal Ministry can request additional information and supplementary opinions from the German Medical Association in the context of the approval process.

<sup>58</sup> See also on this point Angstwurm, in: Pühler/Middel/Hübner 2008, 204; with the statement that this "requires the clarification of not only fundamental medical, but also ethical and legal questions."

<sup>59</sup> Next-of-kin are, in order of enumeration, the spouse or registered partner; children of legal age; parents or custodian (to the extent that the possible organ donor was a minor at the time of death and only one parent, guardian or care provider was responsible for care at that time); the adult siblings; and the grandparents (Section 1a No. 5 TPG). The next-of-kin is only entitled to make a decision about the organ donation if in personal contact with the possible organ donor two years prior to death (Section 4 (2) No. 1 TPG). Equivalent to the next-of-kin is a person of legal age, who has manifestly been close, in a special, personal bond, to the possible organ donor up to his or her death; this person steps in alongside the next-of-kin (Section 4 (2) No. 5 TPG).

organ or tissue donation - if applicable, restricted to certain organs - or any assignment of the decision, during the lifetime, to a named trustee, Section 2 (2) TPG). The statement requires no written form for its validity per se.<sup>60</sup> The next-of-kin should inform the physician in case such a statement regarding organ donation is known. This statement is to be implemented. If no such statement is known to the next-of-kin, then an organ removal is permissible when a physician has instructed the next-of-kin about a possible organ donation and that person has agreed. The doctor has to instruct the next-of-kin to integrate into his or her decision a presumed will of the possible organ donor. With this regulatory conception, the next-of-kin is afforded, when no explicit or presumed will of the possible organ donor can be established, a right to decision "according to one's own ethically responsible discretion."61 This explains the characterization of the legal conception as the "extended consent solution."

Since the revision of the Transplantation Act through the Law on the Regulation of the Decision-Solution in the Transplantation Act, a model of intensified information and education of the population flanks the conception of the extended consent solution.<sup>62</sup> The newly conceived Section 2 TPG specifies and extends the already existing duties regarding education of the population for the competent institutions authorized by state law; for the federal authorities in their respective ambit, especially the Federal Centre for Health Education; as well as for the statutory and private health insurance providers. Education entails:

- >> the possibilities of organ donation (No. 1),
- >>> the preconditions for organ removal from dead donors, including the implications of any statement regarding organ

<sup>60</sup> Nickel/Schmidt-Preisigke/Sengler 2001, Section 2, para. 11.

<sup>61</sup> Deutscher Bundestag 1997, 9.

<sup>62</sup> Regarding the demand for improved education of the population, see also Nationaler Ethikrat 2007.

donation made during one's lifetime, also vis-à-vis an advance directive, and the legal consequence of an omitted statement in view of the right of decision of the next-of-kin pursuant to Section 4 (No. 2),<sup>63</sup>

>> the significance of organ transfer in view of the possible benefit of the medical usage of organs in people who are ill (No. 3).

In doing so, the information should comprise the entire scope of the decision and must be open in outcome (Section 2 (1) No. 2 TPG). The professional institutions committed to informing the public should provide organ donor cards, along with suitable educational documents, and they should place these at the disposal of the population. Notwithstanding these obligations, statutory health insurance companies have to place these documents at the disposal of their insured upon reaching 16 years of age, when they are issued the electronic health insurance card. Every five years along with the contribution statement, the private health insurance companies have to place the said documents at the disposal of their insured members who have reached 16 years of age. As long as the possibility does not exist for storing relevant insured members' declarations regarding organ donation, the statutory and private health insurance

<sup>63</sup> The explanatory memorandum to the Entwurf eines Gesetzes zur Regelung der Entscheidungslösung im Transplantationsgesetz (Draft of a Law on the Regulation of the Decision-Solution in the Transplantation Act) states in this regard: "The general educational duties in Section 2 (1) No. 1 TPG are specified to the extent that they are expressly referred to the next-of-kin's right of decision in the case that no declaration regarding post-mortem organ and tissue donation has been provided. In connection with general education, the consequence of omitting to provide a declaration during one's lifetime concerning post-mortem organ and tissue donation for the next-of-kin in case of death should be more clearly highlighted. The extended consent solution regulated in Sections 3 and 4 TPG remains unchanged. In the future, the relationship of an organ donation declaration to a possible advance directive should also be thematised during education about the significance of a declaration regarding organ and tissue donation that is provided during one's lifetime, in order to prevent a contradiction between the organ- and tissue-donation declaration and any provision in an advance directive" (Deutscher Bundestag 2012a, 16).

companies have to send the said documents to their insured members every two years. With the documents' provision, the statutory and private health insurance companies also have to ask the insured to document a "declaration regarding organ and issue donation." However, no one can be obliged to provide such a statement (Section 2 (2a) TPG). With this request, the statutory health insurance companies must simultaneously also name professionally qualified contact persons for questions regarding organ and tissue donation, as well as regarding the significance of a declaration issued in one's lifetime, and also in relation to an advance directive (Section 2 (1a) TPG).

#### 2.3.3.2 On the permissibility of organ-protective measures

Should an organ donation be undertaken, the potential organ donor requires organ-protective measures that no longer serve the (curative) treatment of the patient, but rather the preservation of his or her organs for carrying out the organ donation. This is primarily an issue of the continuation of ventilation for the purpose of maintaining the blood circulation, but also of medication-related measures (see in particular Section 2.2.4).<sup>64</sup>

Measures that are continued or undertaken regarding organ protection *after certification of brain death* (Section 5 TPG) are legally and ethically unproblematic. They are subject to the general rules of transplantation law. That means that the measures are permissible if the agreement to the removal of the organ is available from the organ donor or next-of-kin or from the trustee charged with the decision by the organ donor. For in this case, one acts on the assumption that the will of the organ donor or person entrusted with the decision is to allow the organs to be preserved for transplantation purposes. Organ-protective measures are not permissible if the person concerned has rejected being an organ donor, or if the person entrusted with the decision rejects organ removal following the individual's death.

<sup>64</sup> See also Schöne-Seifert et al. 2011b, A-2082.

The question is, however, to what extent such measures are ethically and legally permissible prior to or during the diagnosis of brain death, up to the certification of brain death.

In tackling the problem incrementally, it can be initially observed that if the person concerned has expressly consented to such measures, organ-protective measures may in any case already be performed prior to or during brain death diagnostics; this wish can also be expressed in an advance directive or in the context of a declaration regarding organ donation. The same applies, mutatis mutandis, if the patient has previously entrusted this concrete decision to a third person.

Furthermore, it may be assumed that organ-protective measures can be based on a presumed will of the person concerned, if an organ donation declaration is available and brain death diagnostics have already begun. For brain death diagnostics are only initiated when the well-grounded supposition exists from a medical perspective that brain death has occurred. At this point in time, it is simply the definitive evidence that is lacking (whereby its ethical and legal meaning should not be depreciated). With the agreement concerning organ donation, the donor has at the same time expressed his or her will that the organs be preserved in a state that enables a successful transplantation. In its turn, the certification of brain death is a necessary prerequisite to a post-mortem organ donation; during this process, it can therefore not be in accordance with the donor's will that the passage of time necessary for the medical procedure of brain-death diagnostics leads to a deterioration of the organs. Ultimately, intensive care measures are carried on only for a short time during certification of brain death to enable, if applicable, a subsequent organ donation.

When the physicians, however, only suppose that brain death will occur in the near future, perhaps in several days, then it is highly questionable whether organ-protective measures can be based on an expressed or an adequately clear, presumed will of the person concerned regarding readiness for donation, if such wishes do not also expressly include organ-protective measures. Such measures can only be approved, in any case, when it is known that the person ready for donation was aware of the significance of organ-protective measures.

Under current law, profound misgivings exist towards the recognition of next-of-kin's or legal representatives' independent decision-making authority concerning the performance of organ-protective measures before or during brain death diagnostics. The decision-making authority of next-of-kin is fundamentally limited, according to the Transplantation Act, to measures after determination of brain death, since their right of decision is derived from law of custody of the deceased. The same applies for any person who is entrusted with decision by the person concerned. For pursuant to Section 4 (3) TPG, this person stands in the stead of the next-of-kin. A person, who as legal representative in health issues (authorized representative or custodian, Sections 1896 ff. BGB) has to decide about treatments during the lifetime of the concerned, is not allowed as well to consent to organ-protective measures prior to certification of brain death, since this does not serve the therapeutic interest of the concerned, but rather merely the preparation for organ removal.

Further problems arise especially in those constellations in which the readiness for organ donation collides with an advance directive, when the latter – as is quite predominantly the case – contains provisions to limit therapy or omit lifeprolonging measures. Such advance directives collide – at any rate at first glance – with the necessity of an intensive-care intervention for the purpose of organ preservation prior to concluding the determination of brain death. At least three constellations can be differentiated:<sup>65</sup>

<sup>65</sup> On this and further constellations, as well as conflict situations between, on the one hand, next-of-kin and, on the other, authorized representatives/ custodians during decisions about organ donation and the continuation of intensive-care measures to maintain the organs' capacity for transplantation, see Bundesärztekammer 2013.

(1) Both an advance directive to omit life-prolonging measures and a statement in favour of organ donation exist.

(2) An advance directive to omit life-prolonging measures is available, but no written statement in favour of organ donation; the next-of-kin, however, give account of an elsewhere expressed readiness to organ donation or the patient's corresponding presumed will.

(3) Varying from the constellation in (2), a (presumed) will of the person concerned in favour of organ donation cannot be established, and the next-of-kin are called upon to make an independent decision.

If both an advance directive to omit life-prolonging measures and a statement in favour of organ donation are available, then an undoubted basis for organ-protective measures exists when both statements are harmonized with each other – for example, in the sense that the measures necessary for a transplant are expressly exempted from the provision to omit lifeprolonging measures.<sup>66</sup>

If such a harmonization of statements is absent, which frequently may be the case, despite the obligation of the relevant state and federal agencies and of the state health funds to provide education about the requirements of organ and tissue removal, "also in relation to an advance directive" (Section 2 (1) No. 2), then the interpretation of both statements is required to ascertain the author's will. An "organ-donation friendly interpretation"<sup>67</sup> construes the refusal – as a rule contained in an advance directive – of measures to maintain life or, respectively, prevent death as indeed compatible with a simultaneously expressed readiness to organ donation and the maintenance of vital functions necessary for that (i.e., the

<sup>66</sup> A recommendation concerning the advanced directive in the brochure of the Federal Ministry of Justice and Consumer Protection calls, nevertheless, only for expressing a "priority" for one of the two decisions vis-à-vis the medical measures necessary for an organ donation (Bundesministerium der Justiz und für Verbraucherschutz 2014, 29).

<sup>67</sup> So expressly Verrel 2012, 123.

continuation of intensive-care measures) up to the certification of brain death, thus prior to or during brain death diagnostics. According to this interpretation, only temporary measures are concerned, narrowly limited in time,<sup>68</sup> which are in no way opposed to the patient's will to be allowed to die, but rather are in fact directed (in any event from the point in time of beginning brain death diagnostics) at certifying the occurrence of brain death, which would mark a definitive boundary for such measures at preserving life.<sup>69</sup> It still remains unclear, however, to what extent this, in addition to the invariably necessary continuation of ventilation for maintaining heart and blood circulation, is also still valid for additional potentially necessary (primarily medication-related) measures for organ protection.

According to a different point of view, a fundamental contradiction exists between both statements,<sup>70</sup> which allows for no harmonizing interpretation. In this sense, it can neither be assumed without further ado that the person ready for organ donation, who has simultaneously provided an advance directive with a statement forgoing therapy, would agree to the maintenance of vital functions or to the undertaking of organprotective measures up to the certification of brain death, nor can it be supposed that knowledge about the connections between organ donation and brain death diagnostics is available to most organ donors.<sup>71</sup>

If the occurrence of brain death is expected in the near future or is presumed based on clinical findings, then it needs to be ascertained by questioning the persons affiliated with the concerned party whether and to what extent the potential organ donor has given thought to a relationship between both statements. With respect to this respondent, it is not dispositive whether such a person must decide, as legal representative

<sup>68</sup> So also Bundesärztekammer 2013, A-572 f. (B. l. 1.).

<sup>69</sup> Thus Verrel 2012, 122.

<sup>70</sup> See Deutscher Bundestag 2004, 21 f.; Winkler 2010, 93.

<sup>71</sup> In this regard Schöne-Seifert et al. 2011b, A-2082.

(custodian or authorized representative) in health issues during the lifetime or as next-of-kin, about the organ transplantation after death. For such persons – as set forth above – have no right of their own in any case regarding the decision to perform organ-protective measures prior to death, whether it be because these do not serve the therapeutic interest of the individual concerned (so that authorized representatives and custodians may not approve such measures) or because their right of decision only arises with the death of the individual concerned (with respect to the next-of-kin). In questioning these persons, however, it is also not a matter of their own decision as representatives, but rather of their laying claim to the concerned person's own presumed will while it is being ascertained.

Similarly difficult is the ascertaining of the concerned person's views when a written statement in favour of organ donation is available, but the next-of-kin report a presumed will of the patient to omit life-prolonging measures.

#### 2.3.3.3 Necessity for a legal regulation

Against the backdrop of the preceding remarks, it needs to be acknowledged that the existing legal situation with regard to organ-protective measures prior to certification of brain death is inadequate. The following approaches might be considered:

(1) The legislator allows the performance of organ-protective measures already prior to certification of brain death.

(2) The legislator can delegate the decision-making authority to the next-of-kin, who (in a specific order and subsidiary to the concerned person's own decisions) are responsible for the decision about organ donation following death. This would have the advantage that one and the same person can make both the fundamental decision about whether an organ removal may be performed and that of whether the preparatory measures necessary for such may be undertaken. A decision-making authority for this person, which is already in force during the lifetime of the concerned person, is, nevertheless, somewhat incompatible systemically; it can lead to a collision with the decision-making power of those persons who are responsible for therapeutic measures in the interest of the concerned individual. The same problem presents itself for a trustee named by an organ donor in an organ-donation declaration.

(3) The legislator can delegate the decision-making authority to the legal representative. According to current law, this person is already responsible for the welfare of the concerned individual during his or her lifetime. This person's scope of duties would have to be expanded, in any event, to include such measures – like organ-protective ones – that no longer lie in the therapeutic interest of the concerned party.

(4) The legislator can make the decision-making authority of the legal representative dependent on the condition that either the patient's readiness for donation is certain or the nextof-kin, subsidiarily appointed with the decision regarding organ donation, has advocated an organ removal.

(5) In all cases, the legislator can additionally make the permissibility for performance of organ-protective measures dependent on different circumstances.<sup>72</sup> These can be related, for example, to the probability of the occurrence of brain death within a particular period of time.<sup>73</sup>

#### 2.3.3.4 On ascertaining the presumed will

If no declaration regarding organ donation is available and the potential organ donor has also not assigned the decision during his or her lifetime to an appointed person in trust, then the next-of-kin is entitled to make the decision about organ donation (Section 4 (1) No. 2 TPG). In making a decision, the next-of-kin must heed, whether approving organ removal or not, a presumed will of the possible organ donor (Section 4 (1) No. 4 TPG). The physician must advise the next-of-kin

<sup>72</sup> See Article 10 of the Swiss Transplantation Act.

<sup>73</sup> Cf. McKeown/Ball 2014.

to this effect (Section 4 (1) No. 5 TPG). In making a decision, the next-of-kin is bound to the presumed will of the possible organ donor.<sup>74</sup> The fact that the Transplantation Act leaves unpunished any decision deviating from this, changes nothing with respect to this compulsory stipulation of the presumed will. For the next-of-kin's decision-making authority pursuant to Section 4 (1) No. 2 TPG is a "duty-bound right", a fiduciary authorization in the interest of the possible organ donor. There remains, nevertheless, an "interpretation risk" during the ascertaining of the presumed will. The concerned person can best exclude this risk by providing a clear statement during his or her lifetime. If a presumed will is not ascertainable, the next-of-kin is called upon<sup>75</sup> to make a decision, pursuant to the law of custody of the deceased, guided by his or her own "ethically responsible discretion."<sup>76</sup>

The Transplantation Act does not contain a more specific definition concerning the presumed will. In the law's explanatory memorandum, it states that "the conviction expressed in life and other essential indications by which the attitude of the possible organ donor regarding the question of a post-mortem organ donation can be presumed" must be heeded and that decisive to this is the next-of-kin's knowledge at the time of the decision.<sup>77</sup> A legal regulation concerning more specific determination, in terms of content, of the presumed will is only encountered in the later regulation of Section 1901a BGB concerning the advance directive. Nevertheless, this regulation concerns a different circumstance, namely the decision of the legal representative (custodian or authorized representative) concerning medical interventions on a (living) patient; during

<sup>74</sup> See Deutscher Bundestag 1997, 9: "in the event that a stated intention regarding organ donation is not known, No. 3 [now No. 4] makes clear that the next-of-kin, as advocate of the rights of personality persisting beyond death, must pay heed in making a decision to a presumed will of the possible organ donor."

<sup>75</sup> Cf. ibid.

<sup>76</sup> Ibid.

<sup>77</sup> Ibid.

the next-of-kin's decision about an organ donation, in contrast, it is a matter of heeding the potential organ donor's rights of personality, which persist beyond death. One can, however, draw on the regulation of Section 1901a BGB to make concrete the requirements for ascertaining the presumed will. Accordingly, "the presumed will ... [is to be] ascertained on the basis of concrete indications. To be kept in mind are, especially, previous verbal or written statements, ethical or religious convictions, and other personal values" (Section 1901a (2) BGB). At the point in time of the decision, the possible organ donor's presumed will can hence be ascertained solely by means of personal, individually identifiable, concrete indications; general beliefs about values play no role.78 The question of what significance the lack of a lifetime organ donation declaration should be accorded while ascertaining the presumed will, can only be answered in connection with concrete statements or known personal values. Due to lack of an expressed declaration, an attitude of rejection cannot be inferred; this alone does not yield the organ donor's reasons and considerations.

<sup>78</sup> Höfling/Engels, in: Prütting 2014, Section 1901a BGB para. 15, 17.

### 3 NECESSARY DISTINCTIONS: DEFINITION OF DEATH, CRITERIA FOR DEATH, DIAGNOSIS OF DEATH

The preceding assessment poses a series of fundamental normative questions.

## 3.1 Analytic structure

Building on the international discussion, the normative problems that are associated with the concept of death at the basis of post-mortem organ removal can be structured in the following respects: definition of death, criteria for death and diagnosis of death. A *first* step consists in establishing a definition of death. In the process, one can look at death, for example:

- >> as the end of personal life in the sense of the loss of mental functions considered essential for the human condition or in the sense of the loss of human ability for relationship;
- >> as the loss of physical unity, or respectively as the end of the organism's functioning totality;
- » as the complete cessation of all vital processes in the entire body.

In a *second* step, it can be asked on the basis of what criteria one should judge whether the attributes required by the respective definition of death are present or not. A criterion is a factor that marks and warrants a distinction: It can serve to differentiate facts (propositional criterion), or to normatively qualify (operational criterion) actions (or behaviours, habits of acting). The criterion of brain death can function as both a propositional criterion ("death has occurred") and an operational criterion ("the organ removal is allowed"). The following criteria have been proposed as propositional criteria for death:

- >> the condition of persisting unconsciousness;
- >>> the irreversible loss of brain functions (brain death criterion), or the irreversible cessation of the circulatory system;
- »> the complete expiration of all cell activities.

The concept of brain death is characterized by the propositional and operational criterion's coinciding. On the other hand, without committing a logical error, critics of the concept of brain death can accept the complete loss of brain functions as an operational criterion without recognizing this fact as a propositional criterion.

In the *third* step, the question must ultimately be posed about what diagnostic procedures are appropriate to verify the criteria's presence.

In order to answer questions about the definition and criteria of death, anthropological interpretations are needed, where the expertise of philosophy, theology, law and medicine flows in and where simultaneously the interpretations should be plausible from the point of view of lived experience. The question of suitable diagnostic methods for certifying death falls primarily under the competence of the medical and natural sciences.

Definition of death and criteria for death are conventional stipulations and assessed according to their adequacy. Any such judgment is influenced to some extent by values. In contrast, any diagnosis can be questioned with regard to the empirical truth or falsehood of its findings, whereas diagnostic methods can be subjected to an assessment of their appropriateness for certain purposes.

The perspectives of death's definition, criteria for death and diagnosis of death can be differentiated from one another analytically; but in terms of content, they are correlated with one another. A connection in terms of content exists especially between the first and second levels.

## 3.2 Definitions of death

### 3.2.1 On the philosophical anthropology of death

As per the analytic structure introduced in Section 3.1, the criterion of brain death is a propositional criterion for the occurrence of human death, and it is a normative criterion about whether certain medical measures may or may not be undertaken. In order to identify an appropriate criterion, how human death is fundamentally understood needs to be clarified. To this end, neither the sum of compiled opinions of a society's members (empirically collected, as the case may be), nor the more often than not unexpressed explanatory assumptions of the medical discipline is sufficient. Like all human belief systems, definitions of death are also shaped by different ideas. In cultural history, a considerable variance in definitions of death has correspondingly appeared. This is mirrored in philosophical reflection about the phenomenon of death.

The philosophical-anthropological inquiry into defining death becomes ethically relevant when it is a question of differentiating the moral status of a living or dead human being; this status forms the basis for how to treat the human being. To this end, considerations about the question of what in an anthropological respect accounts for life and death are apposite in providing a basis for the moral arguments.

At the beginning of systematic reflection about the phenomenon of death stands the debate around the question of whence humans acquire knowledge about death and how they can agree about it. The apparent paradox formulated by Epicurus shows that this is not a trivial question: "Death, therefore, the most awful of evils, is nothing to us, seeing that, when we are, death is not come, and, when death is come, we are not."<sup>79</sup> Epicurus summarises the scepticism of his philosophical forerunners vis-à-vis the expressibility of evolution and extinction and thereby sets off the extensive considerations of Western philosophy on the phenomenon of death<sup>80</sup>; at times, an "epistemology of death"<sup>81</sup> is spoken of.

One's own death, in Epicurus' observation, is not an event of one's own experience, but rather precisely the complete absence of one's own experience. According to Epicurus, death would as a consequence have a reality only through experiencing by others [durch das Fremderleben]. According to the Heideggerian critique, however, death also has reality in the life of the individual and does so in that the individual exists towards. it, anticipates it, "foreruns" it.82 In its temporal extension, the individual life is "being-toward-death."83 Epicurus and his forerunners, as well as followers, see death only as an event in space and time at the end of life. Martin Heidegger's counterargument formulated in connection to Søren Kierkegaard consists in reconstructing death as a constitutive moment of the mostly implicit experience of self and other in each phase of human life; in this sense, it is a constitutive moment of human self-experience. Accordingly, death is an *a priori* of human existence; we cannot "think it away." Death as being-towarddeath is newly experienced in each phase of life.<sup>84</sup> With that said, no exclusive relationship exists of death to that phase of life that we designate "dying"; in dying, the dying person experiences being "near the end," but each life phase has an *a priori* relationship to death. In each life phase, being-toward-death

<sup>79</sup> Epicurus, *Letter to Menoeceus*, cited in Nickel 2006, 225. For the English translation of Epicurus, see Robert Drew Hicks (1910), for example here: http://classics.mit.edu/Epicurus/menoec.html.

<sup>80</sup> Cf. the overview by Hügli 1998.

<sup>81</sup> Cf. Scherer 1979, 41 ff.

<sup>82</sup> Heidegger 1963, 235 ff.

<sup>83</sup> Ibid.

<sup>84</sup> The sentence becomes analytically true if the life phases are delineated by the different meanings of being-toward-death in the life phases.

means, according to Heidegger, that this experience and this decision are now unique and unrepeatable.  $^{85}\,$ 

Among the philosophical approaches, the idea is particularly influential that in death, the soul separates from the body and simultaneously the living force from the corpus, which as such decays. According to this approach (associated primarily with Plato), the soul is assumed to be immortal; it is at the same time thought of as a substance existing autonomously and independently from the body. Not only are body and soul differentiated between, but both are also understood as separate substances. Death is interpreted as freedom from the ills of human, corporeal life and as the soul's participation in the divine.<sup>86</sup> A tendency is often associated with this to devalue the dying corpse in relation to the immortal soul. This is still seen to operate in points of view that regard the (soulless) corpse as "body having become thing."<sup>87</sup>

In the scope of René Descartes' anthropology, significant for later modernity, a sharpening of the metaphysically-founded Platonic dualism occurs and leads in this context to an understanding of death with reference purely to the body. The starting point for Descartes is the inquiry into those entities that are not imputable to other entities (attributes), but rather require no other entity for their existence (substances). Other than God, as uncreated substance, there are only two types of created substance, namely those designated by Descartes, on the one hand, as incorporeal, spiritual, "thinking substance" (*Res cogitans*) – and, on the other, as physical, "extended

<sup>85</sup> A critique is implied with this of the idea of an endlessly reiterated individual life, propagated principally by the line of thought of so-called Transhumanism; Transhumanism as a movement goes back to the biologist Julian Huxley, who first advocated it in his book *New Bottles for New Wine* (cf. Huxley 1957). A newer version is represented by Kurzweil 2005.

<sup>86</sup> Platon, Phaidon 81a.

<sup>87</sup> Scherer 2002, 633. This does not stand in contradiction to the body's being valid juristically as an object in different respects. This has to do with specific legal functions of this conceptual determination of the corpse as an object.

substance" (Res extensa).88 It should be borne in mind that the determining of the spirit occurs through modes of consciousness such as doubts, cognitions, volitions, while the body, in contrast, is determined through its extension according to the three mechanical, so-called Newtonian parameters of length, duration and weight. In this sense, according to Descartes, spirit and body belong to different spheres of reality, whereas the interaction between spirit and body (for example, blushing as an expression of embarrassment) was for Descartes the actual puzzle to be solved.<sup>89</sup> Death for Descartes can only be understood as destruction of the body; the body disintegrates just as a machine falls apart.90 Since the spirit (in Descartes' sense) is equally a substance, consequently not requiring the body for its existence, death cannot affect the spirit; this is indestructible. One can speak, therefore, of a mechanistic definition of death.<sup>91</sup> By being transmitted through both rationalistic and empiricist philosophy, the Cartesian anthropology has become the widespread anthropological base conviction of modern philosophy and science, so much so that it is frequently taken, as everyday psychology (folk psychology), for the basis of an allegedly incontestable Common Sense.92 This apparent self-evidence has been criticized in the philosophy of the 20th century, both from the point of view of the phenomenological philosophy of Edmund Husserl<sup>93</sup> and Martin Heidegger<sup>94</sup> and the linguistic critique of the philosophy of ordinary language

Meditationes de prima philosophia, Second Meditation (Adam/Tannery 1983, 27).

<sup>89</sup> For many of the authors participating in the mind-body debates, this is still the starting question today; cf. for an overview Beckermann 2010; Beckermann 2011; Borsche/Specht/Rentsch 1980.

<sup>90</sup> Les passions de l'âme, Part I, Section 5, 6 (Adam/Tannery 1974, 330 f.).

<sup>91</sup> Cf. Scherer 1979, 124 ff.

<sup>92</sup> Cf. Eckardt 1994; Churchland 1994; Daldorf 2005.

<sup>93</sup> Erste Philosophie (1923/24), Erster Teil (Boehm 1956, 51 ff.), Die Krisis der europäischen Wissenschaften und die transzendentale Phänomenologie (Biemel 1962, 74 ff.); cf. Landgrebe 1967.

<sup>94</sup> Heidegger 1963, 89 ff.

in Gilbert Ryle<sup>95</sup> and Ludwig Wittgenstein.<sup>96</sup> These have drawn attention to the fact that the Cartesian anthropology is owing not so much to an explication of human world- and self-experience, but rather to the metaphysical inquiry after substance and attribute, and hence to a conceptual construct.

Another tradition is concerned with the concept of life from the point of view of its organismic function. Unlike the tradition dating back to Plato, Aristotle and Aristotelianism – with St. Thomas Aquinas as an important representative<sup>97</sup> – view the soul as the formative principle that organises corporeal processes towards their end, namely the development of the person. With death, this process of formation, understood as entelechy, ceases.

Also dating back to Aristotle and Aristotelianism is the idea of viewing the relationship of the entire living being to discrete physical functional circuits as a relationship of τέλος (*finis*, purpose) to ὄργανον (*instrumentum*, instrument). While Descartes, with reference to the model of machines, viewed this interaction as a "mechanism," natural scientists and physicians like Albrecht von Haller,<sup>98</sup> Caspar Friedrich Wolff<sup>99</sup>, Johann Friedrich Blumenberg<sup>100</sup> and Johann Christian Reil<sup>101</sup> were oriented towards genuine biological and physiological patterns of functions, such as the healing of wounds, embryogenesis, or the circulation of the blood; and they set the idea of the "organism" against that of mechanism.<sup>102</sup> In his natural philosophy in the *Critique of Judgment* (Section 65), Immanuel Kant

<sup>95</sup> Ryle 1949.

<sup>96</sup> Philosophische Untersuchungen, §§ 36-38, 134-155, 306-308, 316-427, 491-653 (Rhees 1969).

<sup>97</sup> Summa contra Gentiles, lib. II cap. 56–59, 68–81; Summa Theologiae, pars I q. 75–76; Quaestiones disputatae De anima, quaestio unica; Sententia libri De anima. Cf. Heinzmann 1986.

<sup>98</sup> De partibus corporis humani sensilibus et irritabilibus (1752), Elementa physiologiae corporis humani (1757–1766).

<sup>99</sup> Theoria generationis (1759).

<sup>100</sup> Über den Bildungstrieb und das Zeugungsgeschäfte (1781).

<sup>101</sup> Von der Lebenskraft (1795).

<sup>102</sup> On the history of the concept of the organism, cf. the overview in Ballauf 1984.

tied these approaches conclusively to the idea of living nature's self-organisation (as opposed to the notion of a mechanistic causality).103 Kant's conceptual analysis was formative for the natural philosophy of German Idealism in Friedrich Wilhelm Joseph Schelling<sup>104</sup> and Georg Wilhelm Friedrich Hegel<sup>105</sup> and for the 19th-century Romantic natural philosophy<sup>106</sup> that was influenced by them. Connected to these traditions - and still in contention with mechanistic conceptions of the structure of the living – are system-theoretical approaches, which interpret the organism as the outcome of specific process-based equilibria.<sup>107</sup> In this context, death is understood not as a loss of discrete, necessary conditions for life, but rather as the disintegration of self-direction and, therefore, as the end of the organism's functional totality. Thus, the concept of the organism evolving in this manner in the 19th century makes reference to a totality that is self-organising in terms of ends.

In distinction to the definitions of death that evolved in the context of Platonic, Aristotelian, or Cartesian anthropologies, the phenomenological philosophy of the 20<sup>th</sup> century developed a new basis for the definition of human death with the differentiation (which relies on a peculiarity of the German language<sup>108</sup>) between the lived body and the material corpus [*Leib* and *Körper*]<sup>109</sup>. Within the framework of philosophical

<sup>103</sup> Kritik der Urtheilskraft (1790), AA V, 165–485 (Kant 1908, 372 ff.).

<sup>104</sup> Erster Entwurf eines Systems der Naturphilosophie (1799).

<sup>105</sup> Enzyklopädie der philosophischen Wissenschaften im Grundrisse (1830).

<sup>106</sup> Thus, Johannes Müller, Handbuch der Physiologie des Menschen (1837–1840); Carl Gustav Carus, Organ der Erkenntnis der Natur und des Geistes (1856); Karl Ernst von Baer, Reden gehalten in wissenschaftlichen Versammlungen und kleinere Aufsätze vermischten Inhalts (1864–1876). Cf. Tsouyopoulos 1984; Wiesemann 2008.

<sup>107</sup> Cf. especially Bertalanffy 1949a; 1949b; 1968.

<sup>108</sup> Cf. Borsche/Kaulbach 1980.

<sup>109</sup> Presumably, Max Scheler first began to deal with a conceptual distinction between "Leib" and "Körper" (Scheler 1966, 397 ff.); cf. Scheler 1928. This approach is then further formulated by Maurice Merleau-Ponty (1966) in connection to Husserl's *Ideen zu einer reinen Phänomenologie und phänomenologischen Philosophie, Zweites Buch* (Biemel 1952, 120 ff.). Cf. further Plessner 1928, 367 ff.; Plessner 1941, 238 ff.; Hengstenberg 1957, 88 ff., 255 ff.; Schmitz 1965–1967; Scherer 1976, 157 ff.; Böhme 2008.

anthropology based on this approach, it is pointed out that the human being does not have a body, let alone possesses one, but that his or her perception and action are bodily constituted. Hence, attacks against one's body [*Leib*] are not also attacks against an object in one's possession, but rather attacks against one's self. This approach claims, on the one hand, to integrate the experience of "being-toward-death" (Heidegger) and the awareness of the corpse; and, on the other, to leave open ideas such as those of a life after death. The corpse is accordingly no longer body, but corpus; death is thereby understood as the transition from a bodily existence to mere corporeality.

# **3.2.2** Significance for the discussion concerning the handling of the corpse

Across threads of tradition difficult to untangle, the various philosophical definitions of death evolved into general social beliefs and thereby raised considerable consequences for answering the question of when death has occurred and hence, as well, raised questions for organ transplantation. For the Platonic concept of the duality of soul and body, further sharpened in the Cartesian dualism of substances, the corpse is a partial substance, separated ontologically from the spirit, whose demise is ultimately without significance for the spirit.<sup>110</sup> For the Aristotelian-Thomistic tradition of thought, the soul is the body's formative principle; this formative principle, nevertheless, loses its substrate with the body's demise. In this respect, the death of the body is also a drama for the finite spirit.<sup>110</sup> The body maintains its own dignity through the moulding

This interpretation is represented by the thesis on the reification of the corpse. According to this, a normative significance must be attached to organ transplantation, if need be in the context of law of personal property – a radical conclusion, to which no one should be ready to assent. On the critique, cf. Scherer 1971, 58 ff.

<sup>111</sup> Cf. more precisely Scherer 1979, 119 ff.

of the spirit, a dignity that continues to have a further normative significance after death. Nonetheless, both the Platonic and Aristotelian lines of tradition reference the problem of death exclusively in relation to the deceased, from the firstperson perspective. Epicurus' apparent paradox is also owing only to this perspective.

Only on the basis of the phenomenological analysis of body and corpus does it become clear that it is not sufficient to view the death of the human being only from the perspective of his or her relationship to self. Rather, one needs to keep in mind that humans are relational beings, for whom the relationship to others and the belonging to a world are equally as constitutive as the relationship to one's self. From this perspective, death has been described as "relationshiplessness" [Verhältnislosigkeit];112 with the death of the human being comes the "inability to execute the foundational acts of human sympathy [Mitmensch*lichkeit*]: to look at others and speak to them."<sup>113</sup> If one draws the individual's death into an intersubjective context, then the corpse cannot be interpreted merely from the perspective of the deceased. The corpse is rather the object of the continuing respect that close associates bring to the deceased. The giving of organs on the part of the deceased or the deputized release of organs by those near to the deceased is, thus, a morally significant process.

A Platonic definition of death, for example, would result in the spirit-abandoned corpse entailing no obligations for bystanders of the deceased. Such an understanding would be irreconcilable with the idea of the respect for the deceased being transferred to and having an after-effect for the corpse. A transplantation legislation that understands this respect for the corpse as morally dictated thereby presumes an understanding of death that is incompatible with the Platonic definition. The example shows that a legal regulation of organ transplantation

<sup>112</sup> Jüngel 1993, 99 ff., 138 f.

<sup>113</sup> Scherer 2002, 633.

draws more or less explicitly on anthropological assumptions and hence, too, definitions of death.

The normative problems surrounding dying and death are not only dependent on the anthropological assumptions of spirit, soul, corpus and body. Rather, it is also a question of whether mankind in itself (that is, the human being as an instance of the species Homo sapiens) deserves moral deference or whether other characteristics or grounds form the basis for a moral status – humanity, hence, only being able to be appreciated indirectly. Where such questions are discussed, one often encounters the distinction between the "human" [Mensch] and the "person" [Person]. With this distinction arises debate about, on the one hand, whether there exist persons beyond the human being (for instance, certain animals or complex machines or, viewed speculatively, extra-terrestrial existences); and, on the other, whether all humans in general (including, for example, fetuses or people with severe dementia) or only those with certain capabilities or skills are persons. According to the characteristic-oriented line of tradition, it is only certain characteristics to be esteemed as morally significant that make an entity into a person to be considered morally: so, for example, the ability to think (René Descartes), self-consciousness (John Locke), consciousness (David Hume), the ability to have feelings (Arthur Schopenhauer), the ability to speak (Johann Gottfried Herder), the capability of suffering (Jeremy Bentham), the ability to feel pain (Peter Singer), and many others besides. For the German Ethics Council's present opinion, this distinction is, however, not of significance for what follows. For those who deem the brain dead as dead, it is irrelevant. For those who do not look at the brain dead as dead, the recognition of a special moral status already follows from one's humanity.

# 3.3 The question of generalisable elements of a concept of death

In many regards, a multiplicity of definitions of deaths, describable in cultural-historical terms, can be understood as the expression of the multiplicity of human interpretations of the world. In the interest of a reliable orientation for action in the area of diagnosis of death and organ removal, it is, nonetheless, necessary to search for a generalizable context for a communicative framework. This context can be characterized through the following five elements, for which a broad consensus can be recognized in the previously sketched philosophical history, as well as in current debate.

*Compatibility with the life-world:* The concept of death must be tied to human experience. It must be not only sufficient to the criteria of the analytic conclusiveness of scientific and abstract ethical arguments, but also, moreover, "anthropologically plausible." Hence, it should, in any case, not blatantly contradict the customary intuitions of a human's "being-dead" [*Totsein*], which belong to the cultural background of evolved life-world experience.

*Reference to biological processes:* The concept of death relates to humans as living organisms; thus, (also) to a complex system of integrated, self-organising biochemical processes, interacting upon one another, as well as with the environment.

*Relation to a living being as a whole:* Death can be meaningfully comprehended only as the death of an integrated, living individual. The concepts of "brain death" or "cardiovascular death" may be misunderstood to the extent that they could falsely imply that it is only the brain or the heart that is dead, and not the organism as a whole – and hence, simultaneously, its possessor, the human being who experienced bodily reality in it.

*Finality:* No further (earthly) life follows death. The event of death is, thus, one-time for each individual.

*Coherence:* A sufficient coherence between definition of death and criteria for death, in the sense of a *concept of death*,

presumes that the fulfilment of the criteria of death yields sufficient evidence for the presence of features constituting a particular definition of death. In the process, the persuasiveness of the concept of death, concretely represented, is contingent on both that the chosen definition of death be accepted as adequate and that the criteria for death portray the assumed definition of death. This double condition means also that objections can be formulated against the concept of death at each level: on the one hand, on the level of the definition of death; on the other, in the verifying of the thesis that the criteria for death represent the assumed concept of death.

In regard to the definition of death in the context of organ removal, closer analysis admittedly shows the limited scope of the agreement regarding those aspects of a concept of death for which a consensus has been assumed prima facie. This is the case particularly for the relation to a living being as a whole; for here it is fiercely contested when the organism as a whole and hence the human being is dead. This also appears in the criterion of compatibility with the life-world, if one considers the cognitive and affective dissonances that arise when the brain-dead individual is viewed as a corpse, contrary to the appearance of being alive. Such dissonances cannot be understood as the expression of a scientifically naïve and uneducated mind. At stake is a situation, which arises only due to modern intensive-care measures, through which other physiological functions are maintained even after the irreversible loss of all brain functions; and which affects not only so-called lay people and next-of-kin of brain-dead people, but also caregivers<sup>114</sup> and

<sup>114</sup> In a nation-wide, albeit non-representative survey of 363 nursing staff from hospitals with transplantation divisions or hospitals with neurological intensive-care stations, the results showed that 27 or, respectively, 29 percent of surveyed caregivers either doubt the equation of death and brain death or are not certain. From the 213 surveyed caregivers that cared for a brain-dead person at least once, 30 percent always experience the care of a brain-dead person as stressing and 52 percent sometimes so (Bundeszentrale für gesundheitliche Aufklärung 2011, 40, 47).

doctors.<sup>115</sup> The reservation against classifying organ functions in the brain dead not as signs of persisting vitality, but simply as physiological processes and reflexes without significance for the recognition of one's counterpart as person, is fed by a basic human experience; that is, to see an expression of embodied, personal life in such vital signs and to be ready for a personal encounter even when the other can no longer respond communicatively.<sup>116</sup>

The divergence of opinions is even more pronounced regarding the following elements situated in the international discussion.

*Disjunctivity (tertium non datur)*<sup>117</sup>: For the majority of those participating in the discussion, the concepts of "death" and "life" designate alternatives that are mutually exclusive. However, there is also the counter-view, whose representatives recognize a "between-state": Under the conditions of intensive-care medicine, a process of dying can be identified that represents a third stage between being alive and being dead.

*Symmetry (Consistency):* The criterion of symmetry suggests that any coherent definition of life and death must suffice for the *symmetry between the beginning and end of life.* Thus, it must be equally applicable to life's beginning and end. Whether an entity is not yet alive or no longer alive must be determined by means of the same criterion.<sup>118</sup> Against this, however, it is held that it would be scientifically and normatively neither

<sup>115</sup> Gesa Lindemann, for example, has elaborated on the cognitive dissonance experienced by intensive care physicians involved in the practice of brain death diagnostics. This dissonance arises when physicians perceive the patient as living during the period of time of brain death diagnostics and have to treat him or her accordingly, in order then to view the person retrospectively as dead with conclusion of the diagnostics. For Lindemann, this operates in everyday life to the effect that "the institutionalised procedure of brain death diagnostics functions like a silent doubt concerning the validity of the concept of brain death" (Lindemann 2001, 338).

<sup>116</sup> Cf. Rehbock 2012, 175; cf. also Fuchs 2013, 171 ff.

<sup>117</sup> A distinction is completely disjunctive if the relevant expressions A and B are joined by an exclusive either-or.

<sup>118</sup> Thus Birnbacher (2012, 28), with reference to McMahan 2002; similarly Höfling 2012, 167.

necessary nor plausible, given the significance of the temporal dimension and the direction of development, to establish the same criteria for the beginning of individual human life as for its end.

### 4 DEFINITION OF DEATH AND CRITERION FOR DEATH IN THE CONTEXT OF ORGAN TRANSPLANTATION

### 4.1 Common basis

#### 4.1.1 Reference to mental abilities

For a long time in the discussion around the human being's death in the context of organ transplantation, an exclusively "mentalist" reasoning<sup>119</sup> played a considerable role.

For the death of the human being, this concept relies on the – reliably diagnosed – irreversible loss of the capacity to perceive, feel, think and decide. This occurs correctly insofar as such a loss is discernibly a necessary condition of human death; and conversely, any presence of this capacity is thus a sufficient condition for human life. No one still experiencing anything in this sense can be called "dead" on any acceptable grounds, be they normative or biological.

This in no way suggests that any person, when lacking the ability to perceive, feel, think and decide, ought already to be designated as dead. Rather, it is contrariwise the case that a person *cannot* be seen as dead when one of the said faculties is present. It is, hence, a case of a negative requirement: The non-expiration of subjective experience excludes the diagnosis of death. Moreover, it should be emphasized that this deathexcluding "experiencing" obviously captures not just clearly conscious events or conditions, such as thoughts, emotions or self-consciousness. Rather, it encompasses, far below this threshold, any humanly possible minimum of sensation. Any

<sup>119</sup> In contemporary philosophy, the expression "mentalism" is used in various contexts (cf. the overview by Mittelstraß 2013). In what follows, under the rubric of mentalism is understood the thesis that all human actions or conditions can be divided completely and disjunctively into two classes, those of the mental and those of the corporeal phenomena.

person for whom external stimuli can still produce some form of pain sensation – even should the stimuli necessary be severe and the sensation of pain only a dull shadow – would not be dead; and indeed, also not when no remote trace of other experiences can be detected in the person besides this minimum of sensory (pain-) feeling. In this sense, mental death is a necessary criterion for human death.

In the international debate, the concept of death is founded, in part, on exclusively mentalistic terms.<sup>120</sup> This applies especially for concepts of partial brain death (for instance, neocortical death): For representatives of this position, the loss of experiential ability associated with the cerebrum is not only a necessary, but at the same time a sufficient criterion of death.

Such partial brain death concepts contradict medicalbiological findings. The neuronal basis of consciousness encompasses not only the cerebral cortex, but also other, more deeply located areas in the brain. The cerebral cortex does not act simply as an "isolated organ"; it is an element of neuronal networks, which also include structures like the amygdala and its interconnections. Additionally, it is unclear and subject to both neuroscientific and philosophical controversy what must be minimally given so that one can speak of "consciousness," as well as how this should, as applicable, be diagnosed empirically. Therefore, clinical procedures to prove the absence of consciousness are much more problematic than clinical tests which, for instance, provide evidence that a state of wakefulness and the entire brain stem reflexes are not (any longer) present or which verify respiratory failure.<sup>121</sup>

<sup>120</sup> See in the German literature, for example, Scheinfeld 2006, 175 f. as a plea for the recourse to anencephalic individuals as organ donors. The author does not claim that his suggestion is in accordance with current law; rather, he argues for its future amendment, albeit only under the condition that at some point a reliable procedure would be available by which complete mental death could already be definitely shown with the occurrence of neocortical death; this condition would currently not be fulfilled.

<sup>121</sup> Laureys 2005.

Exclusively mentalistically-based partial brain death concepts involve, moreover, an ethically and constitutionally unacceptable concept of the human. By making the boundary between life and death exclusively dependent on whether some subjective experience is still possible in the present or future for the human being concerned, it is at the same time decided whether elementary rights, such as protection of life and dignity, are also accorded to this individual. According to this view, anencephalic newborns and possibly also apallic patients should consequently be qualified as dead. The constitutional critique of this points out that the basic right to life - as the Bundesverfassungsgericht (Federal Constitutional Court) has emphasized - protects "the biological and physical existence of every human being [...] independently of the individual's circumstances of life and of his or her physical state and state of mind."122 The constitutional order's inclusive concept of the human and its elementary guarantee of human dignity and human life thus stand in contradiction to a categorical distinction according to purely "mentalistic" criteria.

Against this background, the German Ethics Council recognizes that any concept of death necessarily requires the "mental" death of the human being; at the same time, however, it rejects an exclusively mentalistic definition of death.

#### 4.1.2 Reference to the organism as biological unity

Death can only be spoken of in reference to an organism conceived as a biological unity. In this respect as well, there is agreement in the German Ethics Council.

The organism is constituted in a double sense as unity:

a) through internal interaction: features of vitality, such as, for example, the sensory faculty, metabolism, development,

<sup>122</sup> BVerfG, 1 BvR 357/05, para. 85 = BVerfGE 115, 118 (139).

reproduction, heredity cannot be reduced entirely to single mechanical or physical or chemical processes. The organism of a living being is fundamentally more than the sum of its parts and more than a complex machine. Vital functions are interrelated in causal networks which exclude a complete reduction to single causal processes.

b) through exchange with the environment: The inner workings of the living organism are essentially constituted through its constant interaction with its environment; these change with development and aging, during sicknesses, and as the outcome of learning processes.

Hence, the death of the human organism concerns the inner life functions as a whole and their interaction with the environment.

# **4.1.3** The loss of complete brain functions as caesura and its ethical consequences

In the context of organ transplantation, discussion about the criterion of death is concentrated on the question of whether the irreversible loss of all brain functions qualifies as a criterion for the occurrence of human death. However contentious this question is, the members of the German Ethics Council are in agreement on the following statements:

Brain death diagnostics allows for a reliable assertion about the irreversible loss of all brain functions. In the natural course of events, the irreversible loss of all brain functions accompanies the failure of all organ functions and the decomposition of the human body. Insofar as no technical-medical measures are taken to halt this process, it progresses inevitably into the individual cells. Even when such measures are taken, they do not lead to a restoration of brain functions; no scientific-medical proof exists that any person has ever recovered any brain function following reliable diagnosis of brain death. The irreversible loss of all brain functions has the consequence for medical decision-making that, at the latest following reliable determination of this loss, a medical indication no longer exists for therapeutically oriented measures. For this reason, there is also no longer any duty to maintain breathing or cardiovascular functions.

Beyond dispute, however, are the physician and nursing staff's continuing ethical responsibilities even beyond the diagnosis of brain death. It is of special significance for the morally appropriate handling of the brain-dead that those involved in the preparation and performance of an organ removal enter into a special relationship of responsibility vis-à-vis the braindead patient, in whom the continuation of certain organ functions is enabled by medical intervention.

Relations of responsibility, into which persons enter visà-vis other persons, require not only considerations with an eve to possible consequences, but also immediate duties, in the light of which the respective action is to be assessed.<sup>123</sup> The human being's dignity must be esteemed and distinctiveness respected; in that individual's reliance on help, the necessary care must be provided by those standing in a relationship of responsibility to the said human being. Such a relationship of responsibility reaches beyond death. This is particularly vivid in the care for a dead body and in nurturing the memory of a person. This relationship of responsibility assumes a special character in those cases in which brain death is diagnosed and organ functions are at the same time maintained further. It includes all appropriate measures of care for and the respectful handling of both the still breathing and blood-circulating body (thanks to organ-protective measures), as well as the body following explantation. The enabling and appropriate arrangement of the leave-taking and funeral are part of this as well.

The Transplantation Act takes into account the ethical principle of respectful and responsible interaction with an

<sup>123</sup> On this perspective, cf. Deutscher Ethikrat 2011, 48 ff.

organ donor by making the "respect for the dignity of the organ and tissue donor in a manner according to the physician's duty of care" mandatory for all measures connected to this and by prescribing that "the corpse of the organ and tissue donor ... [must] be handed over for burial in a dignified state"; "prior to this, the next-of-kin must be given the opportunity to view the corpse" (Section 6 (1) and (2) TPG).

# **4.2** The controversy concerning the concept of brain death

The question of whether the evidence of the irreversible failure of all brain functions represents an appropriate criterion for human death is also disputed within the German Ethics Council.<sup>124</sup>

# 4.2.1 Position A: Brain death is a sure sign for the death of the person

According to the concept of brain death that is represented by the majority of the members of the German Ethics Council and that also lies at the basis of the Transplantation Act and the relevant guidelines of the German Medical Association, brain death (in the sense of the irreversible loss of the total function of the cerebrum, cerebellum and brainstem) is a sure symptom for the death of the human being. If all brain functions have expired forever and this is unequivocally determined according to the reliable criteria of brain-death diagnosis, then according to the concept of brain death, this justifies the assumption that the human being is dead. This does not mean in any way that

<sup>124</sup> The aligning of the members of the German Ethics Council according to the subsequently outlined positions A and B is documented in the appendix to the recommendations in chapter 6.

the death of this organ *is* the death of the human being; but rather, that it indicates the death of the human being.<sup>125</sup> This means that no relationship of identity (however determined) exists between the life of a human being and the functional "vitality" of one of that individual's organs. The human being's death is, rather, inferred from the loss of all brain functions. This is no different – with respect to the *modus procedendi* – in the case of irreversible failure of the cardiovascular system, which some critics of the concept of brain death advocate as a criterion of death. The irreversible loss of all brain functions is viewed as a *sure sign of death*; it is, therefore, appropriate as *criterion of death*.<sup>126</sup>

The brain yields the necessary integration of functioning for the entire organism, without which it could not exist as a unity of body and mind. This task of integration encompasses both mental and organismic aspects; mental processes are not conceivable without an organismic basis.

The death of the human being strictly necessitates the prior loss of the integrative performance of the brain. This condition is sufficiently fulfilled with brain death. The fact, adduced in this context by critics of the concept of brain death, that other organs contribute to the maintenance of the entire organism as well, is not opposed to this. For none of these organs can assume the function of integrating itself with all other organs – each one of which may be absolutely necessary for the survival of the entire organism – into precisely that functionally interactive totality that constitutes the *living organism* and that is far more than a set of mutually connected individual organs. The brain is the central organ of integration, regulation and coordination. It integrates sensory and sensitive stimuli from the organism itself and from outside through the so-called afferent nerves; enables motor actions and communication via

<sup>125</sup> Anderheiden 2012, 180; cf. McCrone 2004.

<sup>126</sup> On the distinction between the definition of death and criteria for death, cf. section 3.1.

the efferent nerves (for instance, through speech, gesture, facial expression); regulates the coordination processes within and between the other organ systems across the vegetative nervous system, including hormonal regulation; and, finally, is the basis of the mind and of subjectivity.

The inner processes of the living organism are essentially constituted through its constant interaction with its environment.<sup>127</sup> These interactions with the environment are based in large part on sense perceptions, which are represented and processed in the brain. In turn, they contribute to the changing of brain functions and structures; and lead to a specific reaction or specified behaviour. As an expression of the interaction with the environment, any kind of specific behaviour is controlled by the central nervous system and for this reason is, apart from various reflexes that function exclusively via the spinal cord, dominated by the brain. This physiologically selfinitiated, self-regulated, active as well as reactive behaviour is the central category that constitutes life.

Whereas specific functions of other organs can be technically maintained or substituted for on a temporary basis and, occasionally, over long periods, the functions of the brain cannot be replaced; through external substitution, only mere parts can be maintained on a rudimentary level. The brain's functions are the precondition for the living human being's ability to adapt to constantly changing functional requirements and to react on these (for example, through changed heart rate, respiratory rate, temperature-regulation, but through complex modes of behaviour as well).

The functions of the brain manifest themselves across all of the organism's organisational levels. To explain this complex steering mechanism, a system-biological approach is widespread, which employs the concept of the organism as a complex system organised on multiple levels (molecules, cells, tissues, organs, organism, etc.), whose components are

<sup>127</sup> This is a basic consensus of both positions A and B (see section 4.1.2 b).

functionally integrated with one another.<sup>128</sup> A circular organisational principle mostly underlies these subsystems, with various interactions occurring within the system, as well as with other systems. Various approaches from mathematics and physics – for example, non-linear dynamics – are used in systems biology in order to describe complex systems such as the human organism and to understand the interaction of its subsystems.<sup>129</sup>

For instance, a hierarchical model can be used to describe the respiratory centre, with receptors and effector organs on the periphery and central control in the brainstem. The activity of the heart is controlled in a more complex manner, but this process of regulation is also monitored through a central component in the brainstem. Thus, for example, the heart rate can be raised via the parasympathetic nervous system, with core areas in the brainstem, or the conduction time within the heart can be reduced. Through this, the heart can adapt to continuously changing requirements in interaction with the environment. The brain enables the organism to react dynamically to the environment. Similarly, hormonal production, which occurs "de-centrally" in various places, is regulated centrally via the hypothalamus; hence, it must be replaced artificially when it ceases. Despite their important, specific contribution to the maintenance of the organism, the inner organs involved cannot – in the long run and under shifting conditions – yield their intrinsic function in full autonomy, but rather only on the basis of the brain's regulatory and integrative activity.

There are certainly numerous cases in which an organ is too weak to fulfil its part in the integration of the body as a whole and requires permanent support or even replacement through a transplantation, without this having an effect on the fact that such a person is living.<sup>130</sup> However, these cases must

<sup>128</sup> For an overview to this, see Rosslenbroich 2011.

<sup>129</sup> For an overview to this, see Bizzarri/Brambilla/Gajani 2013.

<sup>130</sup> For example, pacemakers, dialysis, "iron lungs," etc.

be differentiated from those of brain death. Among those who are brain dead, vital functions that have malfunctioned, such as, for example, breathing or blood circulation, are maintained through artificial means and thereby replaced. Nevertheless, the integration of a human body into a functioning unity is no longer an intrinsic performance of the body; the quality and intensity of external support is, hence, of a genuinely different kind than when in a viable organism, partial functions, such as respiration or blood purification, are replaced, which the organism uses autonomously for the maintenance of its unity. During brain death, the continued existence of this integration is ceded to permanent organisational support from outside.<sup>131</sup> Formulated differently: in replacing an organ, its substitute is interpolated into a functionally integrated overall context, which, as such, did exist even without this organ and does now continue to exist. In the future, there certainly will be more success in understanding, modulating or, as applicable, replacing the function of single organs with respect to their biochemical, physiological or pathological reactions. It is conceivable that entire organ systems can be replaced. According to all current knowledge, however, substitution of the brain, as genuine source of the self-initiation of the total organismic behaviour, is not imaginable.

Following the ultimate cessation of brain activity, it can no longer be a case of speaking of a self-regulated integrative performance of (all!) single organs within the organism. Should artificial respiration and the artificially achieved maintenance of blood circulation cease, as well as further functions as a consequence, then cardiac arrest sets in, and the process of decay begins. Given artificial maintenance of breathing and other body functions, not all partial functions in all parts of the body are extinguished following the occurrence of brain death; nonetheless, the unity of the organism as a living totality is irrevocably ruptured. As outlined above, the criterion of brain

<sup>131</sup> More comprehensively in Anderheiden 2012, 189 ff.

death does not define death as an anthropological phenomenon, but rather designates a scientifically certain criterion for when the end of human life as a vital totality has been reached. Aliveness can only be ascribed to an organism that of its own active performance can produce and ensure the central integration of all body functions into an organismic unity.<sup>132</sup>

Following brain death, mental processes, too, expire, along with the functions of the brain directed towards organismic unity; and the basis for subjectivity is irrevocably lost. The brain is the only organ, with which the preceding personal identity would perish, if it were technically substituted for or replaced.

If upon the irreversible loss of all brain functions, the necessary preconditions for mental activity, any faculty of sensation, and hence any possibility of self-driven behaviour or exchange with the environment is permanently lost and, moreover, the unity of the organism is ruptured, then one can no longer speak of the body in this condition as a living human being, even if isolated biological activities, like cell growth, oxygenuse, and blood-circulation, are still possible due to intensivecare measures.

Also, against this background, the reports of the neurologist Alan Shewmon regarding the continuation of various body functions following the occurrence of brain death do not appear pertinent, because the functions outlined there do not concern behaviour that is physiologically autonomous, but rather exclusively somatic-reactive functions. As such, they are also not integrative, as suggested by Shewmon, or at best in a very unspecific and indirect manner. To make such functions

<sup>132</sup> On a medical-biological level of description, it is hence misleading to put aside the loss of the integrative capacity of the organism and designate a brain-dead person as one who is 97 percent living, where only the brain functions have ceased. See, for example, Geisler 2010: "Those who are brain dead are people, in which 97 percent of their body lives; only 3 percent – their brain – is dead." Equally, Tröndle (1997, note to Section 211, para. 30) designates a brain-dead person as one who is "97 percent living, without brain function."

the defining feature of life leads to a dilemma. In modern medicine and research today, the isolated functions of organs and tissues can already be maintained over a long duration. And it is foreseeable that the boundaries now existing in this area will increasingly expand. A functional network of liver, kidneys, lungs, heart and other organs – which at some point may be artificially producible and which then may be stably maintained by a machine via constant stimulation of purely reactive physiological processes – would, nonetheless, certainly not be a living person.

The intrinsic activity of the organism, which enables it to maintain its integrative performance as a whole, is, according to the concept of brain death, an acceptable differentiating feature that distinguishes its living condition from that of a braindead body in which only partial performances of integration are still possible. It is the respirator, which fills the lungs with air and makes the heart beat; it is an artificially ventilated body, which breathes and perspires or emits other signals into its environs. Pursuant to this interpretation of the criterion of brain death, the question of whether those who are brain dead are still alive or already dead may be answered according to whether these physical abilities issue from a self-driven intrinsic performance of the organism and would so justify speaking of the person's aliveness or whether they are evoked as sub-states through external mechanical and medicinal interventions. For representatives of the concept of brain death, the central question put forward is not what sub-functions and integrative processes could still work in this body. The decisive question is, rather, whether a brain-dead body can yield through its own active performance the internal processes of self-integration characteristic for a living organism, as well as external metabolic and neuronal interaction; or whether these processes can only be effected partially and rudimentarily through external inducement. In the first case, there is a real basis for designating its bearer as living, namely that is a genuine property of this organism itself; in the second, however,

the appearance of a living person is inspired through external substitution.

The majority of the US President's Council affirms the concept of brain death in its opinion of 2008, also and precisely having considered the empirical evidence of Shewmon regarding partial integrative performances that can still operate in the brain-dead body during artificial sustenance of respiration and other body functions. In doing so, the White Paper refers to the specific intrinsic activity of the organism of the living person in exchange with its environment. According to the White Paper, among the living organism's vital intrinsic activities that an organism carries out in the interaction with its environment and that can be yielded only by the brain are the following three features:

- 1. "Openness to the world, that is, receptivity to stimuli and signals from the surrounding environment.
- 2. The ability to act upon the world to obtain selectively what it needs.
- 3. The basic felt need that drives the organism to act as it must, to obtain what it needs and what its openness reveals to be available."<sup>133</sup>

The expression "basic felt need" unmistakably contains a metaphorical element, through which the intended meaning may be communicated more graphically than would be possible in a purely technical terminology. Meant by this is above all the genuine intrinsic activity of the organism in exchange with its environment designated above as "self-initiating" (and not only in reaction to its physical stimuli). The White Paper thereby points attention to the decisive anthropological difference that exists between the organism of a living human being and the artificially ventilated body of someone who is brain dead.

<sup>133</sup> President's Council on Bioethics 2008, 61.

The recent debates surrounding the concept of brain death illustrate the assumptions from anthropology and natural philosophy under which the concept of brain death exists. The distinction between active self-regulation through an intrinsic ability of the organism and constant enabling of individual sub-functions through external substitution is only relevant when life and aliveness are conceived of as an ability over which an organism itself disposes. Should life and aliveness, on the other hand, designate a mere condition, independent of how it arises and whereby it persists, then the condition of a brain-dead patient's body sustained by artificial respiration can also be designated as living. However, in distinction to patients in a persistent vegetative state or those undergoing temporary artificial respiration, brain-dead patients can never again achieve the essential ability of creating the physical and mental unity of their organisms that is characteristic for living humans. Other than in the case of a pacemaker, which does not completely replace the intrinsic activity of the heart, but rather supports it, and other than by kidney dialysis, which only partially substitutes for an organ function, the unity of the brain-dead body can be maintained as an organismic whole exclusively on the basis of intensive-care measures. As soon as they are abandoned, this unity disintegrates; and the organism begins to dissolve and decay.

Against this background, the fact, too, that an embryo/foetus can continue to grow in the body of a brain-dead woman, is no counter-argument. If the foetus develops in the body of a brain-dead woman, this is due rather to the functions of the maternal uterus being adequately maintained through intensive-care measures, as well as, if applicable, administration of hormones, and, additionally, due to the circumstance that the independently living embryo is taking over numerous, genuinely autonomous control functions.

The fact that the attempt to maintain a pregnancy in a brain-dead woman frequently does not succeed, shows incidentally how difficult it is to replace even the necessary sub-functions of the brain's highly complex control centre, which yields this performance for the living organism. The idea can be illustrated with a thought experiment: Let it be assumed that in the distant future, it will be possible to produce a functioning artificial uterus, in which the earliest embryos can be implanted and developed until ready for birth. Nobody would think of suggesting that this machine would have the ability to bear children, let alone that it would itself be living. Rather one would say: We or, respectively, the competent intensive-care physicians have the ability, by means of a machine, to sustain an embryo/foetus outside a natural womb until independently capable of life. The same applies to today's possibility of enabling the further development of an unborn child in the body of a brain-dead woman: It is only the stabilizing of certain functions in the brain-dead body of the pregnant woman through intensive-care measures that ensures (occasionally) the continued development of the unborn child until ready for birth; not, however, an enduring intrinsic ability for integration and regulation of a living organism.

Even a systemic concept of life, which critics of the concept of brain death frequently adduce, premises the aliveness of a living being on its capability for autopoiesis, for selfgenerated system unity. In the Aristotelian tradition, too, in many respects still influential today, the concept of life is not conceived of as a mere state of a being, for which it would be indifferent whether it arises through an intrinsic principle of life or through external substitution of individual functions of this lost principle. Rather, the "soul," as this entelechial principle of life is called in this philosophical line of tradition, is imagined as an animating active principle, unifying the organism. If the soul's active principle of formation no longer weaves itself through the body, then, under the requirements of this so-called hylomorphic model of unity, the subjective bearer of this body, the individual living being, or the human being can no longer be conceived of as living.<sup>134</sup> From this philosophical point of view, the "soul" can thus be interpreted entirely without religious connotations. The concept can readily be mapped functionally onto the central instantiation of self-integration outlined above, which expires irreversibly with the complete death of the brain. But even an interpretation of the concept of the soul different from such a functional one leads in this case to no other conclusion.

In philosophical discussion, a dualistic image of the human going back to Descartes is often imputed to the concept of brain death - one that does not take the physical and mental unity of the human being seriously and that defines beinghuman only through mental capacities.<sup>135</sup> However, this charge is levelled at best at concepts of partial brain death, mainly postulated in Anglo-Saxon discussions, but not at that of total brain death, which requires the irreversible loss of all brain functions. Rather, the brain plays an absolutely necessary role in two regards: first, as the source of subjective experience and mental processes; and second, as the central integrative function, which aims at the organism as a whole and which also ensures the physical and mental unity. Would the concept of brain death refer solely to faculties of consciousness of human beings and were it to evaluate their loss as sufficient evidence for the person's death, the charge would apply of a dualistic disregard for the physical and mental unity of the person. And obviously the same would be the case, should one define the organismic aspect of humanity as the sufficient characteristic of the boundary between life and death. Both would be onesided contractions (and as such presupposing dualism) of the Condicio humana. Moreover, neither applies to the criterion

<sup>134</sup> In hylomorphism, matter (hyle) and form (morphe) distinguish two aspects of the unity of a living being, cooperatively bringing it into existence. According to the requirements of this anthropological model of thought, neither form nor matter can exist for itself.

<sup>135</sup> For instance, Anna Bergmann interviewed in the scientific journal 360° (http://www.journal360.de/\_wordpress\_live\_dSJ360/wp-content/uploads/ 2013/12/15\_Glauben\_Wissen\_Spezial\_Interview.pdf [2015-01-17]).

of total brain death valid in Germany. This, in contrast, is tied precisely to the conditions under which the physical and mental unity of the human being can be maintained. The anthropological justification of this approach follows from the fact that the individual organs of the human body only work together through the activity of the brain as the centre of coordination for the integrated unity and totality of an organism. The death of the human being occurs when the integrative principle, which ensures the unity of the organism, can no longer fulfil its functions, and the organism's parts begin to dissolve.

## **4.2.2** Position B: Brain death is not a sufficient prerequisite for the death of the person

According to the perception of a minority of the German Ethics Council, brain death is not a sufficient prerequisite for human death. The representatives of position B hold the above arguments to be unsustainable. Agreement, indeed, exists with position A in terms of "mental death" being a necessary prerequisite for the death of the human being. Fundamental evaluative differences remain, however, in terms of the question of whether a human being with irreversible brain failure can also already be designated as dead in an organismic sense. Where can one set the threshold beyond which the integration of the body into a biological unity is void? The representatives of position B hold that in view of the still possible complex biological capacities during intensive-care treatment, the irreversible and complete loss of brain functions is not so material that the threshold is thereby already overstepped, beyond which the body can be viewed as disintegrated and hence dead. The brain does, indeed, carry out essential functions for maintaining the organism (for example, stimulation of breathing), yet these functions (beyond the "mental") are fundamentally replaceable through intensive-care medicine. From a biological point of view, the brain is not an irreplaceable centre of integration and coordination for the organism. The organism is characterized, rather, by a complex interplay of organ systems serving the self-preservation of the whole (see below, section 4.2.2.1).<sup>136</sup> Neither the fact that the unity of the organism is only enabled with the aid of intensive-care measures, like artificial respiration, is viewed as conclusive for whether a body is to be considered as dead or living in a biological sense. Without doubt, it would be dead without medical support; but under the provision of ventilation and drugs, it is not yet (to this, section 4.2.2.2).

#### 4.2.2.1 Integration of the organism into a unity and totality

One can understand life as a kind of systemic property – as the result of the interaction of different and specific components on various functional levels: on the lowest level macromolecules are involved, such as nucleic acids, amino acids, fatty acids, and so forth; on higher levels, cells and tissues; "after that organs, and on the highest level the whole organism." An interaction ensues, moreover, in between the levels and with the environment. Thomas Fuchs speaks of horizontal and vertical

<sup>136</sup> Hence Ralf Stoecker advocates, for example, the point of view that death is a so-called "thick concept": Several descriptive features, such as those mentioned above, are combined with one another and so imbued with moral significance and social meaning that the impression arises that there is a *single* turn at stake. In the situation of brain death, however, it becomes clear that the assumption of a single descriptive prerequisite is a fiction: "The preeminent moral significance of death, which is expressed in the fundamental ethical assumption about death, is owing on the descriptive level to a fiction of a single turning point, and this fiction cannot be maintained in view of the condition of brain-dead humans" (Stoecker 2010, XLIX). Precisely under the conditions of modern intensive-care medicine, it is possible to experience that such a turning point cannot be determined unambiguously. Thus, significant life functions, such as respiration, cardiovascular functions, consciousness, reproduction, and so forth, can be decoupled from one another through intensive-care interventions. For example, the vital functions of circulation or reproduction can be maintained independently from the functions of consciousness or respiration. On this, cf. the medical-historical analysis by Sebastian Schellong. He shows that through the possibilities of intensive-care medicine, life can be disassembled not only theoretically, but also practically into different vital functions, which is why, according to his perspective, the question of a unitary death of the human being as the moment of transition from life to death can no longer be meaningfully posed (Schellong et al. 1990).

circular causality.<sup>137</sup> Life's organisation consists in the single biological components producing and maintaining themselves by contributing to the production and maintenance of all other biological components. Or formulated differently: The heart maintains itself by contributing to the maintenance of the liver, kidneys and other organs, and vice versa.<sup>138</sup>

The approach to the organism as system is, therefore, based quite essentially on the idea of feedback and interaction, not on the principle of a central control. Each living organism - regardless whether of human or animal nature - is from the here relevant point of view of biology, a system organising itself according to ends, which is why the description of this system's breakdown always requires a reference to these ends. This maintenance of the individual physical or psychological identity - of reproduction, growth, nutrition, etc. - is of a complex nature in humans; as systemic functions, they are entangled with one another. Under circumstances, the organism still commands manifold functions, even after the brain has died, given the intensive-care measures outlined in section 2.2.3 – functions that act not only "partially," but contribute to the integration of the organism as a whole. In a 2001 article in the Journal of Medicine and Philosophy, Shewmon summarizes these integrative functions, which can be detected in at least some of those persons diagnosed as brain dead:

» Homeostasis of a countless variety of mutually interacting chemicals, macromolecules and physiological parameters,

<sup>137</sup> Fuchs 2012.

<sup>138</sup> On this, see Roth/Dicke 1995, 53; further, Hoff/Schmitten 1995, 184 ff. with additional references. Most recently, see Feinendegen/Höver 2013, 158 f.: "The totality of the human organism is *not* tied to the function of a central organ (the brain) – indeed, the aporias of the biological (organic-somatic) justification of brain death show this; it is manifestly a kind of 'emergent' quality or performance of the entire organism. Such a form of totality is [...] in its existence, independent from the presence or function of a single organ (thus, also independent of the brain). Rather, it depends on maintaining the possibility of the cooperation of the differing functions, that cooperation which *is* the organism – also, as need be, by intensive-care replacement of one of the functions necessary for survival."

through the functions especially of liver, kidneys, cardiovascular and endocrine systems, but also of other organs and tissues [...];

- » Elimination, detoxification and recycling of cellular wastes throughout the body;
- » Energy balance, involving interactions among liver, endocrine systems, muscle and fat;
- » Maintenance of body temperature (albeit at a lower than normal level and with the help of blankets);
- » Wound healing, capacity for which is diffuse throughout the body and which involves organism-level, teleological interaction among blood cells, capillary endothelium, soft tissues, bone marrow, vasoactive peptides, clotting and clot lysing factors (maintained by the liver, vascular endothelium and circulating leukocytes in a delicate balance of synthesis and degradation), etc.;
- » Fighting of infections and foreign bodies through interactions among the immune system, lymphatics, bone marrow, and microvasculature;
- » Development of a febrile response to infection;
- » Cardiovascular and hormonal stress responses to unanesthetized incision for organ retrieval;
- » Successful gestation of a fetus in a [brain dead] pregnant woman;
- » Sexual maturation of a [brain dead] child;
- » Proportional growth of a [brain dead] child.<sup>139</sup>

To maintain the functions described above in a human being with irreversible and complete failure of the brain, it is, indeed, necessary that the contribution of the brain to the maintenance of the organism as a whole, especially stimulation of breathing, is replaced by the apparatus of intensive care. On the other hand, the basic functionality of the body's own self-integrating cellular processes of organs and organ systems is, nonetheless,

<sup>139</sup> See Shewmon 2001, 467 f.

a necessary prerequisite for the efficacy of intensive-care measures. This can be made clear through the example of respiration: Ultimately, the respirator can insufflate the lungs with a certain pressure of oxygen-rich air purely mechanically and, thus, can replace the performance of the respiratory musculature, which otherwise provides for the influx of air by generating negative pressure. This would remain without effect, however, if the oxygen was not transported further by blood cells to the tissues throughout the body and if an absorption and further processing in the cells of the body (so-called 'cellular respiration') did not take place. Both latter processes are fundamentally important for all the organism's vital processes; they are not, however, driven by the brain and not replaced by a respirator. This is also the case for alimentation: a feeding tube or parenteral feeding only provides for nutrients being available, respectively, in the intestine or blood. All further processes of consumption of the nutritional components; of transport into the cells; or utilization for the building of cell substance and energy metabolism - are central processes of a living organism, which proceed without external cause.<sup>140</sup>

This holds true in particular for the simultaneous presence of pregnancy and brain death. For the foetus's growth, the pregnant woman's brain – with its functions – is not of essential significance. While it is correct that a pregnancy can only be maintained through external medical interventions, at least in uncomplicated cases it fully suffices to provide for respiration and alimentation, the basal prerequisites for any form of cellular function. The growth of the foetus, however, is the outcome of the unity of the pregnant female organism with the organism of the unborn child. Their respective functions are reliant on a complex interplay of reciprocal regulation, for instance, in the immune and hormone systems. The essential

<sup>140</sup> See also Wikler 1993, 241.

prerequisite for this is the capacity of the respirated maternal organism for integrating self-regulation.  $\ensuremath{^{141}}$ 

The significance of these findings can be appreciated in the 2008 President's Council on Bioethics devoting a separate opinion to Shewmon's assertions and the attempt at their rebuttal. The President's Council, which does in the majority hold the concept of brain death to be valid - albeit now with different reasoning than before (see further in section 4.2.2.2 below) - reduces the findings to a simple denominator: "These mechanisms account for the continued health of vital organs in the bodies of patients diagnosed with total brain failure and go a long way toward explaining the lengthy survival of such patients in rare cases. In such cases, globally coordinated work continues to be performed by multiple systems, all directed toward the sustained functioning of the body as a whole. If being alive as a biological organism requires being a whole that is more than the mere sum of its parts, then it would be difficult to deny that the body of a patient with total brain failure can still be alive, at least in some cases".142

This ought to be emphatically affirmed. It shows that not *one* functional circuit or *one* organ is exceptional for the maintenance of the functional unity of the complex organism. Indeed, the brain is accorded an outstanding importance for the expression of personality and consciousness – this is also beyond dispute for critics of the criterion of brain death; but this itself does not account for the integration of the organism as a whole.

### 4.2.2.2 On the sustainability of the criterion of self-regulation

In its endeavour at a statement of grounds, the President's Council on Bioethics names three conditions that must be

<sup>141</sup> Cf. the contributions in Bockenheimer-Lucius/Seidler 1993; Glover 1993; Wiesemann 1994.

<sup>142</sup> President's Council on Bioethics 2008, 57.

cumulatively fulfilled in order for one to be able to speak of the death of a human being:

- 1. no signs of consciousness,
- 2. absence of spontaneous breathing and
- 3. irreversibility of these findings.

These criteria are verified through brain death diagnostics.<sup>143</sup> While the condition of irreversibility is undisputed, the first can only be agreed to if and when, as the President's Council also does, de facto every form of capacity for perception, feeling, thinking and decision-making is tied to the concept of consciousness (on "mental death" in this sense, see section 4.1.1). Requiring closer observation at this point, however, is the second condition, the absence of spontaneous breathing with which the White Paper conceives anew the "classic" organismic justification. According to this view, spontaneous breathing would be an indispensable function of higher animals that enables metabolism and all other vital functions in the first place. Spontaneous breathing shows, first of all, the receptivity of an organism to the world and at the same time, second, its ability to influence it. Finally, the third fundamental ability that distinguishes a living organism from a dead body also becomes evident in this process, namely, the internal experience of a need.144

For this definition of death, it is thus of central significance to distinguish between spontaneous breathing as a natural activity, on the one hand, and artificial, non-spontaneous respiration, on the other. One could speak of the latter with a view to the passive state of being ventilated whereby one's own breathing is replaced by a respirator.<sup>145</sup> The natural activity of breathing would be a sure sign that the organism is executing

<sup>143</sup> Ibid., 64.

<sup>144</sup> Ibid., 61 f.

<sup>145</sup> Ibid., 63.

and maintaining its activity as a whole. During machine-based respiration, on the other hand, the organism would not be animated by a felt need; the exchange of gases effected in the process would neither be an accomplishment of the organism, nor a sign of genuine aliveness. From this perspective, the usage of the respirator obscures the fact that death has already occurred: simulated breathing, enabled by the respirator, is not conceived as a sign of life.<sup>146</sup>

In this categorical distinction between active intrinsic activity and artificially effectuated maintenance of vital functions, the argumentation of the President's Council on Bioethics coincides with the majority opinion of the German Ethics Council (position A). Position A also relies decisively on the idea that in those who are brain dead, "vital functions that have failed [...] such as respiration or blood circulation, are maintained or replaced through artificial means". The integration of the human body into a functioning unity would, in this case, no longer be an intrinsic performance of this body. Those who are brain dead could, thus, no longer exhibit "self-regulation of breathing". One could only ascribe aliveness to an organism "that of its own active performance can produce and ensure the central integration of all body functions into an organismic unity". Even if position A does not exclusively raise the role of respiration, nonetheless, it refers, in accord with the White Paper, to a self-initiated behaviour and to the process of selfintegration as an active intrinsic performance.

With the argumentative recourse specifically to the loss of spontaneous breathing, which in combination with the irreversible failure of the entire brain is conceived as a sufficient condition for the expiry of the organism as a whole, the proponents of the concept of brain death make reference precisely to that empirical finding that brain death diagnostics delivers.

<sup>146</sup> Ibid.: "The natural work of breathing, even apart from consciousness or selfawareness, is itself a sure sign that the organism as a whole is doing the work that constitutes – and preserves – it as a whole. In contrast, artificial, non-spontaneous breathing produced by a machine is not such a sign."

This does not, however, replace the normative justification for the selection of this criterion. Spontaneous breathing is (only) one accomplishment of the organism that is necessary for life, like others as well, such as the impulse communicated by the cardiac sinus node (Nodus sinuatrialis) for spontaneous beating of the heart. From a systems biology perspective, no hierarchy of importance between different life-essential performances of the organism can be established. In contrast, only the question of whether the respective function may or may not be substituted mechanically is decisive. To that extent, there is no difference between the functional replacement of, on the one hand, an irreversibly sick sinus node by a heart pacemaker and, on the other, the replacement of the "breath pacemaker" in the brain's Medulla oblongata by artificial respiration. Why - one should therefore ask - should the artificially compensated loss of the heartbeat be less significant for the question of the vitality of an organism than the artificially compensated loss of breathing? Why should an irreversibly comatose (although not "brain dead"), yet spontaneously breathing patient with an artificial heart pacemaker be alive; while an equally irreversibly comatose and simultaneously respiration-dependent ("brain dead") patient with an independently beating heart, on the contrary, be dead? At any rate, no sufficient answer can be given with the simple suggestion of an exceptional relevance or centrality of cerebral functions.

In contrast, the following should be emphasized: The neuronal impetus for the breathing function is only *one* organismic function among many that are necessary in their totality for the physiological efficacy of the respiration process. Besides the neuronal impetus for the breathing musculature, the functions of the lung tissue, gas transport in the blood, and cellular respiration are of the same importance. In all these cases we are dealing with active, self-regulated processes in the cells and tissues. Only because a large part of this organismic activity – even in the case of brain death – is still able to function, can the whole process of breathing be maintained through an

artificial replacement of the neuronal respiratory drive via mechanical ventilation.

The concept of self-regulation should, therefore, not be reserved only for neuronal activity. Rather, self-regulation and self-integration of cell and tissue activity occur in the organism in a multifarious manner, not only through the work of nerves, but equally across humoral factors, gas pressure in the blood or cell tissue, or the number of receptors in the cell wall.

Moreover, there is no justification why the loss of individual forms of self-regulation, which are replaceable, should obtain such categorical significance for the differentiation of life and death. The distinction between active self-regulation as an intrinsic ability of the organism and as a persisting external substitution of vital functions is not convincing. To be questioned, especially, is why an apparatus-based replacement of neuronal control of the respiratory drive in intensive-care medicine should be relevant precisely for the differentiation between life and death when it supports the organism of a patient with irreversible brain failure; but not when – in part with even more comprehensive measures - other seriously ill patients are kept alive. In the event that a human being disposes of mental faculties, the criterion of external causation would on no account - including that of the proponents of position A – be grounds for designating that human being as dead.

The majority of the authors of the White Paper assign a further meaning to the loss of the brain's self-regulated activity, which is important for their thesis. In their view, the brain is of all organs the one which is indispensably responsible for the organism's exchange with the environment.<sup>147</sup> If interaction with the environment is no longer possible through one's own activity, a fundamental function of human life would thereby be extinguished. This is based, however, on a foreshortened perspective of what can be understood as interaction with the environment. Any reaction of the organism to external

<sup>147</sup> Ibid., 61 f.

influence must count as an interaction to the extent that it is not only elicited purely passively and mechanically (such as the indentation in the skin caused by finger pressure), but consists rather in independent activity typical for the organism. Such interaction, which accordingly depends on a response characterized by the organism's own activity, is doubtlessly also possible in those who are brain dead. Thus, a brain-dead patient interacts with externally-delivered infectious pathogens in that the immune system actively responds to them through complex processes, for example, in fighting against a wound infection by means of immune cells. For this, numerous active immune processes are needed: the multiplication of immune cells; their targeted migration to the site of infection; and the production of antibodies against the infection. Analogously, the intestine, liver and metabolism react to food coming from outside by disposing, transporting and further processing the dietary components, etc. By no means can all these processes, highly complex and tailored to the prevailing situational needs of the organism, be accomplished purely mechanically from outside.

There are, thus, no identifiable criteria according to which characteristic processes of integration could be described, to which a fundamental significance would then be ascribed for the distinction between active intrinsic performance (in which case, living) and external causation (in which case, dead) (see section 4.2.1). This is relevant neither for the "inner" organismic unity nor for the interaction with the environment. All in all, it is manifest that the correlation of irreversible, total brain failure with the irreversible loss of active self-regulation, particularly through the faculty of spontaneous breathing, is an inadequate argumentative approach. It justifies the concept of brain death by recourse to exactly those two criteria that characterize the condition of "brain death." As criteria for the irreversible break-down of the organism as a whole, they are not suitable. "Mental death" is not constitutive for the function of the organism as a whole, and spontaneous respiration can be replaced through the devices of intensive-care medicine.

Consequently, on evaluation of the decades-long discussion, a minority of the German Ethics Council is of the conviction that the rationale for the concept of brain death is not sustainable. This point of view has, meanwhile, found support not only in ethical<sup>148</sup> and societal debates.<sup>149</sup> It is of particular significance that a considerable portion of German constitutional doctrine has taken a critically oppositional stance.<sup>150</sup>

# 4.3 On the significance of the dead-donor rule

The discussion around the concept of brain death is immediately connected to the question of whether vital organs may be removed only from the dead; that is, whether the socalled dead-donor rule must have a claim to validity. This is

<sup>148</sup> Recently for example Birnbacher 2012; Stoecker 2010; Dabrock 2011; Denkhaus/Dabrock 2012; Wiesemann 2012. Seminal for the German discussion, Hoff/Schmitten 1995.

<sup>149</sup> See, for instance, Evangelische Landeskirche in Baden 2014, 11 f.; Evangelische Frauen in Deutschland 2013; Evangelisch-Lutherische Kirche in Bayern 2014, 32 ff.; Evangelische Kirche im Rheinland 2013. Independent from the soundness of the respectively documented positions, the following fora and blogs impart an impression of the breadth of the discussion surrounding brain death: http://hintoddebatte.wordpress.com [2015-01-15]; http://www.gesundheit-aktiv.de/misch-dich-ein/organspende-wir-wollen-alles-wissen.html [2015-01-15]; http://www.organspende-aufklaerung.de [2015-01-15]; [2015-01-15]; http://www.transplantation-information.de [2015-01-15].

<sup>150</sup> In the legal commentaries on the Basic Law, in the meantime, there is a preponderance of critics of the concept of brain death. To be mentioned as critically oppositional commentaries: Herdegen, in: Maunz/Dürig 2014, section 1, para. 56 (status as of February 2005); Hillgruber, in Epping/Hillgruber 2014, section 2, no. 5.1 and 17; Höfling, in: Friauf/Höfling 2014, section 2 (2) para. 65 ff. (status as of November 2012); Jarass, in: Jarass/Pieroth 2014, section 2, para. 81 (albeit different in the previous edition); Lang, in: Epping/Hillgruber 2014, section 2, para. 81 (albeit different in the previous edition); Lang, in: Epping/Hillgruber 2014, section 2, para. 60 f; Murswiek, in: Sachs 2014, section 2, para. 55. Without any claim to exhaustiveness, the following might be mentioned as additional scholars of constitutional-law who reject the concept of brain death: Fink in: Merten/Papier 2011, section 88, para 31 f; Rixen 1999; Sachs, in: Stern/Sachs/Dietlein 2006, 147 f; Schmidt-Jortzig 1999.

contested not only in Germany, where the dead-donor rule is anchored in the Transplantation Act, but also internationally. Even critics of the concept of brain death hold the transplantation of a vital organ to be ethically admissible under certain preconditions.<sup>151</sup>

## 4.3.1 Position B: Dispensability of the dead-donor rule

For a long time, the critique of the concept of brain death has been accompanied by a plea to abandon the dead-donor rule. One of the suggestions developed in this context is based on the assumption that it is not possible to attain the necessary philosophical certainty and definitude of the concept of brain death, which is the precondition for the applicability of the rule. Instead, ethically adequate modes of dealing should be developed respectively for discrete states of transition from life to death.<sup>152</sup> Organ transplantations could be evaluated as a special form of "allowing to die."<sup>153</sup> Such reasoning is embedded in a larger context of medico-ethical discourse, in which autonomous decisions by patients concerning life and death are ascribed a central significance.

Also the minority of members of the German Ethics Council who reject the concept of brain death doubt the strict claim

<sup>151</sup> The attribution of the members of the German Ethics Council to the subsequently outlined positions A and B is documented in the appendix to the recommendations in chapter 6.

<sup>152</sup> Dieter Birnbacher thus argues, for example, for giving up the dead-donor rule (Birnbacher 2007, 475). In doing so, he bases himself on the turn of phrase shaped by the philosopher Winston Chiong of death as a cluster concept or, respectively, as a "fuzzy concept." Death as a cluster concept is marked by a varying number of features and contextual requirements; not all features must accrue in each situation in order for one to infer the occurrence of death. Birnbacher holds the criterion of brain death to be unsuitable as a criterion for organismic death. Nevertheless, the criterion of brain death offers a high measure of certainty that the "irreversible loss of conscious life" has occurred.

<sup>153</sup> Truog 1997.

to validity of the dead-donor rule. This minority holds the removal of vital organs from people with irreversible total brain failure to be legitimate ethically and constitutionally under certain preconditions. For the representatives of this position, too, brain death forms an important normative caesura (see section 4.1.3). At the latest with the diagnosis of brain death, the duty (and right) of the doctor to take up therapeutically oriented measures is cancelled. Instead, the will of the patient concerned acquires a decisive significance. That patient's decision to end his or her life, not only through concluding lifepreserving measures, but with an act of organ donation, can and should be respected.

Against giving up the dead-donor rule, diverse objections are raised. The most important one consists in the charge that the prohibition of killing is thereby relativized. This would at the same time undermine the moral legitimation of transplantation medicine. The proponents of the minority position hold this critique to be unconvincing.

Critics of the concept of brain death ascribe to brain death the function of bringing about a moral change in status insofar as the moment of its diagnosis describes simultaneously the caesura that allows for organ removal. Although the presence or irreversible loss of the brain's mental functions do not constitute the basis for one's status as living or dead, they do, however, have a quite essential significance for the justification of life-preserving measures and, hence, for the legitimation of medical interventions into the physical integrity. The assessment that a human being whose mental functions have completely and irreversibly expired can be recognized as still being someone living (because he or she fulfils the primary biological criterion of the intact organism as a whole), albeit arrested in a terminal stage of dying, can readily be reconciled with the judgment that a prolongation of this life by medical means cannot as a rule be ethically justified (an exception could be an intact pregnancy) and that discontinuation of life-preserving measures is hence called for. This corresponds, incidentally, to

a recognized practice of ending treatment when a therapeutic indication does not (any longer) exist. In such a case, there is, as well, no longer any constitutional claim of the individual to further treatment.

Coupled with the diagnosis of complete and irreversible brain failure is the finding that the person in question no longer has any faculty of perception and sensation at his or her disposal. Irrespective of how one might like to define the concept of a subjective quality of life, it will always presume the possibility of a minimal capacity for experience, in whatever form. Such experiencing is, for example, possible in the persistent vegetative state – not, however, in a state properly diagnosed as brain death. Here and in numerous other constellations of intensivecare medicine, the decision regarding discontinuation of treatment must be understood as evaluative. Yet, the diagnosis of "brain death" describes a situation in which there is a far-reaching consensus that further treatment of the concerned human being is no longer meaningfully in his or her interest.

In this situation, it appears inappropriate to call organ removal, performed on the basis of an informed consent, a killing in the sense of a condemnable injury to integrity. Rather, what is at issue here – not least when viewed from a constitutionalrights perspective - is the recognition of the individual's right to self-determination regarding the integrity of one's own body and mind. With the removal of vital organs from a patient with irreversible total brain failure, a high-level purpose, also recognized as such by his or her readiness for organ donation, is pursued (respectively, saving a life or reduction of suffering), for whose realization the physician does, indeed, intervene in the ultimate phase of dying, albeit many hours after that point in time at which the process of dying, without readiness for organ donation, would in any case already have been concluded in the absence of the physician's right to act. A construction of this sort and the giving up of the dead-donor rule connected to this, therefore, in no way encounter profound ethical and constitutional misgivings.

This is valid, at any rate, when taking as a basis a consent solution, which requires explicit or presumed consent; to that extent, however, an independent right of decision for a third party does not come into question.<sup>154</sup> A different case holds for the relationship between parents and children, for which Article 6 (2) of the Grundgesetz (Basic Law, GG) creates a special basis for legitimation. In the special case of brain death, the parental rights guaranteed in that article can encompass decisions regarding the arrangement of their child's process of dying.<sup>155</sup> Article 2 (2) No. 1 GG enables the donation of vital organs through advance directives as an expression of self-determination over one's physical integrity. Through the decision for organ donation, considerations about a duty to protect do not stand in opposition, precisely because the omission of lifepreserving measures is bidden in the last phase of the dying process following irreversible total brain failure. Neither - and all the less – can an objection against the concept sketched here be deduced from the guaranty of human dignity in Article 1 (1) GG. When a self-determined and voluntary decision is permitted not to end one's life through the simple discontinuation of intensive-care treatment, but rather to do so through organ removal - following application of organ-protective measures in the case of diagnosis of brain death, the donor's quality as a subject, protected by Article 1 GG, is not put into question. The normative acceptance of such a decision to donate is, in fact, an expression of the recognition of an altruistic attitude in one's own living and dying.<sup>156</sup> However, this altruistic atti-

<sup>154</sup> On this in more detail, Höfling/Rixen 1996, 95 ff.; going further still, Sachs, in: Stern/Sachs/Dietlein 2006, 148 and 159; Sachs 2000, 67; see, moreover, Rixen 1999, 387.

<sup>155</sup> In depth, Höfling/Rixen 1996, 104 ff.; further, Gallwas et al. 1995, 519.

<sup>156</sup> Regarding the unsustainable argument of a violation of human dignity, see also Isensee, in: Merten/Papier 2011, section 87, para. 218: "Constitutionally, it is irrelevant for the admissibility of organ removal whether the right to life terminates with brain death [...] or with clinical (cardiac) death [...]. The will of the donor is respected either way because between both points in time, either posthumous personality rights enter in or the right to life remains in force. [...] In whichever way the scope of the right to life is defined, the dignity of the voluntary organ donor remains intact."

tude does not imply "to sacrifice one's own life in the interest of another."<sup>157</sup> Neither is it a matter of a ritual act of sacrifice, by means of which supernatural powers are to be influenced; nor does the organ donor abandon a life that would otherwise be possible to have, in favour of another person. Additionally, it is misleading to speak of an intervention exclusively for the benefit of others since at stake for the organ donor is precisely the realizing of a value, highly esteemed by him- or herself, through saving another life.

If and to the extent that a collision is seen between the proposed solution and the criminal offenses of Section 216 StGB, which in no way appears conclusive, this can be accounted for by explicitly excluding from its regulatory purview the constellation of organ donation in a diagnosed state of irreversible total brain failure.

Ultimately, the charge of killing (also) does not pertain if - as some proponents of position B see it - a kind of third stage between life and death, a dissociated life, can be assumed, at least upon the irreversible functional failure of the whole brain, i.e., upon dissociated brain death.<sup>158</sup> If one realizes that concepts such as life and death attain their plausibility above all in practical contexts and that they mark out for medicine and law, as little arbitrarily as possible, when medical action finds its limit objectively and someone no longer has to be treated as a living person, then one sees that the phenomenon of those who are brain dead can no longer be adequately understood through the traditional, assumed-to-be-identical, dichotomous distinctions of "living = not dead" and "dead = not living." According to its proponents, what speaks in favour of this interpretation phenomenologically is, on the one hand, that it is counter-intuitive to claim that the brain-dead patient in the intensive-care ward is dead. Physical homeostasis is still

<sup>157</sup> See Section 4.3.2 (3) No. 10.

<sup>158</sup> On this third status, cf. Wiesemann 1995; Dabrock 2011; Denkhaus/Dabrock 2012.

ensured, supported by intensive care. The brain-dead individual does not appear to be a corpse. Correspondingly, the individual is also perceived and treated as having dignity by most next-of-kin and personnel. On the other hand, one who is brain dead can also not be understood as a living human being in the customary sense. The individual has irreversibly lost sensation and even the most basal faculties of communication and capacity for pain. Any return to a personal life is ruled out. It is clear that those who are brain dead find themselves irremediably in the final, sensory- and consciousness-free phase of the process of dying, which is hence justifiably differentiated from other irreversible final phases of dying (for example, in falling from a great height onto a hard surface). At best, one could say of such a third stage, brought about only by modern intensive-care medicine, that people in this condition find themselves in a state of the most minimal vitality.<sup>159</sup>

Whether one can now argue that a human being in such a stage of most minimal vitality cannot be killed, depends upon whether one can agree to the following sentence: "Whoever is no longer living cannot be killed." If one argues, by contrast, that whoever is not dead can still be killed, one cannot agree to the formulation that one who is brain dead can no longer be killed. One should not reproach those, who suggest this third status, for this non-identity of the two formulations and their gravely different normative – above all for criminal law – consequences.<sup>160</sup> Rather, one must admit, according to those proponents of position B who speak of the third status,

<sup>159</sup> This formulation is chosen because "dead" and "living" are non-gradable concepts and hence can be used in the sense of an exhaustive pair of opposites. The concept of "vitality" adjacent to the concept of "living" is, however, amenable to grading and can thereby break up the linguistic dichotomization and come closer to the phenomenon "created" through intensive-care medicine (cf. Denkhaus/Dabrock 2012, 143).

<sup>160</sup> According to the first formulation, terminating the stage of most minimal vitality of a brain-dead person is not a killing; not even in the presence of a statement of consent to organ donation is it a killing by request. According to the second formulation, a killing must be spoken of; whether it can be characterized in turn – according to the above phenomenology – to also fall under criminal statutes as a "killing by request" is not agreed upon.

that this ambivalence has appeared as an effect of the possibilities of transplantation medicine, otherwise esteemed by so many. Whether one now follows the first or second descriptive alternative cannot be decided conclusively. However, that the ending of a stage of most minimal vitality differs significantly from the killing of all other forms of human life (also from that of human beings in deep coma and from those in the stage of severest dementia) cannot be doubted according to this view.

Apart from that, it should be considered that in a practical perspective outside of Germany, as well as in the Eurotransplant region, the significance of the dead-donor rule has already been relativized for many years through the widespread practice in transplantation medicine of non-heart-beating donation (NHBD). If, as in some centres of the USA, organs are removed 120 seconds after monitored cardiac arrest, then this can scarcely be reconciled with a dead-donor rule understood to depend on *de facto* irreversibility. This shows, at least for those who hold a NHBD to be tenable, that the grounding moral function of the dead-donor rule is possibly overestimated. A recent American study suggests this. In it, 71% of those surveyed (n = 1096) spoke in favour of being allowed to donate their organs in the state of "irreversible coma." And 76% of those who consented to a post-mortem organ donation, would also donate their organs in such a scenario when the organ removal leads to death.<sup>161</sup>

#### 4.3.2 Position A: Necessity of the dead-donor rule

From the perspective of the majority of the members of the German Ethics Council, the suggestion to oppose the concept of brain death, yet on pragmatic grounds to ascribe to brain death the function of being a criterion for removal, thus a permission to remove organs, such as the heart, lungs or entire

<sup>161</sup> See Nair-Collins/Green/Sutin 2014.

liver, from the person viewed then as still living, must be rejected both ethically and constitutionally. The same is true for the view, whereby brain death is simply assigned the function of effecting a moral change of status only insofar as the point of its diagnosis denotes at the same time the caesura that allows for an organ removal with consent of the concerned person. Life stands morally and legally under the special protection of the prohibition against killing. This is true for the entire duration of life, without gradations until its end, independent from the expected duration of the individual human life. The Federal Constitutional Court expressly confirmed this in its judgment regarding the *Luftsicherheitsgesetz* (Aviation Security Act).<sup>162</sup> Therefore, the opposing view cannot be constitutionally convincing.

Even if one designates the phase between the occurrence of brain death and the expiration of the entire organ functions to be a "third status" between life and death, one must decide, according to the majority position of the German Ethics Council, whether one associates this third status with life or death; thus, whether one wishes to view it as "dissociated death" or "dissociated life."

If one assumes, according to the critique of the concept of brain death set forth in section 4.2.2, that due to the interaction of various organs, adequate integrative functions are still present to permit designating this organism as a living human being, then the life so described must, nonetheless, end if those organs enabling integration are removed. To still designate a body as "living," whose heart, lungs, kidneys, liver and other organs have been removed, is also scarcely imaginable under the assumptions of that view, which holds the dead-donor rule to be dispensable. But then, the action that effects the transition from one state into another must be considered as killing. Additionally, this cannot be justified through the suggestion that a prolongation of life ostensibly precedes organ removal,

<sup>162</sup> BVerfG, 1 BvR 357/05, para. 119 = BVerfGE 115, 118 (152).

whilst certain organ activities are being maintained on organprotective grounds by means of intensive care. Of internal necessity, the "prolongation of life" changes suddenly into the foreshortening of life when vital organs are removed. A killing remains a killing even if the entry of death was hitherto delayed. A living person, and equally one who is dying, may not be killed under any circumstances for reasons benefitting others. This contradicts the constitutionally commanded protection of life and infringes on the human dignity protected by Article 1 (1) GG, which is untouchable. Neither the morally estimable motive of saving the life of others, nor a potential donor's consent alter anything in that regard. A readiness to sacrifice one's own life in the interest of another "would contradict the effects of objective guarantees of basic rights in their current dominant interpretation by the Federal Constitutional Court and through the opinion prevailing among constitutional experts."<sup>163</sup> "Targeted interventions into the life of a human being, which do not exist in context with the discontinuation of a medical treatment, are not open to justification through consent."164 Section 216 StGB rightly makes this punishable. It is not by chance that a large portion of German constitutional doctrine follows the concept of brain death as the basis of the dead-donor rule.165

The view – that while the brain dead would be living persons, their vital organs would still come into consideration to the extent that they were donors – appears, moreover, to fail to recognize the significance and scope of relinquishing the dead-donor rule. This relinquishing must be legitimated not only in regard to the physical condition of the individual

<sup>163</sup> Anderheiden 2012, 196 f.

<sup>164</sup> BGH, 2 StR 454/09, guiding principle 3 = BGHSt 55, 191 (191).

<sup>165</sup> Schulze-Fielitz, in: Dreier 2012, section 2 (2) para. 30 f.; Münch/Kunig 2012, section 2, para. 49; Müller-Terpitz, in: Isensee/Kirchhof 2009, section 147, para. 32, 103; Starck, in: Mangoldt/Klein/Starck 2010, section 2 (2) para. 192; Sodan, in: Sodan 2011, section 2, para. 20; Di Fabio, in: Maunz-Dürig 2014, section 2 (2) para. 21 ff. (status as of May 2009); Lorenz, in: Dolzer et al. 2014, section 2, para. 442 ff. (status as of July 2012); unclearly, Jarass/Pieroth 2014, section 2, para. 81.

brain-dead donor, but also and above all as a conscious disregard for a basic social norm: the norm that no one may be killed exclusively for the benefit of a third person, even if the donor has previously given consent to this. In the process, the tacitly taken for granted assumption - that the brain-dead donor, due to his or her complete mental death, could no longer be harmed through organ removal - is absolutely correct.<sup>166</sup> The claim to validity of the social norm, according to which killings founded purely on the benefit of others cannot be justified, can, however, very well be harmed even when the person killed has previously given consent.<sup>167</sup> Even if, according to the view of position B, the special situation of the (still living) brain-dead human being may justify his or her organs being removed for the purpose of preserving the life of another (and with the previously stated consent of the first), this can under no circumstances justify the disregard of the stated basic norm. Formulated differently: Whoever holds that it is permitted to remove vital organs from the brain dead, has good reasons for holding at the same time that it is permitted to declare them to be dead. For, with respect to that basic norm, one can in no way hold upon acceptable grounds that it is permitted to kill such individuals through this organ removal.

The dead-donor rule also underlies the Transplantation Act. An organ donation is only allowed if death has been previously certified according to the rules corresponding to the current state of knowledge of medical science. In doing so, the law leaves room for subjective ethical considerations according

<sup>166</sup> In this, proponents of brain death see precisely the decision's authoritative moral legitimation for defining the criterion of complete expiration of all functions of the brain as the central integrative competence of the organism as a whole, as well as for the organismic part of the concept of death, even though internal biological vital processes can still take place in this organism's individual subsystems.

<sup>167</sup> While killings in self-defence are motivated by others' benefit, too, namely from the thought of protecting the one attacked, they do not, however, draw their legitimation from this benefit of the other, but rather exclusively from the responsibility of the attacker, who must, precisely therefore, bear the necessary burden of the defence of his or her unlawful attack.

to which those who are brain dead may still not be dead. Yet, whoever is dead according to a generally valid norm may be treated as a dead person, even when previously the individual has personally assessed his or her current condition otherwise, namely as that of a still living person. Such persons, too, can make a statement for organ donation and thereby donate their organs posthumously, if the objective criteria of the Transplantation Act are fulfilled. And not least, any person can exclude being an organ donor after brain death, without having to substantiate this, through a statement to that effect given during one's lifetime.

The dead-donor rule, as a decisive prerequisite for organ removal, is, moreover, an essential foundation of the professional ethos in medicine. An organ removal leading to death in a living human being, even if this is a dying individual, would not be reconcilable with this ethos. Should the deaddonor rule as prerequisite for organ donation be abandoned and the brain dead qualify as living, physicians would be hindered from removing organs according to their professional self-understanding. Since an organ donation is inconceivable without medical cooperation, transplantation medicine, with the exception of living donations (Section 8 TPG), would come to an end. These grave consequences by themselves would still not be an argument to declare those who are brain dead to be dead. Rather, the anthropological, ethical and legal legitimacy of the concept of brain death must be reasoned on its own terms. This reasoning was comprehensively laid out above in section 4.2.1.

Conversely, in consideration of the significant consequences for the life and health of many people in need of an organ donation, it is necessary that those who reject the dead-donor rule or hold it to be dispensable ethically tackle the real ramifications of their position for transplantation medicine.

Should those who are brain dead not be assessed as dead, but as living or as human beings finding themselves in an intermediate state between life and death, then the prerequisites for an organ donation would urgently have to be regulated differently, even if in all cases brain death ought to be the necessary minimal condition for an organ removal. First of all, it is of significance here that constitutionally there are only the living and the dead<sup>168</sup> and that no intermediate "third" status exists – a view that the majority of position B supports as well. Since the constitution requires an explicit and generally valid demarcation between life and death, there cannot be, viewed constitutionally, an in-between-stage between life and death. Consequently, it is legally imperative to consider those who are brain dead as living human beings, if a status between life and death is assigned to them. The legislature is bound by this precept of constitutional law. Against this backdrop, the Transplantation Act forbids the removal of vital organs, such as the heart and lungs, if the death of the concerned individual has not previously been certified.

For the removal of such organs, the Transplantation Act contains regulations that are materially distinct from those for living organ donation. The organ donation of a deceased donor (in the sense of the Transplantation Act) is even admissible if there is no consenting statement given during his or her lifetime, provided that the next-of-kin or the representative appointed by the potential donor do consent. The right of the next-of-kin to consent or refuse follows from their right to custody of the dead, which only arises with death. As well, assent to organ donation for a deceased child, who could not provide a statement for organ donation during life, is admissible only in the context of the custody of the dead.<sup>169</sup> To date,

<sup>168</sup> Lorenz, in: Dolzer et al. 2014, section 2 (2) No. 1, para. 442 (status as of June 2012); Schulze-Fielitz, in: Dreier 2012, section 2 (2) para. 30; Höfling, in: Friauf/Höfling 2014, section 2 (2) para. 23 (status as of November 2012).

<sup>169</sup> According to transplantation law currently in force, an organ donor statement for a post-mortem organ donation – thus, a statement issued during one's lifetime – can only be given personally; a proxy is not possible. Minors can file a statement for a post-mortem organ donation from sixteen years of age and an opposition to such from fourteen years of age (Section 2 (2) No. 3 TPG).

most organ donations take place on the basis of the consent of the next-of-kin.  $^{\prime\prime\circ}$ 

This possibility of consent through next-of-kin does not exist if one looks at the brain dead as living. An organ removal with lethal consequence could at most occur in those cases where the potential organ donor has made an advance directive in a self-determined and binding manner whereupon an organ donation is allowed to take place in the event of a diagnosis of brain death.<sup>171</sup> For this, a presumed will that can be communicated and certified only by a third party is not sufficient. Additionally, it is legally questionable whether in general a removal of organs leading to the death of a (still) living human being can be effectively consented to. If one assumes that consent during one's lifetime to an action leading to one's death, as represented by the removal of a vital organ, is not admissible,172 then organ donations - with the exception of living donations pursuant to Sections 8 ff. TPG - would no longer be possible. A justification by comparison to advance decisions on refusal of treatment can already be excluded, because in the case of letting die due to refusal of treatment, so-called passive euthanasia, the patient dies of his or her ill-

<sup>170</sup> So, for example, between 8.5% (DSO-regions of Bavaria and Eastern Germany) and 17.9% (central region of Germany) took place on the basis of written consent of the organ donor personally; the figures for other regions lie in between (Deutsche Stiftung Organtransplantation 2014, 45 [Fig. 12]).

<sup>171</sup> Consequently, the position paper of the *Evangelische Frauen in Deutschland* (Protestant Women in Germany), which views the brain dead as living, prompts the legislature "to modify the transplantation legislation to the effect that the personal consent, stated in writing, of the donor (from 18 years of age) is a prerequisite to a legal organ removal following certified brain death" (Evangelische Frauen in Deutschland 2013, 27). With this, pediatric transplantation medicine among small children, who cannot yet receive an adult's organs, would be void.

<sup>172</sup> Di Fabio, in: Maunz-Dürig 2014, section 2 (2) para. 22 (status as of February 2004). The right to life in Article 2 (2) GG contains no right to ending one's own life by the hand of another, and this can also not be deduced from Article 2 (1) GG concerning free development of the personality. Cf. Kunig, in: Münch/Kunig 2012, section 2, para. 50; Di Fabio, in: Maunz-Dürig 2014, section 2 (2) para. 47 (status as of February 2004); Starck, in: Mangoldt/ Klein/Starck 2010, section 2 (2) para. 191; Jarass/Pieroth 2014, section 2, para. 61, 81.

ness and not through a third-party intervention (benefitting others). During the removal of vital organs, the action of the physician, in contrast, has the effect of directly precipitating death, while the discontinuation of life-preserving measures is only a necessary, but not sufficient condition for death. Nor can a parallel be drawn to so-called indirect euthanasia, since this serves the alleviation of suffering of the patient him- or herself; only in view of this goal is the possible shortening of his or her life accepted.

The consequences of turning away from the dead-donor rule would be still more problematic for transplantations in newborns and children, who are still too small to receive an adult's organs. For them, there would no longer be any organs available: an organ removal from children would no longer be possible, because they cannot grant valid consent. The parents also do not have the right - contrary to the view of position B to dispose of their child's basic right to life for the benefit of a third party.<sup>173</sup> Article 6 (2) GG protects the autonomy of the parents with regard to all measures of care and upbringing and protects, moreover, the assessment of what serves the child's welfare. This right is, however, at the same time subject to legal commitments or, respectively, restrictions, above all the commitment to the child's welfare. The welfare of the child is not only the (essential) ground, but at the same time the immanent boundary of parental rights.<sup>174</sup> Although the child's welfare may be an indefinite legal concept, which requires specification, decisions regarding the ending of the child's life, according to the dominant view, do not fall under Article 6 (2) GG's scope of protection.<sup>175</sup> The interpretive primacy of the parents does not extend to that part of the child's welfare whose content - as in the case of the basic right to life - is objectively

<sup>173</sup> On this, see also Evangelische Frauen in Deutschland 2013, 27 (footnote 85).

<sup>174</sup> Uhle, in: Epping/Hillgruber 2014, section 6, para. 55 (status as of 1 March 2014).

<sup>175</sup> Burgi, in: Merten/Papier 2011, section 109, para. 24.

determinable.<sup>176</sup> If one follows position B, according to which brain dead children are still alive, then the situation discussed here involves not only the decision regarding the "arrangement of their child's process of dying", as the obscuring formulation of position B suggests, but rather the consent to killing for the benefit of others.

Against this background, decisions by proxy and consent to therapeutic measures are only possible for parents if they possess a medical benefit for the child itself; measures benefitting others can at most be legitimated by parental right of decision if they contain merely a minimal risk or minimal burden for the child. This is, however, not the case during removal of organs.

A further grave consequence would result from abandoning the dead-donor rule: Regularly, only the question is debated and affirmed regarding whether waiving the dead-donor rule could be justified for brain-dead individuals willing to donate. However, those brain-dead patients are not considered who wish not only not to be organ donors, but in contrast have expressly requested - for example, by advance directive - continued intensive care treatment in the event of the occurrence of brain death. The information given by critics of brain death, always only with regard to organ donors - that the cessation of any life-preserving treatment would not only be allowed, but mandatory both legally and ethically - turns false here. If individuals who are brain dead are living human beings and hence have a basic right to life pursuant to Article 2 (2) GG, then the medically possible prolongation of their lives, which they request, must not be refused. No ethical and no legal argument - for instance, the common reference to the (then in fact only alleged) "meaninglessness" of such continued treatment – could be brought to bear against the basic right to life. A medical treatment is always as meaningful as the success

<sup>176</sup> Uhle, in: Epping/Hillgruber 2014, section 6, para. 57 (status as of 1 March 2014) – with reference to Sachs/Coelln, GG, section 6, para. 71.

achievable through it. If this success consists in a possible and wished-for prolongation of life, then the verdict of "meaning-lessness" is an open self-contradiction on the part of those who insist precisely on the premise of the continued existence of life. A basic right to life, set expressly into legal force, would not be worth anything if it did not stand its ground against the assertion of outsiders that the preservation of *such* life is "meaningless." And should one refuse to comply with it, then one confiscates the basic right itself.

As a consequence, a legal norm that viewed the brain dead as living would perforce imply the command that those patients, who have previously requested so, must receive continued life-preserving treatment. Should sufficiently many patients make use of the possibility of this continued treatment, this would pose scarcely solvable problems for intensive-care medicine, above all financially. The hope that something along these lines will not occur is hardly plausible.<sup>177</sup> Apart from that, it would yield a weak argument, namely just the hope that a claim afforded *de iure*, yet meaningless in fact, would not *de facto* be raised.<sup>178</sup>

# 4.4 Opinion regarding non-heart-beating donation

When organ removal is performed under the condition of irreversible brain failure while cardio-vascular function is maintained, donors are so-called heart-beating donors. In the initial period of modern transplantation medicine, in the 1950's and early 1960's, the situation was different. During all transplantations at that time, organs were removed following cardiac

<sup>177</sup> In the USA, despite the generally well-known circumstance that there, as here, those who are brain dead are legally classified as dead, cases have already become known of requests to continued treatment. See Merkel 1999, 120 (footnote 45 with further references).

<sup>178</sup> Cf. Merkel 1999, 119.

arrest.<sup>79</sup> For a number of years now, transplantation medicine in the USA and in many European countries – including those of the Eurotransplant region – is once again backing NHBD, along with organ removal following certification of irreversible brain failure (and living donation).<sup>180</sup>

As widespread as NHBD is, its manifestations are also quite diverse. In 1995, the First International Workshop on Non-Heart-Beating Donors adopted the so-called Maastricht Protocol with four classifications of different case-constellations.<sup>181</sup> Accordingly, four categories of organ removal are differentiated following cardiovascular arrest:

- >> Maastricht Category I: arrival in the hospital with cardiovascular arrest,
- >> Maastricht Category II: unsuccessful resuscitation,
- » Maastricht Category III: expected cardiovascular arrest following discontinuation of life-preserving measures,
- >> Maastricht Category IV: cardiovascular arrest in patients following diagnosed brain death.

For both Category II as well as for the especially relevant Category III (respectively, so-called controlled cardiac death or controlled donation after cardiac death), the Maastricht Protocol suggests a ten-minute no-touch phase, in the assumption that after this waiting period all brain functions are also irreversibly extinguished.<sup>182</sup> In this respect, however, no uniform international praxis has been able to prevail.<sup>183</sup> Two years

<sup>179</sup> On this, see, for example, DeVita/Snyder/Grenvik 1993, 113 ff.; Institute of Medicine 2000, 7 f.; cf. also Zawistowski/DeVita 2003, 189 ff.; Wiesemann 2000.

<sup>180</sup> See Institute of Medicine 2000, 14 f.; see further the overview in Norba 2009, 44 ff.

<sup>181</sup> See Kootstra/Daemen/Oomen 1995; see also Arnold/Youngner 1995.

<sup>182</sup> On the contentious debate at that time, see also Norba 2009, 49; Arnold/ Youngner 1995, 2913; Kootstra/Daemen/Oomen 1995.

<sup>183</sup> For example, Norba (2009, 49 f.) mentions the following waiting periods: for Great Britain, 5 minutes; for France, 10 minutes; for Spain, 5 minutes; for Italy, 20 minutes; and for the Czech Republic, an "experimentation range" of 5 to 10 minutes.

later on governmental commission, the USA-based Institute of Medicine also produced a study regarding NHBD. In this, the following procedural standards are recommended:

- 1. written, locally approved protocols;
- 2. public openness of protocols;
- 3. case by case decisions about the use of anticoagulants and vasodilators;
- 4. family consent for pre-mortem cannulation;
- 5. safeguards against conflict of interest between patient care and organ procurement;
- 6. determination of death by cessation of cardiopulmonary function for at least five minutes;
- the furthest possible fulfilment of the wishes of next-of-kin in regard to accompanying the dying process, as well as indemnity from liability risks.<sup>184</sup>

Currently, most removal protocols in the USA prescribe a waiting period from a mere two to five minutes.<sup>185</sup>

In Germany, the removal of organs from non-heart-beating donors is impermissible. The problem was already debated in 1996 during the consultations on the Transplantation Act. Section 5 (1) No. 2 TPG expresses the rejection of this category of donation. According to this, sufficient for the certification of death pursuant to Section 3 (1) No. 2 TPG is also "the examination and certification by a physician, if the conclusive, irremediable arrest of the heart and circulation has occurred and more than three hours have since passed." In a joint opinion from the German Medical Association and three professional societies, NHBD was again rejected in 1998 as irreconcilable with the Transplantation Act.

<sup>184</sup> Institute of Medicine 2000, 10.

<sup>185</sup> See President's Council on Bioethics 2008, 80; further, Truog/Miller 2014, 11.

A ten-minute - or even shorter - waiting period following cardiac arrest does not allow one (according to current findings) to confidently conclude the irreversible expiration of all brain functions, which represents, according to the majority view of the German Ethics Council, a necessary prerequisite for the occurrence of death.<sup>186</sup> Standardized brain-death diagnostics, as it is conducted in Germany (see section 2.2.2), promises an essentially greater certainty to the assertion that all forms of pain, sensation or perception have actually irreversibly expired in the potential donor. But even if valid findings exist about how long a waiting period following cardiac arrest is needed before one can confidently assume irreversible brain failure, further ethical objections arise in opposition to NHBD, in particular vis-à-vis the practice of controlled cardiac death. These objections derive from the fact that the handling of (seriously) ill patients is specifically oriented towards the act of organ removal.

In many cases, next-of-kin must be involved in the decision-making, and they are thereby brought into a particularly difficult situation. Next-of-kin can feel compelled to agree to a premature discontinuation of therapy.<sup>187</sup> Moreover, organ removal among non-heart-beating donors requires particular forms of organ-protective measures in order to minimize the danger of the impairment of organ quality that, nonetheless, occurs following cardiac arrest.<sup>188</sup> In distinction to organ removal following brain death, transplantation following cardiac arrest must be commenced very quickly. This represents a special burden not only for the nursing staff and transplantation team, but also above all for the next-of-kin. Often, no

<sup>186</sup> In contrast, the Swiss Academy of Medical Sciences assumes brain death to be certifiable, on the one hand, as "death due to primary brain damage" and, on the other, as "death after permanent cardiac arrest" following at least a ten-minute stand-off period without resuscitation measures (Schweizerische Akademie der Medizinischen Wissenschaften 2011, 5 ff.).

<sup>187</sup> See President's Council on Bioethics 2008, 82.

<sup>188</sup> See ibid., 82, where the question is raised "whether the steps necessary to optimize the circumstances of death for transplant purposes interfere with good palliative care for the patient in his or her last moments."

time remains for the appropriate psychological, emotional and spiritual accompaniment.<sup>189</sup>

A minority is, however, of the view that the Swiss system of NHBD represents a veritable complement to the brain death diagnostics standardized in Germany. In the reasoning behind their position, they see the Swiss model as procedurally, indeed, an instance of NHBD; but one diagnostically flanked or, respectively, finalized by brain death diagnostics.<sup>190</sup> The process itself would allow the "natural" process of death more room and offer the next-of-kin a more intensive possibility of accompanying this dying and, consequently, would not lead to burdens greater than those in the classic procedure of organ donation with standardized brain-death diagnostics.

Nevertheless, for a conclusive ethical evaluation, a differentiated examination of concrete models or practices of NHBD would be required.

<sup>189</sup> See also Sahm 2014, 333.

<sup>190</sup> Lenherr/Krones/Schwarz (2014, 118), hence, do not simply designate the Swiss model as NHBD, but rather as "donation [...] following brain death contingent on cardiovascular arrest"

# 5 COMMUNICATION: INFORMATION, EDUCATION AND COUNSELLING

In multiple ways, organ transplantation is dependent on comprehensive and transparent communication, both in the public sphere and in individual contact with potential donors, their next-of-kin or potential donors' legal representatives. This applies not only for the understanding of the concept of brain death, but also for deciding about organ transplantation on the whole. This realization also underlies the introduction of the new decision-solution and all the deliberations to improve communication with next-of-kin and within the clinic.

# 5.1 The objective of the new decision-solution

The Transplantation Act only permits removal of organs if the concerned individual, during his or her lifetime, or the nextof-kin, posthumously, have given consent (extended consent solution). The newly introduced decision-solution has not changed anything in this regard. Its goal consists in prompting more people to make a statement regarding organ donation. To attain this goal, all citizens have the possibility of informing themselves on a regular basis regarding the topic of organ and tissue donation and of making their own decision. In the process, however, no one can be obligated to make a statement.<sup>191</sup> Regarding the education of the population necessary for

<sup>191</sup> According to investigations by the Federal Centre for Health Education in 2010 and 2013, two target groups can be differentiated in the process: the group with high standard of knowledge, positive basic attitude to organ and tissue donation, but to date no statement regarding organ and tissue donation (this group has dramatically expanded in light of the so-called organ donation scandal) and the group with low standard of knowledge, negative basic attitude, and no statement regarding organ and tissue donation. Both groups require different strategies in terms of information and counselling. Cf. Bundeszentrale für gesundheitliche Aufklärung 2010; 2013.

informed and independent choice, the law states that the institutions responsible, especially the Federal Centre for Health Education and health insurers, should regularly provide information about:

- » the possibilities of organ and tissue donation;
- >> the prerequisites to organ and tissue removal in the case of dead donors;
- >> the significance of a statement regarding organ and tissue donation provided during one's lifetime, additionally with regard to the advance directive and the legal consequence of an omitted statement in view of the right of decision of the next-of-kin;
- >> and the significance of the grafting of organs and tissues in view of the possible benefits for people who are sick.

The law states that information must encompass the entire scope of the decision and be open in outcome. For questions about organ donation, as well as regarding the significance of a statement in favour of donation provided during one's lifetime, with respect additionally to an advance directive, the health insurers have to name professionally qualified contact partners for their insured, in addition to sending them written information on a regular basis. In this way, any interested insured person can be advised, as desired, by his or her health insurer regarding the scope of a post-mortem organ removal.

With this the Transplantation Act contains essential determinations regarding the content of the information; the principle of its open outcome; and the obligation to name counselling parties for the implementation of communication. However, it leaves broad latitude in arranging communication to the offices responsible.

## 5.2 The decision-solution as a public communication duty

In order to fulfil the objectives of the decision-solution, the communicative implementation of the information and counselling duties requires special heed. The German Ethics Council has, therefore, evaluated the first information campaign, conducted on the basis of the new legal provision, of the *Bundeszentrale für gesundheitliche Aufklärung* (Federal Centre for Health Education, BZgA), as well as of the public and private health insurers, which occurred predominantly in the period from January to May 2013.<sup>192</sup> In doing so, the following aspects were inspected closely: the method of sending and form of address; the thematic scope, especially the up-to-dateness and comprehensiveness of the information; the intensity of the thematic preparation; and, in the process, the consideration of concerns and critiques.

Since the German Ethics Council does not aim to undertake an evaluation of individual health insurers, prevailing differences are described without naming individual health insurers, in order to draw general conclusions for the design of the communication of public education.

The method of sending information materials can be differentiated according to whether this information was sent directly, namely in the form of a personal letter to the insured, or as general member information. The personalized letter with a personal form of address predominates, to which further materials in the form of a flyer or brochure, often with a special edition of the member newspaper, were added. In addition,

<sup>192</sup> In addition to the BZgA, the German Ethics Council requested materials from a selection of the largest German health insurers. Both the public health insurers selected on the basis of their size – AOK Plus, AOK Niedersachsen, AOK Nordost, AOK Nordwest, AOK Sachsen-Anhalt, AOK Bayern, AOK Hessen, Techniker Krankenkasse, Deutsche Angestellten-Krankenkasse, Siemens-Betriebskrankenkasse, Knappschaft and Barmer GEK – and the only private health insurer selected, the Debeka (which is also the largest private health insurer), provided access to all documents that were also sent to their insured members.

however, there is the form of a thematic member newsletter with a foreword, which leads into the topic in a general manner.

The health insurers whose materials were evaluated on the basis of this opinion complied (with one exception) with the legal requirement of supplying the insured the model of an organ donation card. In terms of the requirement to make personal counselling available, most of the health insurers indicated their existing customer advisory hotlines, as well as the various respective online-contact possibilities. Only a few have established their own telephone info-line; that is, specialized in the topic of organ and tissue donation. In the event of need for further counselling, some smaller insurers point to the telephone info-line of the BZgA, which the organisation established in collaboration with the *Deutsche Stiftung Organtransplantation* (German Organ Transplantation Foundation, DSO).

All the materials examined take up the legislature's predefined areas in which information is to be provided. Who can provide a statement regarding organ or tissue donation when, under what conditions, and with what scope (e.g., restriction to certain organs) is consistently represented in a manner that is factually correct and appropriate, following the information materials of the BZgA. The same is true for the information on the organisation and course of organ transplantation.

However, considerable differences appear with respect to the thematic scope, up-to-dateness, and comprehensiveness of the information provided. Thus, outdated figures regarding consent in the population, drawing upon the period before the exposure of irregularities in organ allocation, can be found in an array of documents. Only a few health insurers refer directly – for example, in the personal letter to their insured – to this current situation in transplantation medicine and, along with that, to the decline in the number of organ donation statements, which indicates a loss of trust in the population.

In the information materials of many health insurers, adequate information about the various ways of filling out the organ donor card is also lacking. While the possibility of restricting donation to certain organs was mainly explained in a detailed manner, the options of engaging a trustee or filing a refusal were frequently inadequately explained. Likewise, information is predominantly lacking on the legal position of the appointed trustee or on the legal situation and powers of the next-of-kin in the event that no statement on organ donation is available.

Brain death as prerequisite to organ removal is specified in all the materials screened. In doing so, in a predominant number of cases, what brain death entails medically is not only explained in a simple form, but also how it is certified. Only in one case was no explanation of the concept of brain death to be found at all. In a few cases, in contrast, the critical discussion surrounding brain death is also taken up, and the necessity of muscle relaxants during organ removal is explained, as well as the so-called Lazarus phenomenon.<sup>193</sup> However, the screening of the written materials revealed factual deficiencies as well. Thus, in the materials of one health insurer, for example, the question of whether the donor could feel pain was answered by saying that he or she felt no pain because relaxing and anaesthetising medications would be given following brain death.<sup>194</sup>

None of the documents contains references or statements regarding organ-protective measures. This also applies to the materials of the BZgA and the joint brochure of the BZgA and DSO on brain death, which served as the source to many of the

<sup>193</sup> To be understood here under the Lazarus phenomenon are apparent signs of life by the brain dead, such as arm or leg movements or brief raising of the torso, which either occur spontaneously or are triggered reflexively through touch.

<sup>194</sup> In contrast, it would be advisable if the health insurers answered this frequently asked question by pointing out correctly that according to all available findings, all pain sensations are extinguished with brain death and that muscle-relaxing medications are only given in the process of organ removal in order to facilitate the removal itself and, as applicable, to exclude involuntary muscle movements. Moreover, it could be mentioned that if a donor has stipulated pain medication prior to organ removal, for example out of concern for pain, then it is provided even without a medical indication (cf. section 2.2.5).

health insurers. Even in the extensive materials of some health insurers, in which the sequence of actions during organ donation is explicated, this topic is not mentioned.

In part, deficiencies can be found in terms of the question of the compatibility of the advance directive and organ donation statement. On this, a range of health insurers provide their insured members with detailed information and helpful text modules for the respective statements. Others, however, point out merely that the different declarations of intention should not contradict one another and refer to the website of the Federal Ministry of Justice and Consumer Protection.

The documents also differ in the extent to which reservations about organ donation are addressed. Many insurers restrict themselves to information that is predominantly factual, frequently in the form of "Important Questions and Answers," like those drafted by the BZgA. Some health insurers supplement such factual information with personal reports from organ donors' next-of-kin, organ recipients, and doctors or nursing personnel, so that various perspectives on this topic become clear.

The requirement for openness of outcome is implemented in only some materials and in different ways. In the case of one health insurer, for example, it says that the required openness of outcome also includes the right to decide against an organ donation. Another health insurer points out that they do not wish to have any influence on the direction of the decision. They merely state the importance that a decision be made at all, and that there is no generally right or wrong decision. Other health insurers speak of openness of outcome in the foreword to their information or in the personal letter; they do not, however, later take up the critical objections or reservations. Thus, in one case under the "contra" rubric, for example, an opponent of organ donation has a chance to speak, who says merely, however, that he knows too little about organ donation.

Grounds for refusal frequently brought forward, such as encroachment on the physical integrity or obstruction of the personal parting from the deceased following organ transplantation, are not adequately considered. In an array of information materials, it is, indeed, correctly said that the experience of a sensorially perceptible demise on the deathbed would not be possible for next-of-kin in the event of preparation for an organ donation, due to the maintenance of intensive-care measures. It remains unmentioned, however, that the body of the deceased must be handled with dignity after organ removal; that the corpse must be handed over for burial in a dignified state; and that the next-of-kin are to be given the opportunity to view the corpse beforehand. It would be in accordance with the demand for an open and transparent communication if such grounds for refusal were taken up seriously, but also to mention the possibilities existing in practice to refute these concerns.

If one evaluates the findings sketched above against the background of the requirements for a good arrangement of communication, the following conclusions can be drawn, which are oriented towards criteria such as personal address, comprehensiveness of the information, practical feasibility, respect of the communication partners and respect for the individual decision:

- The information regarding organ and tissue donation should be directed in its terms and form of address personally to the respective recipient. In addition to the positive motivation for pursuing the topic of organ donation, reservations and fears should be addressed, which stand in the way of confronting this question. In both respects, written information alone frequently does not suffice. Such being the case, possibilities of personal counselling by qualified personnel are to be indicated supplementary to this. Referral to the health insurer's general hotline is not adequate.
- >> To consider, as well, would be the health insurer's incorporating pieces of advice that members can address

themselves to their family doctor or another person in their trust (e.g., pastor) for a deeper discussion.

- » The information provided should be comprehensive in the sense that all important aspects are addressed. This comprises information regarding the course of the procedure, including organ-protective measures, and explanation of the possibility for a personal leave-taking following organ removal. Moreover, different points of view should be represented regarding the concept of brain death. Members should be informed as well about the different possibilities of filling out the organ donor card and for setting down individual wishes in writing.
- » Consequent to the demand for practical feasibility, information about the compatibility of advance directive and organ-donation declaration should comprise concrete assistance in the form of appropriate phrases.
- » Consideration of the information recipient and respect for that person's individual decision should be clearly addressed. The openness of outcome called for in information and counselling should be underscored through the factual and neutral representation of the issues, permitting an individual's own formation of judgment in any direction.

## 5.3 Communication with next-of-kin and legal representatives

During conversations with next-of-kin, the following caseconstellations can be distinguished:

- » A statement consenting to organ donation is available.
- » A statement consenting to the donation of only certain organs is available.
- » An opposition to organ donation is available.
- >> The organ donation statement is consigned to the charge of the trustee.

In *all constellations*, the delivery of the message of expected or certified brain death requires an empathetic support of the next-of-kin in processing this news. It must be fundamentally assumed that all the situations described here are coupled with heavy burdens for the next-of-kin. Therefore, certain qualitative standards in arranging communication should be heeded, including the comprehensibility of the information; moreover, care should be taken that these conversations are conducted in an appropriate place and over an adequate space of time.

Next-of-kin depict the situation, in which grief and shock coincide with the question of organ donation, as particularly burdensome. As a rule, they are confronted with this not only unexpectedly and unprepared; but even more so, questions about one's own life and its finiteness are touched upon. In the literature, massive emotional reactions, feelings of guilt and pronounced questions of "why" are described.<sup>195</sup> Frequently, if the next-of-kin has to decide about the organ donation because no clear statement by the possible donor for or against an organ donation exists, the inescapability of the situation is often felt in the process as an especially great psychological challenge. Concerned parties experience this situation as burdening as well because a non-answer would also be an answer, namely a "no" decision.<sup>196</sup>

An empathetic support and counselling cannot, indeed, take away the burden from the next-of-kin of coping with the news of a relative's death and having to decide nearly at the same time about an organ donation; nevertheless, to the extent that it is made clear that in the case of an independent right of

<sup>195</sup> Kirste/Muthny/Wilms 1988.

<sup>196</sup> Donauer 2012, 183; also in the Bioethics Forum of the German Ethics Council on the subject of "Duty to declare regarding organ donation. Should the state require that each person make a statement?" from 27 October 2010 (http://www.ethikrat.org/veranstaltungen/forum-bioethik/ aeusserungspflicht-zur-organspende [2015-01-27]).

decision of the next-of-kin or trustee, any decision is accepted, the pressure that the next-of-kin feel can be diminished.

The reform of Section 9b TPG establishes *inter alia* that the transplantation officer is responsible for communication with the next-of-kin; while it is not incumbent upon the officer to conduct the communication personally, this person must ensure that this communication is conducted properly. Concerning the arrangement of discussions with next-of-kin, the Transplantation Act contains only basic points and thereby leaves the specific arrangement to praxis. It is stipulated that when neither the possible organ donor's written consent nor opposition is available to the physician, the next-of-kin is to be consulted about whether he or she is aware of an organ donation statement. If no such statement is known to the next-ofkin, the organ donation is permissible if the physician informs the next-of-kin about the eligible organ donation and the nextof-kin consents to this. The physician must point out to the next-of-kin that the presumed will of the possible organ donor is to be heeded in making a decision. Physician and next-ofkin can also agree in writing that the next-of-kin's statement can be revoked within a certain period (Section 4 (1) TPG).

The content necessary to raise in discussion with next-ofkin follows from the given specific medical situation and the question of whether an organ donation statement is available, as well as potentially an advance directive. In addition, there should be information provided about the rights of the nextof-kin and trustees to inspect the documentation about the certification of brain death and the findings underlying this certification; about the course, content and outcome of the involvement of the next-of-kin and other persons; as well as about the sequence and scope of the organ donation (Sections 3 (3), 4 (4) and 5 (2) TPG).

But in all cases, it is recommended to give the next-of-kin comprehensive medical information. This also encompasses information about a short-term prolongation of life, as well as about organ-protective measures before and during the brain death diagnostics.<sup>197</sup> This is the case even when an organ donation statement is available, because it cannot be assumed "without further ado" that every organ donor in the Federal Republic of Germany, at least thus far, is comprehensively informed about how brain death diagnostics takes place and what medical measures are performed up until the organ removal.<sup>198</sup>

Against the background of these diverse questions, it is striking that only a few empirical studies exist concerning the efficacy of communicative factors during conversations with next-of-kin in the context of organ donation. This is true nationally, as well as internationally. There is a lack of systematic, empirical analyses both concerning the experiences of potential organ donors' next-of-kin with advisors and concerning the factors that have facilitated or hindered their decision.<sup>199</sup> Further lacking are studies about the experiences and problems of physicians conducting conversations.<sup>200</sup> However, obviously there are considerable differences between clinics in the practical conduct and design of discussions with nextof-kin.<sup>201</sup> It would be desirable, therefore, to have standards for the counselling and support of next-of-kin, in order to improve their situation before as well as after organ donation.

Time and again, next-of-kin relate that the entire situation – of how they, as next-of-kin, were received in the hospital ward; how their questions were answered; and how they were encountered in human terms – was decisive for a proceeding

<sup>197</sup> The draft guidelines of the Münster University Hospital consider brain death diagnostics, as well as organ-protective measures, that are indicated in view of the donation as principally ethically tenable if these do not burden patients or harm their dignity: This would also include the limited continuation of intensive care, including the administering of blood products or drugs for stabilizing and restoration of vital organ functions, namely for treating circulatory, endocrine and metabolic problems. Mechanical resuscitation would not fall under this, however. If the danger exists of precipitating a persistent coma, any prolongation of intensive care for the purpose of organ removal must be abandoned. Cf. Schöne-Seifert et al. 201b.

<sup>198</sup> Ibid., A-2084.

<sup>199</sup> Cf. inter alia Muthny/Wesslau/Smit 2003.

<sup>200</sup> Muthny/Smit/Molzahn 2004.

<sup>201</sup> Blum 2007, 105 ff.

experienced as satisfactory by all participants, as well as for the later conversation about a possible organ removal. A ward climate, in which clinic personnel do not feel overextended and where next-of-kin of the terminally ill or dying not only receive medical information, but also are provided with psychosocial assistance, is most certainly more instrumental for conversations possibly introduced later about an organ removal than a station climate in which only meagre information is provided and the next-of-kin are left to themselves.<sup>202</sup> In this connection, next-of-kin report that they already found themselves in a state of emergency prior to the decision about an organ removal; in that state, they experienced the accompaniment by the clinic personnel as helpful and supporting and as a sound basis of trust for the conversations then introduced regarding the possible organ removal.<sup>203</sup>

### 5.3.1 Persons participating in the conversation

Different (groups of) people come into consideration as possible conversation partners of the next-of-kin: doctors, nurses, psychologists, social workers, pastors, the DSO representative or the transplantation officer, who is legally responsible among other things for ensuring the appropriate accompaniment of the next-of-kin. However, not all groups of people named are equally suitable for fulfilling the requirements for conducting an appropriate conversation with the next-of-kin.

In reference to the question of the clinic personnel's participation, it has generally proven helpful that the dialogue partner should change as little as possible during the conversations with the next-of-kin. In the event that this cannot be ensured,

<sup>202</sup> This was also confirmed by a study from New Zealand, in which 31 of the 49 surveyed next-of-kin stated that the greatest help to them was the care, understanding and support by the team in the intensive-care unit (Painter/ Langlands/Walker 1995).

<sup>203</sup> Donauer 2012, 184.

the conducting of the conversation should at least lie in the hands of a person commissioned to that effect – when possible, the clinic's transplantation officer.

However, the literature also contains indications that nursing personnel play a decisive role in communication with the next-of-kin. They have the most contact with next-of-kin; know more about their specific fears; recognize their questions sooner; and witness more of their grief or shock.<sup>204</sup> Accordingly, appointing a team mixed by professional group and gender is recommended.<sup>205</sup> In addition, the conduct of conversations with the next-of-kin should be understood as an interdisciplinary task of the entire team.<sup>206</sup> According to a survey by the *Deutsches Krankenhausinstitut* (German Hospital Institute), conversations are conducted as a rule by two people, usually a medical specialist or senior physician, for the most part in tandem with a second physician. The nursing staff in charge participated regularly in these conversations in only 34.9% of cases; the DSO representative, in only 14.9% of cases.<sup>207</sup>

Finally, at least the main interlocutor or moderator of the group, who also guarantees the continuity of the counselling, should be free from a double mandate; this would, for example, be the case when a counsellor is at the same time the treating physician and transplantation physician. The clinic's transplantation officer, whose task *inter alia* is the appropriate accompanying of the next-of-kin and who thereby has to enable good decision processes, is appointed for this by virtue of his or her statutory mission. Depending on the case at hand,

<sup>204</sup> In a study from Canada, the nursing personnel are accorded a special responsibility for the accompanying of the next-of-kin before and after organ removal. A deflective or defensive conduct among the ward personnel is said to be a crucial factor for a subsequent rejection of an organ donation (Pelletier 1992, 95).

<sup>205</sup> Muthny et al. 2007, 102. While these and other recommendations are based on the experiences of accompanying and counselling during living donations, they can, nonetheless, also be translated in their general message to the counselling of next-of-kin on post-mortem donations.

<sup>206</sup> Muthny/Smit/Molzahn 2004, 260.

<sup>207</sup> Blum 2007, 108.

however, this should be at the hospital's discretion, for example if next-of-kin have built up a relationship of trust with a treating physician and if they could be irritated by a new person entering the scene, such as the not-yet-encountered transplantation officer.<sup>208</sup> DSO coordinators should not be appointed for these conversations, since they have other tasks pursuant to their statutory remit and association bylaws.<sup>209</sup>

### 5.3.2 Point in time of initiating conversation

There are varying responses to the question of when to initiate counselling of next-of-kin in the event of a possible postmortem donation. To date, no standard procedure exists in practice either. Section 7 TPG, in provisions (1) and (3), also hardly makes explicit that a conversation with next-of-kin about the willingness for organ donation can also already be conducted prior to the determination of brain death.<sup>210</sup> Nevertheless, it emerges from a non-representative 2004 study regarding the experience of doctors working in organ donation in having conversations with next-of-kin that about a third

<sup>208</sup> This is also reconcilable with Section 9b TPG, since in this case the transplantation officer is responsible for appropriate communication with nextof-kin, but not for personally conducting this communication in each case.

<sup>209</sup> According to Section 2 of its bylaws from 8 July 2013, the German Organ Transplantation Foundation pursues the goal "of providing the patients on the waiting list with vital organs by facilitating organ donation, as well as by supporting the organisations and persons working in the area of organ transplantation, and of keeping the health risks for them as small as possible" (http://www.dso.de/dso/aufgaben-und-ziele/satzung-der-dso.html [2015-02-02]).

<sup>210</sup> On the relationship between both provisions, see Stockter, in: Höfling 2013, section 7, para. 5a. According to the view of the Federal Government, it is possible to already speak abstractly about a possible organ donation in the lead-up to brain death diagnostics, particularly in the case when nextof-kin pose the question on their part. Nevertheless, a conversation with next-of-kin with the concrete goal of clarifying whether the possible organ donor has provided a statement regarding organ donation and about the substance of that statement would only be permitted, on the basis of Section 7 TPG, following diagnosis of brain death (Deutscher Bundestag 2012b, 1 f.).

of these conversations are begun at the point when an infaust prognosis has been reached (if organ donation is possible and envisaged) and another third each at initiation of brain-death diagnostics and at conclusion of brain-death diagnostics when conveying the news of death.<sup>211</sup>

A point of time as late as possible following the beginning or even conclusion of brain death diagnostics is often put forward in order to avoid unnecessary burdens and anxieties for the next-of-kin. Adduced in opposition to this, in favour of an early initiation of the conversation before beginning brain death diagnostics, is the argument that only through comprehensive and early information can next-of-kin develop trust and have sufficient time for confronting the question of their relative's dying. In the "Leitlinienentwurf des Universitätsklinikums Münster" (Draft Guidelines of the Münster University Hospital), which refers to the treatment of potential organ donors in the pre-final stage, a plea is made explicitly for the conversation with next-of-kin commencing before the start of brain death diagnostics.<sup>212</sup>

Also speaking in favour of an early initiation of the conversation is the point that to the extent possible the confrontation with death and the inquiry regarding the consent to organ removal should be separated in time. As circumstances permit, the burden arising from the concurrence of the news of death and the inquiry about organ donation can be attenuated.<sup>213</sup> With regard to the early initiation of conversations, however, it should also be considered that it can sometimes lead to the impression among next-of-kin that possibly not everything is still being done to save the life of the potential organ donor. This raises further special requirements with respect to the information to be communicated and to the building up of trust.

<sup>211</sup> Muthny/Smit/Molzahn 2004, 258.

<sup>212</sup> Cf. Schöne-Seifert et al. 2011a.

<sup>213</sup> On this, also Simmons/Fulton/Fulton 1989.

Not only the choice of time for commencing conversation plays an essential role, but also the time frame as a whole. On a regular basis, next-of-kin report that they need time for their decisions. Over the course of several conversations, opportunities should be provided to discuss questions, which have arisen in the meantime or demand a consultation within the family. Potentially, the situation may indicate involvement by a family member living far away, who cannot participate personally in the counselling conversations. Some studies also point out the necessity of giving next-of-kin the possibility of being able to draw on the advice of friends or other people important for the family.<sup>214</sup>

### 5.3.3 Design of the conversation

With respect to the fundamental design of the counselling, a broad consensus exists that

- >>> the efficacy of the counselling depends on establishing a relationship based on appreciation for the other person, on understanding, and on easing the burden of strong emotional reactions;
- » the information provided is effective primarily through the manner of modulating the communication of information to the conversation partner, thereby, however, raising the danger of manipulation, which can only be reduced through the training and supervision of the counsellors;
- >>> the efficacy of the counselling increases through integrating the psychosocial aspects of the next-of-kin – what a nextof-kin can do with a piece of information follows from his or her psychosocial background and from the modification of the information process with a view to the possibilities provided by this background;

<sup>214</sup> Ibid., 271.

>> the efficacy of the counselling is markedly curtailed when there is lack of clarity in roles or a double mandate.

It goes without saying that these interactions should always be face-to-face conversations, not telephone calls or written communication. As a matter of principle, the conversations should take place in a quiet room suitable for this, not in the hospital hallway or directly at the sick bed.

#### 5.3.3.1 Directive vs. non-directive conversation style

In principle, two kinds of counselling can be differentiated for the conversation with next-of-kin and trustees appointed to make a decision: a directive conversation style, which, in the interest of organ supply and the potential organ recipients, is geared towards the next-of-kin's or trustee's consent for organ removal; and a non-directive conversation style, which is open in outcome and where decisions both to consent or reject are accepted. Even a non-directive conversation style includes just as much the mentioning of the goal of bringing about a decision - preferably without time pressure - as the possibility, for the purpose of the comprehensiveness of the information, of speaking about the benefits of donor organs. Despite the desire to gain organs for seriously ill patients, hardly any convincing ethical arguments can be found for a directive mode of conversation. When there is no organ-donation statement and no presumed will can be determined, the legally anchored extended consent solution is based on the free choice of respectively the next-of-kin or the trustee named by the potential organ donor in his or her lifetime - a decision yielded by personal judgment and reasoning and usually established firmly only in the course of the decision process. This requires that no moral or other pressure is exerted and that deficits of information and understanding are avoided as far as possible. In 2012, the Federal Government also affirmed once more that a conducting of the conversation directed towards the goal of consent to organ removal is not reconcilable with the intention of the Transplantation Act.<sup>215</sup>

Directive forms of counselling, which many people perceive as instruction by a professionally superior expert, restrict not only the personal capabilities for making one's own decisions, but they can further lead to an internal attitude of protest, which is detrimental to the process as a whole. It should be added that during a directive mode of conversation, the next-of-kin may at a later point in time regret their consent and then correspondingly reproach themselves, as well as the clinic. If they make their charges public, they can, moreover, damage the general objective of increasing the willingness to donate.

In contrast, a non-directive conversation style leaves the outcome open and is oriented towards a good process. It builds up no pressure with respect to a certain result and leaves adequate time for decision-making, although it needs to disclose, of course, objective limitations, such as, for example, a definite time limit. In addition to the medical information, indications about the goal of organ donation are part of the conversation, whereby it needs to be considered that the inordinate emphasizing of the shortage of organs and the possibility of saving another person's life also harbour the risk of putting moral pressure on the next-of-kin. As mentioned above in connection to the Münster University Hospital model, equally a part of the comprehensive information is education about organprotective measures (cf. section 2.2.4). A non-directive style of conversation implies the disclosure of all information and at the same time the encouragement that the advised person can and must come to a personal decision and may trust that he or she will not subsequently regret this decision, if held to be well grounded.

A non-directive counselling style contributes as well to the next-of-kin's feeling of being taken seriously and of being able

<sup>215</sup> Deutscher Bundestag 2012b.

to openly address their doubts and fears – frequently existent – that a certain decision is desired. Nevertheless, they can also feel burdened in a specific way by the responsibility for this decision. While this burden cannot be taken from them in the context of a consent-solution, it can at least be alleviated through accompanying and counselling. In keeping with the non-directive counselling model, the counsellors understand themselves as the next-of-kin's partners, working out a decision together with them.

Practice shows that decisions made in this manner are also evaluated positively in the long term by the next-of-kin concerned and can be beneficial to increasing the availability of organs to donate.<sup>216</sup>

#### 5.3.3.2 Rituals concerning leave-taking and aftercare

As appears from reports by next-of-kin, for a communication process to succeed, it is also necessary and helpful, in addition to the conversation and direct support on the part of clinic personnel, to enable small rituals before the decision and, as applicable, after the organ removal. Under certain circumstances, such rituals can very well be carried out even in the intensivecare unit. In doing so, it is important that the leave-taking is understood as a process, which should already be initiated prior to brain-death diagnostics, although the conclusiveness of death is only inferred in a sensory manner when the nextof-kin see the corpse once again following the organ removal and can potentially also say goodbye then with a ritual.

The long-term aftercare for next-of-kin is also part of a good communicative design. Here, different methods present themselves, from examples such as placement into next-of-kin self-help groups and the subsequent anonymized information about the successful transplant of the organs, to anonymous expressions of thanks from recipients, which are passed on through the clinic and Eurotransplant. The recipient's

<sup>216</sup> Regarding concrete suggestions, see Donauer 2012, 188.

anonymous expressions of thanks can contribute to the stability of the decision made by the next-of-kin as much as to alleviating the grief for the deceased. On the other hand, further information, especially the disclosure of donor families and recipients, must be strictly rejected. To do so could evoke feelings of guilt on the part of the recipient and false expectations of gratitude on the part of the donor family.<sup>217</sup> However, studies assess the general and anonymous notification about the recipient to be helpful and consoling. Grief over the loss of the relative can, of course, not be overcome with such expressions of thanks; however, a consolation can be seen in that a meaningful treatment was still enabled with the organs of the deceased.<sup>218</sup>

## 5.3.4 Special challenges: ascertaining of the presumed will and next-of-kin's own decision

If no organ-donation statement is available, the next-of-kin or trustee charged with the decision by the potential organ donor decide about an organ removal. In making their decision, the next-of-kin have to heed (see section 2.3.3.4) a presumed will of the potential organ donor (Section 4 (1) No. 4 TPG).

If one draws on regulations on advance directives to determine the presumed will, this means that in establishing the presumed will, the decision-maker must refer to concrete indications, including earlier oral or written remarks, ethical or religious convictions, and other personal values. This can additionally contribute to the next-of-kin's feeling more assured in their decision and their ability to advocate it vis-à-vis third parties.

Under the terms of the new decision-solution, should the concerned party not have provided any statement, this may be

<sup>217</sup> Simmons/Fulton/Fulton 1989, 279 f.

<sup>218</sup> Painter/Langlands/Walker 1995.

for different reasons, which can be difficult to interpret. The determination of the presumed will, which may be behind the non-statement regarding organ donation, does not become any easier with the decision-solution and the information and invitations sent regularly to all insured by the health insurers, especially if the concerned party has not expressed a will over a long time, despite repeated information and invitation.<sup>219</sup>

A person-centred conjecture and an external assessment about the motives and intentions of the person concerned can lie closely side-by-side. As far as possible, to surmount such difficulties in ascertaining the presumed will, as in other medical areas as well, an agreed upon decision can and should of course be reached between the participating, closely affiliated individuals. However, it is always a prerequisite that actual remarks or attitudes regarding the question of organ removal, as well as remarks or situations that led to not filling out the organ donor card, are remembered and reflected upon.

If the case occurs that the next-of-kin or the commissioned trustee must form a judgment on his or her own part, this can only be based on that person's own standards of value and assessments. Studies attest that this decision weighs heavily on approximately half of next-of-kin; however, if the reasons underlying the decision were communicated understandably and adequately to third parties, in 90% of the cases the decision is stable – that is, it is not regretted in a subsequent survey or the same decision would be made today.<sup>220</sup>

<sup>219</sup> For this constellation, the statement of grounds to the draft of a law regarding the regulation of the decision-solution in the Transplantation Act reads as follows: "The general duties to inform in Section 2 (1) No. 1 TPG are specified insofar as explicit mention has to be made of the right of decision of the next-of-kin in case no statement regarding post-mortem organ and tissue donation has been provided during one's lifetime. Thereby, in connection with the general information, the consequences of omitting to provide a statement regarding post-mortem organ and tissue donation during one's life for the next-of-kin in the event of death should be emphasized more clearly" (Deutscher Bundestag 2012a, 16).

<sup>220</sup> Muthny/Wesslau/Smit 2003, 118.

## 5.4 Motives underlying decisions about organ donations

### 5.4.1 Outcomes from surveys of next-of-kin

Recognition of the motives leading next-of-kin to their consent to or rejection of organ donation is important for the design of a good counselling process. In the literature, the most frequently mentioned motives for a consent to organ removal are the altruistic motive of helping other patients and the motive of thereby giving meaning to death. In doing so, however, the existing studies do not differentiate between the ascertaining of the presumed will and the decision based on one's own values.

In the Münster study, which is, however, not representative, 131 next-of-kin were assembled who had had to make a decision regarding organ removal. The respondents could choose which deciding motivations were of weak, middling, or strong relevance to them. 71% of respondents stated altruism and empathy for the organ recipient as a strong motive; 39%, the consideration of giving the death a certain meaning through the donation as a middling deciding motive and 26%, as a strong motive. Religious grounds played a minor role.<sup>221</sup>

As motive for rejection, 48% of respondents stated the harm to the physical integrity as a strong motive; 30%, not being able to accept the death; 13%, religious grounds; and only 3%, a lack of trust in brain death diagnostics. The categories "Fears related to organ trafficking" and "Dissatisfaction with the treatment in the hospital" were not stated by any of the respondents as a strong motive and only in 5% of cases as a middling motive.

More recent outcomes are available in the 2013 Annual Report of the DSO. This survey is non-representative as well. 451 respondents stated the favourable attitude of the deceased

<sup>221</sup> Muthny/Smit/Molzahn 2004, 259.

towards organ removal as their reason for consent; 218 stated altruistic motives; and 208 referred to the possibility of thereby giving meaning to the sudden death of the relative. 20 respondents gave as the basis of their decision "Affected people in one's circle of acquaintances" and 41, other reasons.<sup>222</sup>

161 of the respondents stated the reason for their rejection as the corresponding negative attitude of the concerned person; 94, that the attitude of the deceased was unknown to them; 31, disagreement in the family; 23, harm to the physical integrity; 14, the non-acceptance of the death; and 16 respondents offered religious grounds. Only five respondents stated a lack of trust in brain death diagnostics as grounds for rejection; seven respondents expressed fears concerning misuse, albeit 37 respondents also referred to "other grounds."<sup>223</sup> It is not clear from the survey whether under these "other grounds," grounds for rejection can be found related to the manipulations in organ allocation brought to light in the middle of 2012.

Earlier DSO surveys had revealed that consent to organ removal had only a minimal influence on the grieving process. Thus, in the period between 2004 and 2009 in the context of a non-representative survey of next-of-kin, 83.7% of respondents stated that no aggravation of grief was connected to the organ removal. And conversely, to the question of whether an alleviation of grief ensued, 49% answered "no" and 36.7% "yes."<sup>224</sup>

<sup>222</sup> Deutsche Stiftung Organtransplantation 2014, 47.

<sup>223</sup> Ibid.

<sup>224</sup> See the talk by Thomas Breidenbach on 27 October 2010 at the German Ethics Council's Bioethics Forum on the subject of "Duty to declare regarding organ donation. Should the state require that each person make a statement?" in Berlin (Breidenbach 2010, 26 f.).

### 5.4.2 Results from surveys of the population

In representative population surveys regarding consent to organ donation, the most frequently mentioned causes are awareness of the benefits of organ donation, altruistic motives, and, in case of willingness to donate, the hope to receive an organ oneself in the event of need.<sup>225</sup>

In a representative survey by Emnid in 2013, in which 989 people took part, 94% agreed with the proposition that organ donation means lifesaving; 81%, that organ donation is a possibility to give something to other people; and 73%, that organ donation is an act of charity.<sup>226</sup> The motive that "something of me lives on in another person" through organ donation also plays a role when surveying the population. 69% agreed with this proposition, while 64% rejected the proposition that organ donation is a possibility to live on after death.<sup>227</sup>

However, the Emnid study also shows that at least 28% of respondents agreed with the proposition that "brain-dead patients should not be used as organ donors"; and 37%, that if they themselves needed a foreign organ, they would prefer an artificial organ or one grown from stem cells to an organ from a brain-dead donor. The authors interpret this to the effect that in the population, thoroughly ambivalent ideas are connected to brain death.<sup>228</sup>

In regard to knowledge about brain death, the 2013 Emnid study comes to the following conclusions: The proportion of respondents, who agreed with a medically correct description of brain death ("irreversible loss of brain functions"), is indeed high at 82%; at the same time, however, 79% agreed with the proposition that brain death is an irreversible condition of the

<sup>225</sup> Bundeszentrale für gesundheitliche Aufklärung 2010; 2013.

<sup>226</sup> Kahl/Weber 2014.

<sup>227</sup> Ibid., 14.

<sup>228</sup> Ibid., 16.

process of dying; and 55%, with the proposition that brain death is a state between life and death.<sup>229</sup>

The Emnid study also finds that only 47% of respondents trust the organisational process in the hospital; 70% conjecture that doctors earn a lot of money with the organ donation; and 81% see problems in allocation being fair. 51% state that the media's coverage about manipulations during of organ allocation negatively influenced their attitude; and 30%, that as a result, they will not fill out an organ donation card.

In a representative FORSA survey from 2011 commissioned by the DAK, in which 1003 people were questioned, still other grounds for rejection prevail. 44% of those who reject organ donation stated that they were afraid that doctors would no longer do everything in order to save their lives. 39% stated that they did not yet want to be concerned with death, and a third of respondents rejected removal because they could not know what would happen with their organs.<sup>230</sup>

### 5.4.3 Results from surveys of clinic personnel

A different picture emerges from a (non-representative) survey of intensive-care personnel, which was conducted in December 2012 at the convention oft the *Deutsche Interdisziplinäre Vereinigung für Intensiv- und Notfallmedizin* (German Interdisciplinary Association of Critical Care and Emergency Medicine) and in which 1045 people participated, who for the most part were directly involved in a professional capacity in organ transplantation. According to this, 81% were in favour of donating organs themselves, whereby only 45% had filled out an organ donation statement. 40% of those who rejected organ donation for themselves indicated lacking acceptance of the concept of brain death; 29%, fear of abuse through organ

<sup>229</sup> Ibid., 9.

<sup>230</sup> Deutsche Angestellten-Krankenkasse 2011.

trafficking; and 11%, the lack of physical integrity following death. As reasons for the low availability of organs in Germany, 29% of respondents cited citizens' insufficient information; 22%, organisational deficiencies in the field of transplantation medicine; 21%, citizens' fears; and 9%, deficiencies in the Transplantation Act – which deficiencies were meant, however, was not explained further.<sup>231</sup>

In a 2013 survey in 50 Bavarian hospitals, of medical personnel trained in specialties relevant for organ donation, 71% were in favour of donating organs themselves, whereby a marked difference existed between the group of physicians - at 82% - and that of nursing staff - at 66%. In clinics without a transplantation programme, this proportion was higher (73%) than in clinics with one (68%). 56% of nursing staff and 68% of physicians indicated that they had filled out an organ donation statement. 90% of surveyed physicians and 78% of surveyed nursing staff accepted brain death as the death of the human being. 28% of all respondents stated that their attitude was negatively influenced by the manipulations that became apparent in the organ allocation process. 43% were of the opinion that post-mortem organ allocation was not fair. 42% of all respondents indicated that they had never participated in advanced training on the topic of organ transplantation. 90% desired more advanced training especially in the areas of supporting next-of-kin (46%), organ-preserving intensive care (41%), and brain death (41%), as well as regarding ethical aspects of transplantation medicine (38%).232

### 5.4.4 Interim conclusion

What role a lack of knowledge about brain death, lack of trust in brain death diagnostics, or difficulties in accepting brain

<sup>231</sup> Söffker et al. 2014, 43 f.

<sup>232</sup> Grammenos et al. 2014, 1292.

death as death actually play in rejecting organ donation – and all the more among the large number of those who have provided no statement about organ donation while in principle being in favour – cannot be determined explicitly in these surveys. This is also true given that ambiguities or reservations in regard to the concept of brain death may be concealed behind some responses, particularly those of surveyed next-of-kin about not being able to accept death or make a decision. Studies from other countries may also speak to this issue.<sup>233</sup>

## 5.5 Education about organ transplantation and interculturality

Depending on what cultural background the next-of-kin of the brain-dead person comes from, their being informed on these issues frequently entails additional difficulties. Among these are, for example, language barriers, which represent an important obstacle for communication. For this reason, essential information about brain death and organ removal cannot be adequately conveyed and the presumed will of the braindead individual cannot be determined. In turn, this situation impedes the goal of bringing about a non-directive mode of conversation that is open in outcome. Solving this problem through "accidental interpreters," who as a rule are next-ofkin or acquaintances, is in many regards unsatisfactory and ethically problematic. In most cases, these people lack qualification in translating and can be partisan. Not infrequently, mistranslations, omissions, distortions or the concealing of information occur, which cannot be checked by the advising

<sup>233</sup> Thus, a Canadian study broaches the issue of a "cognitive dissonance" between knowledge about brain death and the experience associated previously with death as loss of the activity of the heart and respiration (Pelletier 1992, 95 ff.); a US-American study from Minnesota explains not only the intellectual, but also emotional incomprehension of many next-of-kin towards the concept of brain death (Simmons/Fulton 1989, 273 ff.).

physician.<sup>234</sup> On that account, a non-partisan, professional translator is required in such situations. However, recourse to such services is connected to a range of problems on organisational and financial grounds.

In addition to difficulties of communication, cultural problems can also emerge.<sup>235</sup> Sometimes, cultural or religious questions arise, which pose the advisor special challenges. It cannot be expected that every advisor can answer culturally-specific and, for the next-of-kin, decisive questions. Hence, being able to contact competent institutions and religious authorities acquires a special meaning in such situations.

In counselling interviews in intercultural contexts, it can be important for the next-of-kin with respect to their decisionmaking whether or not it is possible to perform specific religious rituals on an individual who has undergone a transplantation (for example, ritual washing following death for Muslim or Jewish deceased). Taking into consideration such aspects in the context of a consent discussion would positively influence the communication process.

Unfortunately, there are no valid data in Germany regarding the above-mentioned problems. Equally, we lack empirical research in terms of the attitudes of people from different cultural backgrounds regarding organ donation and brain death, as well as regarding their willingness to donate organs. The stock of data in the USA and Great Britain is, in contrast, more abundant. In these countries, accompanying research related to transplantation medicine exists since the 1990's.<sup>236</sup>

The studies attest that these population groups are disproportionately highly represented on waiting lists and at the same time were less willing to donate organs.<sup>237</sup> A further

<sup>234</sup> David/Ilkilic 2010.

<sup>235</sup> Holznienkemper 2005; Ilkilic 2012.

<sup>236</sup> Significantly higher incidence of certain common illnesses and, frequently connected to that, kidney failure among ethnic minorities were important points of departure for these studies, among which Callender 1987; Lange 1992; Sehgal/LeBeau/Youngner 1997; Yuen et al. 1998.

<sup>237</sup> United Network for Organ Sharing 1999.

finding was that the waiting time for an organ among African-Americans was significantly longer than among white US-Americans.<sup>238</sup> In a study from the United States with over 1200 participants, it was determined that only 39.1% of African-Americans surveyed, but 64.9% of white US-Americans had documented their consent to organ donation with a corresponding endorsement on the driver's license.<sup>239</sup> There are also further studies, which attest to a low willingness to donate among ethnic minorities.<sup>240</sup> Other analyses could convey the reasons for this attitude. Some of the reasons highlighted in these analyses for this low willingness to donate are markedly worse opportunities for education in regard to organ donation; lack of trust in different agencies due to individual and historical discriminatory experiences; or doubt about an earmarked use of the donated organ (for example, utilization of organs for medical experiments).241

To what extent these facts are applicable to Germany is a valid and open question. For an adequate handling of interculturality regarding organ donation, corresponding representative studies are necessary for a disclosure of the medical and cultural facts. If one considers the reality that approximately 20% of the people living in Germany have an immigrant background, then the urgency of the scientific and social debate on these topics becomes all the more evident.

## 5.6 Communication, cooperation and coordination in the clinic

For many years, good communication and cooperation between the different professional groups in the clinic, nursing staff, and physicians has been seen as an indispensable

<sup>238</sup> Siminoff/Burant/Ibrahim 2006, 995.

<sup>239</sup> Ibid., 997.

<sup>240</sup> Hartwig et al. 1993, 1331 ff.; Siminoff/Lawrence/Arnold 2003, 149 ff.

<sup>241</sup> Plawecki/Plawecki 1992, 36 ff.

requirement for high-quality health care, but also one still urgently requiring improvement. This can also be assumed to a special extent for those hospital areas where brain-death diagnostics and organ removal may be carried out. On the one hand, next-of-kin indicate, as explained in section 5.3, that the whole situation and atmosphere in the hospital ward in which the conversation evolved was critical for their decisionmaking process. On the other, it is repeatedly apparent that differences in assessments between nursing staff and doctors in regard to organ donation possibilities of the commonly cared-for patients and in regard to the different medical measures connected to that may considerably disrupt the process of preparation for decision-making. In addition to informational deficits, deficits in communication and conflict-solving can be mentioned especially as causes for this.

Till 2008, for instruction on the professionally contentrelated conducting of the conversation with next-of-kin, the DSO offered one-day EDHEP (European Donor Hospital Education Programme) seminars for doctors and nursing staff, but also for others involved in counselling next-of-kin in the intensive-care unit, such as pastors or psychologists; these were developed under the leadership of Eurotransplant. Pursuant to different critiques,<sup>242</sup> the new programme "Entscheidungsbegleitung für Angehörige" (Support for the Decision-making of Next-of-Kin) was introduced. The object of this programme is training in the professional support of decision-making by next-of-kin, which combines assistance in grief with the decision regarding organ donation.

In addition to this programme, pertinent reference projects exist in the model project "Interprofessionelle Kommunikation und Kooperation" (Interprofessional Communication and Cooperation, InterKiK),<sup>243</sup> sponsored by the Federal Ministry of Health, and the organisational concept "Kooperation Pflege

<sup>242</sup> Cf. inter alia Deutscher Bundestag 2012b, 5.

<sup>243</sup> Lecher et al. 2003, as well as Lecher et al. 2002.

und Medizin" (Cooperation Care and Medicine, KoPM),<sup>244</sup> which can also be drawn upon for improving practice. Their focus is broader than the consent interviews with next-of-kin regarding organ donation and includes the entire interaction and communication process vis-a-vis patient care in the ward.

Shared "patient-related responsibility" is the designated goal of KoPM. Pertaining to this are, for example, conversations conducted in common by nursing staff and physicians with patients and next-of-kin. Accordingly, an important prerequisite for such an inter-professional cooperation being successful is a shared value-orientation on the basis of an equitable understanding regarding goals and standards. A further prerequisite is a stable and bindingly regulated communication and information structure. Both conditions apply for a successful outcome, and in special measure for the process of organ donation. The possibility of contributing to the decision process is especially important when it is a matter of multi-perspectival assessment processes.<sup>245</sup> In concordance with the Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen (Advisory Council on the Assessment of Developments in the Health Care System)<sup>246</sup>, it is understood that for all the disparity of core competencies of nursing and medical staff in the areas of case management and psychosocial care, overlaps do exist that would allow for a pooling of competencies in interdisciplinary teams.247

Transferred to the preparation for a possible organ removal and the pending communications with next-of-kin, this recommendation means that the case management and parts of the communication could also be conducted by nursing staff

<sup>244</sup> Dahlgaard/Stratmeyer 2006–2008; In an abridged version, also Dahlgaard 2010.

<sup>245</sup> Dahlgaard 2010, 33.

<sup>246</sup> Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen 2007.

<sup>247</sup> Dahlgaard 2010, 37.

suitable for this or, as applicable, should be designed in common by both professional groups.

The final report of the InterKiK model and the report regarding KoPM are in agreement that the improvement of communication and cooperation has as a consequence "transaction costs that are not to be underestimated," which can be justified, however, in view of optimized processes and better work results.<sup>248</sup> For the clinical areas involved with transplantation medicine, such incremental costs can doubtlessly be justified if this would contribute to the restoration of trust in transplantation medicine among the population and to an increase in organ donations.

<sup>248</sup> Ibid.

## 6 SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

The German Ethics Council holds organ transplantation to be an important area of medicine, which can contribute to saving the life of critically ill individuals. It is hence all the more important that people have trust in this area of care provided by physicians and nursing staff. In recent months, that trust has been shaken for many people by the irregularities in organ allocation. Additionally, the controversy surrounding the question of whether or not brain death is identical with the death of the human being has continued to occupy many people since the introduction of the concept.

In order to strengthen the public trust in transplantation medicine in Germany, transparency and an open societal discussion are necessary. In this sense, the German Ethics Council would like to emphasize with this opinion, which exclusively considers organ donation following brain death, the far-reaching consensus about many elements of the concept of death and about an appropriate handling of brain-dead individuals. It would also like, however, to promote the public discussion of existing controversies. These controversies involve the question of whether the criterion of brain death is a convincing one for the death of the human being. They also involve the question of whether brain death is an adequate prerequisite for the ethical and constitutional legitimacy of an organ removal even if brain death is not equated with the death of the human being. What should be considered an appropriate course of action in the situation of brain death does not fall exclusively under the competence of scientific experts or those of the medical profession, but rather requires an ethical reflection as well.

Against this backdrop, the opinion of the German Ethics Council on "Brain Death and Decisions regarding Organ Donation" addresses two topics: (1) Initially, it processes the many-layered and controversial discussion about the concept of brain death as the basis of post-mortem<sup>249</sup> organ donation, including the problem of organ-protective measures.

(2) A second point of emphasis in the opinion relates to the conditions for transparent and open communication in connection to organ donation.

# I. Taking stock and defining the problem (chapter 2)

#### Sequence of an organ donation

- For the removal of organs "from dead donors," the Transplantation Act establishes that the removal is only allowed if the death of the organ donor has been certified. Moreover, it establishes that the removal is prohibited if the final and irreversible loss of the entire function of the cerebrum, cerebellum and brain stem has not previously been certified for the organ donor. This condition of final loss of the functions of the entire brain, while blood circulation is maintained, is designated in short as "brain death."
- 2. In the guidelines of the German Medical Association, it is stipulated how the certification of brain death is to occur, with consideration taken for the medical history of the patient. The physicians can only certify brain death once a series of prerequisites is fulfilled, clinical symptoms of loss have been attested, and proof of their irreversibility is obtained through a second, time-delayed clinical examination process. The clinical symptoms of loss include unconsciousness (coma), absence of brain-stem reflexes, and respiratory arrest. Where applicable, the brain death

<sup>249</sup> On the concept, cf. footnote 1.

diagnostics must be supported by additional, instrumentbased findings.

As a rule, a phase precedes brain death diagnostics in 3. which the affected individual is treated through intensive care as a critically ill patient. At a certain point in time, the question may pose itself for the treating physicians of whether a continuation of therapy is generally indicated. If this question is answered in the negative, intensive-care interventions are either limited or concluded. Where the patient concerned comes under consideration as an organ donor, however, the vital functions are provisionally maintained further. In this case, these measures no longer occur in the therapeutic interest of the patient (the potential organ donor); rather, they serve exclusively to ensure the quality and transplantability of the organs. Thus, from that point in time they are designated as organ-protective measures.

#### The legal regulatory framework for post-mortem organ donation

- In its provisions, the Transplantation Act falls back on 4. those organisational structures and actors that were already in place prior to its coming into force: the German Medical Association, which is vested through the Transplantation Act with far-reaching authority to issue guidelines; the German Organ Transplantation Foundation, as the coordinator; as well as the Dutch foundation Eurotransplant, as the agency for allocation. Since 1 August 2012, at least one professionally qualified transplantation officer must be appointed in all removal hospitals; this person is independent and free from others' instructions in the exercise of his or her tasks. Within Germany, further details should be determined through state law, but so far this has occurred only partially and in quite divergent ways.
- 5. The so-called extended consent solution underlies the Transplantation Act. Should neither a written consent

nor a written objection from the potential organ donor be available, the next-of-kin is to be consulted on whether a statement from the potential organ donor is known. If this is the case, the statement must be implemented. Otherwise, the law concedes the right to decide to the nearest next-of-kin. In making a decision, the next-ofkin has to heed the presumed will of the possible organ donor. If no such will can be ascertained, the next-of-kin decides according to his or her own ethically responsible judgment. Since the middle of 2012, this conception of the extended consent solution is flanked by a model of intensified information for and education of the population (the so-called decision-solution). This education has to encompass the entire scope of the decision and must be open in outcome (Section 2 (1) No. 2 TPG).

- 6. To date, so-called organ-protective measures remain inadequately regulated.
  - 6.1 These are legally and ethically unproblematic for the phase *after certification of brain death*. Organprotective measures may, however, be performed *before certification of brain death*, if the affected person has personally consented to such treatment. Moreover, it can be assumed that organ-protective measures can be based on a presumed will of the affected individual if an organ donation statement is available and brain death diagnostics has been initiated.
  - 6.2 The situation is different when doctors expect brain death to occur in the near future. In this case, it is questionable whether organ-protective measures can at this point be based on a stated or presumed will of the concerned party regarding a willingness to donate. One would only give approval to this if it were known that the person willing to donate was aware of the implications of organ-protective measures.

- 6.3 According to current law, grave misgivings exist about the recognition of an independent decisionmaking power of next-of-kin and legal representatives concerning the implementation of organprotective measures before and during brain death diagnostics.
- Problems in ascertaining the will concerning organ 6.4 donation can appear most notably in constellations where the willingness to donate collides with an advance directive, in which life-prolonging intensivecare measures are rejected or where their limitation is requested. If the will of the concerned party in relation to organ-protective measures, vis-à-vis the advanced directive, cannot be clarified through interpretation, it must be ascertained through consulting with individuals closely related to this person whether and, as applicable, to what extent he or she had given thought to the relationship between both statements. The ascertaining of the presumed will can only take place by means of personal, individually certifiable, concrete points of reference.

# II. Analytic structure: definition of death, criteria for death, certification of death (chapter 3)

7. The normative problems associated with the concept of death underlying post-mortem organ removal can be structured according to the following steps. In a *first* step, a *definition of death* must be identified (for example, the end of personal life, loss of physical unity, complete cessation of all vital processes). In a *second* step, the *criteria* are to be investigated, on the basis of which a judgment should be made about whether the feature postulated in the respective definition of death is present (for example, a condition of persistent unconsciousness, irreversible

loss of all brain functions, complete expiration of all cell activities). In a *third* step, the question is finally posed of what *diagnostic procedures* are appropriate to reliably verify the presence of the criteria.

- 8. In order to respond to questions about the definition of death, philosophical and anthropological interpretations are required. Definitions of death are informed by various ideas of what constitutes the human individual. Accordingly, considerable variation in definitions of death is evident in cultural history. This is also reflected in philosophical investigations on the phenomenon of death.
- 9. The varying philosophical definitions of death have via strands of traditions that are difficult to untangle contributed to general societal convictions and, moreover, have considerable consequences for answering the question of the difference between life and death. In this sense, one can discern that the regulation of organ transplantation falls back more or less explicitly on anthropological assumptions and understandings of death. Precisely the diversity of concepts of death that can be described in cultural-historical terms makes it necessary, however, to seek for generalizable elements of a definition of death.

# III. Definition of death and criteria for death in the context of organ transplantation (chapter 4)

#### Common starting point

10. All members of the German Ethics Council are of the opinion that an exclusively mentalistic definition of death, which is based solely on the irreversible loss of all functions of consciousness, must be rejected. The irreversible loss of the faculties of perception, sensation, thought and decision is, indeed, a necessary condition for human death, but not a sufficient one. Concepts of death grounded exclusively on mentalistic terms involve

an ethically and constitutionally unacceptable concept of the human being.

- 11. Death can only be spoken of in relation to an organism as a biological unity. The organism here constitutes a unity in a dual sense: through internal interactions of its parts and through exchange with the environment.
- 12. Finally, the members of the German Ethics Council are also in agreement that the loss of all brain functions represents a caesura with far-reaching ethical consequences. The certification of brain death implies that a medical indication for therapeutic measures no longer exists. Therefore, there is also no longer any obligation to maintain respiration and cardiovascular functions.

#### The controversy surrounding the concept of brain death

Nevertheless, it is disputed within the German Ethics Council whether the irreversible loss of all brain functions is to be recognized as the criterion of death.

#### Position A: Brain death is a sure sign for the death of the human being.

13. According to the view of the majority of the German Ethics Council, brain death is a sure sign for the death of the human being. The brain is the central organ for integration, communication and coordination. It integrates the sensory and sensitive stimuli from within the organism itself, as well as stimuli from without; enables motor activities and communication; and regulates the coordination processes within and between the different organ systems via the vegetative nervous system, including hormonal regulation. Ultimately, the brain is the organismic basis of mentality and of subjectivity. The inner processes of the living organism are essentially constituted through its continuous interaction with the environment. These interactions are based in large part on sense perceptions, which are processed and represented in the brain and which, for their part, lead to the alteration of brain functions and structures, as well as to a specific reaction or certain behaviour.

- 14. Whereas the specific functions of other organs can be technically maintained or substituted for on a temporary basis and occasionally for long periods of time, the functions of the brain cannot be replaced. Only sub-systems can be maintained on a rudimentary level through external substitution. If the vital functions that have failed in a brain-dead individual, such as respiration or blood circulation, are maintained or replaced through artificial means, then the integration of the human body into a functioning unity is no longer an intrinsic performance of this body. Quality and intensity of the external support is of a genuinely different kind than when sub-functions, such as respiration or blood circulation, are replaced in a viable organism.
- 15. If, due to the irreversible loss of all brain functions, the necessary preconditions for mental activity, any faculty of sensation, and hence every possibility of self-guided behaviour or exchange with the environment have for-ever expired and, moreover, the unity of the organism is broken, the body found in this condition can no longer be spoken of as a living human being. Pursuant to the concept of brain death, the intrinsic activity of the organism is an admissible distinguishing feature that marks its living condition in distinction to that of a brain-dead individual, within whom only partial integrative activities are still possible.

### Position B: Brain death is not a sufficient prerequisite for the death of the human being.

16. According to the view of a minority of the German Ethics Council, brain death is not a criterion for the death of the human being. The integration into an organism as a totality still exists even in a patient with irreversible total brain failure. One can understand life as a kind of system property. The concept of the organism as system is not based on the principle of central control, but rather and quite essentially on the idea of various components interacting with each other on different functional levels and with the environment.

- 17. Even after the brain's death, the organism, assuming support from the apparatus of intensive-care, still has at its disposal a multitude of functions, which have an effect not only "partially," but instead have integrative functions for the organism as a whole. These include, for example, maintaining the balance of a variety of interacting physiological parameters through the function of the liver and kidneys, as well as of the cardiovascular and endocrine systems; they also include the sexual maturation of a child and a successful pregnancy in a brain-dead pregnant woman.
- 18. A human being with irreversible total brain failure is even capable of interaction with the environment. One example is in the fight against infections and foreign bodies through interaction between the immune system, lymphatic system, bone marrow, and microvessels. Similarly, the intestines, liver and metabolic processes react to the food supply through the breaking down, transporting and further processing of the nutritional elements. It is obvious that such physical activities require the functioning of the organism as a whole.
- 19. Of significance for the normative evaluation is that the concept of self-regulation cannot be reserved only for central nervous system activities. Self-regulation and self-integration occur in the organism in diverse manners and not only through the action of the nerves.

#### On the significance of the dead-donor rule

- 20. The discussion surrounding the concept of brain death stands in direct connection to the question of whether vital organs, as anchored in the Transplantation Act, are only permitted to be removed from the dead (the so-called dead-donor rule).
- According to the view of position B, the dead-donor 21. rule is dispensable. The minority of the German Ethics Council holds the removal of vital organs from human beings with irreversible total brain failure to be ethically, as well as constitutionally, legitimate, provided that this corresponds with the expressed or presumed will of the concerned individual. Linked to the diagnosis of "brain death" is the finding that the human being concerned no longer has any faculties of perception and sensation. At the same time, a broad consensus is connected to this diagnosis that the further treatment of the affected individual is no longer meaningfully in his or her interest. In this situation, it appears inappropriate to qualify an organ removal performed on the basis of an informed consent as a killing in the sense of a reprehensible violation of integrity. What is at stake is rather the recognition of the self-determination of the individual regarding his or her integrity of body and mind. In this case, a high-level purpose for this person is pursued through the removal of vital organs, for whose realisation the physician intervenes in the ultimate phase of dying on the basis of a corresponding statement of will by the person concerned, albeit many hours after that point at which, without a willingness to donate organs, the dying process would in any case already have been concluded for lack of a right of the physician to further treatment. For the relationship between parents and children, Article 6 (2) GG creates a special legitimation basis for making this decision.
- 22. In contrast, the majority of the German Ethics Council (position A) holds it to be imperative to adhere to the

dead-donor rule. Life stands morally and legally under the special protection of the prohibition of killing. This applies to the entire term of life, thus without gradations till its end, independent from the prospective duration of the individual human life. A killing remains a killing even when the occurrence of death has been previously delayed. Pursuant to German constitutional law, a living person may not under any circumstances be killed solely for reasons benefitting others. Even more, a killing cannot be based merely on a presumed will. Moreover, it is also the case that organ removal in children occurs in compliance with the dead-donor rule, namely on the basis of a consent from the parents in the context of their right to custody of the dead. Parents may not, however, consent to an organ transplantation leading to the death of their still living child. Parental rights pursuant to Article 6 (2) GG do not reach that far. In abandoning the dead-donor rule as the prerequisite to an organ donation, the removal of organs from children would have to be prohibited; as a consequence, the transfer of organs to children, who are still too small to receive an adult's organ, would no longer be possible.

23. As the decisive prerequisite for an organ removal, the dead-donor rule is according to position A also an essential foundation of the medical professional ethos, which does not permit an organ removal leading to the death of a living person. Should the dead-donor rule be abandoned and the brain dead be regarded as living persons, it would not be possible for physicians, according to their professional self-understanding, to remove organs.

#### On donations following cardiac arrest

24. In Germany, organ removal following cardiac arrest without certification of brain death (non-heart-beating donation) is inadmissible. According to current knowledge, a mere five- to ten-minute waiting period following cardiac arrest – widespread abroad – does not permit concluding with certainty that all brain functions have irreversibly expired. But even should valid knowledge become available in the future after what specific waiting period irreversible brain failure could be reliably assumed following cardiac arrest, further ethical reservations remain in opposition to non-heart-beating donation, independent of the various positions described above: for example, due to possible effects on the medical efforts to resuscitate a patient following cardiac arrest.

# IV. Communication: information, education and counselling (chapter 5)

- 25. In many respects, transplantation medicine is dependent on a comprehensive and transparent communication both in the public sphere and in individual contact with potential donors, their next-of-kin or legal representatives. This realization also underlies the introduction of the new decision-solution.
- 26. In order to fulfil the objective of the decision-solution, the communicative implementation of information and counselling duties requires special attention. The German Ethics Council has, therefore, evaluated the first information campaign of the Federal Centre for Health Education, as well as of the public and private health insurers, which took place primarily in the period from January to May 2013. This screening revealed a considerable need for subsequent improvement.
- 27. The conveying of the tidings of expected or certified brain death invariably requires empathetic support of the nextof-kin for processing this news. Admittedly, the nextof-kin's burden, due to the coincidence of the confrontation with death and the question concerning an organ donation, cannot be absolved through good support and

counselling. It can, however, be diminished by a careful focus on the individual circumstances and through the advisor's empathetic, supportive attitude. In doing so, it can be made clear that in the event of an independent right of decision by the next-of-kin or the trustee, any decision is accepted.

- 28. Different (groups of) people can be considered as possible discussion partners with the next-of-kin: physicians, nursing staff, psychologists, social workers, pastoral workers, representatives of the German Organ Transplantation Foundation, or transplantation officers. However, not all the (groups of) people mentioned are equally suitable for ensuring an adequate conversation with next-of-kin. Nursing personnel plays an important role; as a rule, they have the most contact with next-ofkin. Generally, the conducting of the conversation with next-of-kin should be understood as an interdisciplinary action and as a task of the entire team.
- 29. Despite the interest of obtaining organs for critically ill patients, no convincing ethical arguments speak in favour of conversations led in a directive manner with the next-of-kin who are called upon to make a decision about organ removal. A non-directive conducting of the conversation can be designed to be open-in-outcome and to that extent also corresponds to the legal intention of the decision-solution.
- 30. Additional difficulties can arise in informing the next-ofkin of a brain-dead individual from a minority cultural background. Here, linguistic barriers often pose a formidable obstacle to achieving good communication. Additional cultural challenges can occur as well. Especially in counselling conversations in an intercultural context, it can be important for the next-of-kin and their decisionmaking to know whether the performing of certain religious rituals (such as ritual washing) is still possible with an individual who has undergone a transplantation. With

a view to the aforementioned difficulties, it is of great significance to ensure that an impartial, professional interpreter is available.

### The German Ethics Council comes to the following conclusions and recommendations on the basis of its considerations.

#### A. Brain death as removal criterion

- A1. Every person must have the chance to make his or her own individual choice regarding post-mortem organ donation on the basis of adequate information. Post-mortem organ donation poses fundamental anthropological and ethical questions to which there are no simple answers. Therefore, a transparent approach to the discussion is imperative. In doing so, one has to present the arguments brought forward for and against the irreversible expiration of all brain functions (brain death) as a criterion of death. The institutions concerned with providing information about organ donation should bear this in mind.
- A2. The majority of the German Ethics Council is of the opinion that brain death is a sure sign of death. They are of the view that the donation of vital organs may only be permitted if the death of the possible organ donor is certified (dead-donor rule). The dead-donor rule also underlies the Transplantation Act, medical guidelines and current practice of transplantation medicine in Germany.
- A3. In contrast, a minority of the German Ethics Council does not consider brain death to be the death of the human being. They consider the dead-donor rule to be noncompulsory and ascribe brain death merely the role of a necessary criterion for removal.
- A4. The German Ethics Council is unanimously of the opinion that brain death should be retained as a prerequisite for post-mortem organ removal.

- A5. A statement by which the possible donor has personally and effectually consented to a post-mortem organ donation is still effectual if that person has provided it in the belief that one's brain death is not one's death.
- A6. The German Medical Association should continuously adapt the methods of brain death diagnostics to the progress of knowledge in science. Their use in practice must be assured.
- A7. At the same time, scientific research in connection to brain death diagnostics and organ donation should be supported with respect to the natural-scientific foundations; medical practice; and psychosocial support and counselling.
- A8. The performance of brain death diagnostics requires a high level of professional medical competence among the examining physicians, who, pursuant to the legal guide-lines, must examine the donor independently from one another and are not allowed to be involved in the transplantation. The medical associations should ensure the professional training, advanced training and continuing education necessary for this, and the offices responsible should take care that professionally competent physicians stand available for brain death diagnostics in any place and in a timely manner.
- A9. On the basis of current knowledge, the German Ethics Council recommends, according to the majority view, that the prohibition against non-heart-beating donation be retained.

#### B. Information and communication

B1. Pursuant to current law, if the possible organ donor has not provided a statement during his or her lifetime for or against an organ donation and has also not named any specific trustee for a decision, the next-of-kin of the possible organ donor are called upon to make a decision about an organ donation in the framework of their right to custody of the dead. This decision is difficult and, as a rule, associated with great burdens for the next-of-kin. The German Ethics Council is of the view that in the communication about obtaining a decision from nextof-kin, considerable improvements are necessary. This includes initiating conversations as early as possible, in a quiet environment and an appropriate space of time. The counselling should be conducted in a non-directive manner and open in outcome. Any decision by the nextof-kin, including a rejection of organ donation, should be respected. After organ donation, the grieving next-of-kin must be enabled to bid farewell to the deceased in a suitable manner; an appropriate after-care of the next-of-kin must be ensured.

- B2. It should be clarified in Section 7 TPG that conversations with and counselling of persons who have to make a decision about an organ donation and organ-protective measures may already be begun prior to the certification of death.
- B3. Likewise, the provisions extended through the amendment of the Transplantation Act for the content of the education of the population (Section 2 TPG) need improvement: The German Ethics Council is of the opinion that the naming of professionally qualified contact persons through the health insurers for questions from the insured, prescribed in Section 2 (1a) TPG, cannot be fulfilled by reference to a general hotline of the insurance company.
- B4. The Federal Centre for Health Education should regularly update their materials for health education, which in practice serve as the basis for the education through the health insurers, and should supplement them with the following points:
  - » explanation of the various possibilities for filling out the organ donor card, especially explanation of

the possibility of naming a trustee for the decision regarding organ donation;

- >>> the information that the sensation of pain is precluded following brain death; but even if there is no medical indication for pain management, a corresponding wish of an organ donor for such is, nevertheless, to be made allowance for, provided that the person has given consent only under this condition;
- » education regarding organ-protective measures (see also recommendation C1);
- » education about a possible collision between advance directive and organ donor statement, as well as the provision of text modules for their compatibility.
- B5. The materials of the Federal Centre for Health Education should contain, as is already currently the case with some health insurers, information about what regulations pertain to organ removal in other countries (e.g., non-heartbeating donation, dissent solution). This enables travellers to inform themselves as needed and, as applicable, to take precautions.
- B6. In implementing the duties of the health insurers for information and counselling and in communicating with next-of-kin in the hospital, allowance should be made for the linguistic and cultural barriers of people with a migration background. Therefore, the information letters of the health insurers should also be sent in the native language of the insured (insofar as this is known).
- B7. Section 4 (1) TPG should be amended to the effect that a professional interpreter is to be consulted in conversations with next-of-kin that do not have an adequate command of the German language. The financing of such services should be regulated legally, as well as non-bureaucratically, and should be assured in the appropriate time frame.

- B8. Upon the wish of the next-of-kin, contact to religious institutions and representatives should be enabled. To that end, cooperation among religious communities, German Organ Transplantation Foundation, hospitals and health insurers is necessary.
- B9. The education of the population about "the entire scope of the decision" (Section 2 (1) TPG) regarding organ donation must encompass the nature, extent and point in time of organ-protective measures, which are already necessary prior to concluding brain death diagnostics in order to preserve the organs to be transplanted from the possible donor.
- B10. In the case that an organ donation has been agreed to, templates for advance directives should include the possibility of a stipulation regarding the decision about performing organ-protective measures following the discontinuation of therapeutic measures in anticipation of brain death.

#### C. Organ-protective measures

- C1. In regard to organ-protective measures, the need for statutory revision exists. On the precondition that there is a statement by the potential donor in favour of an organ removal, these may currently only be undertaken prior to a concluded brain death diagnostics if the brain death diagnostics have already been initiated. The admissibility of such measures can then only be assumed prior to the beginning of brain death diagnostics if the possible organ donor had been informed about these measures and had consented to them.
  - a) In the event that the organ donor's consent to organ-protective measures cannot be established, it should be legally regulated which person – that is, legal representative (authorized representative or custodian) and/or next-of-kin – is allowed to make the decision about the performance of necessary

organ-protective measures prior to the certification of brain death.

b) The admissibility of the conducting of organ-protective measures up to the conclusive certification of brain death should be bound legally to additional requirements, for example, the maximum duration of organ-protective measures and the probability of the occurrence of brain death within a specific time limit.

#### D. Transplantation officers

D1. The federally legislated obligation to appoint transplantation officers with broad competencies in all removal hospitals has thus far been fulfilled by the federal states in quite divergent ways. The detailed regulations required pursuant to Section 9b (3) TPG have to date still not been created by a number of states so that occasionally no transplantation officers exist there. Other states have only inadequately developed the competencies and legal status of the transplantation officers. By and large, the financing of the transplantation officer is regulated unsatisfactorily. The German Ethics Council - given the central function of the transplantation officers for the entire process of the organ donation, including the accompanying of next-of-kin - holds it to be imperative in all states that the legal preconditions for this be created so that transplantation officers are appointed in the removal hospitals in compliance with the provisions of federal law. This is an indispensable prerequisite for the guaranteeing of a suitable and successful communication and cooperation among those persons involved with organ donation in medical centres and with the next-of-kin of possible organ donors.

The members of the German Ethics Council are assigned to positions A and B, outlined in sections 4.2 and 4.3, as follows:

#### Position A

Katrin Amunts, Constanze Angerer, Wolf-Michael Catenhusen, Frank Emmrich, Christiane Fischer, Carl Friedrich Gethmann, Thomas Heinemann, Ilhan Ilkilic, Leo Latasch, Anton Losinger, Reinhard Merkel, Herbert Mertin, Eckhard Nagel, Ulrike Riedel, Eberhard Schockenhoff, Elisabeth Steinhagen-Thiessen, Jochen Taupitz, Michael Wunder

#### Position B

Peter Dabrock, Martin Hein, Wolfram Höfling, Edzard Schmidt-Jortzig, Silja Vöneky, Claudia Wiesemann, Christiane Woopen

### **DISSENTING VOTE**

In section 2.2.4, there is an attempt to differentiate the goal of intensive-care therapy in patients with craniocerebral traumas primarily from legal points of view: that is, centring on the patient versus focusing on organ donation. From a medical perspective, this is misleading. Intensive-care treatment measures are fundamentally directed towards patients, thus always patient-oriented. In the event that the therapy does not lead to an improvement of the patient's state of illness due to the severity of the injury or the disease; a massive clinical deterioration occurs; and the suspicion exists that the patient stands irreversibly just short of brain death or has already died due to this, the question then poses itself dependent on the underlying medical circumstances of whether an organ removal is possible. If brain death diagnostics are conducted in this context, intensive-care measures are continued until the conclusion of the examination in order to maintain vital functions. Up until the certification of brain death, these intensive-care measures are in equal measure patient-centred and "organ-protective."

The suspicion resonating in some of the opinion's formulations that the preserving of vital functions through intensive care in the context of brain-death diagnostics instrumentalises the dying individual, has nothing to do with clinical practice in intensive-care units. Especially irritating from a clinical perspective is the hypothetical supposition that a persistent vegetative state could be a side effect of intensive-care treatment (cf. section 2.2.4, concluding paragraph) associated with the goal of implementing an organ donation or, respectively, a pending brain-death diagnostics.

The opinion acknowledges that not a single case is to be found in the literature and medical experience where such a constellation is described. It is therefore a speculation that leads to grave irritation in the public and thereby creates uncertainty in a field of reliable scientific knowledge. Likewise, the final sentence to section 2.2.4 changes little in this extremely mistakable impression: in contrast, it can be asked why this speculation is included so pronouncedly.

Any intensive-care therapy has as its goal to stabilize the organ systems in their complex interaction and to prevent the permanent loss of individual organ systems. As a matter of principle, this happens with the intention of saving the life of the patient concerned. In doing so, it is, as a matter of course, never precluded that this goal may not be achieved and that the patient may either bear remaining impairments from this or die due to brain or circulatory death. The assumption that the formation of a vegetative state might be an undue complication in the process, which the legislator can or must avert, implies that such a development would be foreseeable and possibly a medical malpractice. This assumption is erroneous from a medical perspective.

Possible legal interventions into medical therapeutic freedom would presumably lead to a further fostering of the tendency, which is already recognizable today in the assessment of risk in intensive-care therapy, of limiting or discontinuing treatment measures at an early stage and thereby reducing chances for survival through risk avoidance.

Recommendation C1 b also misleads the reader. Here, a legislative need for action is claimed for highly specialized medical questions, such as the maximum duration of so-called organ-protective measures or the probability of the occurrence of brain death. This recommendation is formulated in conjunction with the remarks in section 2.2.4, under the assumption that "organ-protective" measures could in principle run counter to the interests of a critically ill patient. This interpretation not only contradicts applicable legal requirements (Transplantation Act), but also fundamentally puts into question efforts by physicians and nursing staff at saving critically ill patients in intensive-care units. Given clinical-medical practice, a firm objection to this is raised. The medical mission

of treatment is concentrated on the welfare of the patient and not on a theoretical possibility of organ donation.

Considering recommendation C1 b, which could not produce consensus, in conjunction with the misleading train of argument in section 2.2.4 of the opinion, the assessment in the first sentence of section 2.3.3.3 must likewise be rejected, according to which "the existing legal situation is inadequate for organ-protective measures prior to certification of brain death."

Especially against the background of the diversity of possible case-constellations and individual patient's wishes and fortunes, it is desirable to conduct a more differentiated analysis of the relationship between advance directive and organ donation statement. In the working paper of the German Medical Association available on this (see the references or footnote 68), it can be clearly seen even beyond the individual caseconstellations how the participants can come to a decision through individual appraisal of a patient's situation of whether or not the continuation of intensive-care measures until the conclusion of brain death diagnostics is reconcilable with the patient's wishes. Moreover, this also applies to the introductory finding for recommendation C1: The legal regulation generally demanded there regarding the admissibility of continuing intensive-care measures prior to brain death diagnostics can already nowadays be decided by the patient representative in conformity with the law.

It should thus be noted: A separate intervention of the legislature is not required on this point.

Frank Emmrich, Leo Latasch, Eckhard Nagel

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### **ABBREVIATIONS**

AA	Akademie-Ausgabe (Academy Edition)
AS	Amtliche Sammlung (Official Compilation)
BGB	Bürgerliches Gesetzbuch (Civil Code)
BGBI.	Bundesgesetzblatt (Federal Law Gazette)
BGH	Bundesgerichtshof (Federal Court of Justice)
BGHSt	Entscheidungen des Bundesgerichtshofs in Strafsachen (Decisions of the Federal Court of Justice in Criminal Cases)
BVerfG	Bundesverfassungsgericht (Federal Constitutional Court)
BVerfGE	Entscheidungen des Bundesverfassungsgerichts (Decisions of the Federal Constitutional Court)
BZgA	Bundeszentrale für gesundheitliche Aufklärung (Federal Centre for Health Education)
DSO	Deutsche Stiftung Organtransplantation (German Organ Transplantation Foundation)
EEG	electroencephalogram
GG	Grundgesetz (Basic Law)
InterKIK	Interprofessionelle Kommunikation und Kooperation (Interprofessional Communication and Cooperation)
КоРМ	Kooperation Pflege und Medizin (Cooperation Care and Medicine)
NHBD	non-heart-beating-donation
No.	Number
OJ	Official Journal of the European Union
para.	paragraph*
StGB	Strafgesetzbuch (Criminal Code)
TPG	Transplantationsgesetz (Transplantation Act)
vol.	volume

\* In the original German citations, "Rn." (*Randnummer*, or literally "number on the margin") refers to the practice of numbering paragraphs in the margin of many German legal opinions. Here, "Rn." is translated as "para.".

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