Presidenza del Consiglio dei Ministri

ITALIAN NATIONAL BIOETHICS COMMITTEE

CRITERIA FOR ASCERTAINING DEATH

24th of June 2010

INTRODUCTION

The opinion *Criteria for ascertaining death* was approved unanimously by the NBC in the plenary meeting of the 24th of June 2010 by those present (Prof. Salvatore Amato, Prof. Luisella Battaglia, Prof. Stefano Canestrari, Prof. Lorenzo d'Avack, Prof. Emma Fattorini, Prof. Carlo Flamigni, Prof. Romano Forleo, Prof. Laura Guidoni, Prof. Demetrio Neri, Prof. Laura Palazzani, Prof. Rodolfo Proietti, Prof. Monica Toraldo di Francia, Prof. Giancarlo Umani Ronchi, Prof. Grazia Zuffa, Doctor Riccardo Di Segni) with the exception of Prof. Lucetta Scaraffia, who voted against it. Prof. Maria Luisa Di Pietro, Prof. Emma Fattorini, Prof. Silvio Garattini, Prof. Aldo Isidori, Prof. Claudia Mancina, Prof. Alberto Piazza, absent from the meeting, expressed their agreement with the document. To explain the reasons for her vote against, Prof. Lucetta Scaraffia drew up a personal remark, attached to this opinion and published with it.

The document was coordinated and drafted by Prof. Lorenzo d'Avack and Prof. Giancarlo Umani Ronchi, with the participation of all the Committee members (in particular with written contributions by Prof. A. Bompiani, Prof. A. Da Re, Prof. M. Gensabella, Prof. D. Neri, Prof. L. Palazzani and Prof. R. Proietti) and after consulting illustrious scholars: F. Procaccio, Complex Structure director of Anesthesiology and intensive care neurosurgery department, Agenzia Ospedaliera Universitaria in Verona; A. Nanni Costa, director of the National Transplant Centre; Doctor P. Geraci, in charge of the donations and transpants coordination Centre, Policlinico San Matteo in Pavia; G. Azzoni, professor of legal and biolegal Philosophy, Law Department, Universita' degli Studi in Pavia; P. Becchi, professor of Philosophy of Law, Law Dapartment, University of Genova; G. Miranda, professor of Bioethics, Pontificio Ateneo, Regina Apostolorum and R. Proietti, professor of Anesthesiology and reanimation, Università Cattolica del Sacro Cuore, Rome.

The Italian National Bioethics Committee (NBC) tackled the problem of the criteria used to declare human death. It is known that although there is only one death, its diagnosis can today be ascertained with the traditional cardio-circulatory criterion (irreversible cessation of the circulatory and respiratory functions), as well as with the neurological criterion (irreversible cessation of all the functions of the brain, including those of the brain stem). However, both these criteria have caused in the last few decades widespread scientific and ethical debate, also in consideration of the advancement of medical knowledge. The NBC has therefore deemed necessary to carry out a new and in depth discussion, capable also of integrating the document *Definition and detection of human death,* drafted by the same Committee in 1991.

In this document the NBC intentionally kept the problem of ascertaining death separate from that of organ transplants, on the basis of the precise premise that defining and ascertaining death must not have any ulterior motives, in the sense that we must always maintain the principle that declaring death is independent from the eventual removal of organs and from any utilitarian consideration relative to the social-healthcare costs of assisting post-anoxic patients. However, the Committee is aware that the link between them is now part of a widespread social feeling about this topic and that organ transplants, even in this document, must be taken into account especially when the issue is seen in a practical perspective.

After an ample clinical and ethical analysis, which took into account the different and opposing arguments, the NBC concluded that both neurological and cardio-pulmonary criteria are clinically and ethically valid to ascertain the death of an individual and completely avoid any chance of error. In particular the Committee, with regards to the neurological criteria, believes that only those referring to the so-called “whole brain death” and “brainstem death” are acceptable, intended as an organic, irreparable brain damage, developed to an acute stage, which has caused a state of irreversible coma, where artificial support has intervened in time to prevent or treat an anoxic cardiac arrest. The Committee however believes that any explanations of this concept to the public should be corrected and updated especially with regards to terminology, with definitions that are more in line with current clinical practice.

The adopted criteria must also fulfil the condition of rigorously and meticulously respecting the clinical pre-requisites of the metodology, the procedures and the eventual use of verification tests. For this reason we recommend the highest possible uniformity in the protocols, both with regards to the cardio-pulmonary and the neurological criteria, which at the moment seem often different from country to country, causing confusion in public opinion with negative effects on the relative belief in the reliability of the criteria themselves.

In particular, the NBC’s criticism towards the definition of death by cardio-pulmonary criteria, focuses on those protocols, found in other countries, that establish very short times (between 2/5 minutes) to ascertain death. The risk is that the patient could still “be alive”, as the extremely short time elapsed from the cardiac arrest is insufficient to declare the irreversible loss of encephalic functions. The NBC stresses the importance of respecting the “dead donor rule” in the field of donations and in removing organs, which must not translate into the “dying donor rule”.

Finally, the NBC recognises that Italian legislation on ascertaining death, supported by current guidelines, is extremely protective and prudent and has allowed medical institutions to adopt homogeneous practices. However, it recommends to be always open to further analysis of the problem, especially when new or previously overlooked scientific data emerge.

Rome, 10th of July

The President

Prof. Francesco Paolo Casavola

CRITERIA FOR ASCERTAINING DEATH

1. Premise: previous NBC opinion "Definition and detection of human death" (1991)

The National Bioethics Committee, with the opinion *Definition and detection of human death* (1991) already tackled the issue of ascertaining death on the basis of the neurological criteria[1], for a long time considered in many countries as a valid criteria, together with the traditional one (cardio-respiratory).

The document's conclusion is that, already formulated by the Harvard Commission (1968) and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research (1980), of the concept of death defined as "total and irreversible loss of the organism's ability to autonomously maintain its own functional unit". It follows that in order to declare an individual "dead", the Committee believes that it is clinically and ethically acceptable only the so-called whole brain death criterion "intended as an organic, irreparable brain damage, developed to an acute stage, which has caused a state of irreversible coma, where artificial life support has happened in time to prevent or treat an anoxic cardiac arrest"[2].

Therefore, with regards to the problem of ascertaining human death, the NBC accepts, like all western countries even before the 1990s, whole brain death as an additional criterion of death, with all the legal consequences that this implies (interruption of medical treatments, declarations of death, possibility of removing organs, burying the body, succession, etc.).

The NBC's document at the time proved to be of great importance to the Italian legislators, who, in the Law 578/93 *Regulations to ascertain and certify death*, took it largely into account, establishing in Art. 1 that "Death is identified with the irreversible cessation of all encephalic functions".

However, we can see how the NBC tackled this issue without discussing the bioethical debate already present in the 1990s, which on the one hand saw the definition of death as a philosophical and moral problem (What is death? What is the meaning and dignity of human life in the condition of absence of conscience and serious cerebral lesion?) and on the other hand doubted the notion of brain death. In addition, the interaction between the different conceptual levels seems fully expressed in the cultural debate and in the many critical contributions of these last twenty years, after the Committee's document.

This statement deserves further clarifications.

The Committee's main interest – following the debate that for various reasons was already going on in society at the time – was to make the reader understand the profound distinction that in "real" terms (that is, in the clinical events at the basis of the bioethical evaluation of human death) exists between the expression "brain death" and "whole brain death", not always used correctly in the philosophical debate and source of great misunderstanding, at least potentially, in the behaviour of the doctors resuscitating an individual.

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[1] For an explanation and the meaning of the different terms used to refer to the issue of "brain death" see *ultra* "Glossary".

[2] National Bioethics Committee, *Definition and detection of human death,* 1991, p. 7.

In addition, few members of the public knew the complexity of the structures of the “central nervous system” (that is, those contained in the cranium) and were aware that from a descriptive-anatomical point of view, the term “brain” is only applicable to the “higher” cortical area (telencephalon) and to the one immediately below it (diencephalon). Therefore, with the expression “brain death” it was to be intended only death caused by an extensive lesion, such that it would lead to the substantial and irreversible loss only of the functioning of the telencephalon/diencephalon, whilst with the expression “whole brain death” it was to be intended the same substantial and irreversible damage also to the central nervous structures below – in the architecture of the central nervous system – the diencephalic structures, that is, the mesencephalon (cerebral peduncles and quadrigeminal plate), the metencephalon (pons and cerbellum) and finally the myelencephalon (medulla oblungata).

The adjective “whole” – applied to the noun “brain” – especially in what has become its common usage in public opinion and in the press to define the concept of encephalic damage, has come to mean a “global” irreversible functional lesion, that is, of all endocranial (encephalic) structures, strictly linked not only by a myriad of nervous connections, but also by an articulated circulatory system.

Proof of the accuracy of this interpretation is the fact that no-one (either in Italy or elsewhere) put the term “whole” before the word “brain” writing “whole brain death”, an expression that would have supported – if it had been adopted - the accusation, already made by some at the time, of ignoring any residual function, a weak electrical signal, of the cortex’s cellular structure, even when the total “brain death” has been declared and verified.

On the basis of the incontrovertible clinical experience of decades, in conclusion, the NBC’s primary interest in 1991 was to stress that a serious endocranial lesion capable of leading to the subject’s death had to cause irreversible effects on the “central nervous system” overall (“whole”), and not only stop cortical functions (“the so-called cortical death”).

The NBC however, to be in line with the international terminology already established for many years, used the term “whole brain death” and not the term “encephalic death”, although it clearly argued to that effect.

Finally, it must be pointed out that a further “proof” of the correct use of the concept of totality is given by Italian legislation (as seen above) in its mention of the irreversible stress that is placed on *all* the possible functions of the central nervous system in the cranium, in order to be able to talk of death ascertained with a neurological method.

With the “legal” expression of encephalous – adopted by the legislator – every possible doubt or misunderstanding of the concept of “brain death” (which, without the descriptive adjective, indicates almost necessarily “cortical” stress) is removed.

2. Reasons for a further NBC reflection

The current Committee felt that it was necessary to carry out a new reflection on this issue in order to integrate the 1991 document, especially in consideration of the progress of medical knowledge, which has produced a more in depth scientific and ethical debate with regards to ascertaining death with a neurological criterion.

The NBC, in tackling this issue, could not overlook the other criterion for ascertaining death: the cardiocirculatory criterion. This, in consideration of the fact that the same advancement in circulatory reanimation techniques and

extracorporal support require increasingly more accurate tests, which are not limited to a flat line EEG for a few minutes, as it happens – in various European Countries but not in Italy – in different protocols aimed at shortening as much as possible the observation period, due to the growing responsibility of organ removal from donors whose heart has stopped.

In this document the NBC intentionally kept the problem of ascertaining death separate from that of organ transplants, on the basis of the precise premise that defining and ascertaining death must not have any ulterior motives, in the sense that we must always maintain the principle that declaring death is independent from the eventual removal of organs and from any utilitarian consideration relative to the social-healthcare costs of assisting post-anoxic patients. However, the Committee is aware that the link between them is now part of a widespread social feeling about this topic and that organ transplants, even in this document, must be taken into account especially when the issue is seen from a practical point of view.

Finally, the NBC in this second document also reaffirms what the Committee stated in 1991, that is, how in public opinion the scientific criteria in this field are often unknown or badly interpreted so that they cause misunderstandings about the exact definition of death and the identification of the moment when it happens. "Unfortunately, in the widespread scientific debate, the frequent lack of clarity has contributed to raise or perpetuate fears or prejudices about a correct diagnosis of death"[3]. These preoccupations are still current today and demand a new in depth study of the issues that can help the eventual reformulation of definitions that are now inadequate, due to the advancement of scientific knowledge and technological applications, and therefore cannot be used in contemporary clinical practice any longer.

3. Ascertining death with neurological criteria

3.1 A short history

On the 5th of August 1968, "JAMA", the journal of the American Medical Association, published the Report of the Harvard Committee *A Definition of Irreversible Coma*, which indicated the innovative criteria for defining-ascertaining death, in addition to the traditional cardiorespiratory one. The comatose patient, when not receptive and responsive, was considered to be in a state of brain death if, once the ventilator had been switched off for three minutes, no respiratory activity had taken place, all spontaneous or induced movement had ceased, all reflexes had stopped, including those of the spinal cord and the EGG line did not show any electrical activity[4].

The document caused a lot of criticism: first of all, because of the lack of reference to any primary pathology that would have caused the irreversible coma and its possible interference with the prognosis and the eventual reversibility of the coma. Expecting the ending of *all* reflexes seemed unwise and confusing, although mitigated by the statement that there could be spinal reflexes, in particular the cutaneous plantar one. Then, the demand that all encephalic structures be destroyed and all functions interrupted was highly questionable, as the proposed criteria were not capable of exploring all of them. Finally, the Committee's

[3] National Bioethics Committee, *Definition*, cit., p. 10.

[4] This test was completely abandoned after a year, as more in depth considerations led to the conclusion that the clinical examination was in itself sufficient for the diagnosis.

statements seemed to some *mostly theoretical* because unsupported by scientific references directly expounded in the text, or – on the basis of the "clinical trials" criteria – evaluated with observations able to confirm, also from a predictive point of view, the validity of the thesis being advanced, despite the fact that clinical experts were part of the Committee[5].

After the Harvard document, some States in the USA started using neurological standards and criteria to ascertain death, others continued with the traditional methods. The American historian M.S. Pernick identified a lot of confusion in the interpretation and application of the Harvard criteria, not only by doctors but also by judges.[6] Determining death could be dependent on geography because of the criteria used: patients who died in one State could be considered still alive if moved to another State.

Amongst the most authoritative attempts at scientifically justifying the Harvard document, there is one presented at the beginning of the 1980s by the American neurologist James Bernat, together with his colleagues Charles Culver and Bernard Gert.[7] Their work was important to pave the way for the following scientific justifications of the notion of brain death and put forward an exclusively biological definition of death through the so-called theory of the "central integrator".

In 1980 the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research was created in the USA, and a year later published the document *Uniform Determination of Death Act* (UDDA)[8] with the aim of bringing uniformity to the definition of death and giving medically-biologically adequate answers.

According to the Commission "the individual who has sustained either irreversible cessation of respiratory and circulatory functions, or irreversible cessation of all functions of the entire brain, including the brain stem, *is dead*. A determination of death must be made in accordance with accepted medical standards". Therefore, the Commission identified as brain death, the death of the whole encephalous (*whole brain death*), considered to be the critical organ for corporeal integration. The irreversible cessation of all cerebral functions meant the irreparable loss of the integration of the various components of the organism and consequently the death of the individual. The Commission moved from the conviction that the notion of whole brain death was coherent with tradition, as this

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[5] On the other hand, it's true that at the basis of this statement there were international scientific experiences fixed over decades, amply consolidated although not cited by the Committee: thanks to P. Mollaret and M. Goulon' studies on the coma depasse' (*Le coma depassé. Memoire préliminaire*, in "Revue Neurologique", 1953, 101, pp. 3-15) and M. Jouvet studies on the nervous system (*Diagnostic électrosouscorticographique de la mort du système nerveux centrale au cours de certains comas*, in "Electroencephalography Clinical Neuropsycology", 1959, 3, pp. 52 ss.;) to the outcomes of two very important conventions: the Ciba Foundations one in 1966 and the American Collge of Physicians one in 1967, to the experience of numerous surgeons operating in this field. In addition, there had been a heart transplant carried out in 1967 by Barnard, a heart transplant carried out in Europe by Prof. Cabrol a few months before the Harvard declaration, and the Jeanneney circular that defined brain death. Only in 1977 a research supported by the National Institute for Health was published, which confirmed the thesis of the Harvard Committee.

[6] M.S. Pernick *Brain death in a cultural context. The reconstruction of death*, 1967-1981, in S.J. Youngner, R.M. Arnold R. Shapiro (eds.), *The definition of death. Contemporary controversies*, Baltimore-London 1999.

[7] J.L. Bernat, CH. Culver, B. Gert, *On definition and criteria of death*, in "Annals of Internal Medicine", 1981, XCIV, 3, pp. 434 ss.

[8] *Defining death: A report on the medical legal, and ethical issues in the determination of death*, Washington, D.C. 1981.

was not a radical change of the concept of death, but only the consequence of technological progress, which had made available to medicine more reliable instruments to measure the loss of cerebral functions.

This judgement was accepted, although with some marginal changes, in the legislation of the majority of European countries, with the exception of Great Britain. In this country medical associations are in favour of a definition of death that identifies it with the irreversible loss of consciousness and breathing, the necessary condition of which, from a physiopathological point of view, is the necrosis of the brainstem. It has been highlighted that the physio-pathological contradiction between the concept of death based on "whole brain death", which includes the brainstem, and the one accepted in Great Britain based on the necrosis of the brainstem, is only apparent. "The irreversible loss of the capacity for waking consciousness, associated with the loss of spontaneous respiration constitute the common essence of the two concepts and summarise their *core* physio-pathology of death, clearly distinguishing it from any other clinical situation".[9]

3.2. Criticism

It is necessary to remember that in those same years in the UDDA document, and then subsequently, doctors with different specialisations, philosophers and jurists, with a variety of cultural and anthropological leanings, raised objections about the reliability of the notion of "brain death", believing that this criteria is a "conventional" solution, as it is functional to the need of finding organs for transplant purposes. A criticism that is still raised today and that has forced quite a few ethics committees and medical associations to come back to the issue.

a. The scientific point of view

There are those who state that there is no adequate basis for a scientific justification in favour of neurological criteria for the identification of death.

The main scientific and clinical criticism regards two aspects that – on the contrary – had been identified by the President's Commission as the findamental reasons to consider the neurological criteria of death, valid.

The first criticism is aimed at the so-called irreversible loss of all functions, which would be present when whole brain death is declared. The second is aimed at the "permanent cessation of the functioning of the organism as a whole" and at the idea of assigning to the brain the role of giving an organic direction to all the functions that make up the organism of each living being.

With regards to the first, it is important to recall the article published in 1992 by doctors D. Truog and James C. Fackler[10], which enumerates – on the basis of medical research documents - the reasons why patients considered death on the basis of neurological tests do not necessarily show the irreversible loss of *all* cerebral functions. In proof of this statement, they cite some cases in which

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[9] Centro Nazionale Trapianti, *Determinazione di morte con standard neurologico. Elementi informativi essenziali*, 2008, p. 14.

[10] R.D. Truog, J.C. Fackler, *Rethinking brain death*, in "Critical Care Medicine", 1992, XX, 12, pp. 1705 ss.; additionally R.D. Troug, *Is it time to abandon brain death?*, in R. Barcaro, P. Becchi (eds.), *Questioni mortali*. *L'attuale dibattito sulla morte cerebrale e il problema dei trapiant*i, Napoli 2004, pp. 205 ss.; Id., *Organ transplantation without brain death*, in "Annals of the New York Academy of Science", 2000, 913, pp. 229 ss.; Id., *Role of brain death and the death-donor rule in the ethics of organ transplantation*, in "Critical Care Medicine", 2003, XXXI, 9, pp. 2391 ss.

patients declared brain dead show a variety of functions: the endocrine-hypothalmic function and in particular the hormonal activity of the neurohypophysis and the hypothalamous which controls it; an electrical activity, although weak, which can be found in some areas of the cerebral cortex; finally, spinal reflexes. On this basis, the Authors believe that the current clinical tests used to ascertain the irreversible cessation of all encephalic functions are not able to do so and demonstrate, consequently, that the neurological criteria of death based on some clinical tests adopted in various protocols is unreliable.

A critical argument that is repeated also in the scientific literature which followed the cited article.

With regards to the second criticism, not only the American neurologist D. Alan Shewmon[11], but also other neurologists and anestheticians state that the encephalous is not the organ responsible for the integration of the different corporeal parts which make the organism an organised and functioning unit. The body's "critical system" or "core integrator" cannot be found in a single organ, even an important one like the encephalous[12]. The neonatologist Paul A. Byrne states that the encephalous is not made up of one part, but many parts that are closely correlated (cortex, cerebellum, mesencephalon, brainstem, spinal cord, etc.). From this statement follows that the encephalous does not have a function that can be physiologically identified, or functions that can be accurately called "vivifying function or functions". "Rather, there exists – writes the author – a large multiplicity of different functions that are characteristic of the different parts. Although the characteristic functions of the brain-parts normally are closely coordinated, the parts have different functions that often cannot be carried out without the other parts. Futher, none of these parts is in complete control of the others".[13]

From a medical point of view, the organism of a person believed to be brain dead, according to neurological criteria, is practically kept alive "as a whole" by using technologies that substitute cardiac and respiratory functions. The individual organs stay interconnected and alive, just like transplant medicine demands they are. There are no signs of deterioration, we cannot see an increase in the disorganisation of the body's organs, tissues and cells. On the contrary, we observe a considerable order, coordination and integration: the spinal cord, temperature control, blood circulation, metabolism, immunological system and the gaseous exchange in the lungs, work. Pregnant women are even able to deliver the baby. And this shows the presence of very complex interactions between numerous organs (heart, lungs, liver, kidneys, etc.), which, in this perspective, is evidence of integration.[14]

Additionally, it must also be recalled that the source of life might not be the brain but the heart. The neurocardiologist John A. Armour stresses how in the last few decades there has been an accumulation of proof in favour of a "functional brain" of the heart, able to satisfy the body's daily needs. In addition it is said that the heart, with its internal nervous system, is capable of processing the information coming from the internal organs as well as centripetal information (directed to the brain) and centrifugal information (coming from the brain), in order to maintain the

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[11] D.A. Shewman, *"Death of the cerebral trunk", "brain death and death": a critical re-examination of their perceived equivalence*, in Barcaro, Becchi (eds.), *Questioni mortali,* cit., pp. 177-204.
[12] *Ivi*, pp. 197 ss.
[13] P. A. Byrne, *Death: the absence of life*, in R. De Mattei(ed.) *Finis vitae. Is brain death still life?*, Soveria Mannelli 2007, p. 85.
[14] R.. Beckmann*, Ascertaining death: is cerebral death reliable?, ibidem*, cit., pp. 46 and following.

internal *milieu* and this represents a new perspective from which we can understand in more depth the human body as a whole.[15]

From these observations and interpretations (although not fully shared by the majority of the scientific community) Armour arrives at a first conclusion: only the interruption of life support leads the patient rapidly to death. This situation should be distinguished from that identified as whole brain death, as it precedes it. These are situations with different peculiarities. After the so-called "total" brain damage or lesion, a man is near death: he is dying. Some cerebral functions remain and the integration capability, although diminished, is still present: these signs are believed to be respectable manifestations of human life. In this state it is therefore not appropriate to declare a human being dead and to treat him like a corpse. This will be possible only when the "characteristics of death" become evident, that is, when all cerebral functions will cease and the organism will start to disintegrate. But these characteristics are not reliably indicated, from this point of view, by the criteria of brain death.[16]

If therefore a widespread conviction is possible, that the brain of the patients in that particular condition is irreparably compromised, as a result of the trauma suffered or of the progress of the pathological process that caused the brain damage, – according to this perspective – a residual life is not excluded.

Edmund D. Pellegrino, the then President of the American Council on Bioethics, makes this idea explicit: "When a ventilator supports the body's vital functions, this technological intervention obscures our view of the phenomenon. What seem to be signs of continued life in an injured body are, in fact, misleading artifacts of the technological intervention and obstacles to ascertaining the truth. To consult brain-based functions, then, is to look through a "second window" in order to see the actual condition of the body". And it is precisely the rejection that there is a reliable "second window" of the phenomenon of death, in the abovementioned perspective, which is the object of criticism at the scientific level. "If its presence is not made known by the signs that have always accompanied it – breathing lungs and beating heart – then there is no way to state with confidence that death has occurred".[17]

b. At the philosophical level

On the basis of the scientific criticism to the criteria of whole brain death, philosophical criticism has been added and integrated.

Well know are the objections advanced by Hans Jonas, since the end of the 1970s, towards the Harvard Commission. Jonas stresses how we must not expect a knowledge of the object that is more precise than what the object itself allows. From this perspective, the definition of death would be affected by a congenital flaw of error and impropriety: wanting to define with certainty something that, for its

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[15] J. A. Armour, *The heart of the question, ibidem,* p. 3 and following. In reality, the issue of an *autonomous characteristic* of the electric stimulation of the heart's contractility – through the "bundle" of HIS and the atrioventricular node conductor - has been known for a long time, but just as known is the functional adjustment (already starting in embryonic life) of the heart's contractility in its different parameters through antagonistic, balanced, sympathetic and parasympathetic innervation.

[16] Beckmann, *Ascertaining death,* cit., p. 47.

[17] *Controversies in the determination of death: A white paper by the President's Council on Bioethics,* Washington, December 2008 (www.bioethics.gov)

own nature, cannot be defined precisely.[18] At the root of the new definition of death – according to the A. – there are two "practical reasons": on the one hand freeing the patients, the relatives and the healthcare structures from the burden of caring for an indefinitely prolonged coma; on the other hand avoiding ethical problems and controversies about the removal of organs. Both reasons cannot justify the definition itself, as they function not on the level of scientific knowledge, but on that of practical interest, which places the suspicion of exploitation on the definition itself.

Jonas believes that the theoretical definition in itself cannot have, not even in light of the new scientific knowledge, a rational justification. The death of the brain cannot be identified with the end of the organism's integration: in fact, not only local subsystems continue to function, but respiration and blood circulation, although supported artificially, also carry on, the activity of which extends to the whole system and ensures the preservation, both functional and substantial, of all the other parts. Therefore, although presented as an eminently scientific problem as a broadening of medical knowledge, the movement from the traditional definition of death (cessation of the cardio-respiratory activity) to the following neurological one is for the German philosopher an option dictated fundamentally by practical interests, left to doctors and then accepted by the law. The correct question is not: "Is the patient dead?" but "what can we do with him", who is still a patient? And this question cannot be answered with a definition of death, but with a definition of man.

The criticism and the doubts raised by Jonas, initially overlooked, were given growing attention from the beginning of the 1990s by some Catholic philosophers.

Josef Seifert moves from an ilemorphic metaphisical idea that identifies in the human being the presence of body and spiritual (rational) soul: in his opinion the human being ontologically trascends the sum of the parts that constitute the body, as an integrated organism. The cessation of the physiological and biological integration coincides with the death of the vegetative soul; the cessation of conscience with the death of the sensorial soul; only the "complete and irreversible cessation of all vital signs (including cardiorespiratory activity and total brain infarction)"[19] is evidence of an individual's death. The Author believes that the philosophical premises (unjustified in his opinion) of the notion of brain death are an empirical reduction of the human body to biological life, the functional reduction of the human being to his actions and capabilities (therefore to consciousness and rationality) and the identification of the brain as the absolute embodiement of the soul. According to Seifert, even if there was still a doubt, as there is no objective moral certainty of the death of an individual through the observation of brain death, we should tutioristically abstain from actions that could be homicides.[20]

Robert Spaemann, in the context of the same ilemorphic perspective, believes that, as the human being cannot be ontologically reduced to the function of thinking

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[18] H. Jonas, *From ancient creed to the technological man, Philosophical essays,* Englewood Cliffs, New Jersey, Prentice-Hall, Inc. 1974, pp. xviii, 349.

[19] J. Seifert, *On "cerebral death" in short. Philosophical arguments in favour and against the equivalence between cerebral death and real death*, in De Mattei (ed.), *Finis vitae,* cit., p. 272; Id*., Is "brain death" actually death? A critique of redefining man's death in terms of "brain death*", in R.J. White, H. Angsturm, I Carrasco De Paula (eds.), *Working group on the determination of brain death and its relationship to human death*, Città del Vaticano 1992, pp. 95-143.

[20] J. Seifert, *Is "brain death" actually death?*, in "The Monist", 76, 2, 1993, pp. 175 ss.; Id., Cerebral death and real death. Philosophical arguments, in Barcaro, Becchi (ed.), *Questioni mortali*, cit., p. 95.

and to the brain as the organic condition of thinking, his death cannot coincide with the cessation of cerebral functions, but it must be identified with the cessation of all vital functions (including the cardio-respiratory ones).[21]

This idea has been accepted by the jurist John M. Finnis, who felt that, from a Christian point of view, identifying brain death with a person's death is not justifiable.[22]

Although he starts from anti-metaphysical and utilitaristic philosophical premises, Peter Singer also expresses a criticism of the concept of whole brain death, using arguments similar to those put forward by Jonas[23]: the decision to abandon the traditional definition of death and opt for a new definition in terms of brain death, moved from ethical and non-scientific motivations. The Australian philosopher stresses that the definition of brain death is a definition which tries to overcome the obstacle of removing a beating heart, by declaring that the patient in that condition is already dead. Like Jonas, Singer is not convinced by the theoretical reasoning underlying the definition of brain death, namely, the thesis that the death of the brain and the death of the organism as a whole coincide. The organism's integration can continue, if properly supported with coordinated intensive therapy procedures, even in the brain dead patient. We must re-think the current notion of death from an anthropological and ethical point of view, keeping clearly separate two issues: "when is a human being dead?" and "when is it legitimate to interrupt the artificial treatment and/or intervene on his body?".

However, despite some analogy of arguments and the shared criticism of brain death, there are considerable differences about the behaviour due to the individual in a state of whole brain death with regards to transplants. The authors who move from the ilemorphic notion see the rising, behind the debate on ascertaining death, of the threat of *euthanasia* through the suppression of living individuals declared *non-persons* following their whole brain death.[24]

From Singer's point of view, which is shared by others, the weak ethical and scientific basis of the current definition of death as death of the entire brain and the utilitarian premises already found in the Harvard report (the importance for the community of defining death in practical terms), lead to the belief that it is more convenient, as well as morally justified, to conventionally fix, as the key moment of the process of dying, the loss of consciousness, determined by the so-called cortical death (instead of whole brain death), starting from the notion that we can reduce a person to his manifestation of rational capabilities. Taking for granted that these would not be "corpses", Singer therefore believes that it is morally legitimate to proceed with the removal of organs when cortical death has been ascertained without the shadow of a doubt.[25]

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[21] R. Spaemann, *Is cerebral death the human being's death? The current debate,* in De Mattei (ed.), *Finis vitae,* cit., p. 333 ss.; also in Pontificia Academia Scientiarum (ed.), *The signs of death*, *The Proceedings of the Working Group 11-12 September 2006, Scripta Varia*, Vatican City, 2007, pp. 130 ss.

[22] J.M. Finnis, *For an ethics of equality in the right to life. A comment for Peter Singer,* in Barcaro, Becchi (eds.), *Questioni mortali,* cit. pp. 123-39.

[23] P. Singer, *Rethinking life and death. The collapse of our traditional ethics*, New York-Oxford 1994 and P. Becchi, *Un passo indietro e due avanti. Peter Singer e i trapianti*, in "Bioetica", 2002, 2, p. 227 ss.

[24] In contrast, Jonas' preoccupation is that the patients in an irreversible coma become organ warehouses or object of experimentation.

[25] P. Singer, *Rethinking life,* 2000, pp. 64 and following.

The neurologist Carlo Alberto Defanti also highlights the difficulty of whole brain death and the problem of considering dead an individual in a body that is still biologically alive.[26] Some jurists hold similar viewpoints. Ubaldo G. Nannini asks himself whether "from an ethical and then legal point of view an extreme space of suspended existence between life and death is better and less risky than forcing its qualification with a positive definition of death"[27]. Further, Paolo Becchi states: "I believe that the time has come to overcome not only the definition of *whole brain death* but any definition of death in neurological terms (...). The troubling problems posed by patients in a state of brain death or in a persistent vegetative state have a profoundly ethical and legal nature and cannot be resolved with an allegedly scientific definition of death (the definition of brain death for those in a state of brain death, that of cortical death for those in a permanent vegetative state)".[28]

This does not mean that these authors exclude the possibility of: a) suspending all life support measures unable to benefit the patient; b) believing that it is legitimate to remove organs with the individual's explicit or implicit consent, when he has irreversibly started the process of dying.

3.3 The possible consequences

In the face of this criticism, three different lines of thought generally take shape:

- abandoning any definition of death in neurological terms and going back to the traditional definition of death based on the interruption of breathing and blood circulation;
- considering *whole brain death* as a still valid criteria, although needing the reformulation of its definition, supported by scientific reasons and philosophical arguments that can justify it;
- giving greater importance to those functions of the brain that support the phenomenon of conscience and stating that individuals who have permanently lost their consciousness are dead; an approach known as "*higher-brain criterion*".[29]

3.4 The arguments in favour

In the face of this criticism to the neurological criteria of death, the NBC has felt it necessary to listen to the opinion of neurologists, anaesthetists, ethicists and jurists and to take into consideration the content of a number of recent documents about ascertaining death with neurological criteria, in order to draw from them essential information.[30]

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[26] C.A. Defanti, *Soglie. Medicina e fine della vita,* Torino 2007, pp. 205-206; ID., *La morte cerebrale come paradigma della bioetica*, in BARCARO, BECCHI (edited by), *Questioni mortali*, cit., pp. 231-250.

[27] U.G. Nannini, *Valore della persona e definizione legale di morte*, Padova, 1996, p. 112.

[28] P. Becchi, *Relazione presentata all'Assemblea plenaria del CNB il 25.09.09*, p. 6; ID., *La morte nell'età della tecnica. Lineamenti di tanatologia etica e giuridica*, Genova, 2002.

[29] SINGER, *Rethinking*, cit

[30] The following were consulted: Doctor F. Procaccio (Complex Structure director of Anesthesiology and intensive care neurosurgery department, Agenzia Ospedaliera Universitaria in Verona); Doctor A. Nanni Costa (director of the National Transplant Centre); Doctor P. Geraci (in charge of the donations and transpants coordination Centre, Policlinico San Matteo in Pavia); Prof. G. Azzoni (professor of legal and biolegal Philosophy, Law Department, Universita' degli Studi in Pavia); Prof. P. Becchi (professor of Philosophy of Law, Law Dapartment, University of Genova); Prof. G. Miranda (professor of Bioethics, Pontificio Ateneo, Regina Apostolorum) and Prof. R. Proietti, member of the NBC (professor of Anesthesiology and reanimation, Università Cattolica del Sacro Cuore, Rome).

a) With regards to scientific criticism

a.1. On the irreversible loss of all brain functions

Even the supporters of the validity of the neurological criteria of death accept that correct clinical experience, also when involving mechanical instruments, in some cases can highlight some "residual" encephalic functions in the condition of brain death. These are "islands" of cerebral activity, mostly verifiable exclusively with investigations by instruments, but which can coexist with the loss of all possible brain functions. The eventual permanence of metabolically active cells within the cranium does not invalidate the concept of death of the individual. These functions, maintained thanks to an artificial breathing and therefore circulatory support, are considered conceptually similar to some functions which manifest themselves just after death by cardio-circulatory arrest (growth of hair, nails, etc.).[31]

It is also explained that analgesic and anaesthetic drugs are administered to the corpse (in view of the organ removal), because artificially maintaining the cycle is functional to the oxigenation of organs and tissues, including the spinal cord. This allows the preservation of a very low level of activity which however, in the absence of higher control encephalic functions, is capable of unexpected and paradoxical manifestations (at the minimum stimulus corresponds at times a very strong vegetative reaction: tachycardia, arrhythmia, hypertension, etc.). These phenomena are not the individual's vital signs, but are triggered by an elementary reaction in the spine. The drugs used in procedures of organ removal do not have, therefore, the aim of eliminating pain, but of avoiding phenomena like bleeding or movements (spinal reflexes) which can hinder the removal.

The document by the National Transplant Centre states that all the cases published and the clinical experience of "hundreds of thousands of cases" in these first forty years of application of the Harvard criteria, confirm that, despite the

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The documents taken into account are: Centro Nazionale Trapianti, *Determinazione di morte,* cit.; Pontificia Accademia delle Scienze, *Perché il concetto di morte cerebrale è valido come definizione della morte. Dichiarazione da parte di neurologi e altri e Risposta alle obiezioni*, Città del Vaticano 2008; President's Council on Bioethics, *Controversies*, cit. and P. Geraci, G. Azzoni, *Prelievo di organi da donatore a cuore non battente. Protocollo Alba,* 2005. In addition, the most recent bibliography on this topic has been taken into consideration.

[31] Centro Nazionale Trapianti , *Determinazione*, cit., pp. 3-4; cf. also G. Miranda, *Relazione presentata all'Assemblea plenaria del CNB del 25 settembre 2009*; R. Proietti, *La diagnosi clinica di morte: sua evoluzione* and the NBC's plenary consultation of the 30th of October 2009; C. Manni, *A Report on cerebral death*, in J.D.D. Vial Correa, E. Sgreccia (edited by), *The dignity of the dying person,* Proceeding of the Fifth Assembly of the Pontificial Academy for Life (Vatican City, 24-27 February 1999), Città del Vaticano, 2000, p. 115 and *L'accertamento di morte*, in R. Poli (edited by), *Ai confini della vita*, *1, Corso di formazione in bioetica*, Milano 2008, pp. 246 ss.

Also the ability to continue a pregnancy in brain dead women is believed not to be proof that the death is reversible, therefore not to be proof of life: "The mother's uterus and her other organs are supported as a technical vessel for the pregnancy in a way that is similar to what is done to keep the heart or kidneys perfused" (Centro Nazionale Trapianti , *Determinazione,* cit., p. 45). The NBC believes that reducing maternity to a mere mechanical gestation and the uterus to a mere vessel is, in any case, a bioethical problem; although it recognises that the woman's body, in this case, is a corpse, and blood circulation is maintained for the only purpose of allowing the foetus to be born. It must also be mentioned that the legal certification of death follows the baby's birth, even when the death has been ascertained with neurological criteria. The understandable delay in the certification of death to the moment of giving birth, cannot translate in a lack of respect (from an healthcare but also linguistic point of view) for the woman's body which is already a corpse (as she is brain dead), but still "mother".

possible presence of a minimal intracranial residual activity and the permanence of some physical functions due to the support given to breathing and circulation during a prolonged reanimation, "no recuperation of brain functions is possible, the loss of which is therefore irreversible".[32] Consequently, what matters is not whether some cells or limited islands of encephalic nervous tissue remain alive, but whether the encephalous carries out or can carry out its coordinating functions for the body. As Gonzalo Miranda explains: "There is no need for all brain cells to be dead in order to determine the death of an individual, even with cardio-respiratory criteria. In fact, they can survive even some hours after death by cessation of heartbeat, some cells of the hypothalamous (as we can see from the absence of diabetes insipidus) or of the cerebral cortex (as we can see from some isolated electrical activity or from the possibility of cultivating living neurons taken from individuals declared dead by cessation of heartbeat some hours previously)".[33]

a.2. The encephalous as the supreme organ coordinating the whole organism.

In reality, there's no denying that, as demonstrated by current clinical experience in reanimation, intensive care techniques (support with breathing and blood circulation) can replace even for months the loss of encephalic functions. The supporters of the neurological criteria accept that from the point of view of terminology, the expression "whole brain death" should be reformulated, if we want to give it the implied meaning that the encephalous is the organ that has the exclusive ability to integrate all organs and functions. But this does not invalidate at all, from a clinical point of view, the individual's state of death, seen as life does not reside exclusively in the encephalous.[34] What we find is that the cessation of all encephalic "critical" functions (namely, the functions that guarantee coordination) leads to the cessation of the organism as a whole. We stress that, despite the criticism, the progress in our knowledge of the mechanisms of the brain confirms that the body is directed "by that marvellous organ that is the brain" and that this must be seen as the receiving centre of all sensory, cognitive and emotive experiences, so that it acts "as the neuronal central motor of existence".[35]

Therefore, a critical position is taken towards Shewmon, who tried to prove that the integration and coordination of all physical sub-systems are not carried out exclusively by the brainstem and the hypothalamus.[36] "It is unclear – says the document by the Pontificia Accademia delle Scienze – which sub-systems Doctor Shewmon is referring to; the rare individuals who are brain dead, but whose organs survive for weeks or months demonstrate that some organs, like the kidneys and the digestive system, can function independently from the brain, but whether they can integrate each other is less clear. On the contrary, as some reports demonstrated, if the technical support is adequate, it is possible to maintain some organs (e.g. the heart) for days, isolated from the body in a system of perfusion".[37] Eventual "integrative sub-systems" of the rest of the body are few,

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[32] Centro Nazionale Trapianti , *Determinazione*, cit., p. 6.
[33] *Relazione*, cit. Similarly Pontificia Academia Scientiarum (ed.), *The signs of death*, cit., c. XXXIII.
[34] Procaccio, consultation, cit., and MIRANDA, *Relazione*, cit.
[35] Pontificia Accademia delle Scienze, *Perché il concetto,* cit., p. 47.
[36] A.D. Shemon, *The brain and somatic integration: insights in to the standard biological rationale for equating brain death with death*, "Journal of Medicine and Philosophy", 2001, 26/5, pp. 457 ss. and *"Morte del tronco cerebrale",* cit.
[37] Pontificia Accademia delle Scienze, *Perché il concetto,* cit., p. 50.

fragile and scarcely coordinated, and they are impossible to sustain once the brain is dead. With regards to this, it has been observed that "it is better to make a distinction between integration and interaction". Different cells, organs, and systems interact with each other, sending and receiving messages and reacting according to the signals received. "This happens in the living organism, but it can also happen in a body that is already dead and as long as it is oxygenated by mechanical ventilation, some of its tissues, organs and systems still continue to work, receiving messages from each other and reacting autonomously to those messages. We could even find this same interaction outside of the body, if we maintained a connection between still functioning organs (...). This interaction has nothing to do with the concept of integration of an organism as a living unit."[38]

From a clinical point of view these concepts have been mentioned in the document by the National Transplant Centre, in which it is highlighted how in ascertaining whole brain death, verification tests rarely show the presence, even residual and temporary, of cortical electrical activity and the basic perfusion of the cerebral vessels (particularly in the presence of direct and exclusive lesions of the brainstem). And when this happens, these patients are not considered dead. "On the other hand, the tests demonstrate without a shadow of a doubt, through very detailed and refined *imaging*, the complete absence of a cerebral hematic flow which represents at its best, both in physiopathology and communication, the simple concept of "decapitation" of the individual as the basis to ascertain death."[39] The criticism aimed at the data of the "permanent cessation of the functioning of the organism as a whole" regards especially the definition of death as the permanent interruption of encephalic activity and not so much the biological consequences of an anatomic situation that is equivalent to a real decapitation. And we have wondered whether a person without a head is still alive if the body is kept functioning with reanimation techniques.[40]

The supporters of the validity of these criteria, however, stress the need for a complete clinical examination and the apnea test, with a standardised and rigorous methodology, in order to exclude extreme situations, described in literature as "almost total damage" of the brainstem. Control standards that are even more indispensable in neonatal and paedriatic medicine because of the particular anatomical and physiopathological characteristics of the encephalous and the cranium in children below the age of five.

It is indispensable to be accurate: in fact, it is said that the majority of arguments against brain death are based on the erroneous or imprecise application of the brain death criteria to acts or events, or on the bad interpretation of the data of neurological examinations. Even the lack of uniformity in the criteria for ascertaining death adopted by the different specialist groups is used as argument against neurological criteria.

But another fundamental clinical data must be taken into account in favour of the neurological criterion: the irreversibility of this state of death. The complete necrosis of the brainstem and of the cortex implies the total and irreversible loss of spontaneous respiration and consciousness. These two data differentiate it in an exact, reliable and accurate manner from any other clinical situation of "cerebral lesion", even the most serious and compromised, that is not total and irreversible. Although neurosciences progress, they do not today allow us to foresee the

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[38] Miranda, *Relazione*, cit.; similarly Proietti, *La diagnosi,* cit.
[39] Centro Nazionale Trapianti , *Determinazione*, cit., p. 5.
[40] Proietti, *La diagnosi*, cit.

possibility of coming back after the specific moment of the cessation of all encephalic functions.[41]

b) With regards to philosophycal criticism

According to the perspective prevalent in philosophical anthropology, whole brain death is believed to be a valid criterion as it is a sign of the cessation of life in the human organism. The presence of the organism is a necessary condition, although not sufficient, to be able to talk about human being: therefore the cessation of vitality in the human organism is a sign of the death of the individual. And the organism is alive not because its parts are alive (cells, tissues, organs) or the interaction between the parts, but because it works as a "whole", which is more than the sum of its constituting parts[42]. The presence of some limited encephalic functions or some biological activity of its parts, as well as the persistence of signs of interactions between the parts, does not indicate the presence of integration or coordination.

Also according to the supporters of the ontological-metaphysical perspective, the fact that the encephalus is scientifically considered the switchboard of the organism (and therefore the irreversible lesion of it is condition for the organism's disintegration) does not mean – according to the supporters of the metaphysical point of view – the reductionist and functionalist identification of the individual with his/her brain, just as ascertaining death with the parameters of cardiac and respiratory activity cessation do not mean the identification of man with his heart and lungs. The encephalus is identified as the organ that manages organic integration, the cessation of which causes the "disintegration" of the organism, therefore of the human being. The individual dies not before or after the death of the human organism, but "with" the death of the human organism. The death of the human organism identified with brain death is the empirical evidence (which can be observed directly with a clinical investigation) of the ontological breakdown of the individual unit (ontological death is not directly accessible to the senses, but we can observe its signs and effects through clinical assessment criteria of the death of the organism), as there is a convergence between the life of an individual and the existence of the corporeal organism[43]. Death exhibits the cessation of the organism's autopoietic capability, the ability to maintain its own functional and psychosomatic unit.

The premise that death occurs because of the loss of the "organism's fundamental functioning" to justify the validity of neurological criteria has been accepted also by the President's Council on Bioethics in the United States in the abovementioned document *Controversies in the determination of death.*

The traditional ilemorphic perspective that implies the identification of the soul with the ontological form of the body is compatible with the identification of the organic physiological unit with the encephalus. If the whole of the different parts (listed above) that make up the encephalus (which common language identifies as the brain) ceases to guarantee the functional unity and the integration of the organic body, the body is not alive anymore, that is, from this point of view it is no longer able to be vivified by the soul. The language of metaphysics and ontology is also preoccupied with highlighting the inevitable mystery of death and the difficulty of identifying precisely the moment in which it becomes irreversible; in the

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[41] Centro Nazionale Trapianti , *Determinazione*, cit., p. 6.
[42] F. D'Agostino, *Bioetica nella prospettiva della filosofia del diritto*, Torino 1996, p. 186.
[43] M.P. Faggioni, *La vita nelle nostre mani. Corso di bioetica teologica,* Torino 2004, pp. 194 ss.

meantime, this language and even more the language of religious faith express the conviction that beyond death there is still a spiritual element of man. However we cannot ask science what death is and what is its existential significance for man; at most we can ask science what are the signs that can be associated more confidently with death. The signs identified by science to ascertain the loss of the organism's integration by observing the cessation of encephalic activity are believed to be necessary and sufficient to determine the individual's death, identified with the disintegration of the unit and the "separation of the individual's vital source, or soul, from his/her corporeal form"[44].

3.5. The position of the NBC

Despite the scientific and philosophical criticism against whole brain death (encephalic death), the NBC believes that the neurological criterion has biological and moral validity.

Whole brain death means the irreversible interruption of all brain activity (hemispheres and brainstem). When it is proven that the encephalus has totally and irreversibly lost its activities and functions, we can say that the individual is dead, because the organism has ceased to exist.

Let's examine the following clinical condition: we cannot find a structured cerebral electrical activity; the production of the anti-diuretic hormone is absent (presence of diencephalic syndrome); awareness, consciousness and breathing are absent; all brainstem reflexes are absent; the endocranial hematic flow is totally absent; any metabolic activity is absent from the encephalus. When facing this situation, is it possible to believe that this is a body "without a head" and that therefore the individual is dead although some parts of his/her body can be kept – artificially – still functioning?

The Committee believes that in this condition it is scientifically and ethically accurate to define the individual as "dead". The presence of some cells or of other organs that are still vital – thanks to technology – in the current state of scientific knowledge is not sufficient to state that the passage from life to death has not happened for the individual.

The Committee agrees with what, in interpreting the neurological criterion, derived from human physiopathology, supported by the clinical observation of the last few decades: namely, it believes that in the condition described the human being is "dead". In fact, the endocranial damage, in its complex "pathogenic dynamic", interrupted the coordination between its parts exercised by the central nervous system.

However, if what some now call a "corpse with a beating heart" can benefit from mechanical ventilation which ensures an efficient gaseous exchange in the lungs and manifests a cardiac activity helped by the intrinsic contractility of the cardiac myocytes (supported pharmacologically), there still is (for a certain amount of time) a connection between the various organs due to circulation, which provides for their metabolic needs through the many active substances exchanged through blood circulation. No-one – in this physio-pathological interpretation – denies the existence of a connection between the parts, or the general action

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[44] E. Sgreccia, *Manuale di bioetica. Fondamenti ed etica biomedica*, vol. I, Milano 2007, p. 845; G. Cottier, *Discussion on Prof. Spaemann's Paper*, in Pontificia Accademia Scientiarum, *The signs of death*, cit., p. 143; Pontificia Accademia delle Scienze, *Perché il concetto*, cit., p. 56 and Miranda, *Relazione*, cit.

exercised on the organism by other specific systems (like the immunitary system, the hormonal system, ect.), which act through the vascular connection.

In addition, it must be stressed that, clinically, the use of the neurological criterion to declare the death of the biological human being must be carried out very rigorously, without being affected by other purposes, even if they are understandable and respectable. To be specific, the state of so-called “whole brain death” (better, “encephalic death”) can be recognised from a number of signs:

- irreversible loss of the capability of awareness and therefore of consciousness (receptiveness and response to stimuli and signals from the surrounding environment);
- contextual loss of the ability to breath unaided;
- flat line EEG for a period considered clinically adequate;
- absence of brainstem reflexes;
- certain knowledge of the cause of the destruction of the encephalus.

It is indispensable, in reading the “signs”, to take into account a series of variables: the circumstances of the state of coma (toxic coma, coma due to primitive profound hypothermia, coma due to a serious endocranial insufficiency or other metabolic pathologies); the difficulties arising in ascertaining the death of young children. When however the abovementioned signs can be observed “thoroughly”, for a sufficient amount of time, encephalic death is certain: encephalic death does not “lead” to death but “is” the death of the individual, because the self-regulated functional unity that is typical of the living, cease. The condition of life or death is still determined by the structural and functional integrity of the organ that has the specific task of preserving that structure or structures, which turns the different corporeal parts into an organic whole. Therefore, it is possible to confirm what the NBC already stated: “In practice, it can be said that death *happens when the organism ceases to “be a whole”, whilst the process of dying ends when “the whole organism” has reached complete necrosis”.*

However, the Committee is aware that some critical arguments about the brain death criterion must be taken into consideration, demanding (for those who are convinced of the validity of the thesis of whole brain death) a critical discussion from a scientific and ethical point of view, the elaboration of an adequate justification of this position and – where necessary – a reformulation of the concept and of the arguments supporting it, in particular with regards to the possibility that the process of necrosis in the encephalus is not immediately identified with the necrosis of all encephalic cells and that considering the encephalus the only organ integrating the organism is merely paritally reliable. This, as we have said, does not affect the validity of the concept of death defined with neurological criteria, but it implies most of all the need for neuroscientists and doctors to give information that is more in line with the current clinical situation, due to reanimation and extra-corporeal support techniques. In fact, it appears more accurate to devise a different terminology from that in current use. Specifically, it is better to say that the patient is dead because of a “whole brain damage” rather than referring to the “cessation of all encephalic functions” or to a “brain dead” patient. Also, it is advisable to use the terms “keeping alive” and “medical treatment” when referring to procedures of mechanical ventilation or pharmacological treatment, which are eventually carried out on the body that is already a corpse, once the death has been ascertained without a shadow of a doubt with neurological criteria.

The NBC, on the other hand, as it already stated in its previous document, does not agree with those who believe that, in order to talk about encephalic death,

it is sufficient to observe the permanent cessation only of the functions of the cerebral cortex. In fact, when the so-called "cortical death" occurs, the paleoencephalic centres remain intact and the capability of centrally regulating vegetative homeostatic functions remains active, including autonomous respiration. This kind of clinical situation (*brain failure*) implies the preservation of brainstem functions, which is the pre-requisite for the capability of awareness and consciousness, with the permanence of spontaneous respiration.

With regards to the criteria of death identified with the "cessation of activities in the brainstem", we arrived at partially different conclusions from the previous opinion by the NBC. Criterion that, as already indicated, is adopted in Great Britain and supported especially by the Academy of Medical Royal Colleges. The NBC, in its previous opinion, considered it a criterion sufficient in itself, a judgement that we believe then influenced our legislation. It was observed that the empirical identification of a brainstem lesion is a prognostic sign of the cessation of the organism's unity (cessation of respiration and, consequently, circulation) and a prognostic sign of the cessation of cortical activity (following the lack of oxygen in the brain). In the condition of limited brainstem lesion, as it has been said, it is still possible to keep the organism alive with artificial respiration (which allows oxygenation and oxygen circulation), as well as still witnessing cortical functions (with the appropriate stimulation of some cerebral areas).[45] The lack of investigation of the cortical activity with any instruments (the exclusion of EEG) – which can be found in some protocols based only on the analysis of the signs of lesion in the basal stem (e.g. examining the functionality of cranial nerves only through clinical observation was common at the time) – raised doubts, because the permanence of areas of uncertainty could give rise to the idea that a person whose cerebral cortex is still whole and functioning could be declared dead "and it is not right to put on the same level the inevitability of death and death itself".[46]

Probably this point of view is influenced by the then prevalent preoccupation of the NBC of avoiding (as already some proposed in other Countries but also in Italy) sanctioning the idea that the loss of function in the cerebral cortex (which would be in any case defined as "cortical death") is the same as the irreversible loss of "all" the functions of nerve coordination exercised by the various "sections" of the encephalus on the organism as a whole.

Additionally, the inclusion of the serious and irreversible lesion of the stem area (which is notoriously made up of various functional nuclei) in the concept of "whole" brain death, was taken for granted. A very different situation is that of the rare "locked-in" syndrome, caused by a lesion in the pons area (which is part of the mesencephalon like the stem and closely connected to it): this condition shows that there can be lesions which do not prevent awareness and most cortical functions, but eliminate the possibility of communication. The example invites to be very prudent in identifying the relationship between confined encephalic lesions and general consequences.

We must focus our attention on a careful reading of the English regulations published in 2008 by the Academy of Medical Royal Colleges.[47] This legislation stresses how the doubt is unfounded in the case of very extensive damage, so that observing a flat line EEG in the condition in which it is possible to adopt

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[45] This can happen because the blood flow towards the cortex is not completely compromised; when for at least some time there has not been a complete occlusion of all arterial flow.
[46] Comitato Nazionale per la Bioetica, *Definizione*, cit., p. 13.
[47] *A code of practice for diagnosis and confirmation of death.*

neurological criteria to ascertain death, would not add anything to the irreversible interruption of “all encephalic functions”, both of the brainstem and cortical. In those conditions, in fact, the necrosis of the brainstem is inevitably associated with the complete and definitive interruption of cortical activity as well, so that registering the EEG is superfluous and would not add to the level of certainty.

We must not, in fact, forget the premise: neurological criteria for ascertaining death can be used only when the cause of the brain damage is known (cranial trauma, brain haemorrhage, cerebral anoxia). In these conditions it can definitely not be hypothesised that the cortex is even only partially functioning, when the total necrosis of the brainstem has occurred because of an endocranial hypertension of such gravity that it causes the interruption of the endocranial haematic flow. In addition, when the clinical investigation aimed at demonstrating the absence of the trunk’s reflexes is impossible to carry out in a complete and reliable manner, even the English regulations expect validating investigations with instruments (listed in appendix 3 of the abovementioned document). It is interesting to observe how they are believed to be reliable: cerebral angiogram (to document the absence of endocranial blood flow in both the brainstem and the cortex); single photon emission computer tomography (which documents the absence of metabolic activity in the whole encephalus); the evoked potentials (which document the absence of electrical activity both in the cortex and in the brainstem). It is not instead felt that the EEG is completely reliable and a variety of medical protocols agree with this conclusion.

Therefore, the criteria are different (but only for what concerns the EEG), however the basic clinical concept is not different: the absence of all encephalic functions must be documented (awareness, consciousness, spontaneous respiration and stem reflexes) due to a known cause that has interrupted the endocranial haematic flow and the metabolic activity of encephalic tissue.[48]

4. The cardiopulmonary criteria

4.1. The recent debate

Within the discussion about the criteria for ascertaining death, in most recent years there has been a return of interest towards the cardiopulmonary criterion, used when kidney transplants started (1960s – 70s) and then pretty much abandoned because of its modest “productivity” in terms of success.[49] This new interest has happened due to the need of increasing the pool of donors[50] and programmes have been initiated of organ removals not only from “heart-beating donors”, after having ascertained death with neurological criteria, but from “*non-heart-beating donors*”[51], after a diagnosis of irreversible cardiac death.[52]

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[48] R. Proietti, *La diagnosi*, cit

[49] In 1997 this approach was called “innovative”, because it re-employed, with new methods and technologies compared to the past (cf. KOOTSTRA, J.K. KIEVIT, E. HEIMAN, *The non heart-beating donor*, “British Medical Bulletin”, 1997, 53, 4, p. 844).

[50] Due to the decrease, amongst young people, of death caused by brain damage brought on by cardio-vascular pathologies and the improvement in the diagnosis and care of serious brain damage. The removal of organs from “heart-beating donors” represents in some European countries – like the United Kingdom and Spain – 10% of the contribution of kidneys and – a little less – of liver and they are set out to be, with some care, also the source of lung removals.

[51] The expression “donation after cardiac/cardiopulmonary death” is also used.

A possibility that has been realised – in some way – thanks to the advancements in transplant surgery and in organ preservation techniques. The success of the removal of organs from "non-heart-beating donors", however, is affected by the decrease of the waiting period after the cardiac arrest (which allows to minimise the absence of blood circulation, which permeates the organs) and by the speed of the attempt – although failed – to treat the patient in cardiac arrest and transport him/her to an intensive care unit. Finally, a team that is adequately prepared from an organisational and technical point of view, must be available.

Therefore, the removal of organs in non-heart-beating donors today focuses our attention back on the organisational complexity and the difficulty of diagnosing death with cardiological criteria. An aim, this, which requires – as already mentioned – the shortening of the observation period of the organs' warm ischemia, and this happens (in this phase, which can be considered in many ways still experimental) with the use of increasingly more accurate investigations to ascertain death. It is about determining the time period considered sufficient for the duration of resuscitation attempts and for the tests indentifying the permanent interruption of the cardiac function to certify that anoxia has in effect caused the irreversible destruction of the whole encephalus.[53]

The central ethical question, therefore, concerns respecting the "dead donor rule" (similarly to what happens with regards to ascertaining death with neurological criteria), according to which organs can be removed only after the patient's death. Consequently, it is essential to determine the criteria that allow ascertaining death, the way it is expected when ascertaining death with neurological criteria, in terms of equivalent diagnostic certainty.[54]

In literature and in international protocols we find a consensus about the diagnostic criteria for cardiac arrest, but there is no consensus in determining which observation time periods for the cessation of circulation and respiration are necessary but also prudent in order to declare the cardiac death irreversible. We find a variable time, which fluctuates between 2 and 20 minutes. The time is decided on the basis of more or less prudent empirical experiences, namely, on the basis of the observation that, after a certain amount of time from the cardiac arrest and after interrupting all attempts at assisting with medical instruments, the heart does not start beating again and it is not able to start beating again, believing that the cessation of circulation implies an irreversible whole brain damage.

It must also be said that determining an observation time that guarantees ascertaining the death of the individual, is in effect strongly linked in many countries to the different categories of donors, to which they refer for the removal of organs.

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[52] By ascertaining the irreversible interruption of the heartbeat, to which follows also the interruption of blood circulation, breathing functions and ischemic brain damage up to the colliquation of the encephalic mass.

[53] The "cardio-pulmonary" criterion is also linked to the neurological criterion of ascertaining death, on the basis of the organismic reality of the so-called Bishat tripod, which unavoidably links, in the case of the lack of (substitutive) human intervention, the loss of one of the three functions: respiratory, cardiac, neurological, to the subsequent loss of the others, independently from the order with which the first of the functions has suffered the catastrophic damage of the organism's external or internal noxa.

[54] Valko, *Ethical implications of non-heart-beating organ donation*, "Medicine and Morality", Michaelmas 2002, vol. XVII, n. 3; J.B. Shea, *Non-heart-beating organ donation*, 1 September 2003, www.lifeissues.net

The Maastricht protocol (1995)[55] identifies 4 categories: I- patients who have had the cardiac arrest outside the hospital and whose death is declared when arriving at A&E; II- patients who die in hospital after ineffective resuscitation[56]; III- dying patients, especially those in intensive care units, whose care is interrupted after a certain fatal prognosis[57]; IV- patients whose cardiac arrest follows their brain death. Afterwards, a category V was added, proposed by a Spanish study group in Madrid: patients in cardiac arrest or suffering from an unexpected cardiac insufficiency during intensive care.[58]

Category III, which includes non-heart-beating donors in a so-called "controlled situation", has led various protocols in the USA to adopt a timeframe for ascertaining death that is extremely short and varies between 2 and 5 minutes.

It must be clarified that this category includes patients in intensive therapy units, dependent from a ventilator, who, on the basis of their expressed will (or their family's will), are disconnected from the machine. These are patients for whom the cessation of artificial ventilation is not due to it being a futile or objectively heavy treatment, but to a personal decision, which can also take into account the lack of dignity of those living conditions. In these cases the patients intentionally disconnected from the machine are not resuscitated, respecting their will to die and wait for their heartbeat to cease for a fixed period of time.[59]

The Pittsburgh protocol (1993) reduces the observation period of warm ischemia and anticipates the organ removal (including the heart) even after only 2 minutes from cardiac arrest and the interruption of artificial ventilation.[60] Other

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[55] G. Koostra, J.H. Daemen, A.P. Oomen, *Categories of non-heart-beating donors*, "Transplant Prod.", 1995, 27, 5, pp. 2893-2894. The Maastricht protocol, which identified the categories of non-heart-beating donors, came from the first international Workshop on these issues. The protocol has quickly become a point of reference in European and international literature from a practical perspective, in order to group different categories for healthcare purposes and to verify the outcomes of transplants in different clinical conditions, in which the policy of acquiring transplant organs from individuals who died from cardiac arrest is trialled. Therefore, it is possible to compare statistics, which are necessarily still limited (survival after the transplant, rate of rejection or lack of functioning of the transplanted kidney, etc.).

[56] This represents the majority of the pool of non-heart-beating donors in Europe.

[57] This represents the majority of non-heart-beating donors in the USA. It is a category of patients that in Italy cannot be considered legitimate according to the laws in force: the law imposes the primary obligation of "carrying out all the interventions suggested by science" in the attempt of bringing back heartbeat and respiration and blood circulation, conditions that are indispensable to keep the individual alive.

[58] S. Ridley S. Bonner, K. Bray, S. Falvey, J. Mackay, A. Manara, *UK guidance for non-heart-beating donation*, "British Journal of Anaesthesia", 2005, 95, 5, pp. 592-595.

[59] This position is considered ethically legitimate with different arguments. Some authors recognise that patients in these conditions are "dying" but that the removal of organs is legitimate nevertheless (D.W. EVANS, *Seeking an ethical and legal way of procuring transplantable organs from the dying without further attempts to redefine human death*, in "Philosophy, Ethics, and Humanities in Medicine", 2007, 29, pp. 2-11; J.L. Verheijde, M.Y. Rady, J. McGregor, *Recovery of transplantable organs after cardiac or circulatory death: transforming the paradigm for the ethics of organ donation*, in "Philosophy, Ethics, and Humanities in Medicine", 2007, 22, pp. 2-8.); others believe that patients in these conditions are "dead", changing the concept of death with regards to the intention to not resuscitate/not be resuscitated (S. Shemie, *Clarifying the paradigm for the ethics of donation and transplantation. Was 'dead' really so clear before organ donation?*, in "Philosophy, Ethics, and Humanities in Medicine", 2007, 24, pp. 2-18).

[60] University of Pittsburg Medical Center Policy and Procedure Manual, *Management of terminally ill patients who may become organ donors after death*, in "Kennedy Institute of Ethics Journal", 1993, 3, pp. A1-A15; M.A. Devita, J.V. Snyder, A. Grenvik, *History of organ donation by patients with cardiac death*, in "Kennedy Institute of Ethics Journal", 1993, 3, pp. 113-29; M.A. Devita, J.V. Synder, *Development of the University of Pittsburgh Medical Center Policy for the care of terminally*

hospitals in the USA extend the observation period to 5 minutes, torn between the need of ascertaining the irreversibility of the cardiac arrest and the urgency of preventing organ deterioration.[61] The guidelines of the Ethics Committee of the Society of Critical Care Medicine (2001)[62] define the minimum timeframe as not shorter than 2 minutes, but believe that it is useless for it to be more than 5 minutes "if the objective is the removal of organs". The President's Council on Bioethics, USA, in the document *Controversies in the determination of death,* also identifies 5 minutes as the observation period generally applied in "controlled situation" cases.[63] The progressive reduction of the observation periods adopted by these protocols implies the sliding from the diagnosis to the prognosis of death.

With this timeframe it is possible to remove, together with the kidneys, the liver and in some cases the lungs, the heart as well. The heart that has ceased to beat in the individual declared cardiologically dead is removed in order to make it beat again in a recipient who needs a new heart to live. To the question, asked critically: how is it possible that a heart is removed from a dead donor and brought back to life in its functions in another recipient? We answer that the donated organ is removed from a context that cannot support the metabolism of myocardial cells, which can alive again once they are transplanted in another organism capable of supporting this cellular metabolism. The heart of a patient declared dead on the basis of cardiopulmonary criteria (in a "controlled situation") can therefore beat again when transplanted, as long as the autolytic processes cease in the recipient. The problems are the same as those in the case of other organs removed from a donor whose death has been ascertained with both cardiopulmonary and neurological criteria, fully expecting that they can work again in the recipient.

The situation in Europe, with regards to ascertaining death with cardiopulmonary criteria, is quite varied. The University Hospital in Holland adopted the Maastricht Protocol, which establishes a waiting time of 10 minutes, including both patients in a "controlled situation" and in an "uncontrolled situation".[64] Similarly the Zurich Hospital in Switzerland. In Spain the diagnosis of death with cardiorespiratory criteria implies specific clinical tests during an observation period not shorter than 5 minutes, after an "adequate period of resuscitation attempts".[65] In France, only the removal of the kidneys and liver from

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ill patients who may become organ donors after death following the removal of life support, in "Kennedy Institute of Ethics Journal", 1993, 3, pp. 131-143; G. Kootstra, *Statement on non-heart-beating donor programs*, in "Transplant. Proc.", 1995, 27, pp. 2965 ss.

[61] The Institute of Medicine suggests a wait of 2 minutes and 5 minutes at the most between the cardiac arrest and the interruption of resuscitation attempts (Institute of Medicine, *Non-heart-beating organ transplantation: medical and ethical issues in organ procurement*, Washington, D.C. 1997).

[62] R.D. Truog et al., *Recommendations for end-of-life care in the intensive care unit: The Ethics Committee of the Society of Critical Care Medicine*, in "Critical Care Medicine", 2002, 29, p. 2343: "these solid organ procurements are performed under protocols that call for life-sustaining treatments to be withdrawn (usually mechanical ventilation) under controlled-conditions (usually in the operating room), with death declared by cardiac criteria following 2-5 mins of pulselessness". Later it is stated: "alternatively, non-heart-beating organ donation can proceed after a failed attempt at resuscitation": the definition of cardiac death in a "uncontrolled" situation is considered an "alternative".

[63] Chapter 6: *Non-heart-beating organ donation.*

[64] Kootstra, Daemen, Oomen, *Categories of non-heart-beating donors*, cit.

[65] In Spain the issue is regulated by the "Anexo 1" "Protocolos de diagnostico y certificaciòn de la muerte para extracciòn de òrganos de donantes fallecidos" del Real Decreto 2070/1999 "Regula las actividades de obtenciòn clinica de òrganos humanos y la coordinacion territorial en materia de

non-heart-beating patients is allowed, in specific efficiency conditions of the procedures, which can ensure the usefulness of the removal, after "resuscitation attempts have ceased for 5 minutes".[66] In the United Kindgom, the "non-heart-beating donor" is called "asystolic donor" and the timeframe is at least 5 minutes.[67]

In Italy death must be ascertained – not only in the case of organ and tissue donation – by having proof of the absence of cardiac electrical activity and registering a flat line ECG for at least 20 continuous minutes, after an eventual resuscitation time.[68]

4.2. The position of the NBC

The NBC intends to recall attention on the ethical discussion about determining cardiac death, which received more or less widespread criticism with regards to the diagnosis of death with neurological criteria.

The NBC, in this document aimed at updating previous and already mentioned works, felt it necessary to offer a few first clinical and bioethical reflections raised even by this traditional criterion for ascertaining death, reserving, however, a broader study on the topic for a time when eventually a more direct and extensive Italian experience has matured, which is at the moment confined to the activity of a programme started a few years ago at the University of Pavia, limited to the removal of kidneys.[69]

The ethical controversies about the abovementioned protocols are mostly focused on the fact that the patient, due to an extremely short timeframe (2/5 minutes) for ascertaining death, could still "be alive", because of the very short time elapsed from the cardiac arrest to declaring the irreversible loss of encephalic functions. The conclusions reached by the Pittsburgh Protocol and other similar documents are the object of clinical criticism[70], also considered that the record of cases show the existence of spontaneous recuperations – although rare – after an asystolic interval of more than 5 minutes. In these documents the "irreversibility" of the cessation of the cardiopulmonary function is defined in "weak" terms (not absolute), as it is still possible for the heart to start beating again after medical intervention. The limit of the observation period is then "conventional", as it is not based on scientific evidence. It is believed that the heart will not beat again, but it is a prognosis, prediction or presumption without real proof. On the contrary, it is possible that the observation period for the cessation of the heartbeat can be longer, as the heart is not "ill" but the cessation of the heartbeat is caused by the

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donacion y trasplante de òrganos y tejidos". On the basis of this directive, the 5 minutes timeframe was adopted by the Hospital Universitario 12 de Octubre in Madrid.

[66] In France, a number of Centres started trials on the basis of applicative decree n. 949 of the 2nd of August 2005 (which authorised the Protocol of the Agence de Biomedicine) of law n. 800 of the 6th of August 2004, updating the "Lois de Bioéthique". The removal from non-heart-beating donors is authorised (explicitly excluding category III), after resuscitation attempts.

[67] E. Chaib, *Non heart-beating donors in England*, "Clinics", 2008, 63, 1, pp. 121-134; Ridley, Bonner, Bray, Falvey, Mackay, Manara, *UK guidance*, cit.; British Transplant Society, *Guidelines relating to solid organ transplants from non-heart-beating donors*, London 2004.

[68] Law 578/93 and Decree 582/94, adjourned in 2008 with the attached scientific guidelines.

[69] In Italy, at the Policlinico "San Matteo" in Pavia, transplants of kidneys removed from a "non-heart-beating donor" are carried out following the guidelines found in the Alba Protocol: *Removal of Organs from a non-heart-beating donor (NHBD).*

[70] There has been criticism in the USA as well. Cf. J.L. Bernat et al., *Report of a National Conference on donation after cardiac death*, in "Am. J. Transplant", 2006, 6, p. 282; J.L. Bernat, *The boundaries of organ donation after circulatory death*, in "New England Journal of Medicine", 2008, 359, p. 669.

interruption of artificial ventilation; it is possible that after being disconnected from the ventilator, the patient starts breathing autonomously again, with a subsequent increase of the timeframe; in any case, the return of blood circulation is still possible if a resuscitation attempt is carried out. A recent study on "Critical Care Medicine" (2010)[71], on the basis of an analysis of scientific literature, believes that in a "controlled situation" there is no certainty for fixing a temporal limit on waiting for autoresuscitation in the absence of medical interventions.[72]

The Committee believes that ascertaining cardiac death needs the elaboration of independent, definite criteria for organ donation: the reduction of observation periods, functional to the removal of organs, is not believed to be ethically acceptable. The "rush" to remove the organs must not reduce the time necessary to ascertain death or decrease assistance or the quality of care to patients in intensive care or who are terminally ill. Therefore, a "prognosis of death" is not sufficient, as a prediction or probability, but it is indispensable to have scientific evidence of a diagnosis of irreversible cardiac death (similarly to brain death). The irreversibility must be intended "in strong terms", as an absolute condition that implies the impossibility of spontaneous recuperation or, with the technology available, cardiac activity.[73]

The Committee believes that it is indispensable to clarify the distinction between patients in a "controlled situation" and those in an "uncontrolled situation". The first situation raises considerable ethical issues, as it involves the early decision of interrupting life support therapies when they are not considered futile by the doctor (or clinical persistence), but are personally unwanted by the patient or his/her family. In literature it is not always clear if observation periods necessary for cardiac death refer to one or the other situation. The Committee does not intend to discuss in depth the issue of the "controlled situation", which implies a refusal or renunciation of health treatments (a problem already tackled in the opinion *Refusal and conscious renunciation of health treatments in the patient-doctor relationship,* 2008). Here, we simply stress that observation periods from the cardiac death must be guaranteed, regardless of organ removals and the category of the eventual donors.

The bioethical problem is therefore essentially linked to the temporal clinical determination of cardiac arrest, which, if we don't intend to overlook the *dead donor rule* in transplants and substitute it with another, that of the *dying donor rule*, must be long enough to guarantee with absolute certainty brain death by anoxia.

The NBC believes that, due to the difficulties of ascertaining death with cardiopulmonary criteria on the basis of current scientific knowledge, the 20 minutes expected in the Italian legislation (Law 578/93) allow a necessary cautious guarantee. In addition, in the Law there is no mention of a minimum or maximum time period in which the resuscitation attempts must be carried out, which are also linked to the specific circumstances of the cardiac arrest and to the competence of

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[71] K. Hornby, L. Hornby, S.D. Shemie, *A systematic review of autoresuscitation after cardiac arrest*, in "Critical Care Medicine", 2010, 38, 5, p.1247.

[72] The authors believe that it is necessary to implement observational studies to determine cardiac death in patients following the cessation of mechanical ventilation (*ibidem*).

[73] This is the position of: M. Potts, *Truthfulness in transplantation: non-heart-beating organ donation*, in "Philosophy, Ethics, ad Humanities in Medicine", 2007, 24, 2-17, pp. 2-17; A.R. Joffe, *The ethics of donation and transplantation: are definitions of death being distorted for organ transplantation?*, in *ibidem*, 25, pp. 2-28; T.S. Huddle, M.A. Schwartz, F.A. Bailey, M.A. Bos, *Death, organ transplantation and medical practice*, in *ibidem*, 2008, 4, pp. 3-5; F.L. Delmonico, *The concept of death and organ donation*, in "Transplantation", 2009, 88, pp. 123-126.

who, by necessity, is carrying out the resuscitation attempt. This obligation to resuscitate is certainly applied in the case of "unforeseen" cardiac arrests, due to causes that are internal (e.g. arrhythmia) or external (e.g. incident, mortal trauma) to the organism, whilst it is subject to different medical and ethical assessments when it is an event due to serious illnesses, in advanced state and terminal.[74]

Although a 10 minute period of absolute lack of cardiac activity – ascertained with certainty – is to be considered an element of high likelihood of the death of the human being, caution forces us to avoid reducing below 20 minutes the temporal limit of the wait before starting, on the body of the dead patient, the "technical" procedures that will allow the subsequent removal of organs. It follows that in Italy – should this practice develop – the eventual protocols used in the various hospitals for the purpose of removing organs from a non-heart-beating patient are not and must not be due to isolated or autonomous decisions, but must be elaborated following the law and its foundation, approved by the national guarantor authority (National Transplant Centre).[75] The centres that will eventually be authorised, will also need to be made up of particularly qualified personnel, trained in the specific needs of these cardiological damages, and a public support network for those individuals suffering from cardiac arrest will have to be guaranteed, endowed with high efficiency and fast intervention times, with the aim of ensuring first of all a better chance of resuscitation.

The NBC believes that it is also indispensable to consider the international scientific debate and to increase the observational studies to verify the scientific possibility to anticipate the certain and irreversible identification of cardiac death or the eventual possibility of a temporal limit susceptible to variation case by case, also taken into account the difference between the diagnosis of cardiac death in adults and children. The Committee recommends that in determining this, there should be no place for economical or pragmatic reasons.

At the basis of this issue is also the question of whether it is ethically legitimate to interrupt resuscitation procedures that don't cause suffering, but "stabilise" the individual's vital signs (although precarious). For some, the problem turns into that of therapeutic persistence, for others medical assistance is intended as an act due to the individual who still shows vital signs. In addition, at least in the experience already documented on various occasions in the USA, it is not the individual's expression of will to "not be resuscitated" or to interrupt resuscitation treatments objectively considered unproductive (situation of therapeutic futility), but the assessment of the relatives and/or the legal representative, which is considered important. The situation is therefore often extremely complex from an ethical point of view.

Within these protocols, even before ascertaining death with cardio-circulatory criteria (flat line ECG for 20 minutes) and only after an evident lack of reaction to cardio-respiratory resuscitation attempts, the NBC believes that some technical actions that do not damage the patient are legitimate, if they are aimed at "achieving control for donation purposes after cardiac death" and as long as they are necessary to allow the patient's positive and clear will to donate. It must always

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[74] In the cases included in the first hypothesis, assistence must be as quick as possible, because after a few minutes from the cardiac arrest (asystole) the damage – particularly brain damage – is serious and frequently fatal. The faster the transport and the care of hospital experts (A&E and intensive therapy centres), with the application of all the adequate criteria of cardiopulmonary resuscitation (mechanical and pharmacological instruments), the higher the chance of survival.

[75] As the already mentioned Alba Protocol currently does.

be a cautious and proportionate action, so that any medical intervention does not cause harm to the dying patient or an earlier occurrence of death or any damage to his/her dignity. Declaring death must never happen prematurely or early. It must be stressed that the protocol on ascertaining death, even when foreseeing the possibility of a transplant, must always respect the principle of equal dignity between the donor's will and the recipient's interest, considered individuals with equal rights. It is appropriate to have a cautious and prudent attitude, which always supports the privilege of life in uncertain situations.

5. Conclusions and recommendations

5.1. First of all the Committee states that, however different the criteria for ascertaining death, there is only one death.

5.2. It is the Committee's opinion that both neurological and cardiopulmonary criteria are clinically valid to ascertain the death of a human being.

5.3. The Committee rejects the idea that death can be defined on the basis of a mere "convention", even if justified by other humanitarian reasons and by solidarity, like organ donation. In light of this premise and when facing complex situations, the shared position is that a human being, if his/her clinical death is uncertain, must be considered alive and protected.

5.4. With regards to ascertaining death with cardiopulmonary criteria, the Committee:

- believes that in the current state of scientific knowledge, it is not ethically acceptable to reduce the observation period of cardiac death below what is today expected in the Italian legislation;
- recommends that the methods currently used to classify non-heart-beating potential donors must be taken into account only in fully equipped centres, explicitly authorised and operating particularly quickly to assist the unfortunate patient and through the adoption of an operative protocol, established nationally in line with the law in force.

The Committee reserves the right to reconsider the complex issue of ascertaining death with cardiocirculatory criteria as soon as an adequate assessment of the experimental phase currently being carried out in Italy is available.

5.5. With regards to ascertaining death with neurological criteria, the Committee:

- believes that the only criteria acceptable are those referring to the so-called "whole cerebral death" and the so-called "brainstem death", intended as total brain damage, which is irreparable and has caused an irreversible coma, where artificial support has occurred in time to prevent or treat an anoxic cardiac arrest;
- believes that – in the current state of scientific knowledge – other neurological criteria for ascertaining death are unacceptable, like that of the mere cessation of cortical functions.

Although the brain death criteria – intended as "encephalic death" – has been adopted by the most important academies of neurology in the world and is

accepted in the legislations of almost all the Countries that have tackled these issues, the Committee believes that the way this concept is explained to public opinion must be updated and clarified, especially with regards to the terminology, with definitions that are more in line with current medical practice. In addition, it recommends that public opinion is made aware of the anthropological, social, ethical and legal implications of the criteria for ascertaining death.

5.6. The criteria adopted to ascertain death require following methods, procedures and the eventual recourse to verification tests. For this reason we recommend the highest level of conformity in the protocols both of neurological and cardiopulmonary criteria, which often appear different from Country to Country, causing confusion in the public opinion with negative effects on the relative belief in the reliability of the criteria themselves.

5.7. The NBC believes that Italian legislation on ascertaining death, supported by guidelines[76], adequately guarantees the public and is cautious enough to allow medical structures to adopt homogeneous practices.

5.8. With regards to the ethical validity of the criteria for ascertaining death, the starting point can only be the factual reality of death, as shown by clinical diagnosis. However, we must always be open to further analyses of the problem, especially when new or previously overlooked scientific data emerge.

[76] Law 578/93 and Decree 582/94 updated in 2008 with the addition of scientific guidelines.

GLOSSARY

Generally we refer to the following clinical situations.
= **Cortical death:** lesion of the cerebral cortex, in which the paleoncephalon remains unaffected and the ability to centrally regulate homeostatic and vegetative functions is still active, including autonomous respiration.

= **Vegetative state,** also known as **apallic syndrome** or **wakeful coma**: the particular and extremely rare condition of patients suffering from severe brain damage (lesion of the cerebral cortex), in which the coma has developed to a state of wakefulness that does not lead to a state of awareness or consciousness. The eyes are open, usually the mobility of the eyes and of the eyelids is maintained, but the patient does not follow a visual stimulus with his/her eyes. In addition:

- he/she has no awareness of him/herself or the surrounding environment;
- the cycle sleep-wakefulness is present;
- he/she has reflexes that cause involuntary movement in response to pain stimuli;
- he/she makes spontaneous, routine movements without purpose;
- he/she can have some archaic reflexes including mastication, swallowing, facial movements, yawning, grasping;
- he/she can regain autonomous respiration and swallowing.

= **Brainstem death:** state that follows the total and definitive loss of all encephalic functions of the stem, with the irreversible loss of consciousness, wakefulness, respiration and other vegetative functions.

= **Locked-in syndrome:** condition characterised by tetraplegia, facial diplegia, labioglossopharyngeal paralysis, laryngeal paralysis; most of the time this condition is associated with a lesion of the ventral pons of various etiology (hemorrhagic, ischemic, contusive, etc.), which leave unaffected somatic sensitivity, the reticular formation of the brainstem responsible for wakefulness and alertness, some mesencephalic neuronal groups which allow the patient to raise his/her eyelids and move his/her eyes vertically, the diencephalon and the cerebral hemispheres, whilst the cortico-bulbar and cortico-spinal ways are interrupted, depriving the patient of the ability to respond, except by vertical eye movements and winking (which allow the patient and the doctor to establish a code of communication).
It is very difficult to carry out a cognitive and emotive assessment in the acute patient, due to fluctuating wakefulness and eye movements that are inconsistent and limited in variety.
The diagnostic criteria anticipate:

- present consciousness;
- sleep-wakefulness pattern;
- quadriplegia;
- permanence of auditory functions;
- permanence of visual functions;
- communication: anarthria (or inability to speak because of a cerebral lesion);
- permanence of emotive state.

= **Whole brain death:** state of total encephalic lesion (brainstem and cortical structures).
From a clinical point of view, both “whole brain death” and “brainstem death” identify the definitive loss of wakefulness, consciousness, respiration and brainstem reflexes.
We stress that the “**brain**” represents all of the parts of the central nervous system found in the cranium, which should be more properly called “encephalus” (from the Greek encephalon: “inside the head”). The cerebellum, scientifically, is the combination of telencephalon and diencephalon.

- telencephalon: it is the most superficial part made up of the *telencephalic cortex*, the *white substance* and the *base nuclei*
- diencephalon: it is situaied inside the telencephalic white substance, and it is made up of five parts (*thalamus, epithalamus, metathalamus, hypothalamus, subthalamus*), it carries on below with the mesencephalon through the two cerebral peduncles
- cerebellum: the part of the encephalon situated in the posterior cranial fossa
- brainstem: functionally connected with the cerebellum, it is itself made up of three parts, in the caudal-cerebral sense:

- mesencephalon: higher continuation of the diencephalon, made up by the two *cerebral peduncles* and by the *quadrigeminal plate;*
- pons: positioned ventrally to the cerebellum;
- myelencephalon: also called midolla oblungata, which carries on below, without interruptions, with the spinal cord.

PERSONAL REMARKS

Personal remark signed by Prof. Lucetta Scaraffia

Little more than forty years from the introduction of a new neurological criterion to define and ascertain death, the criticism towards it, initially voiced by a few scholars, is today considerably widespread, also in the light of new scientific knowledge, both in the medical and in the ethical-philosophical sphere. It is significant that the United States' bioethics commission felt it appropriate to tackle the issue again, publishing, in December 2008, an important document to discuss the issue in more depth. The topic of brain death is again the centre of attention also in other Countries. We can find a precise summary of this in the recent contribution by Sabine Muller, published online on the authoritative Ethik Med, with the title *Revival der Hirntod-Debatte: Funktionelle Bildgebung für die Hirntod-Diagnostik*.

It has therefore been very appropriate for the NBC to return on an issue already tackled in the past and on which, at the time, unanimous consensus had been reached. After a discussion which is at times considerably interesting – here I simply observe that Prof. d'Avack stated "the notion that the brain is the integrator of every function of the organism is now outdated", a thesis that is instead reaffirmed in this opinion – it seems to me that the outcome is unsatisfactory. In fact, I believe that the way the consultations have been carried out, their evaluation in drawing up the opinion and the other three documents which it was felt important to take into account, is imbalanced. Having consultations in this case was very appropriate, as those who raised the problem in Italy are not NBC members. Essentially, they are Prof. Paolo Becchi (professor of Philosophy of Law at the University of Genoa) and Prof. Carlo Alberto Defanti (one of the most authoritative neurologist in Italy, very experienced and with a considerable bibliography on the topic in question). Certainly, from a medical point of view, one of the top experts about the issue under consideration.

The first was consulted, the second wasn't. Neither of them, however – directly - left a significant mark on the NBC's opinion. Only a brief mention of two monographies by Defanti and his numerous articles. It is also questionable that out of seven consultations, of at least five it was already known from the beginning that they would defend the brain death criteria and only one would explicitly criticise it. I was especially surprised that on a topic of this nature, the NBC did not feel appropriate to consult at least one neurologist, that is, someone who certainly has better medical-scientific competence on the issue at hand.

The NBC's opinion states that they have "intentionally kept the problem of ascertaining death separate from that of organ transplants"; this however is clearly contradicted by the fact that a large part of the document deals with the cardiopulmonary criterion and " this return of interest has happened due to the need of increasing the pool of donors...". In addition, out of seven consultations, three concerned people directly or indirectly involved in the activity of the NTC. Actually four, as Prof. Azzoni was consulted with regards to the issue of organ donation from a non-heart-beating donor. Therefore it is not surprising that the document referred to in the Opinion is that of the NTC. In short, an opinion that

should not have anything to do with transplants is based on the consultation of the director of the NTC, of two collaborators of the same centres and on a document by the NTC, signed by two people who were consulted (Dott. Procaccio and Dott. Nanni Costa).

In addition, the way in which the second document has been used, that of the Pontificia Accademia delle Scienze, is partial and full of gaps. In the opinion, the fact that the Pontificia Accademia in the last few years has been quite torn about this issue, has remained completely unmentioned. It is correct to say that in the end the line now also adopted by the NBC, prevailed, but we must not forget that a considerable minority in the Pontificia, during the work carried out in February 2005, expressed itself against the brain death criterion. This is evident in the antology edited by De Mattei, which largely (although not exclusively) reports all the dissenting texts presented to the Pontificia Accademia delle Scienze (Evans, J. Evers, D. Hill, J. Seifert, A. Shewman, R. Spaemann, W. F. Weaver). The Opinion quotes the anthology edited by De Mattei, but without even mentioning the fact that it collects the contributions of the work of those who, in the Pontificia Accademia delle Scienze, opposed brain death.

It seems that the Opinion has some difficulty in revealing that the Catholic world – which moreover is also testified by the abovementioned case of Prof. Vincent Pellegrino – is not completely in favour of the brain death criteria.

Let's come to the Opinion. My observations refer to points 3.2 and 3.3, point 3.4 and point 3.5. I start with point 3.2 and 3.3, which, after a short history (in which a thesis that will be developed later is announced in the final part), mention the criticism put forward towards brain death from both a scientific and a philosophical point of view. Here there is only a summary of the antology edited by Becchi and Barcaro and published in 2004, quoting some essays translated in it. The only "original" things in this part are the idea, supported by the NTC and adopted by the NBC, that there isn't, in essence, any difference between whole brain death and brainstem death and the mention of Singer as a supporter of cortical death, when it would have been enough to read the article by Becchi to realise this scholar's progress, which has led him today to openly support the idea of a return to the traditional criterion of cardiac death.

What is most surprising, in all this section, is the almost total censoring of the work published on this issue in our country. We have already spoken about Di Defanti. Becchi is referred to only as the curator of an antology, no mention is made instead of his 2008 book *Morte cerebrale e trapianto di organi* (a very widespread publication) and most of all of the work published soon after with his collaborators, R. Barcaro, P. Becchi, P. Donadoni *Prospettive bioetiche di fine vita.* This is the most exhaustive study about this topic in Italy, which takes into account the international scientific debate until 2008 and includes a dozen of pages of selected bibliography. With the result of underestimating the debate of the last few years.

The use of the anthology edited by De Mattei has not had better fate. Only three out of 18 contributions collected in it are mentioned, obviously forgetting to discuss, amongst others, a contribution by Cicero Galli Coimbra, a Brasilian neurologist who conducted accurate studies on brain dead patients. Finally, little use has been made of the three contributions presented by Becchi when he was asked to participate to this document, and attached to the documentation. And yet, all three documents presented at that time by Becchi would have required in depth analysis. In particular, if the document presented by him with the title *I segni della*

morte e la questione dei trapianti had been read, we would immediately have realised that scientific literature is definitely not inclined to consider – as believed by the NCT and, along with it, by the NBC – “brainstem death” and “whole brain death” as equivalent. As further confirmation we could now recall the article by Sabine Muller cited at the beginning. From the diagram found in this article (p. 4), it is evident that on the basis of *Brainstem death* as adopted in Great Britain, a patient affected by the last stage of *locked-in syndrome* would be dead, whilst for us he/she is still alive.

It is a serious mistake, from a medical-scientific point of view (and this is further evidence of how important a neurologist’s opinion would have been!) and in any case devoid of any truth, the statement that the Academy of Medical Royal Colleges, with its 2008 document, moved closer to the criterion of whole brain death. The contrary is quite true: it is the NBC that, distancing itself from its previous opinion, recognises – without obviously being able to say it – what the English have always stated, namely, the scientific unreliability of the whole brain death criterion.

Point 3.4 leaves me perplexed: there was an expectation of at least a serious discussion about the existing scientific literature that continues today to support the validity of the neurological criterion of death, stressing however, at the same time, the need to use a more precise diagnostic (recurring to cerebral angiography, functional magnetic resonance and positron emission tomography), but there is only a faint trace of this, with the mention of the last work by the Academy of Medical Royal Colleges.

In point 3.5, in which the NBC’s position is presented, we find a confirmation of the thesis expounded in an online document by the NTC (we must not forget that this document – however we want to judge it – had the only purpose of giving “some essential elements of information”); that means that in the current situation the distinction between “whole brain death” and “brainstem death” has disappeared. With regards to the rest, the NBC stresses how right its 1991 document was and accepts without discussion the theses in favour of keeping the definition of death in neurological terms.

Essentially, what should have been a serious discussion about brain death criteria, starting with the lively and abundant scientific literature about this topic published in the last few years, resulted in a wider opening towards transplants, making possible the possibility of brainstem death and the removal from non-heart-beating donors, which is in effect at the moment merely “tolerated” because – with the exclusion of the corneas – currently the only methods properly regulated by our legislation are those based on brain death criteria.

Therefore, I conclude stating that the document does not adequately respond to the challenge offered by the most recent scientific debate.

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