



NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES

76/CNECV/2013

**NATIONAL COUNCIL OF ETHICS  
FOR THE LIFE SCIENCES**

**Opinion on the Ministerial Order regarding  
organ removal in people with irreversible  
cardiopulmonary arrest**

**(September 2013)**



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### INTRODUCTION

#### **Opinion**

Upon request of the Office of the Secretary of State Assistant to the Minister of Health, the «*Proposal of Ministerial Order that determines the necessary requirements for organ removal in deceased donors*» has been analyzed, and the National Council of Ethics for The Life Sciences considers the following:

#### **A) Questions of opportunity**

1) It is unquestionable that organ and tissue removal for transplantation purposes with origin in people who had a cardiopulmonary arrest is justified in terms of usefulness, compared to the invoked reduction of transplants with origin in people with diagnostic of brain death and the (growing) need of organs to save or improve quality of life. However, these are arguments that, from the ethical point of view, must be relegated to a second position in relation to others, being its use only acceptable if measures are taken in terms of principles and safety which are sustainable, also from the ethical perspective.

2) An analysis made to the donation rates in 88 countries relative to 2000-2010 concluded that “although the results do not indicate a causal relation between the increase of donation rates by cardio circulatory death and their reduction by brain death, the significant correlation between higher rates by cardio circulatory death and lower rates by brain death, associated with the short number of transplanted organs by donor in cardio circulatory death, suggests that a national policy centered in the latter may lead to a global reduction in the number of transplants performed” <sup>(1)</sup>. In this sense, the proposal should be contextualized in the aim of a global policy, which details are unknown.

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#### **B) Ethical questions**

3) In terms of principles we must point out that transplants of organs and tissues removed from deceased people, having raised a wide discussion at their inception, are nowadays globally accepted, considering the benefit for the receivers and with duly respect for the deceased person and its body. In this perspective and from the ethical point of view, there are no considerable differences between the situation of organ removal in people with irreversible cardiopulmonary arrest and people with brain death.

4) According to the principle of autonomy, the presumption of consent in force in our country has been object of discussion: we are all potential donors unless we express our opposition by registering in the National Register of Non Donors. Also in this particular aspect, we do not verify any differences in both situations of organ removal in a deceased person, being extemporaneous to

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<sup>(1)</sup> Bendorf A. et al. An international comparison of the effect of policy shifts to organ donation following cardiocirculatory death (DCD) on donation rates after brain death (DBD) and transplantation rates. PLoS One. 2013 May 7;8(5) - <http://www.plosone.org/article/info:doi/10.1371/journal.pone.0062010>



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question a practice that has been globally accepted in our society and which justified a timely favourable assessment of this Council in its Opinion No. 3/1993 <sup>(2)</sup>.

5) In terms of prudence, it can be stated that the rules and methods in force (in Portugal and other countries) are nowadays acknowledged as sufficient to guarantee maximum certainty in confirmation of death, as recommended by the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin <sup>(3)</sup>, on which CNECV pronounced itself in Opinion 73/CNECV/2013 <sup>(4)</sup>. Such is the case of people whose death is verified, despite having heart beats and being connected to mechanisms of respiratory assistance in intensive care units, in which the criteria published by the Medical Association in 1998 apply <sup>(5)</sup>. These criteria have also been assessed by CNECV in its Opinions No. 6/1994 <sup>(6)</sup> and No. 10/1995 <sup>(7)</sup>. It is equally important, in case of removal of organs in people with irreversible cardiopulmonary arrest, therefore pronounced dead, the need to define the criteria now submitted to ethical assessment, which seem to have sufficient scientific and technical basis.

6) The project of regulation proposed by the Secretary of State Assistant to the Minister of Health restrains organ removal to the two first situations of death by irreversible cardiopulmonary arrest: “death upon arrival” and “unsuccessful resuscitation”, defining them. Other situations are therefore excluded, as the ones referred by Kootstra *et al.*: “expected cardiac arrest” and “cardiac arrest during or after brain death diagnostic” <sup>(8)</sup>. Such limitation is wise, considering the inconvenients and risks resulting from connecting organ removal to measures with tendency to “rush” the cardiac arrest, in a context of end of life, in an infirmary environment<sup>(9)</sup>.

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<sup>(2)</sup> CNECV: Opinion on the National Register of Non Donors (RENDA) (5/CNE/93)  
[http://www.cneqv.pt/admin/files/data/docs/1273059577\\_P005\\_RENDA.pdf](http://www.cneqv.pt/admin/files/data/docs/1273059577_P005_RENDA.pdf)

<sup>(3)</sup> Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin [Art 16 – Confirmation of death: The removal of an organ or a tissue of a deceased person cannot be made until death is duly confirmed, according to the law. Doctors who confirmed a person’s death must be different from the ones who directly participate in the organ or tissue removal of that person or in subsequent phases of transplants, as well as they must be different from the ones who provide medical care to eventual receivers of those organs or tissues.]  
<http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?CL=ENG&NT=186>

<sup>(4)</sup> CNECV: Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (73/CNECV/2013)  
[http://www.cneqv.pt/admin/files/data/docs/1376056646\\_P73%20CNECV%202013%20Prot%20Adic%20Transplantes.pdf](http://www.cneqv.pt/admin/files/data/docs/1376056646_P73%20CNECV%202013%20Prot%20Adic%20Transplantes.pdf)

<sup>(5)</sup> Guide of diagnostics on brain death from OM in Minutes-Med-Port, 1998, Vol. 11, No. 1, pages 91-95

<sup>(6)</sup> CNECV: Opinion on criteria of confirmation of brain death (6/CNE/94)  
[http://www.cneqv.pt/admin/files/data/docs/1273059552\\_P006\\_CriteriosMorteCerebral.pdf](http://www.cneqv.pt/admin/files/data/docs/1273059552_P006_CriteriosMorteCerebral.pdf)

<sup>(7)</sup> CNECV: Opinion on the death criterion (10/CNECV/95),  
[http://www.cneqv.pt/admin/files/data/docs/1273059437\\_P010\\_CriterioDeMorte.pdf](http://www.cneqv.pt/admin/files/data/docs/1273059437_P010_CriterioDeMorte.pdf)

<sup>(8)</sup> G Kootstra, J K Kievit and E Heineman, The non heart-beating donor,  
<http://bmb.oxfordjournals.org/content/53/4/844.long>

<sup>(9)</sup> Chaten FC. The dead donor rule: effect on the virtuous practice of medicine. J Med Ethics. 2013 Jun 12.  
<http://www.ncbi.nlm.nih.gov/pubmed/23760730>



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### C) Question needing revision

7) The referred proposal also adopts measures meant to avoid possible conflicts of interest by imposing that confirmation and certification of death is made by other doctors and not the ones connected with the removal and transplant. The formulation might however be improved, namely if the word “independently” were replaced by the word “independent” or “with independence regarding those who”, in requirement c) - *«after confirmation and certification of death (...), performed according to the requirements comprised in the annex to this dispatch by doctors with adequate qualification and specialization for that purpose, regardless of those who perform removal or transplants. »*

8) In subsection e) of item 1 of the Annex to the proposal the distinction between death diagnostic, confirmation, and certificate is not straightforward; it is not clear which doctors are competent for those acts; and it is not clear the articulation with item 2 of the mentioned Annex <sup>(10, 11)</sup>. The communication with the person’s relatives must be object of special care.

9) The requirements for diagnostic that are contained in the annex to the proposal in question contain technical rules presumably based on bibliography that, unfortunately, is not indicated. It is noted that, in literature, there is reference to periods of cardiopulmonary arrest shorter than the recommended 10 minutes without circulatory recovery <sup>(12)</sup>.

10) Considering safety issues, it is registered the absence of any requirement, or at least any reference, about measures with tendency to minimize the risks of transmission of diseases to the receiver, as demanded by the abovementioned Additional Protocol to the Oviedo Convention.

11) The proposal in question should also guard against the situations that may involve the need of an eventual legal procedure, assuring an adequate description of eventual existing traumatic lesions which may be altered by the procedure of organ removal, as well as an adequate removal and preservation of evidence or clues with eventual forensic relevance. In fact, it is not ethically acceptable that the procedures for the removal of organs in deceased donors may jeopardize a forensic investigation, damaging it, sometimes irremediably and therefore conditioning the court decision. It is considered that it might be convenient to also hear the opinion of the National Institute of Legal Medicine and Forensic Sciences [Instituto Nacional de Medicina Legal e Ciências Forenses, I.P.] on this matter.

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In conclusion, CNECV considers that:

- a) This legislative proposal should be integrated in the development of a wider strategy that allows to globally improve the number of organ removals destined to transplantation;

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<sup>(10)</sup> Law No. 12/93, of 22 April <http://dre.pt/pdf1sdip/1993/04/094A00/19611963.pdf>

<sup>(11)</sup> Declaration of the Medical Association (DR, I series, B, No. 235, 11/10/94) <http://dre.pt/pdf1s/1994/10/235B00/61606160.pdf>

<sup>(12)</sup> Bernat JL *et al.* Circulatory Death Determination in Uncontrolled Organ Donors: A Panel Viewpoint. *Ann Emerg Med.* 2013 Jun 21. <http://www.ncbi.nlm.nih.gov/pubmed/23796628>

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- b) The proposal is opportune, globally acceptable and ethically supported; however it ought to be submitted to a wording revision in the sense of securing the aspects pointed out in paragraph 7 and following.

Lisboa, 20 September 2013.

The President, Miguel Oliveira da Silva.

Rapporteurs: Counsellors Rosalvo Almeida and Duarte Nuno Vieira.

The present opinion was approved in the plenary meeting of 20th September 2013. Besides the President, the following Counsellors were present:

*Ana Sofia Carvalho; Carolino Monteiro; Francisco Carvalho Guerra; Isabel Santos; João Ramalho-Santos; Lígia Amâncio; Lucília Nunes; Maria do Céu Patrão Neves; Michel Renaud; Rita Lobo Xavier; Rosalvo Almeida.*