Presidenza del Consiglio dei Ministri

COMITATO NAZIONALE
PER LA BIOETICA

DETERMINATION OF DEATH ACCORDING TO CARDIOCIRCULATORY CRITERIA AND "CONTROLLED DONATION": ETHICAL AND LEGAL ASPECTS

9 December 2021

Presentation

The Committee returns to the issue of the determination of death and organ donation for transplantation, in response to a request for clarification of the emerging bioethical aspects, received from the Italian Society of Anesthesia Analgesia Resuscitation and Intensive Care (SIAARTI), from the Italian National Transplant Center (CNT) and the Italian Organ Transplant Society (SITO), request attached to the opinion.

The document deals with the problem of determining death according to the cardiocirculatory criterion and "controlled donation" which concerns patients who die in healthcare facilities in intensive care, whose death is subsequent to the limitation of treatments and the withdrawal of treatments, due to their ascertained ineffectiveness and non-proportionality from the point of view of the clinical outcome or by decision of the patient (refusal or renunciation). The Italian Committee for Bioethics (ICB) elaborates this reflection within the framework of the ethically relevant principles of respect for the dignity of the dying person, respect for the body of the deceased, sharing in the grief of the relatives of the deceased, solidarity towards those seriously ill and those awaiting transplantation.

The opinion highlights some ethical requirements for "controlled" donation after circulatory death: the requirement for the declaration of death to be determined according to criteria validated by the scientific community to guarantee the "*dead donor rule*"; retaining the observation time of 20 minutes after cardiac arrest, a protective rule, with regard to the certainty of declaring death; the necessary independence of the medical team that carries out the withdrawal of treatments from the donation team for transplant purposes; the importance of the clinical bioethics service or of an ethics committee at the time of identifying cases of unreasonable obstinacy of treatment and the separation of the withdrawal of treatments from the donation, to the extent possible given the strict time constraints; the independence of the medical team determining death from the medical team retrieving the organs; the importance that the procedures prior to the determination of death be aimed exclusively at organ preservation in view of donation, without causing any harm or suffering to the dying person and without hastening death, and for which adequate information has been provided; the importance of providing information to citizens (with the implementation of Law No. 91/1999) and for the information given to family members to be delivered in a manner that respects both the situation and setting aside adequate time. Given the organisational complexity, the Committee underlines the bioethical importance of introducing a single operational model coordinated by the competent authority, communication with family members is to take place in such a way as to be of real support for informed choices, providing transparent information for citizens.

The opinion was drawn up by Lorenzo d'Avack and Laura Palazzani. All the members of the Committee participated in the debate. In particular, Professors: Salvatore Amato, Bruno Dallapiccola, Antonio Da Re, Riccardo Di Segni, Marianna Gensabella, Maurizio Mori, Assunta Morresi, Stefano Canestrari, Monica Toraldo di Francia have made written contributions.

Our heartfelt thanks go to Prof. Alessandro Nanni Costa for the valuable contribution made in the implementation and revision of the text in its technical, clinical and organizational aspects and his participating in numerous plenary sessions to explain the ways in which healthcare facilities, respecting the end of life and the dignity of the dying person, deal with the possibility of organ donation. As part of the preparation of the opinion, important contributions were provided by the hearings of Prof. Flavia Petrini, President of SIAARTI (Italian Society of Anesthesia Analgesia Resuscitation and Intensive Care); Dr. Marco Vergano, Coordinator of the SIAARTI Bioethics Study Group; Dr. Massimo Cardillo, Director of the National Transplant Center (CNT); Prof. Alessandro Nanni Costa, former Director of the National Transplant Center and President of the Ethics Committee of the Bambino Gesù Pediatric Hospital. Prof Francesco Procaccio, expert in resuscitation at the CNT, also made a valuable contribution.

The opinion was approved by the majority of the ICB: Profs. Luisella Battaglia, Stefano Canestrari, Cinzia Caporale, Carlo Casonato, Antonio Da Re, Lorenzo d'Avack, Riccardo Di Segni, Silvio Garattini, Mariapia Garavaglia, Maurizio Mori, Laura Palazzani, Tamar Pitch, Massimo Sargiacomo, Monica Toraldo di Francia and Grazia Zuffa. Prof. Lucetta Scaraffia abstained.

Profs: Salvatore Amato, Carlo Caltagirone, Bruno Dallapiccola, Mario De Curtis, Silvio Garattini, Marianna Gensabella, Assunta Morresi, Lucio Romano, Luca Savarino, absent from the plenary session, subsequently assented.

Despite their not having the right to vote assent was given by: Dr. Carla Bernasconi, the delegate for the President of the National Federation of the Orders of Italian Veterinarians; Dr. Giovanni Maga the delegate for the President of the National Research Council; Prof. Carlo Petrini, the delegate for the President of the National Institute of Health. Dr. Maurizio Benato, the delegate for the President of the National Federation of MDs and Dentists Colleges; Prof. Paola Di Giulio, the delegate for the President of the Superior Health Council.

While largely endorsing the opinion, Profs. Antonio Da Re and Assunta Morresi wished to put forward some considerations in a personal remark. Also Profs. Cinzia Caporale and Maurizio Mori, having voted in favour of the opinion, considered it appropriate to point out their critical stance on some aspects in a personal remark. Both personal remarks are attached to the text.

The letter from the President of SIAARTI, Prof. Flavia Petrini, to the President of the ICB, Prof. Lorenzo d'Avack, is also attached.

Prof. Lorenzo d’Avack
President of ICB

1. Premise

The Italian Committee for Bioethics (ICB) has dealt with the problem of the criteria for the determination of human death and the consequent possibilities of organ donation in various opinions. In particular, the first opinion in1991 was dedicated to the *Definition and detection of human death* and subsequently the issue was resumed and updated in 2010 in the opinion on the *Criteria for ascertaining death*[1]. The 2010 ICB opinion in dealing with the determination of death placed at the centre of attention the determination of death using neurological criteria, which at that time was the most widespread criteria in situations of donation. Moreover, this document also mentioned the cardiocirculatory criterion and “non-heart-beating” organ donation in this case "uncontrolled" or "unexpected" donation, recently started in Italy in 2009, at the Policlinico San Matteo in Pavia (Alba Protocol). Subsequently, in 2015, at the San Giovanni Bosco Hospital in Turin, "controlled" or "expected" donation after circulatory death began in our country[2].

The ICB now intends to examine this last situation, namely the determination of death using cardiocirculatory criteria after cardiac arrest and "controlled" or "expected" donation, which in recent years has become increasingly widespread throughout the world and particularly on national territory. This form of donation has led to increase the number of donors, thanks to certain factors (specifically progress in transplant surgery and organ preservation techniques, particularly mechanical perfusion, which allows irrigation of organs) but also, in some contexts, to organisational improvements[3].

Intervening once again on the issue of organ transplants, the IBC intends to respond to a request for analysis and clarification of the emerging bioethical aspects of the problem of organ donation, taking into account medical innovations that have taken place in recent years. This request was received from the Italian Society of Anesthesia Analgesia Resuscitation and Intensive Care (SIAARTI) which, together with the National Transplant Center (CNT) and the Italian Society of Organ Transplantation (SITO), is preparing a document, still in the process of being drawn up, on the subject[4].

The theme of the so-called "controlled donation" is to be placed in the context of detection of the shortage of organs which, still today, constitutes the main obstacle to the expansion of transplants in the world. Ethical reflection must not neglect the procedures for the determination of "expected" death and organ

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[1] In addition, the topic of the end of life and the ethical issues related in various respects to organ donation have received particular attention in recent decades by the Committee in the context of the so-called Samaritan donation (2010), *post mortem* body donation (2013), illegal trafficking of human organs between living beings (2013), and, at the invitation of the National Transplant Center, the problem of anonymity of donor and recipient (2018).

[2] With regard to the procedures and contents of the two criteria for death and organ donation, see *ultra* § 3.1

[3] B. DOMINGUEZ-GIL et al., *Expanding Controlled Donation After the Circulatory Determination of Death: Statement from an International Collaborative*, in “Intensive Care Medicine”, 2021; M. LOMERO et al., *Donation After Circulatory Death Today: an Updated Overview of the European Landscape*, in “*Transplant International*”, 2019; N. MURPHY et al., *Controlled Donation After Circulatory Determination of Death: a Scoping Review of Ethical Issues, Key Concepts, and Arguments*, in “Journal of Law, Medicine and Ethics”, 2021, 49 (3), pp. 418-440.

[4] See Letter dated 21 June 2021 from Prof. Flavia Petrini, President of SIAARTI, addressed to Prof. Lorenzo d'Avack, President of the Italian Committee for Bioethics (ICB), attached to the opinion.

preservation, which are different from those of organ donation following the determination of death using neurological criteria.

These elements in turn presuppose reference to some ethically relevant principles such as: respect for the dignity of the dying person, respect for the body of the deceased, sharing in the grief of family members, effective solidarity towards those seriously ill and those waiting perhaps for a long time, for transplantation.

The Committee believes that the clarification of ethical aspects is essential to promote the culture of donation and to ensure full transparency in the various procedures involved in the determination of death and organ transplantation. This will also make it possible to strengthen citizens' trust, hopefully favouring their free and conscious choice of organ donation, as a highly altruistic and meritorious act.

2. The law on organ donation in Italy

The removal and transplantation of organs and tissues are regulated in Italy by Law No. 91/1999. It enforces both the principle of explicit consent or dissent (*opting in*) and that of silence/assent (*opting out*); in both cases – whether there is or is not an explicit statement regarding the willingness to donate - it is presumed, however, that the subject has been adequately informed about the opportunity to donate.

The objective of the Law n° 91/1999, therefore, consists above all in leveraging the importance of appropriate information of the subject, from which either an explicit consent/dissent may arise – an obviously preferable solution, which also envisages the possibility of modifying the declaration of intent made previously - or an implicit consent, expressed in the form of silent assent. The law then establishes that, based on "Transitional provisions" (Article 23), if the deceased has not expressed any opinion with regard to consent or dissent to donation, family members have the possibility to consent or oppose organ retrieval.

In summary, on the basis of Law No. 91/1999, in order to hypothesise *post mortem* donation, determined by both neurological and cardiovascular criteria, the willingness of the person to donate organs must have been expressed and certified. In the event of absence of an expressed preference, for or against donation, by the person when in life (situation of silence), it is still possible for it to take place. In fact, after the "observation period" for the purpose of determining death, as provided for by art. 23, paragraphs 1-2[5], proceeding with the removal of organs and tissues is allowed, provided that entitled family members - who must be consulted according to established procedures[6] - have not submitted written opposition to the donation of organs for transplant purposes.

Without entering here into the merits of an in-depth bioethical assessment of current legislation, it cannot fail to be noted that Law No. 91/1999 intended to regulate the practice of organ donation, promoting in the first place the provision of information to the public in order for citizens to make informed decisions. For this purpose, it was also provided, in art. 5 of the law, that within ninety days of its entry into force the Ministry of Health, with its own decree, would initiate a

[5] In addition to Law No. 91/1999, consider Decree No. 582/1994, which in art. 4 indicates the duration of the observation period, updated by the Ministerial Decree of 11 April 2008.

[6] The law identifies in detail and with a scale of priority: the spouse or cohabitant *more uxorio*, the children, the parents or the legal representative. See *ultra* § 3.7.

widespread work of awareness-raising and information. Years later, this objective still remains valid and, if anything, needs to be further strengthened: it is important to constantly prepare effective communication and dissemination measures, to encourage informed choices by citizens and nurture the culture of donation. For this reason, it may be useful to propose to citizens the possibility of including the indication of consent or refusal to donate their organs in the event of death on their identity card, as required by Law No. 25/2010, of conversion of Law Decree No. 194, of 30.12.2009.

3. The cardiocirculatory criterion for the determination of death: medical and ethical aspects

3.1. Definitions

It must be noted, from the outset, that there is only one way of being dead, and it is identified with the irreversible cessation of all brain functions. There are two clinically valid criteria for the determination of death: the neurological criterion and the cardiocirculatory criterion.

The application of the cardiocirculatory criterion to determine death consists in observing a complete absence of heartbeat and blood circulation for the time necessary[7] to be certain of an irreversible loss of all brain functions. After this verification, controlled donation after circulatory death is possible, in two modalities: "uncontrolled" or "unexpected" donation and "controlled" or "expected" donation. "Uncontrolled" or "unexpected" donation involves those who, outside health facilities or even within these facilities, without any adequate preparation, suffer a cardiocirculatory arrest and for whom death is not predictable: consequently, the donation of their organs is carried out following non-heart-beating donation protocols that do not provide for a controlled pathway of dying[8].

“Controlled” or “expected” donation concerns patients who die in intensive care healthcare facilities, as a consequence of the withdrawal of health and life sustaining treatments. In these cases, death occurs in the presence of specialized healthcare professionals and the donation of organs, if authorized by the patient or family members, is carried out according to non-heart-beating protocols that provide a controlled pathway of dying, in intensive care.

The Committee wishes to point out that in the case of withdrawal of life-sustaining treatments based on the assessment of the physician, identifying the condition of ineffectiveness or futility of treatments[9], it is appropriate to seek the opinion of an ethics consultancy service or a clinical ethics committee, if present in the facility, compatibly with the strict time constraints. If the expected death arises from the refusal or renunciation of treatments by the informed patient, the Committee recommends that particularly vigilant attention be paid to the patient's communication with the physician, so that the latter communicates to the patient,

[7] The time refers to 20 minutes, see *ultra* § 3.4.

[8] In these cases, it is a question of determining the times considered sufficient for the duration of the resuscitation manoeuvres and the tests of non-resumption of cardiac function.

[9] Law No. 219/2017, art.2, *Pain therapy, prohibition of unreasonable obstinacy in treatment, and dignity in the end-of-life phase.*

and if there is agreement also to family members, the consequences of these provisions as well as the alternatives[10], in the appropriate manner and time.

In any case, the definition of the futility/ineffectiveness of treatments, as well as the acceptance of refusal and renunciation of life-sustaining treatments, and the evaluation of Advance treatment directives or shared care planning must be strictly separate from possible organ donation and must not be influenced by this possibility in any way.

The donation of organs after determination of death using cardiocirculatory criteria in a "controlled" or "expected" setting provides a quality of organs comparable to the standard of donation after the determination of death by neurological criterion.

3.2. The dead donor rule

The general rule and necessary prerequisite to consider legitimate, from an ethical and legal point of view, the removal of organs for the purpose of therapeutic transplantation - both for the determination of death using neurological criteria and for its determination using cardiocirculatory criteria - is that the donor must be declared dead before the retrieval of organs for transplantation purposes (*dead donor rule*) and that the death of the donor has been determined according to criteria validated by the scientific community, according to the regulations of the country where the organs are retrieved following expected death and controlled donation[11].

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[10] See Law No. 219/2017, Art.1 c.5; see ICB *Conscious refusal and renunciation of healthcare in the patient-doctor relationship*, 24 October 2008.

[11] A lively bioethical reflection is underway on the "*dead donor rule*", which began with the classic intervention by H. Jonas in 1974 on the definition of death, taken from the first Report of the Danish Ethics Committee, "*The Criteria of Death*" (1988) and continued afterwards. See also R. DE MATTEI (edited by), *Finis vitae. La morte cerebrale è ancora vita?* Rubbettino 2007. The lively debate on the "*dead donor rule*" intensified with the possibility of resuming organ perfusion, and therefore with the possibility of determining death by cardiocirculatory standards. In this regard, the situation in Europe is quite varied: the Maastricht Protocol (1995) establishes waiting for 10 minutes after death, including both patients in a "controlled" and "uncontrolled" setting. In some countries (United States, Canada, Great Britain, Spain), the cardiac arrest time required to determine death is generally 5 minutes, and there is no talk of electric silence, but only of circulatory arrest. The category of donor patients at the end of life, with non-beating heart in the so-called "controlled situation", especially in intensive care departments, for which treatment is withdrawn after determination of a definitely poor prognosis, is the one that has led to several protocols in the USA to settle on a timeframe for the determination of the occurrence of death after an extremely short time period which fluctuates between 2-5 minutes. This category also includes patients in ventilator-dependent intensive care units who, on the basis of their expressed wishes (or the wishes of family members), are disconnected from machines. These are patients whose clinical condition is well known to the healthcare facility, for which the cessation of artificial ventilation can be established either on the grounds of futility or objective burden of treatment, or also because such patients request to be disconnected from the machine. This position is deemed ethically licit with different arguments. Some authors believe that patients withdrawn from life-sustaining treatments are now "dying" with no return possible, and therefore organ removal is licit regardless of the debates on the definition of death. 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 already "dead" in as much as they modify the concept of death to include in this notion also reference to the intention not to be resuscitated (S. SHEMIE, *Clarifying the Paradigm*

3.3. Necessary *ante-mortem* medical procedures in the context of "controlled" donation

As part of the clinical-organizational protocols in preparation for "controlled" donation, some medical intervention is performed a few minutes before verification of death is carried out: e.g., blood samples to assess clinical suitability for donation, heparin administration in the final phase of the agonal period, isolation, and insertion of guides/probes with minimally invasive manoeuvres and subsequent cannulation of the femoral blood vessels.

All this occurs after the withdrawal of life support in the final phase of the agonal period (which is usually short) when cardiocirculatory deterioration that precedes cardiac arrest is already underway. In this phase, severe insufficient oxygenation of organs precedes death by a few minutes. This period is not shortened, but with the administration of heparin the damage caused by ischemia to organs is attenuated, preserving their functionality. Heparin is administered in this period only, after consideration of the disease in progress and on clinical judgment, when there is no risk of causing harm to the patient[12]. After the administration of heparin, it is a rule to monitor the level of anticoagulation also during perfusion *in situ post mortem* up to the removal of organs.

The insertion of the guides, possibly using the catheters already positioned for therapeutic purposes or using minimally invasive methods with a low risk of complications, is carried out to facilitate the positioning, following confirmation of death, of the larger diameter cannulas used in the extracorporeal circuit which allows, for a few hours, perfusion *in situ* with oxygenated blood and evaluation of the functional recovery of the organs before their retrieval.

These actions have no therapeutic or palliative care purposes, they are aimed exclusively at preserving the organs in view of donation and constitute a central element of "expected" donation compared to "unexpected" donation. The necessary separation of the dying process from the subsequent pathway of organ donation may in fact appear in conflict with interventions aimed directly at organ donation performed on the patient whose death is imminent.

Therefore, in order to be legitimate, these interventions on the body of the dying person must always result in prudent and proportionate action, so that such interventions do not cause suffering, much less result in hastening death or infringement of the dignity of the dying person.

It is evident that the medical team that carries out the withdrawal of treatment and accompanies the patient approaching death must be aware of the decision to donate for the purpose of transplantation, in order to be able to adequately apply the protocols for "expected" donation. And at this stage, the donor patient,

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for the Ethics of Donation and Transplantation. Was 'Dead' Really so Clear Be for Organ Donation? in "Philosophy, Ethics, and Humanities in Medicine", 2007, 24, pp. 2-18). However, death is declared at an earlier stage of the dying process (the dying donor), so in these cases it is also possible to donate the heart with a stopped heart, because cardiac activity can still restart in the recipient. In our country, a 20-minute observation period from the cessation of heartbeat is envisaged for the determination of death from cardiac arrest, see § 3.4.

[12] In the potential "controlled" DCD (*Donation after Circulatory Death*) donor, the administration of heparin is recommended to prevent thrombotic complications and consequent widespread damage to organs during the prolonged ischemic time which includes the twenty minutes required to determine death. In situ perfusion of organs after the determination of death is however always recommended, in the Italian context, to attenuate ischemic damage to organs before removal and transplantation (source CNT).

if possible, or his/her trustee in the case of Advance treatment directives[13], and family members[14] should be informed about the medical procedures that the dying person will undergo.

3.4. The timing of the determination of death using cardiocirculatory criteria

It should be borne in mind that the successful retrieval of organs from "controlled" donors is conditioned by the observation period after cardiac arrest, which must be established in such a way as to make less possible any ischemic damage due to the absence of circulation of the blood supplied to organs, to prevent them from being damaged and no longer usable for transplantation. In literature and in international protocols there is agreement regarding the possibility of removing organs from "non-heart-beating" donors, but there is no consensus on the determination of the observation times for the cessation of circulation and respiration necessary to declare with certainty the irreversibility of death determined by cardiocirculatory criteria. The debate on the subject is, as already mentioned[15], lively. But whatever length of time experts and countries intend to establish, the Committee reaffirms the general and indispensable rule of the "*dead donor rule*": donation is legitimate from an ethical point of view only after the donor's death.

Our country provides the most protective guarantees in terms of legislation, as the declaration of death from cardiac arrest requires recording 20 minutes of flat electrocardiogram[16] in order to determine the irreversible loss of all brain functions due to lack of cerebral perfusion. The Committee believes that this time period may also be re-discussed in future in the light of better scientific knowledge. However, it notes that our scientific community[17] currently deems it appropriate to maintain the time of 20-minutes for confirmation of death: this threshold offers absolute guarantees as regards the certainty of declaring death. With the "*dead donor rule*" we are speaking of the diagnosis of death. Certainly our 20 minutes guarantee us, beyond all reasonable doubt, that the process of organ donation takes place exclusively in the context of a definite diagnosis of death.

It should also be considered that technology allows for perfusion of the removed organs, which can be adequately preserved to ensure benefit for the recipient. Scientific evidence shows that possible alterations in the functionality of organs due to the longer observation times established by Italian law is not

[13] Law No. 219/2017, art. 4. It should be considered that from the data of the CNT it appears that in the current Italian reality all the cases of donation with controlled stopped heart so far presented patients suffering from acute cerebral pathologies (more frequently devastating cerebral haemorrhages or anoxic damage caused by cardiocirculatory arrest) with consequent clinical condition of a complete absence of consciousness (coma) which in no way allows for expression of one's wishes.

[14] See *ultra* § 3.7.

[15] See back note 11.

[16] Law No. 578/93 and subsequent decrees of 2008.

[17] Lucia MASIERO, Francesco PROCACCIO, Francesca VESPASIANO, Francesca PUOTI, Sergio VESCONI, Chiara LAZZERI, Tiziana CIANCHI, Andrea RICCI, Letizia LOMBARDINI, Massimo CARDILLO, Italian DCD Working Group ESOT CONGRESS 2021 (Milan), *Donation After Circulatory Death (DCD) Strategy in Italy: the Barrier of a Prolonged No-touch Period Can Be Overcome.*

irreversible: the full functionality of the removed organs can in fact be re-established with their appropriate perfusion according to protocols already in use.

3.5. Post mortem medical procedures

The perfusion and simultaneous purification of the blood with extra-corporeal circulation for abdominal organs, such as kidneys, liver, pancreas takes place *in situ*, i.e., inside the dead donor's body, it lasts a few hours, to allow the organs to recover from the damage caused in the agonic period and during warm ischemia time (phase in which circulation is stopped and the organs are not perfused by blood circulation), for the period of time to determine death. An *ex-situ* perfusion, i.e., outside the dead donor's body, can also take place after retrieval and before transplantation.

3.6. Organization of facilities

The National Transplant Center considers "controlled" donation as a qualifying aspect of the set of services and care provided in a hospital and an indicator of quality of patient care in intensive care. The retrieval of organs from "controlled non-heart-beating" donors today brings attention back to its organizational complexity and related problems. It is therefore of the utmost bioethical importance that there is a single operational model coordinated by the competent authority, in order to extend this possibility of donation and procurement homogeneously throughout the Italian territory, to ensure equality and non-discrimination. The Centres that will perform these techniques must also be equipped with qualified personnel trained for specific needs and must use protocols approved by the competent institutional authorities[18].

In this context, what was underlined in the context of death determined by neurological criteria should also be remembered, namely that the team that determines brain death must be independent from the team that deals with the retrieval and transplantation of organs: this independence guarantees that the determination of death is based on objective data and that it is not subject to any influence or conditioning induced by the purpose of donation. Any possible conflict of interest between the teams involved in the various phases of the determination of death and procurement process must therefore be excluded.

3.7. Times and methods of informing/communicating with the family

Communication with family members must take into consideration a multiplicity of aspects, scientific, ethical, religious and social, inherent to the "controlled" donation of organs, and it must take place in an understandable way, in an adequate space of time and in environments suited to the delicacy of the moment, in order to be of real support in making informed choices. The procedures for the determination of death by cardio-circulatory criteria for "expected" donation allow for communication with the family to take place in an unhurried manner without haste.

[18] Some regions in the north-central - Piedmont, Lombardy, Emilia-Romagna and Tuscany - have very advanced non-heart -beating donation programs. Veneto is also starting to increase this program, while in the centre-south this activity is rather sporadic, as is, in general, that of donation.

There is time to nurture a relationship of care and support towards family members also in the perspective of donation. Therefore, with the determination of death using cardiovascular criteria, the process that leads to "controlled" donation is, in many respects, qualitatively more mindful. In “uncontrolled" donation, the moment resuscitation manoeuvres are suspended in a heart that fails to restart, artificial circulation must be started immediately, contact made with the family, resulting inevitably in speaking hurriedly. It is also for these reasons, on a global level, that “uncontrolled” donation is becoming marginal compared to “controlled” donation.

In this context, as already mentioned above, the possible expression of the person’s willingness to donate (*donor identification*) must be checked. In the absence of an expression of unwillingness to donate, or even the willingness to donate, family members must be informed about the procedures for the determination of death by cardiovascular criteria, and about the *ante and post mortem* procedures aimed at the eventual donation itself, even more so if in the face of silence on the part of the subject it is up to them to decide whether to oppose donation. This moment of information/communication with family members must take place before the withdrawal of life support and start of the agonal period, at a separate moment that is subsequent to the decision to limit treatment.

Family members should be informed that death in some cases may not occur in the intensive care unit, but in an environment that allows for the necessary procedures for organ procurement, sometimes even in the operating theatre. It is desirable that family members in this decision-making period are helped by health professionals, especially by a donation coordinator, who is also adequately trained on the psychological and bioethical aspects. This supportive relationship can help to overcome moral suffering, due both to the weight of responsibility in deciding on behalf of the donor and regarding doubts from a scientific, ethical and religious point of view, and at the same time, can help to overcome the phase of denying the inevitability of the death of the loved one and the transition to the altruistic choice of organ donation.

It should not be forgotten that family members' consent to donation is certainly favoured by being able to place their trust in doctors and in the transplant medicine system, a trust that is further strengthened by transparent decisions.

3.8. Informing citizens

On the part of public opinion, the criteria for the determination of death, both neurological and cardiocirculatory criteria, are often not adequately known or misinterpreted: this contributes to generating misunderstandings about the exact definition of death and the methods of determining death.

Providing information can be of great importance to avoid errors and prejudices that hinder donation, including ignorance regarding the organs that can be donated even in old age (such as the liver, even for those over 80 years of age); suspicion of alleged conflicts of interest between end-of-life management, patient care and donation management; the idea that in our country there may be illegal forms of organ trafficking.

Potential donors must also be informed about the determination of death using cardiocirculatory criteria, about the methods, procedures and implications, before being able to express their wishes. It is always ethically desirable that the

decision to donate be made personally by the potential donor when still alive, rather than through family members, in the dramatic moment of imminent death.

This is an element which the ICB intends to draw attention to in the discussion. The partial application of Law n° 91/1999 depends on the not yet realized informing of citizens for the full expression of their decision regarding donation, as mentioned. The changes in medical practice require information to be complete, up-to-date and precise and to be addressed, with the proper organization and training of operators, to all citizens.

In this context, there is a need to rethink the set of existing rules based on silence/assent. And it may seem necessary to reset the debate on these issues, placing strong emphasis on the need for an expressed, voluntary, conscious, informed, free act by the donor to accept that some of his/her organs can be transferred after death, in order to save other individuals in need of transplantation. In this sense, also indication of the subject's consent or refusal to donate their organs in the event of death through their identity card must always presuppose having been given adequate information by expert and specially trained personnel.

Another parameter that could be evaluated is the possibility of choosing the type of determination of death of the subject, at the time of the expression of the willingness to donate. However, it should be considered that today this decision is made on the basis of the patient's clinical conditions and therefore it is desirable that it be made without excluding *a priori* one or the other death criterion (neurological or cardiocirculatory criteria) and this in order to avoid that the choice results in an undesirable reduction in the availability of organs. Furthermore, at present, it should also be considered that health facilities where the patient ceases to live are not always able to proceed clinically and according to the rules established in the context of both criteria.

4. Recommendations

The ICB underlines the ethical importance of organ donation, as a highly meritorious and altruistic act, in favour of those who are seriously ill and need a transplant, always guaranteeing strict respect and protection of the dignity of the donor and the dying process.

The ICB recommends in the application of the criteria for the determination of cardiocirculatory death in the context of "controlled" donation to:

1= promote provision of adequate, updated and complete information to citizens to make a free and informed choice regarding organ donation after the determination of death according to cardiocirculatory criteria;

2= always consider as essential the "*dead donor rule*" and maintaining an adequate period of observation established by doctors (20 minutes for the confirmation of death);

3= always guarantee the separation of the moment of the decision to interrupt life-sustaining medical treatments (following the determination of futility/ineffectiveness of treatments or acceptance of refusal or renunciation of treatments or the implementing of Advance treatment directives) and the evaluation of the possibility of organ donation; it is advisable to seek the opinion of an ethics consultancy service or a clinical ethics committee, if present in the facility, compatibly with the strict time constraints;

4= guarantee the independence of the healthcare professional who treats the person in intensive care and the person who takes over as donation coordinator, as well as that of the perfusion team and the transplant procurement team;

5= consider the person a donor if he/she manifested willingness to donate in life or entitled family members have not expressed opposition to donation;

6= inform the donor patient, in a conscious state, or his/her trustee in the case of Advance treatment directives or family members, about the medical procedures to which the dying person will be subjected, as well as the nature and circumstances of organ removal; the information must be given before the withdrawal of life support and before the agonal period begins;

7= legitimise some interventions on the patient (administration of heparin, use of intravascular probe-guides of limited calibre, etc.), to the extent to which they are necessary and proportionate, do not harm or cause suffering to the patient, or interfere with the dying process (i.e., do not hasten death) and for which adequate information has been provided;

8= make use of qualified personnel trained for specific needs in the Centres in which, controlled and uncontrolled, donation is carried out following the determination of death by cardiocirculatory arrest;

9= implement organisational models that allow the resuscitation units and transplant Centres of all regions to put donation into effect after the determination of death using cardiocirculatory criteria, also by means of a national protocol.

Personal remark by Professors Antonio Da Re and Assunta Morresi

This opinion constitutes an important contribution to ethical reflection on Controlled Donation after Circulatory Death (CDCD). To complete the reflection, a second document dedicated to the various end-of-life scenarios would be necessary, as a prerequisite for this specific type of donation, in the scenarios also described by the Italian Society of Anesthesia Analgesia Resuscitation and Intensive Care (SIAARTI) in its request to the Italian Committee for Bioethics (ICB). As illustrated in the opinion, CDCD in consequence of the withdrawal of health and life sustaining treatments, proceeds along pathways that can radically differ from each other in terms of the ethical aspects involved. These issues have already been addressed by the ICB in previous documents which, however, did not take into consideration the possible connection with organ transplantation. For this reason, it would be important to carry out a specific and dedicated in-depth analyses before dealing with the aspects strictly linked to the criteria for the determination of death and the procedures for organ donation examined and discussed in this text.

Antonio Da Re
Assunta Morresi

Motion of partial dissent by Professors Cinzia Caporale and Maurizio Mori: the opinion points in the right direction, but instead of giving an ethical response appropriate to the innovative challenges it reiterates the old received schema.

The opinion points in the right direction but responds without momentum to the innovative challenge.

The undersigned approved the opinion because, in essence, it points in the right direction: it affirms the «ethical relevance of organ donation, as a highly meritorious act» and supports the practice of “controlled” donation after circulatory death (cDCD) with the cardiocirculatory determination of death. These are important and qualifying conclusions endorsed with enthusiasm and without reservation.

The basic shortcomings of the opinion

In the end, there are two points on which we disagree, arising however from the observation that the opinion is characterised by a certain inadequacy in the theoretical approach, deeply rooted in a never faded attitude of circumspection towards science and reluctance to embrace ethical changes and reforms. This approach has led the majority of the ICB to propose ethically inadequate solutions, because they are unable at least in part to take on the appropriate requests put forward by the scientific world. A more correct and more robust ethical reflection open to readily embrace the contributions of science would have led to the proposal of more solid solutions better able to facilitate “controlled” donation after circulatory death.

The request for innovative reflection and the inadequate attitude of the opinion

In the letter sent to the ICB on 21 June 2021 by Prof. Flavia Petrini, President of SIAARTI (Italian Scientific Society of Anaesthesiologists, Intensivists) in agreement with Dr. Massimo Cardillo, Director of the CNT (National Transplant Center), it is explicitly highlighted that donation after circulatory death is «in many respects an innovative practice» and its increasing spread is placed in «a scenario in progressive evolution on the slope of the "end-of-life", an essential prerequisite for controlled donation after circulatory death». By underlining the scientific advances in transplantation and the rapid ethical-social evolution on the "end of life", SIAARTI and CNT called for an ethical reflection capable of keeping up with the new situation and ready to respond to new challenges with the same tenor: innovative situations require equally innovative responses.

In this sense, on the ethical level, the opinion should have reiterated more forcefully that transplantation is an ethical practice to be incentivised with urgency and commitment, and that in this regard there is still a lot to be done: not only is transplantation provided for in the Essential Levels of Assistance, (LEA), but it must be strongly sustained because every slightest delay leads to avoidable and therefore unjustified deaths. From a scientific point of view, it would have been appropriate to point out that in Europe now more than 25% of transplanted organs come from "controlled" donation (cDCD) and that the practice is constantly expanding: such an order of magnitude can help clarify that this is not a marginal question, but a central and decisive one for the life and death of many people. In Europe, the cDCD is a long-established practice. On the regulatory level, the

opinion should have better clarified that end-of-life issues are completely different and independent from those of transplants. It is obvious that there are links between the two areas, but seeing how one dies is one thing, and the possible further opportunity of donation is quite another. They are two distinct and separate issues, and this is especially true in Italy where the end of life is now regulated by the Lenzi Law n° 219/17: a recent and adequate law, which has provided a solid overall framework of reference on the value of self-determination at the end of life. On the contrary, with regard to transplants, the regulatory framework is more uncertain as there are various laws on the subject made in different contexts and years, some of which are still waiting to be fully applied, so the perspective is not always organic and updated to accommodate the latest scientific innovations.

Instead of accepting the ethical challenge posed by a context in turmoil and responding on the basis of an open horizon ready for change, the orientation of *quieta non movere et mota quietare* seemed to prevail in the ICB: there was no intention to reject the new practice of cDCD, but instead of embracing and enhancing the scope of the innovation, it has been brought back within the value-regulatory framework that is currently in force and taken for granted. That is, the possibility that that regulatory framework could or should be reformed was not taken into consideration. Immediately after the brief introductory notes, the opinion presents the Italian law on organ donation without any critical evaluation, and in doing so accepts the validity of the prevailing situation as being evident and cannot be improved upon. The new cDCD practice is indeed accepted, but without enthusiasm and as a mere extension of the existing one, thus becoming implicitly evident that the new aspects exceeding the consolidated framework should be subjected to special control and even limited.

As often happens in many fields, scientific innovations struggle to be accepted and placing constraints and limitations effectively slow down the practice. Two constraints in particular prompt our dissent.

First point of dissent

The opinion presents “controlled” donation as the practice concerning “patients who die in healthcare facilities in intensive care, as a consequence of the suspension of health and life sustaining treatments” (§ 3.1 Definitions). This way of categorizing cDCD is misleading and distorts the whole perspective, since placing a consequential link between (the donor's) death and the withdrawal of treatment foreshadows the false notion that continuing therapies would have granted a further length of time, that life had by no means come to an end, and that death occurs as a result, or precisely «as a consequence of the withdrawal of health treatments».

This is not the case: it is not that in intensive care units treatment is withdrawn to bring about, as a consequence, death (and proceed with donation), rather, it is that at a certain point it is recognised that the process of dying has become inevitable and therefore It no longer makes sense to continue with life support, which is withdrawn to let nature take its course as any further continuation would constitute "clinical persistence": a practice which, moreover, is expressly prohibited by art. 16 of the current Code of Medical Ethics. Death (determination of death) and donation are two different issues, independent and with no direct connection: on the one hand there is a person whose death is taking its own course, and whose death is "expected" because thanks to scientific advances we are able to predict in certain circumstances the inevitability of death. It is death

that is "expected" not donation, instead the opinion improperly states the opposite. On the other hand, instead, there is the opportunity of organ donation, which can be facilitated by the new ability (offered by science) to know exactly when death will occur, but which is a separate issue from the process of dying. In fact, the two issues are dealt with by two different institutions, SIAARTI and the CNT.

In the (correct) perspective outlined here, the new scientific capacity that allows us to know when death is "expected" is something positive, precious and welcome, as it can favour and increase the opportunities for donation. It should therefore be valorised and favoured, and not limited or constrained. If instead, the problem is set out assuming that death in intensive care occurs "as a consequence of the withdrawal of health treatments", then this new ability to predict "expected" death becomes suspicious and perhaps even dangerous. It is because it adopts this (incorrect) perspective that in cases of "controlled" donation the opinion subjects the exercise of the new capacity to a specific constraint, noting that when proceeding with «withdrawal of life-sustaining treatments based on the assessment of the physician, identifying the condition of ineffectiveness or futility of treatments, it is appropriate to seek the opinion of an ethics consultancy service or a clinical ethics committee, if present in the facility, compatibly with the strict time constraints».

The affirmation of this new constraint is mostly "symbolic" because the opinion already provides that the very short timeframe will then make the further required step unfeasible in practice. But the clause is significant on a theoretical level: while in usual clinical situations the faculty to evaluate the futility of treatments is left (only) to the medical team without further constraints other than those already foreseen by clinical practice, when in intensive care in the context of a "controlled" donation this evaluation of futility must be subjected to special control. Here the distrust in science emerges: the increase in knowledge is not envisaged as an opportunity that can promote donation, but as something threatening that must be controlled. Here we dissent.

Second point of dissent

In a different form, the diffidence towards science manifests itself also and above all in the reaffirmation reiterated by the opinion of 20 minutes for the declaration of death using cardiocirculatory criteria. On the subject, the opinion clearly states that «there is only one death» (that of the brain), while there are two valid criteria for its determination: neurological and cardiocirculatory criteria. Having reasserted the *Dead Donor Rule*, that is the rule according to which donation is licit only after the donor has been declared dead, the problem remains of the amount of time that must pass before the declaration of death can be made using cardiocirculatory criteria.

In this regard, the opinion notes that there is no unanimous consensus, that there are various positions and an open debate. The extensive footnote n.11 states, that the Maastricht Protocol (1995) requires a 10-minute wait, while in other advanced countries such as the United States, Canada, Great Britain, Spain the required cardiac arrest time is typically 5 minutes, and it concerns only cardiac arrest and not electrical silence (detected by electrocardio-thanato-diagnostics). In other countries again the required time is even shorter. In this regard the opinion notes, «Our country provides the most protective guarantees in terms of legislation, as the declaration of death from cardiac arrest requires recording 20 minutes of flat electrocardiogram». It is not excluded «that ~~that~~ this

time limit may also be re-discussed in future in the light of better scientific knowledge». but for the moment the opinion accepts and reproposes the 20 minutes for the following reasons:

a) «our scientific community currently deems it appropriate to maintain the time of 20-minutes for confirmation of death»;

b) «this threshold offers absolute guarantees as regards the certainty» of death which in Italy after the required 20 minutes is certified «beyond all reasonable doubt»;

c) «the longer observation times established by Italian law» would in no way preclude «the full functionality of the removed organs» [which ...] can in fact be re-established with their appropriate perfusion according to protocols already in use». In this sense, the benefit for the recipient would still be guaranteed.

The *third* reason put forward presupposes the improper direct connection between death and donation which is valid in the inadequate perspective examined above. The reasoning behind this is: given that little or nothing changes for the recipient whether death is determined after 5 or 20 minutes, we might as well keep the current 20 minutes, a condition which accommodates the *quieta non movere*. We reiterate that the theoretical perspective is wrong and must be abandoned: the determination of death which depends on the certain and definitive irreversibility of the process of organic disintegration is one thing, what eventually follows from the determination of death is quite another. Having reiterated this, we note that even if one reasoned on the basis of the wrong perspective, the thesis supported does not correspond to what is found because there is a very significant difference between retrieving an organ after 5 minutes and doing so after 20. It is true that perfusion manages to make it possible to obtain appreciable results even after the required 20 minutes in Italy, but it would be better, much much better to proceed sooner. The point does not hold.

As for the *second* reason mentioned above, we note that in the (adequate) perspective followed here, which excludes consequential connections between possible donation and the declaration of death, death must be determined on the basis of the criterion of the irreversibility of organic integration. If «absolute guarantees ... beyond all reasonable doubt» are required for the declaration of death, it would really be a long time to wait. Fortunately, science makes it possible to declare death with certainty even sooner, and as we have seen there is debate on the time required. It is true that Italian legislation provides for a period of 20 minutes as reaffirmed by the opinion, but on this point it is worth recapitulating a little history: in Italy on April 3 1957 the first transplant law (no. 235) was approved, whose art. 5, paragraph 1 establishes: «The ascertainment of the fact of death is carried out with the methods of medical-forensic semeiotics established by order of the High Commissioner for hygiene and public health». To better clarify the situation, four years later, on November 7, 1961, the Ministry of Health issued a Decree in which it is expected that «the early assessment of death must be carried out with the method of electrocardio-thanato-diagnosis», thereby introducing the 20 minutes: from then on, almost by inertia, this clause has remained unchanged.

An immediate observation promptly arises: in 1961 the required 20-minute electrocardio-thanato-diagnosis concerned *early* determination of death. One wonders whether in today's intensive care units we can still speak of "early determination" in the sense in which it was used 60 years ago. Again, we must ask ourselves if after 60 years the scientific instruments and methodologies for determination of death are completely analogous and comparable to those of the

time, also in consideration of the fact that then death was only cardio-circulatory (cerebral death was not recognised/determined). These are the problems to be examined to determine whether or not 20 minutes is justified. The Committee did not deal with them, but limited itself to its reaffirmation, acknowledging however the possibility that this timeframe «may also be re-discussed in future in the light of better scientific knowledge». The recognition of the possibility of change is welcome but postponing it to the future is another way of expressing mistrust in science: instead of deciding today on the basis of what science tells us, we put off until an unspecified tomorrow. If the situation in today's intensive care units is very different from the situation of the 1961 early determination of death, it is almost certain that even today the best available knowledge tells us something new and interesting to at least attempt to revise that time limit.

The point suggests a further consideration: it is true that in international protocols there is no unanimous consensus among scientists about the time required for declaring death and that there is debate on the issue. But the debate is about whether 10, 5, or 3 minutes are sufficient in those circumstances. As far as we know, no one in the world supports the 20 minutes provided for in Italian legislation. It is valid only for us but in the rest of the world the consensus is almost unanimous in the belief that it is not necessary. In all other scientifically advanced countries, the time required is less than 20 minutes, and although the undersigned are not scientific experts on the specific subject, the question arises whether the reaffirmation of 20 minutes really responds to an effective "protective guarantee" or whether it is not a reflection of the *quieta non movere* that we were talking about. The second reason is not sufficient to reaffirm the 20-minute timeframe.

It remains for us to examine the first and main reason that led in the opinion to reaffirm the 20 minutes introduced in 1961: «our scientific community», the Italian one, would agree in maintaining this time limit, and note 17 indicates the document that would attest the widespread scientific consensus in this regard. For the sake of convenience, the note is given here: “Lucia Masiero, Francesco Procaccio, Francesca Vespasiano, Francesca Puoti, Sergio Vesconi, Chiara Lazzeri, Tiziana Cianchi, Andrea Ricci, Letizia Lombardini, Massimo Cardillo, Italian DCD Working Group ESOT CONGRESS 2021 (Milan), *Donation After Circulatory Death (DCD) Strategy in Italy: the Barrier of a Prolonged No-touch Period can Be Overcome*”.

At first glance, it should be noted that this is not a scientific article published in an accredited and *peer-reviewed* journal, but a report to a Congress, albeit a prestigious one. This is the ESOT (European Society for Organ Transplantation) Congress which was held in Milan from 29 August to 1 September 2021. Scrolling through the program you can see that the speech was held on 31 August in the "Brief Oral Presentation" session (5 minutes).

Since the recording of the oral presentation is not available, it is not possible to know precisely which thesis was being supported. However, from reading the title it would seem to suggest that the speech was dedicated to presenting «the Italian strategy on DCD: the barrier of a prolonged *no-touch* period can be overcome». The literal translation of the words of the title would almost seem to indicate the hope of overcoming the established 20 minutes: a thesis opposite to the idea of a broad widespread consensus on this point.

The 13 *slides* that made up the outline of the oral presentation are available. Their reading offers further insights on the subject. *Slide* n. 3 states: «DCD programs suffered from self-exclusion due to the 20-min no-touch period for

death declaration by cardio-circulatory criteria in Italy: only a pilot study (uDCD) 2008-2014»: proposition in line with the title, as it is emphasised that the 20 minutes of *no-touch period* penalized DCD. Finally, *slide* n. 11, presents the conclusion 1: «The Italian experience proves that DCD organs can be successfully transplanted despite 20 min no-touch period»: notwithstanding the 20-minute *no-touch* period, in Italy we are able to transplant successfully. Even this proposition does not confirm at all the presumed widespread consensus on 20 minutes, as it limits itself only to pointing out that "we can manage to do it anyway": not a convinced consensus on 20 minutes, but if anything, the observation that despite the 20 minutes it is still possible to do it anyway (fortunately).

In any case, it seems difficult to believe that such a brief oral presentation is representative of a sort of official *Consensus statement* by Italian scientists on the subject. The idea that «our Italian scientific community» endorses the 20 minutes is therefore neither adequately supported nor confirmed. However, this thesis was accepted by the majority of the ICB, but not for justified scientific or ethical reasons.

It is necessary as a matter of urgency for Italian scientists to draw up a *Consensus statement* on the subject and to make it public in an appropriate journal: "controlled" donation (cDCD) is too important a practice for there to be no updated position on the topic and for it to continue to be based on the criteria of 1961. Therefore, we hope that Italy will align itself as soon as possible with other scientifically advanced countries and we express our dissent against the unjustified reaffirmation of the 20 minutes.

Cinzia Caporale
Maurizio Mori

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For the attention of Prof. Lorenzo d'Avack-President of the Italian Committee for Bioethics

Rome, June 21, 2021

Subject: SIAARTI opinion on donation after circulatory death

Dear Prof. d'Avack

Donation after circulatory death (DCD) is a constantly evolving reality in Italy in recent years.

In particular, the so-called "controlled" donation, following an "expected" death in the Intensive Care Unit, has become increasingly widespread, throughout the national territory and is on the way - as is already the case in other Western countries - to constituting in the next few years a significant proportion of the total number of multi-organ donations from cadavers.
The peculiarity of the detemiination of death using cardiological criteria (specifically the length of the observation time of the circulatory arrest) makes Italy difficult to compare with the experience of other countries.

The ICB document of 24 June 2010 "Criteria for the ascertainment of death" touches upon discussion of the issue, without analysing it in detail. The practice of DCD donation was at the time however limited to the pioneering experience of a single center (Policlinico S. Matteo di Pavia) and only concerned "uncontrolled donation".
In the years to come, in 2016 the ICB document on deep palliative sedation, in 2017 Law 219, in 2018 the SIAARTI recommendations on the management of the dying patient, up to 2019 with the ICB opinion on medical assisted suicide, all of which have dealt with different aspects of a scenario in progressive evolution with regard to the "end of life", an essential prerequisite for controlled donation alter circulatory death.

Currently, numerous centres in Italy have a DCD program underway and others are in the process of starting.
A consensus document, on the initiative of the National Transplant Center (CNT) and in collaboration with the Italian Society of Anesthesia Analgesia Resuscitation and Intensive Care (SIAARTI) along with the Italian Organ Transplant Society (SITO), is being prepared.
The document aims to harmonise the practice of DCD with regard to the various clinical, technical, ethical and organizational aspects.

While believing that the current "best practice" is absolutely respectful of the ethical, deontological and regulatory boundaries in Italy, since DCD donation is an innovative practice in many respects, we feel the need for a shared reflection on the issue.
We remain at your disposal for any further clarification and send you our best regards.

Prof. Flavia Petrini
President of SIAARTI 2019-21

(in agreement with Dr. Massimo Cardillo, director of the National Transplant Center)

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