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Minerva Anestesiologica 2016 March;82(3):359-68

EXPERTS' OPINION

"Why can't I give you my organs after my heart has stopped beating?" An overview of the main clinical, organisational, ethical and legal issues concerning organ donation after circulatory death in Italy

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ABSTRACT

Donation after circulatory death (DCD) is a valuable option for the procurement of functioning organs for transplantation. Clinical results are promising and public acceptance is quite good in most western countries. Yet, although DCD is widespread in Europe, several problems still persist in Italy as well as in some other countries. This paper aims to describe the main clinical, organisational, ethical and legal issues at stake, bearing in mind the particular situation created by Italian legislation. Currently, as regards DCD, Italy is somewhat different from other countries. Therefore, every effort should be made for the safe and effective implementation of DCD programs: uncontrolled DCD programs should be promoted and encouraged, within the framework of shared and authoritative rules. At the same time, we need to tackle the question of controlled DCD, promoting debate among all involved subjects regarding the fundamental issues of end-of-life care

within protocols that best integrate the highest standard of care for the dying and the legitimate interests of those awaiting a life-saving organ.

(*Cite this article as:* Giannonio A, Abelli M, Azzoni G, Biancofiore G, Citterio F, Geraci P, *et al*. "Why can't I give you my organs after my heart has stopped beating?" An overview of the main clinical, organisational, ethical and legal issues concerning organ donation after circulatory death in Italy. Minerva Anestesiol 2016;82:359-68)

Key words: Tissue and organ procurement - Transplantation - Ethics.

Donation after circulatory death (DCD) is a valuable option for the procurement of functioning organs for transplantation. Clinical results are promising and public acceptance is quite fair in most western countries. Yet, in spite of large diffusion in Europe, several problems still persist in Italy as well as in some other countries.

The Italian Society of Anesthesiology, Analgesia and Intensive Care (SIAARTI) and the Italian Society for Organ Transplantation (SITO) are particularly involved in this issue and in 2014 a joint multidisciplinary *ad hoc* Working Group (WG) was activated in cooperation with the Italian National Transplant Centre (CNT), in order to address the various aspects of this subject.

This manuscript presents the report of the WG and consists of two parts: firstly, a description of the current situation of DCD both in Italy and in the international context, taking into account the clinical, ethical and organizational aspects; secondly, an outline of the road map for achieving the implementation of DCD programs in Italy.

Transplantation is often the only treatment for end stage organ failures, such as liver and heart failure, and the most realistic option for organ failures in otherwise fit and healthy individuals, such as those with renal failure.[1] However, organs from multi-organ donors available for transplantation are far less than the number of potential recipients, so that many people die while on a waitlist: at December 31, 2014, 8758 patients were on the waitlist, with a mortality ranging from 1.7 (kidney) to 9.2% (lung) *per annum*.[2] For this reason, organ donation from deceased persons has recently been affirmed as "having a fundamental role in maximizing the therapeutic potential of transplantation".[3]

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The clinical pathway that can lead to organ donation was recently coded by the World Health Organization (WHO) in a well-defined algorithm of critical pathways.[4] This included both donors whose death has been declared using neurological criteria (donor/donation after brain death, DBD) and those who have been declared dead using cardio-circulatory criteria (donor/donation after circulatory death, DCD). DBD and DCD are replacing the expressions, less common today, heart-beating-donor/donation (HBD) and Non heart-beating-donor/donation (NHBD) respectively.

Although the history of transplantation started with procurement of organs from non heart-beating subjects, there has recently been renewed, increasing interest in DCD.[5, 6] In the period 2000-2008, 5004 organs from DCD were transplanted in Europe (4261 kidneys, 505 livers, 157 lungs, 81 pancreases) [7] with encouraging results, approximately 75% of DCD recovered organs being finally utilized. Transplants of kidneys procured from DCD show outcomes comparable to those of DBD. The feasibility of both lung [8] and liver [9] transplants with organs procured from DCD has also been shown, even if data for these organs are preliminary. The heart itself may be recovered and utilized from DCD donors, particularly if timely reperfusion is performed in the donor after declaration of death.[10, 11]

DCD donors were classified into categories after a Consensus meeting held in Maastricht in 1995 [12]. These categories were recently modified during the 6th International Conference on Organ Donation after Circulatory Death organized in Paris in February 2013 (Table I). These different categories allow for differentiation of DCD as controlled (cDCD) or uncontrolled (uDCD): "uncontrolled" refers mainly to unwitnessed and/or unexpected

TABLE I.—*Modified European Maastricht categories of donation after circulatory death (DCD) classification.*[12]

Category	Sub-category	Description	Type
Category I Uncontrolled Unwitnessed CA	I A – in-hospital I B – out-of-hospital	Sudden-unexpected-irreversible CA; no attempt of resuscitation by a medical team. WIT to be considered according to national recommendations in place. In- or out-of-hospital setting.	Uncontrolled
Category II Uncontrolled Witnessed CA	II A – in-hospital II B – out-of-hospital	Sudden-unexpected-irreversible CA; unsuccessful resuscitation by a medical team. In- or out-of-hospital setting	Uncontrolled
Category III Controlled Awaiting circulatory death	—	Planned, expected CA; withdrawal of life-sustaining treatment; Euthanasia Excluded	Controlled
Category IV Alternative death determination during/ after procedure	IV A - uncontrolled and controlled CA while brain dead	Sudden* or planned** CA during or after brain death diagnosis process, but before retrieval	Uncontrolled* or controlled**
	IV B - death diagnosis during ECMO-ECLS	Death determination by circulatory (DCD) or neurological (DBD) criteria	Partially controlled

CA: cardiac arrest; WIT: warm ischemia time; ECMO: extra-corporeal membrane oxygenation; ECLS: extra-corporeal life support

sudden death from cardiac arrest, both within an in-hospital or out-of-hospital setting; "controlled" refers to expected cardiac arrest, mainly following withdrawal of life-sustaining treatment in the intensive care unit (ICU).

Even if there is general agreement on the concept of DCD, only 16 out of the 27 European Union countries (61.5%) defined the determination of circulatory death (death declared upon cardio-circulatory criteria) by legislation; only in half, death must be mandatorily confirmed by the use of electrocardiogram (ECG),[13] which allows determination of loss of electrical function.

In 2011, DCD was performed in 10 European countries (Austria, Belgium, France, Italy, the Netherlands, Switzerland, Latvia, Czech Republic, Spain and the UK). Notably, the Netherlands and Belgium do not have specific rules regulating determination of circulatory death. In Germany, Finland, Turkey, Sweden and Denmark DCD is not allowed.[7] Data for DCD kidney and liver transplantation in 2013 are reported in Table II.[14]

Ethical issues

The practice of DCD is increasing and protocols are currently applied with good quantitative and qualitative results. Yet some ethical issues about DCD are still under discussion.

The first one is the forgoing of life supports. Withdrawing of life-supports is a common feature of end-of-life care both in many European countries and in the USA,[15, 16] although specific standards and laws to guide this practice are frequently absent. In order to reconcile this practice within DCD protocols, the fundamental prerequisite is that the clinical decision to withdraw disproportionate treatments must be clearly independent of the possibility of organ donation. In some countries (for instance in

TABLE II.—*Deceased Cardiac Donation (DCD) organ transplantation in 28 Countries of the European Union (EU) during the year 2013 ("utilized donors").*

	Austria	Belgium	Czech Republic	France	Ireland	Latvia	Netherlands	Spain	UK	Italy + 18 EU countries
Kidney	4	78	2	78	11	20	249	200	832	0
Liver	1	50	0	2	0	0	48	41	146	0

(From Council of Europe, Newsletter Transplant, September 1st 2014)

Israel), withdrawing vital supports is clearly forbidden, because it would be considered the direct cause of death.[17]

In Italy, treatment limitation in ICU is relatively common (roughly in one third of ICU deaths), but unfortunately the decision is shared with family only in less than half of cases and is still mainly under the physician's responsibility, while the nurses are seldom involved.[18]

This urges our community to address this issue with specific educational initiatives aimed at implementing the *SIAARTI recommendations on the management of the dying patient*,[19] to clarify the clinical and legal aspects of the end-of-life phase. This must necessarily precede any discussion on cDCD.

Tissue donation (corneas, skin, tendons, etc) is relatively frequent after deaths occurred in ICU, but we have no information to date that donation of solid organs has ever taken place in this setting. This is most probably due to cultural and organizational issues, as there are no legal constraints that could limit this approach. Such a situation is disturbing from a bioethical point of view, because organ donation could be the best way to respect the wishes of persons who want to donate their organs after death, and consequently to promote their dignity by favouring the accomplishment of their life project.

As regards the uDCD protocols, the problem seems to be less important, because life-supports (cardiopulmonary resuscitation and drug administration) are withdrawn after they have proved ineffective, *i.e.* unable to produce a viable recovery of spontaneous circulation.

A second ethical issue is the definition of the patient's vital status and the strict respect of the "dead donor rule", which states that patients must be declared dead before organs are removed and that interventions aimed at organ retrieval do not accelerate or cause the death.[20-22]

As concerns the uncontrolled protocols, a problem lies in the duration of resuscitative efforts: no standard time has ever been established, and good outcomes after up to three hours of cardiopulmonary resuscitation (CPR) have exceptionally been reported.[23] Another problem is the time interval between the loss of cardiac function and the declaration of death ("no-touch period") which goes from 5 (most European countries) to 20 minutes (Italy).[24] According to the recommendations of the Society of Critical Care Medicine (SCCM) Ethics Committee, the US current practice (which relates above all to cDCD) is that "*no less than two minutes is acceptable, no more than five minutes is necessary*".[25] Yet, the shorter the interval between asystole and incision, the greater the possibility that the irreversible loss of intracranial functions, and hence brain death, has not yet occurred; consequently, death risks being certified using cardio-respiratory criteria when the neurological ones are not yet met for certain. So, it seems that different diagnoses of death exist that clinicians can use at their convenience.[26] We wish to emphasize that this is not a problem in Italy: the 20 minutes of recorded absence of cardiac electrical activity guarantees that the whole brain is completely destroyed after such a period of no cerebral blood flow and the dead donor rule is fully respected.

Controlled protocols also present other problematic aspects. The most important one relates to the fact that, in order to fit within the DCD protocols, the dead donor rule has to be interpreted. In most countries, cessation of circulatory function is intended as loss of effective mechanical myocardial function, while in Italy the electrical cardiac function (detected by the electrocardiogram, ECG) is considered. Supporters of the mechanical cardiac function claim that life depends on effective circulation of oxygenated blood, not on ECG activity. Furthermore, the mechanical cardiac function ceases much earlier than the electrical function, thus avoiding minutes of dangerous warm ischemia. Again, the term "irreversible" should be intended in the weakest possible way, as spontaneously irreversible, meaning that no effort should be made to restore effective circulation — even if this is usually possible. Indeed, this is coherent with the clinical decision of withdrawing life support procedures. Also this choice, opposed to

the strong interpretation of irreversibility (circulation cannot be restarted even by external intervention) leads to a significant shortening of the no-touch period. The purported distinction between the loss of effective circulation and the vitality of the cardiac muscle explains the fact that — in some countries — viable hearts can be retrieved from cDCD donors and can be successfully transplanted.[11, 27, 28] This aspect does not concern Italy, as the legislator, imposing a 20-minute observation of complete cessation of cardiac electrical function, overcomes this issue by implying a complete and irreversible brain function cessation and the likely loss of myocardial viability.

A third ethical issue — at least in uDCD — is the *donor informed consent* to procedures aimed at reducing the time of warm ischemia and improving organ preservation. These procedures include large vessel cannulation, infusion of organoplegic solutions and heparin up to use of extracorporeal membrane oxygenation (ECMO).[24] Countries such as France and Spain have passed legislation allowing presumed consent: organ-preservation measures may be initiated unless the patient has specifically opted out.[28, 29] In Italy an explicit *in vita* consent or, in the absence of such declaration, a "non-opposition" by relatives is required for organ and tissue donation.

This raises the question to what extent invasive manoeuvres are allowed whilst the final decision is pending. In fact, on one hand, there is the need to avoid further damage and to preserve the dignity of the person; on the other hand, there is the need for organ preservation in order to best respect the recipient.

In the literature, this aspect is still debated. The moral and legal permissibility of *post mortem* organ preservation with chest compressions, mechanical ventilation, and ECMO remains controversial in many countries and has been the subject of many peer-reviewed publications. Moreover, the ethical acceptability of *pre mortem* interventions to facilitate cDCD is also controversial, and some official statements have offered divergent opinions.[23, 30, 31] The WG shares the concept of "minimal donor risk" and shares the opinion that those manoeuvres with a "low invasiveness", mainly necessary for diagnostic work-up (as, for instance, blood sampling, laboratory tests, bronchoscopy, etc.) are fully acceptable. Other manoeuvres with higher invasiveness that could be useful for organ preservation (in particular heparin administration and vessel cannulation) and so close to the end of life, are ethically acceptable if they honour the donor's wishes and allow an act (organ donation) considered by him/herself (or by the next of kin) as the best way to accomplish his/her life project.

DCD in Italy

uDCD

In Italy, the first and to date only program of uDCD has been developed and run in Pavia since 2007.[32] The so-called "Alba program" is based on ECMO, which starts immediately after death has been declared using the circulatory criteria established by the Italian law. Selective abdominal normothermic venous-arterial circulation then follows.

All the steps of the protocol have been assessed for consistency with Italian law and approved by the Italian National Committee for Bioethics (NCB).[33] Cooperation among first-aid and emergency services represents a major challenge, as does availability of resources for the on-call dedicated DCD task force.

To date, 32 kidneys have been retrieved through uDCD, 14 of which have been transplanted, with only 7% of "primary non function" and good long-term results in comparison with DBD grafts, in spite of an increased rate of delayed graft function (86%) [Abelli M, Geraci P. Personal communication], as described in other series.[34]

A cost-effectiveness analysis of the Alba program shows that changing the current practice and increasing the availability of kidneys from DCD would result in a cost-effective policy to expand the pool of kidney donors.[35]

Undoubtedly, the 20 minutes of "no-touch period" represents an important problem in terms of warm ischemia and graft damage. The Italian NCB has recently suggested main-

taining the 20 minutes of "no touch period".[33] Notwithstanding this, we strongly believe that it would be appropriate to reconsider this time interval also in Italy, because it has no substantial scientific basis. However, at present we are bound to respect this rule, using all the possible tools to preserve and assess organ function.

The clinical experience in Pavia has clearly shown that the prolonged duration of "no touch period" needed to declare circulatory death according to Italian legislation should not discourage the spread of uDCD programs even in our country. It is worth noting that recently, after the approval of a new program of uDCD lung donation, the first lung transplantation from a DCD donor was successfully performed in Italy (Policlinico of Milan) [Valenza F, personal communication]. The donor died due to acute myocardial infarction and aortic rupture. After unsuccessful resuscitation, the subject was declared dead by cardiac criteria. According to the protocol, the lungs were kept inflated during the 20 minutes of no touch period and, once consent to donation from the next of kin was obtained, the lungs were retrieved, submitted to e*x vivo* lung perfusion reconditioning and functional evaluation, and finally successfully transplanted.

Table III summarizes a useful practical framework for interventions aimed at possible uDCD organ donation, preserving safety and the expressed donation wishes of the person, if known and accessible, but also allowing initiation of organ preservation manoeuvres.

cDCD

In Italy organ procurement after cDCD is legally and ethically conceivable within the current legal framework. However, although formal impediments do not exist, we are faced with many obstacles which hinder the implementation of these programs, mainly of cultural nature.

As previously discussed, the issue of cDCD must be seen only in the context of a comprehensive approach to the end-of-life care in ICU and, at present, this aspect of critical care in Italy is still largely undervalued.

Once more these considerations urge the scientific community to address this particular issue, with two main objectives: 1) towards the professionals (both ICU teams and transplant teams), to improve their knowledge concerning issues like end-of-life care, organ donation and cDCD, and to provide sound frameworks for medical decision in these fields; 2) towards public opinion, to give correct information and to preserve public trust regarding organ procurement.

In particular, in Italy every possible effort must be made to promote the cultural growth

TABLE III.—*The 6-step protocols for organ donation in uncontrolled donation after circulatory death (Maastricht categories II).*

	Steps	Notes
1	Clinical decision on treatment futility or inefficacy in the asystolic patient: intensive supports should be stopped, non-conventional ECLS is not indicated	The treating medical staff which identifies a potential organ donor must be different and independent from the on-call dedicated DCD Multidisciplinary Taskforce (DCD-MT)
2	Death diagnosis by internationally accepted criteria (immediately after stop of life-support therapies)	Invasive manoeuvres with proportional risk of complications (laboratory tests, I.V. heparin, vessel cannulation) are allowed with the aim of preserving the possibility of organ donation – in the meanwhile, consent/opposition should be verified
3	Declaration of death	Flat ECG must be recorded (for 20 minutes in Italy)
4	Information to the family (*treating doctors*) and donation proposal (*DCD-MT*)	After declaration of death, organ retrieval organization and invasive manoeuvres (including ECMO) can be adopted with the aim of preserving organ functionality while the family may express non-opposition to donation (DCD-MT)
5	Complete evaluation of organ suitability as soon as the family agrees with donation	
6	Organ retrieval	*Ex situ* perfusion if indicated

DCD: donation after circulatory death; ECLS: extra-corporeal life support; ECMO: extra-corporeal membran oxygenation.

of caregivers on end-of life issues, proportionality of treatment and on withdrawing of life support treatments that have become disproportionate.

In Italy, almost all multiorgan donors are patients with catastrophic brain damage who die in the ICU and are declared brain dead. It is at present difficult to assess potential donation: we know that of the many patients who die with acute cerebral lesion in the ICU (27,490 in 5 years in Italy),[36] far more die with diagnosis of cardio-circulatory arrest rather than brain death (60.1% *vs.* 39.9%). We have no information about their clinical course, but we can conjecture that a not negligible number could be considered for organ donation after cardiac arrest. Moreover, according to the GIVITi study, at least 17.1% of ICU patients (irrespective of diagnosis) die after withdrawal of life support treatments (WLST) and a recent French study, in a quite similar context, shows that a significant number of patients who died under WLST conditions would have been eligible for organ donation (more than 50% of brain-injured patients who died).[37]

The implementation of cDCD programs in Italy might therefore generate a number of potential donors. Hopefully, this should not result in a simultaneous decrease in DBD, as observed at an early stage of the DCD programs in some countries (as in the Netherlands, Belgium and the UK in the decade 2000-2009).[36]

DBD and DCD programs must be pursued by implementing a complementary model. Moreover, the average availability of organs from a single donor is 2.1 in the case of DCD compared to 3.6 in DBD.[31]

We want to point out that treatment withdrawal must not be performed with the goal of allowing donation from Maastricht type III donors. In particular, according to the recent position statement of the Ethics Committee of the French Intensive Care Society, we believe that "*treatment withdrawal aims to allow death to occur, that is, to avoid prolongation of the dying process by interventions that are useless, costly, and possibly degrading. The treatment-withdrawal decision can only be fully legitimate when placed in the clinical context, which is unique to each patient. As long as the patient is alive, he or she cannot be viewed as a potential reservoir of organs or other materials that could be put to use, failing which the patient would be robbed of his or her death and considered, not as a finality, but as a means put prematurely to use by others. Giving priority to the desire to save lives via organ retrieval by instrumentalizing a dying patient at the expense of providing care and ensuring dignity throughout the dying process (...) is ethically unacceptable.*"[24]

We strongly recommend that: 1) the WLST decision is made independently of the possibility of organ donation; 2) the organ retrieval procedure must neither cause nor hasten death; 3) "the dead donor rule" is strictly respected; and 4) reference to an updated national guidance for the WLST is used.

Moreover, we suggest that a first useful step could be to restrict DCD to severely brain-injured patients, once confirmatory investigations predicting a catastrophic prognosis have been performed, following protocols which take into account specific issues, such as sedation (for reasons of comfort), extubation, and palliative care.

We also suggest that organ donation after WLST should be authorized only in pilot centres with a locally agreed WLST policy, and a local team familiar with DBD and DCD protocols. The nature of the confirmatory investigation required should be formalized by the Italian CNT, in order to help preserve population trust regarding organ procurement and provide a framework for medical decision-making.

New opportunities

The recent introduction of machine perfusion devices to assess and recondition "on the bench" (or *ex situ*) organs after retrieval from marginal donors has great potential to improve the process of DCD, even under Italian law, which implies a significant increase of the warm ischemia time.

Machine perfusion is included in the Alba program to evaluate the function of the procured organs, being a fundamental step in the

decision whether or not to transplant organs. On-the-road Italian programs for lung DCD recovery will take advantage of *ex situ* lung perfusion techniques which allow the so-called "reconditioning" of these organs, recovery of their function as well as their exhaustive assessment before grafting.[39, 40] Particularly in uDCD programs, *ex-situ* evaluation of procured organs is a mandatory step to guarantee patients' safety.

In selected emergency cases, ECMO is used as part of extracorporeal life-support in non-conventional resuscitation protocols.[41] In those patients who do not recover, death may be declared under extracorporeal circulation (see category IV B in Table I) by neurological criteria including the apnea test [42] or by circulatory criteria. These subjects represent a considerable pool of donors that need to be considered, as these donors may be either DCD-like-donors or heart-beating DBD donors when neurological criteria are used.

Conclusions

At present Italy is markedly different from other countries with respect to organ donation after circulatory death. Despite the "20-minute flat ECG" rule, and provided that steps are taken to respect national and regional regulations, uDCD programs should be encouraged in selected experienced centres, and possibly within clinical trials. The Alba experience has demonstrated the feasibility and the efficacy of this program and helped in addressing many ethical and clinical issues. At present the main obstacle to its implementation seems to be related mainly to organizational and economic aspects.

As far as cDCD is concerned, the time has come also in our country to promote a debate among all involved subjects. Starting from the existing documents released by several Scientific Societies about the end of life [19, 43], the debate should assess the concrete possibility of implementing a specific program in this field. The recent statement of the Ethics Committee of the French Intensive Care Society [24] could represent a useful road map to follow.

The high level of expertise of Italian intensive care physicians, combined with the high profile organization of the transplant network; the protective Italian law with respect to moral issues raised by DCD programs; the availability of new extracorporeal techniques: all constitute a promising platform for the safe and effective implementation of DCD programs in Italy. The next steps should therefore include:

1. actions directed at promoting the spread of uDCD programs in selected centres under NCT coordination;
2. initiatives aimed at promoting the debate among all involved subjects and making recommendations in the matter of cDCD in the context of end-of-life care of ICU patients.

The latter is a very complex issue, with many controversial aspects: however, we do not have to start from zero. We may take into account the statements released in 2003 and 2006 by SIAARTI and its Study Group for Bioethics about end of life care in the critical care setting,[18, 44] which represent an important basis for this debate. We believe that the issue of cDCD should also be addressed in this context.

DCD is one of the new strategies available to overcome the problem of organ shortage and we are bound to address this issue.

Key messages

— To date DCD has not been implemented in most European countries, in spite of its proven efficacy and the increasing number of persons on waiting lists for transplantation.

— The quality and appropriateness of critical care management are the ethical prerequisites for organ donation after death determination both by neurological and cardiocirculatory criteria.

— An open and clear debate on DCD following limitation of treatment in ICU is necessary among both healthcare professionals and the public, where the clinical decision of withdrawing disproportionate

treatment is completely independent of the possibility of organ donation.

— A 6-step protocol in uncontrolled DCD is suggested to regulate the inclusion of some invasive manoeuvres before and after declaration of death with the aim of preserving the possibility of donation and the quality of transplantable organs.

— In Italy it has been proved that the 20 minutes of silent ECG, provided by law to over-guarantee brain death and the 'dead donor rule', does not impede organ donation. Although we believe that the current 20-minute period should be reconsidered and shortened, the issue of mandatory prolonged warm ischemia can be mitigated by the high level of expertise of the intensivists combined with the high profile organization of the transplant network and the innovative organ protection and reconditioning by ex vivo perfusion techniques.

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Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Article first published online: September 16, 2015. - Manuscript accepted: September 10, 2015. - Manuscript revised: September 8, 2015. - Manuscript received: February 1, 2015.