BELGISCHER BERATENDER AUSSCHUSS FÜR
Bioethik

Gutachten Nr. 63 vom 12 Oktober 2015 über bestimmte Aspekte des Protokollentwurfs „Donation after Circulatory Death“ (DCD) des Belgischen Transplantationsrates und der Belgischen Transplantationsvereinigung

1. Befassung des Ausschusses

Am 8. April 2015 bat Frau Maggie De Block, Ministerin für Soziales und Gesundheit, den Beratenden Bioethik-Ausschuss um ein Gutachten zu einer Reihe von Aspekten eines Protokollentwurfs über die Problematik der „Donation after Circulatory Death" (nachfolgend abgekürzt als „DCD"[1]), den der Belgische Transplantationsrat und die Belgische Transplantationsvereinigung ihr vorgelegt hatten[2]:

„Der Belgische Transplantationsrat hat ein Gutachten zu einem Protokoll für Organspenden nach einem Kreislauf- und Atemstillstand erstellt. Dieses Protokoll ist beigefügt.

Ich bitte Sie um ein Gutachten dazu, unter anderem bezüglich der für die Auswahl der potentiellen Spender vorgeschlagenen Methode und der von ihnen zu erfüllenden Bedingungen. Ethische Überlegungen gibt es zu drei kritischen Punkten.

Erstens die Feststellung der Zwecklosigkeit, bestimmte Handlungen bei einem Patienten fortzusetzen, bei dem die Genesungsprognose gestellt werden muss. In bestimmten Fällen wird beurteilt, welche Lebensqualität den Patienten bei einer eventuellen Genesung erwartet. Zu hinterfragen ist, ob die diesbezügliche Entscheidung eines behandelnden multidisziplinären Mediziner- und Pflegeteams nicht von einem medizinischen Experten bestätigt werden sollte, der nicht diesem Team angehört.

Zweitens die – gegebenenfalls – restriktiven Auflagen, die die medizinisch-pharmazeutische Umschreibung des potentiellen Spenders erfüllen muss; in dem Dokument ist diesbezüglich von „utilitaristischer Sterbehilfe" die Rede. Ich nehme an, dass hiermit ein medizinischer Eingriff gemeint ist, der während der Agonie unüblich ist und der keinen unmittelbaren therapeutischen Wert für den betroffenen Patienten hat.

Die dritte Frage, die sich stellt, ist, ob das Prinzip des „presumed consent" im Sinne des Gesetzes vom 13.06.1986 über die Entnahme und Transplantation von Organen auch auf NHBD angewandt werden kann. Das Gesetz ist in einer Zeit verabschiedet worden, als Entnahmen bei hirntoten Spendern geläufig waren. Früher wurde NHBD nicht angewandt. Schließlich kann man sich fragen, ob die gesellschaftliche Akzeptanz von Organspenden nach einem Kreislaufstillstand genauso groß ist wie bei festgestelltem Gehirntot. Der Gehirntot wird allgemein als unwiderruflich empfunden, während man in dem vorgelegten Protokoll erhebliche Eingriffe in einen Sterbeprozess vorsieht, bei dem grundsätzlich nicht immer ein Zustand entsteht, in dem eine Organentnahme noch relevant sein kann. Schließlich kann bei einigen der falsche Eindruck entstehen, in Einrichtungen, die NHBD anwenden, würden nicht alle lebensrettenden therapeutischen Mittel in ausreichendem Maße eingesetzt. Es scheint daher angebracht, die Bevölkerung hierüber gezielt zu informieren."

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[1] In der internationalen Fachliteratur wurde lange der Begriff "Non Heart Beating Donors" (NBHD) verwendet, der jedoch mehr und mehr durch den korrekteren Begriff „DCD" verdrängt wird; noch neuer ist die Benutzung der Begriffe DCDD („donation after circulatory determination of death) und cDCDD (controlled DCDD) (siehe zum Beispiel die Augustausgabe 2015 der Zeitschrift The American Journal of Bioethics). All diese Begriffe verweisen auf dieselbe Prozedur der Organspende nach einem Kreislauf- und Atemstillstand.

[2] Am Ende dieses Gutachtens hinzugefügt.

2. Überlegungen und Empfehlungen

Die DCD-Problematik wurde in dem vorliegenden Protokollentwurf des Belgischen Transplantationsrates und der Belgischen Transplantationsvereinigung ausführlich behandelt, der auch weitreichende rechtliche und ethische Betrachtungen enthält. Angesichts dieser Grunddaten konzentriert sich das vorliegende Gutachten auf die Fragen der Ministerin.

1/ Was die Zwecklosigkeit angeht

Der Protokollentwurf verwendet zwei Begriffe.

a. In Paragraph 4.2.2.1. ist von Patienten die Rede, bei denen eine weitere Behandlung als „medical futility" bezeichnet wird. Hiermit ist nach der weiteren Beschreibung zu urteilen eindeutig der internationale Begriff „physiological futility" gemeint. Es geht um Patienten, bei denen eine weitere Behandlung zwecklos ist und das Leiden nur verschlimmert wird. Für jeden gewissenhaften Arzt ist selbstverständlich, dass therapeutische Verbissenheit vermieden werden muss. In seinem Gutachten Nr. 41 vom 16. April 2007[3] über die Einwilligung nach Aufklärung und „DNR"-Kodes hat sich der Ausschuss im Detail mit dieser Thematik befasst. Weil weitere Behandlungen hier zwecklos sind, ist es besser, die Angehörigen hier auf die Möglichkeit von Organspenden vorzubereiten. In diesem Fall kann von „utilitaristischer Sterbehilfe" – wie es im Text heißt – keine Rede sein, sondern von einer unter Achtung der Person sorgfältig ausgeführten medizinischen Handlung. Wegen der Diskussion, die es manchmal über diese Entscheidungen gibt, ist – wie in Gutachten 41 vorgeschlagen - eine multidisziplinäre Konzertierung auch hier wünschenswert. Der Transplantationsarzt und sein Team können hier keine Rolle spielen. Ferner wird das Einschalten eines zusätzlichen neutralen Arztes das Vertrauen in die Ärzte sicher stärken und die Chancen einer positiven Haltung der Familie gegenüber Spenden erhöhen. Dies steht vollkommen im Einklang mit der Entscheidung des Gesetzgebers, bei einer so einschneidenden und unumkehrbaren Entscheidung einen zweiten neutralen Arzt hinzuzuziehen (siehe die Gesetzgebung über Sterbehilfe). Obschon keine gesetzliche Pflicht dazu besteht, lautet die explizite standesrechtliche Regel, hierüber mit den Angehörigen des Patienten (z.B. mit seinem Vertreter im Rahmen des Gesetzes über die Patientenrechte) zu kommunizieren. Dieses Gespräch ist wünschenswert und notwendig, weil unter diesen Umständen eine für den Patienten „nutzlose", aber für die Transplantation „nützliche" Zeitspanne vergehen wird, ehe der Kreislaufstillstand eintritt.

b. In Paragraph 4.2.2.2 ist von „treatment withdrawal", Verhältnismäßigkeit und gesellschaftlicher Akzeptanz die Rede. Unter diesen Umständen geht es nicht um „medizinische zwecklose" Therapien: Man möchte den Boden für das vorbereiten, was man „qualitative futility"[4] genannt hat: „eine Behandlung wird dann als zwecklos betrachtet, wenn sie lediglich einen permanenten Zustand von Bewusstlosigkeit aufrechterhält oder die Abhängigkeit von einer Behandlung, die nur in einer Krankenhausabteilung für akute Pflege angeboten werden kann, nicht beenden kann". Hier ist große Vorsicht geboten. Denn es geht hier nicht um rein medizinisch-technische Überlegungen, sondern um das Abwägen zwischen medizinischen Überlegungen, den Erwartungen des Patienten an die zukünftige Qualität seines Lebens und den Kosten der intensiven, chronischen Behandlung für die Gesellschaft. Unter diesen Umständen

[3] Einzusehen auf http://www.health.belgium.be/bioeth, unter der Rubrik « Gutachten ».

[4] Schneiderman und Jecker behaupten: "a treatment should be considered futile if it merely preserves permanent unconsciousness or cannot end dependence on treatment that can only be provided in an acute care hospital" (Schneiderman, L. J. en N.A.S. Jecker. 2011. *Wrong Medicine: Doctors, Patients, and Futile Treatment*, 2nd ed. Baltimore: John Hopkins University Press.

könnte die Entscheidung der Ärzte für die Spende oder die Entnahme von Organen zwecks Transplantation auch von wirtschaftlichen Beweggründen geleitet werden. Eine Ausweitung der Spenden auf solche wirtschaftlichen Indikationen wäre ein unannehmbarer ethischer Schritt.

c. Wenn der Abbruch der Behandlung von der Entscheidung des Patienten ausgeht, nicht mit dieser eingeschränkten Lebensqualität weiter leben zu wollen, muss dies selbstverständlich respektiert werden. Dies ergibt sich aus dem Gesetz über die Patientenrechte und aus dem Autonomieprinzip. Hier kann sowohl eine vorgezogene Willenserklärung als ein aktuell geäußerter Wunsch wertvoll sein. Die Funktion des Vertreters kann helfen herauszufinden, was der Patient zu dem Zeitpunkt gewollt hätte, wo er seine Entscheidung angesichts der Umstände nicht mehr mitteilen kann.

Wegen der besonders heiklen Materie wird auch hier – wie unter 1.a angegeben – zusätzlich zur Meinung des behandelnden Arztes die Meinung eines anderen Arztes verlangt. Dieser Arzt wird sozusagen als „Anwalt" des Patienten (*donor advocate*[5]) auftreten, wie bei der Organentnahme bei lebenden Spendern. Diese zusätzliche Meinung garantiert eine größere Objektivität bei der Entscheidungsfindung und überzeugt die Bevölkerung, dass hier kritisch hinterfragte und wohlüberlegte Entscheidungen getroffen werden.

2/.Was den Begriff „utilitaristische Sterbehilfe" angeht

Der Beratende Bioethik-Ausschuss meint, dass dieser Begriff hier absolut nicht angebracht ist. Es sei ja nicht die Rede von Sterbehilfe im Sinne des belgischen Gesetzgebers. Deshalb schlägt der Ausschuss vor, den Begriff „utilitaristische Sterbehilfe" nicht im Protokoll (Kapitel 4.2.) zu verwenden. Ferner ist vorgesehen, dass sich innerhalb des Ausschusses ein verkleinerter Ausschuss mit der Anfrage eines Gutachtens zur Problematik der Organspende nach einer Sterbehilfe befasst.

3/ Was das Prinzip der Einwilligung nach Aufklärung angeht

Der Beratende Bioethik-Ausschuss betont zuallererst, dass das belgische System der impliziten Einwilligung in die Organspende (auch „presumed consent oder „opting-out"-System genannt) eine gute Information der Bevölkerung voraussetzt. Deshalb ist der Unterschied zwischen „medical of physiological futility" und „qualitative futility" sehr wichtig. Bei einer zu starken Betonung der „qualitative futility" ist die Wahrscheinlichkeit groß, dass das Vertrauen der Bevölkerung in das System der impliziten Einwilligung untergraben wird. Angesichts der immer größeren Organknappheit wäre das ein ernsthaftes Handicap. Eine schlampige Erweiterung der Spendemöglichkeiten könnte dann paradoxerweise zu einer Verringerung der Anzahl Spendenanwärter führen.

4/ Die 5-Minuten-Regel

Wenn man das weiß, ist auch die Textangabe, dass fortan zwei Minuten Herzstillstand ausreichen sollen, um mit der Transplantation zu beginnen, ein gefährlicher Präzedenzfall. Sie steht im Widerspruch zum internationalen Konsens[6], der mindestens 5 Minuten verlangt. Obschon eine kürzere Spanne wahrscheinlich besser ist für die Qualität der Spenderorgane, hält der Ausschuss es für wünschenswert, den Konsens in Erwartung neuer empirischer Daten einzuhalten.

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[5] Siehe hierzu den Briefwechsel des Ausschusses vom 19. März 2003, nachzulesen auf http://www.health.belgium.be/bioeth unter der Rubrik « Gutachten/Briefgutachten».

[6] Brody B, Halevy A, Is futility a futile concept? *J Med Philos*, 1995, 20, 123-144; Bernat JL, Capron AM, Bleck TP et al, The circulatory-respiratory determination of death in organ donation, *Crit Care Med* 2010, 38, 963-70; Anderson T.A., Bekker P, Vagefi P.A, Anesthetic considerations in organ procurement surgery : a narrative review, *Can J. Anest*, 2015, 62, 529-539.

Das Gutachten wurde im verkleinerten Ausschuss 2015-2 vorbereitet, der wie folgt zusammengesetzt war:

Co-Vorsitzende	Co-Berichterstatter	Mitglieder	Vorstandsmitglieder
R. Rubens	R. Rubens	D. Bron	P. Cosyns
J. Herremans		E. Heinen	
		R. Kramp	
		R. Reding	
		P. Schotsmans	
		S. Sterckx	

Mitglied des Sekretariats
L. Dejager

Die Arbeitsunterlagen des verkleinerten Ausschusses 2015-2 - Fragen, persönliche Eingaben der Ausschussmitglieder, Sitzungsprotokolle, eingesehene Dokumente - werden als Anlagen 2015-2 im Dokumentationszentrum des Ausschusses aufbewahrt, wo sie eingesehen und kopiert werden können.

Dieses Gutachten kann auf der Internetseite www.health.belgium.be/bioeth eingesehen werden.

ANHANG ZUM GUTACHTEN NR. 63

Protokollentwurf "Donation after Circulatory Death" (DCD) des Belgischen Transplantationsrates und der Belgischen Transplantationsvereinigung

1.Introduction

P.Evrard MD, PhD and H.VanVlierberghe MD PhD

Organ transplantation improves the quality of life and increases the life expectancy of patients with end- stage organ failure. The Belgian law supports the opting out system to approach possible donors. As a consequence and due to governmental campaigns, the number of brain death donors per million inhabitants in Belgium is amongst the highest in the world. Still patients do not reach transplantation as the number of patients on the waiting list outnumbers the amount of organs available. Therefore alternative sources of organs need to be sought. Living organ donation, splitting of organs… could contribute and diminish the gap between the number of listed and transplanted patients. These sources will not be covered in this document.
"Non Heart beating donors (NHBD)" or in a more recent and international definition «Donors after Circulatory Death (DCD)" are a potential and additional group of deceased persons, being able to add organs to the pool. DCD describes the recovery of organs for the purposes of transplantation that follows death confirmed using circulatory criteria. This differs in respect with the actual model for deceased donation, which is the donation after the confirmation of death using neurological criteria ("Heart beating donation (HBD)" or "Donation after brain death (DBD)"). In the beginning of the era of transplantation, the most of the donors were DCD, whereas later (and due to better outcome), DBD became the standard. Recent re –interest rose in DCD donors, as a consequence of better preservation techniques and a better insight in different categories of DCD donors (the so-called Maastricht classification). In recent literature, more and more data are available that the results after organ (kidney, liver, lung…) transplantation using DCD are acceptable or good. Also in Belgium, different organs were transplanted with DCD donors.
Since organ donation is based on a broad platform (general society and professionals), it is important to communicate on this in a transparent and uniform manner. Therefore the Belgian Transplantation Council and the Belgian Transplantation Society organized a working group on DCD covering its aspects (Legal and ethical aspects, aspects about retrieval and perfusion, surgical aspects…). This working group consisted out of experts from all universities and university hospitals and from experts of some non-university hospital.
This document is the result of several meetings and is the result of a consensus between the experts.
It is the most sincere hope that this document finds its way to the general and professional society and in this way contributing to the acceptance of DCD donors as a valuable and necessary way to enlarge the numbers of donors.

2. DCD categories

P.Evrard MD, PhD

2.1. Actual classifications

The *NHBD Maastricht classification* (Table 1)[1] has been largely used over the last 15 years. This classification has the advantage of characterizing the DCD processes that may have their own particularities, including ethical or surgical aspects. It also has the advantages of simplicity and usefulness. Up to now, all other attempts to improve the Maastricht classification added new categories based on different ischemic graft insults leading to potential different transplant results, despite the fact that the DCD situation was already included in the Maastricht classification.

A Spanish national consensus proposed a "Modified Maastricht classification for DCD (Madrid 2011)" adapted to the reality and experience of its country with category 1 and 2 (table 2)[2]. The Eurotransplant organization officially recognized the particular donation after euthanasia in The

Netherlands, Belgium, and Luxemburg. The modified and more complete categorisation proposed by Detry et al better define the different situations encountered in the different groups and countries with active DCD program (table 3)[3]. The WHO Critical Pathway for deceased donation classified DCD according to the phase of the process as possible, potential, eligible, actual and utilized donor (fig 1)[4,5]. These last classifications are more complex.

2.2. Belgian modified Maastricht classification for Donation after Circulatory Death

The proposed new classification conserves the skeleton for further improvement, as it is simple, clear, and **classifies easily the different DCD types by processes** for ethical issues and for the non-medical or non-specialised reader interested in the field (table 4). This is also an argument for public consideration and trust in the difficult field of organ donation.

All the relevant times should be defined and reported separately for ischemia calculation.

The first level of definition is simple and based on whether the situation is controlled or not. These are usually kept from the old into the new classifications.

2.2.1. Uncontrolled

2.2.1.1. Category I: Dead on arrival

Includes victims of a sudden death, whether traumatic or not, occurring out or in the hospital and who, for obvious reasons, have not been resuscitated. Once the circulatory death is certified by a physician on the scene, the dead body can be transferred into hospital for organ recovery depending on country regulation and laws.

2.2.1.2. Category II: Unsuccessful resuscitation

Includes patients who suffer a CA and in whom CPR has been applied and resulted unsuccessful. CA occurs out or in the hospital, being attended by health-care personnel with immediate initiation of CPR. The circulatory death is only declared after a no touch period which excludes possible auto-resuscitation.

2.2.2. Uncontrolled

2.2.2.1. Category III: Awaiting cardiac arrest

Includes patients in whom withdrawal of life-sustaining therapies is applied, as agreed upon within the health-care team and with the relatives or representatives of the patient. DCD procurement is a medically planned, controlled procedure in an ICU patient in whom further medical treatment is deemed futile (fig 2). It is the treating physician who is responsible and takes the medical decisions concerning the end of life (MDEL): consensus about limiting orders like do not resuscitate (DNR), do not start new treatments (withholding), stop useless (ineffective) treatments (withdrawal), start comfort therapy and/or palliative care. The intention of comfort therapy is to promote the wellbeing of the patient; some types of comfort therapy can be life shortening as non-intended side-effect (Principle of Double Effect). Negative side-effects (life shortening) are proportionally acceptable. The highest value is a human dying process for the terminally ill patient. Once the decision is taken, the transplant team is informed and procedures for organ donation may start. The patient's death results from stopping of ventilation followed by cardiac arrest, correctly humanly and medically supported Resort to a type III DCD donor remains the consequence of the decision to stop a treatment becoming useless, going against patient's dignity. The distinction of decisional places and decisional times will avoid any intentional causal link between the decision of stopping treatment in the Intensive Care Unit and of stopping ventilation in the operating theatre. A cross information to all intervening people concerning the aims seeked will allow each of them to take on their own ethical responsibilities.The circulatory death is only declared after a no touch period which excludes possible auto-resuscitation.

2.2.2.2. Category IV: Cardiac arrest while brain death

Includes patients who suffer a CA after the determination of death by neurological criteria, but before the aortic cross clamping in the operating theater has been performed. It is likely that restoration of cardiac activity is first attempted, with a switch to the surgical protocol of donation, if this fails.

2.2.2.3. Category V: Euthanasia

Includes patients who grant access to medically-assisted circulatory death. Euthanasia is legally approved in some countries and defined as the "act practised by a third party who deliberately puts an end to the life of a person, on request of this one". Some individuals who have granted access to euthanasia expressed their willingness to have their organs procured after death. Organ donation after euthanasia is allowed under the scope of donation after circulatory death. Most patients who require euthanasia in Belgium and in the Netherlands are cancer patients who are clearly not candidates for DCD donation. But a small proportion of these cases are patients with e.g. severe, stable neurological deficits, whose medical affectation cannot be transmitted through organ donation. These patients are potential DCD donors. Most euthanasias are performed at home by the regular family physician, but DCD donation after euthanasia requires one to perform the euthanasia in an OR (or in a preparation room close to the OR to allow the presence of the family at the time of death).

Table 1: Maastricht Categories for Donation after Circulatory Death (Kootstra, 1995).

UNCONTROLLED DCD	**I**	**Dead on arrival**	Includes victims of a sudden death, whether traumatic or not, occurring out of the hospital and who, for obvious reasons, have not been resuscitated.
	II	**Unsuccesful resuscitation**	Includes patients who suffer a CA and in whom CPR has been applied and resulted unsuccessful. CA occurs within the hospital, being attended by health-care personnel with immediate initiation of CPR.
CONTROLLED DCD	**III**	**Awaiting cardiac arrest**	Includes patients in whom withdrawal of life-sustaining therapies is applied, as agreed upon within the health-care team and with the relatives or representatives of the patient.
	IV	**Cardiac arrest while brain death**	Includes patients who suffer a CA in the process of the determination of death by neurologic criteria or after such determination has been performed, but before the transfer to the operating theater. It is likely that restoration of cardiac activity is first attempted, with a switch to the protocol of donation after circulatory death, if this fails.

CA: cardiac arrest, CPR: cardio-pulmonary resuscitation

Table 2: Modified Maastricht Classification for Donation after Circulatory Death (Madrid 2011)

UNCONTROLLED DCD	**I**	**Dead in the out-of-hospital setting**	Includes victims of a sudden death, whether traumatic or not, occurring out of the hospital and who, for obvious reasons, have not been resuscitated.
	II	**Unsuccesful resuscitation**	Includes patients who suffer a CA and in whom CPR has been applied and resulted unsuccessful. **II.a. Out-of-hospital** CA occurs in the out-of-hospital setting and is attended by an extra-hospital emergency service which transfers the patient to the hospital with cardiac compression and ventilatory support. **II.b. In-hospital** CA occurs within the hospital, being attended by health-care personnel with immediate initiation of CPR.
CONTROLLED DCD	**III**	**Awaitingcardiacarrest**	Includes patients in whom withdrawal of life-sustaining therapies is applied*, as agreed upon within the health-care team and with the relatives or representatives of the patient.
	IV	**Cardiac arrest while brain death**	Includes patients who suffer a CA in the process of the determination of death by neurologic criteria or after such determination has been performed, but before the transfer to the operating theater. It is likely that restoration of cardiac activity is first attempted, with a switch to the protocol of donation after circulatory death, if this fails.

**Includes withdrawal of any type of ventricular or circulatory support (i.e. ECMO)*

Table 3: Modified Maastricht Classification for Donation after Circulatory Death (Detry, 2012)

UNCONTROLLED DCD	**I**	**Dead in the out-of-hospital setting**	**1A** Cardiocirculatory death outside hospital with no witness. Totally uncontrolled **1B** Cardiocirculatory death outside hospital with witnesses and rapid resuscitation attempt. Uncontrolled
	II	**Unsuccesfulresuscitation**	**2A** Unexpected cardiocirculatory death in ICU. Uncontrolled **2B** Unexpected cardiocirculatory death in hospital (ER or ward), with witnesses and rapid resuscitation attempt. Uncontrolled
CONTROLLED DCD	**III**	**Awaitingcardiacarrest**	**3A** Expected cardiocirculatory death in ICU. Controlled **3B** Expected cardiocirculatory death in OR (withdrawal phase > 30 min). Controlled **3C** Expected cardiocirculatory death in OR (withdrawal phase < 30 min). (Highly) controlled
	IV	**Cardiac arrest while brain death**	**4A** Unexpected cardio circulatory arrest in a brain dead donor (in ICU). Uncontrolled **4B** Expected cardiocirculatory arrest in a brain dead donor (in OR or ICU). (Highly) controlled
	V	**Euthanasia**	**5A** Medically-assisted cardiocirculatory death in ICU or ward. Controlled **5B** Medically-assisted cardiocirculatory death in OR. Highly controlled

Table 4: Modified Maastricht Classification for Donation after Circulatory Death (Belgium 2013)

UNCONTROLLED DCD	**I**	**Dead on arrival**	Includes victims of a sudden death, whether traumatic or not, occurring out or in the hospital and who, for obvious reasons, have not been resuscitated.
	II	**Unsuccessful resuscitation**	Includes patients who suffer a CA and in whom CPR has been applied and resulted unsuccessful. CA occurs out or in the hospital, being attended by health-care personnel with immediate initiation of CPR.
CONTROLLED DCD	**III**	**Awaiting cardiac arrest**	Includes patients in whom withdrawal of life-sustaining therapies is applied, as agreed upon within the health-care team and with the relatives or representatives of the patient.
	IV	**Cardiac arrest while brain death**	Includes patients who suffer a CA during a DBD procedure.
	V	**Euthanasia**	Includes patients who grant access to medically-assisted circulatory death.

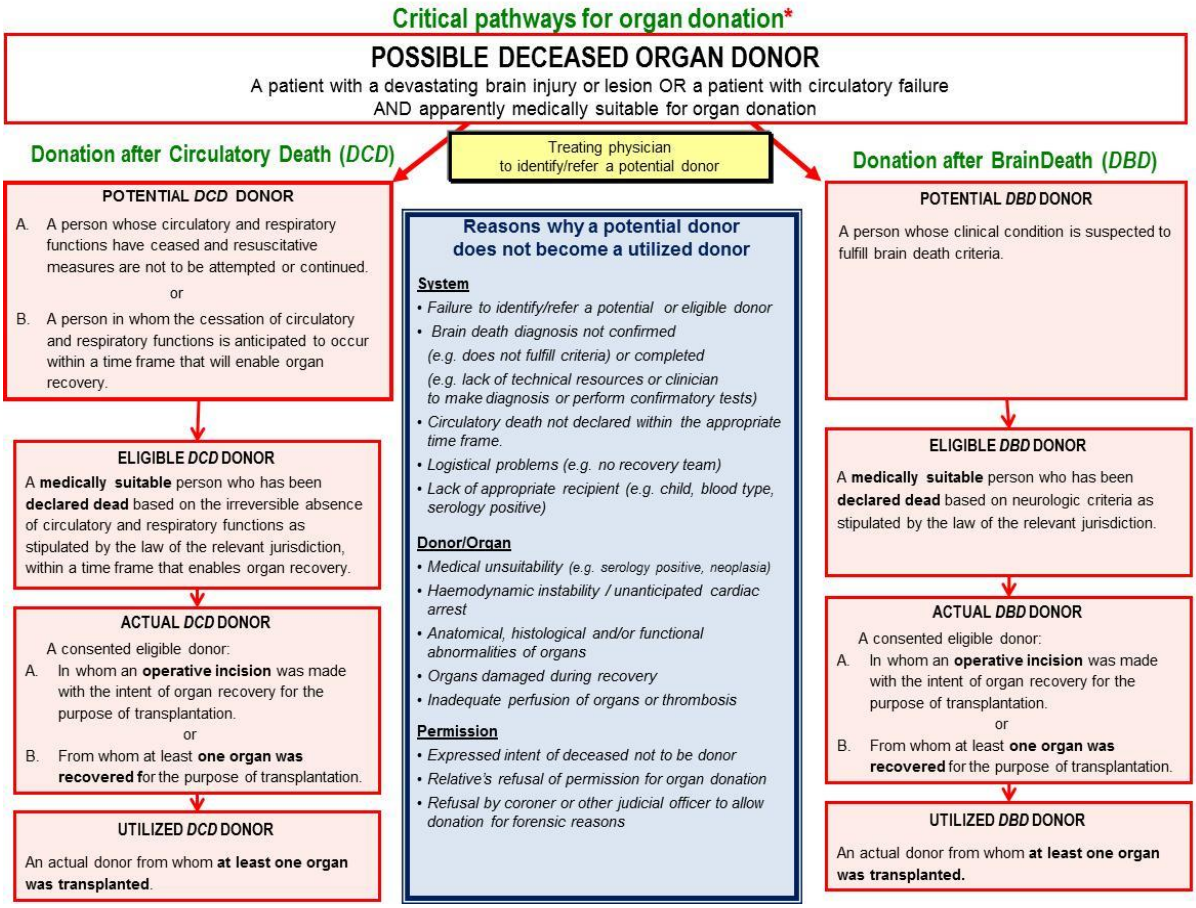


Figure 1: WHO Critical Pathway for deceased donation[4]

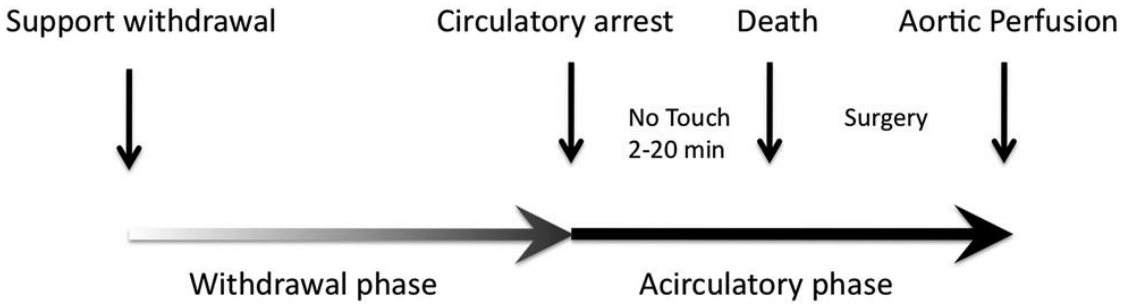


Figure 2. Process of controlled donation after circulatory death[3]

3. Legal aspect

An Vijverman and Geneviève Schamps

3.1. Introduction

The legal aspects of DCD organ donation in Belgium are laid down in the Law of 13 June 1986 on the organ donation and transplantation, as modified by the Royal Decree of 22 December 2003 and by the Laws of 25 February 2007, 19 December 2008 and 3 July 2012.
The Law of 3 July 2012 implemented the Directive 2010/45(53)/EC of 7 July 2010 on standards of quality and safety of human organs intended for transplantation.
The legal aspects of end of life care are laid down in the Law of 22 August 2002 on the patient's rights.
The Law of 19 December 2008 defined more specifically the recovery and use of human tissue for medical application or scientific research.

3.2. Patients unsuitable for DCD donation in Belgium

There are four categories of DCD donors according to the Maastricht classification but patient declare dead by the physician on the scene could not be transported by ambulance (category I: dead on arrival outside the hospital).

3.3. Protection of deceased donors

3.3.1. Selection of donors
A physician must ensure that donors are selected on the basis of their health and medical history.

3.3.2. Transplantation centre
In Belgium, only physicians from a transplantation centre can remove and transplant organs from deceased donors in a recognised transplantation centre (= a hospital service recognised as such) or in a hospital that has concluded a collaboration agreement with the transplantation centre which is responsible for the transplantation.

A transplantation of a heart or a heart-lung can also be carried out by a team of a health care program "cardiac pathology T" that has concluded a collaboration agreement with a transplantation centre.

3.4. Conditions for recovering organs from deceased donors

3.4.1. Who is a donor?
Organs and tissue intended for transplantation may be removed from anyone who is registered in the Belgian population register or in the foreigners' register since more than 6 months. The donor may moreover not explicitly have opposed against organ donation (= opt-out system).

A person who is not registered in the Belgian population register or in the foreigners' register since more than 6 months, can only be a donor when he/she has expressly agreed with the donation (= opt-in system).

Moreover, each person who is able to express his will may also specifically express his will to be a donor after his death.

3.4.2. Who can oppose?

A person who has reached the age of 18 and is able to express his will can express his opposition alone.

A person younger than 18 but able to express his will can oppose either alone during his life or the opposition can be expressed by one of his parents or his tutor.

If a person is younger than 18 but is not able to express his will, the opposition can be expressed (as long as this person is alive) by one of his parents or his tutor.

If a person not capable to express his will due to his mental state, the opposition can be expressed – provided that this person is alive - by his legal representative, his provisional administrator or – in their absence– by his closest relative.

3.4.3. How to oppose ?

According to the Royal Decree of 30 October 1986 (and the Circular of 19 February 1987), the opposition can be recorded in the Belgian population register.

It is however also possible to oppose in any other way, (e.g. a written document, an oral declaration to a close relative or a trusted person, et cetera).

3.4.4. Surviving relatives

Since the Law of 25 February 2007, a physician who recovers organs or tissue has not to take into account the opposition by the surviving relatives of the donor. The surviving relatives can be informed on an organ donation, but they cannot oppose against the procurement, nor is the informed consent of the surviving relatives required.

But the physician who intends to remove the organ has to inquire about the existence of an opposition expressed by the potential donor.

3.4.5. Voluntary and unpaid

Donations of organs of living and deceased donors are voluntary and unpaid (living donors can however receive a compensation for direct and indirect expenses and loss of income related to the donation). A Royal Decree will be adopted in the future to define the conditions of this compensation.

3.5. Confirmation of the donor's death

3.5.1. Three physicians

The death of the donor must be established by three physicians, excluding the physicians who are treating the recipient or who will perform the removal or the transplantation. This confirmation must be based on the most recent state of science in establishing death.

3.5.2. Official report

The physicians shall state the time of death and the way in which the donor's death was confirmed in a dated and signed report. This official report shall be kept for a period of ten years.

3.6. Cause of death

3.6.1. Respect for the deceased

Recovering of the organs and closing of the dead body must be carried out with respect for the deceased and for the feelings of the family.

3.6.2. Violence

If the cause of death is violence, the physician carrying out the Recovering of organs must draft a report which is forwarded immediately to the Procureur des Konings/Procureur du Roi.

3.6.3. Unknown or suspicious

If the cause of death is unknown or suspicious, no organ may be removed, unless the Procureur des Konings/Procureur du Roi is informed in advance and does not oppose.

3.7. Anonymous donation

The identities of the donor and of the recipient may not be disclosed.

3.8. Requirements for recipients

Organs or tissue can be allocated in Belgium to recipients having the Belgian nationality; to recipients being resident in Belgium since at least 6 months; or to recipients having the nationality of a country sharing the same allocation organism as in Belgium (Eurotransplant) or being domiciled in such country since at least 6 months.

3.9. Quality and safety

3.9.1. Characterisation of recovered organs and donors

All recovered organs and all donors must be characterised before the transplantation. This characterisation must be done on the basis of a model document attached to the Law of 3 July 2012.

3.9.2. Transportation of organs

Appropriate operating procedures must be in place to ensure the integrity of the organs during transport and a suitable transport time.

3.9.3. Traceability

All organs procured, allocated and transplanted in Belgium must be traced from the donor to the recipient and vice versa in order to safeguard the health of donors and recipients. This traceability implies the implementation of a donor and recipient identification system. All data required for full traceability is kept for a minimum of 30 years after the donation.

3.10. Reporting system

There must be a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning serious adverse events that may influence the quality and safety of organs and that may be attributed to the testing, characterisation, procurement, preservation and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities. An operating procedure must be in place for the management of serious adverse events and reactions.

3.11. Euthanasia

The Law of 28 May 2002 decriminalizes euthanasia if the legal conditions are observed. Euthanasia is defined as an “act performed by a third party who intentionally puts an end to a person’s life at this person’s request”. This third party must be a physician.
There is no legal provision in Belgian Law that prohibits the possibility for a person who asks for euthanasia to express also his will to give his organs after his death.
The Law of 22 August 2002 on patient’s rights set the right to refuse a treatment on a free and well-informed decision. The compliance with this decision mustn’t be confused with an act of euthanasia.

4. Ethical considerations

P. Schotsmans and D. Jacquemin

4.1.Ethical Considerations and Recommendations Concerning Organ Donation after Circulatory Death

4.1.1. Introduction

Organ shortage remains a real challenge for transplantation medicine. After having developed effective organ recruitment procedures after brain death, the possibilities of integrating organ donors after circulatory death (DCD) are now considered.
DCD is a new terminology: "non heart beating donation (NHBD) and its four categories type I, II, III and IV" were more common. It is however medically more adequate to speak in terms of DCD. Organ recruitment after DCD confronts us with several ethical, but also practical challenges. We concentrate on the ethical aspects.
An overview of the challenges:

- the decision to withhold and withdraw therapy (treatment limiting orders);
- the non-predictability of the moment of death based on irreversible circulatory arrest;
- the time of death and the (un)certainty of the diagnosis of death;
- the necessary extremely short time window between the confirmation of death and the withdrawal of the organs;
- the observation that patients are not yet dead at the moment of the decision making to start the procedure of DCD, and therefore the inclusion and application of patients' rights law (in essence the communication and deliberation with the family members);
- emotional reactions of physicians, nurses, family members and patients at the moment of transfer to the operation room where the patient will die;
- concerns about provoking more suffering for the donors (administration of e.g. *Heparine*, invasive procedures like catheters induction, reperfusion of the brain after declaration of death).

4.1.2. Recommendations: from patient to potential donor

- Decision to limit treatment: the **treating** physician and his team are making totally independent this decision.
- The treatment limitation is postponed in order to prepare the patient to become a potential donor. A fully documented limiting treatment order guarantees a clear distinction between the end of curative treatment and the start of the caring process for the potential donor.
- The continuing care for the patient as potential organ donor cannot be considered as therapeutic aggression and/or obsession.
- The procedures are openly discussed with the patient (if possible), family members and the caring team. Notifications of these conversations are written down in the medical records of the patient.
- The organ preserving measures may not provoke any suffering for the patient.
- Comfort care must always be provided. Eventually this may shorten the dying process, although this may not be the intention.
- The global procedure (limiting orders, confirmation of death and organ donation) must follow an explicit and openly communicated written protocol.

4.1.3. Some important considerations

4.1.3.1. Selection of patients for DCD procedures

It is extremely important that the eventuality of organ donation is not influencing the treatment of the patient. The treating physician remains fully responsible for the care of the patient: she or

he decides about the efficiency of further treatment and eventually to write down limiting treatment orders.
Communication with family members is necessary: in accordance with the concrete organization of the medical environment, this communication may be done by the treating physician and/or the local organ donation or the transplant coordinator.
This communication gives family members the opportunity to express their opinions concerning the DCD procedure. It should be clearly explained to them that the moment of death is not certain and that eventually the DCD procedure must be canceled. Tissue donation remains however always a possibility.

4.1.3.2. Comfort therapy
After the decision to stop further curative treatment, the moment of death remains uncertain: it is important to preview comfort therapy in order to avoid anxiety, pain and distress. It is eventually indicated and certainly ethically justifiable to apply these therapies, even in the awareness that these therapies may shorten the dying process (i.e. the centuries old principle of double effect). It is ethically unacceptable to end intentionally the life of the patient in order to make him ready for organ donation.

4.1.3.3. Organ preserving therapies
Organ preserving therapies are ethically acceptable, under the condition that they do not provoke more suffering

4.1.3.4. Definition of death
While dying is a process, to be dead is a moment. It is extremely important to withdraw organs only after the moment the patient has died. Death must be certified by three independent physicians (Belgian Legislation on Organ Transplantation). In contradiction with the criteria for brain death, there is still an ongoing debate on the criteria for the irreversible character of circulatory arrest. A "no touch" period of at least 2 but not more than 5 minutes is therefore indicated.

4.1.3.5. Organ retrieval
Organ retrieval may only start after the confirmation of death by 3 physicians, excluding those who are treating the recipient or who will perform the procurement and/or the transplantation of organs.

4.2. Can ventilator switch off followed by organ procurement be considered as utilitarian euthanasia?

4.2.1. Introduction
To answer to the question: "Can ventilator switch off followed by organ procurement be considered as utilitarian euthanasia?", it is important – to avoid any confusion – to clarify the meaning of three concepts: 1) NHBD of the category 3 (the term "Donation after Circulatory Death (DCD) determination of Maastricht category 3" should be preferred to NHDB), 2) euthanasia and 3) the ethical rule of treatment proportionality. It is clear indeed that an approach that would be insufficiently argued and that would disregard the action finality – i.e. withdrawing treatments that have become futile – could not only result in a blurring of roles between stakeholders but could also be seen as an act of killing instead of an interruption of therapies that are no longer beneficial for the patient.

4.2.2. Explanation of terms

4.2.2.1. Donation after Circulatory Death (DCD) of Maastricht category 3
This procurement technique is applicable to patients for whom treatment continuation would be considered as medical futility since, although they are not brain dead, the poor outcome is inescapable. In this context of medical futility, prolonging treatment would be useless or even deleterious for the dignity of the patient and hence withdrawal of care appears to be the best option.

4.2.2.2. Treatment withdrawal
The withdrawal of treatments that have become futile is ethically justified, based on the principle of proportionality – i.e. the choice of treatments has to be balanced with risks, costs, feasibility and expected results according to the condition of the patient and available resources[6].
It is fundamental that the decision-making process leading to treatment withdrawal strictly remains based on the determination of futile therapy and in accordance with the ethical principle of proportionality. To guarantee that this is respected, the withdrawal decision should be the result of a consensus obtained within the medical team in charge of the patient. The discussion on organ donation must always take place after the decision to withdraw medical treatments. In those cases where the physician who will accomplish treatment withdrawal (operating room) is not involved in the end-of-life decision (intensive care), he must have acquired the moral conviction that the decision to withdraw therapies was indeed the best option. As soon as organ donation is discussed a formal meeting should take place between both physicians.

4.2.2.3. Euthanasia
The article 2 in the Law of May 2002 defined the euthanasia as : "*act performed by a third party who intentionally puts an end to a person's life at the request of the said person*"[7]. Given this definition, the act of stopping therapies cannot be considered as euthanasia since the aim is not to intentionally and actively terminate the life of the patient but instead to guarantee a respectful and peaceful end of life.
The "utilitarian" terms needs some clarification. It is indeed important to bear in mind that, although the concept of *donation after circulatory death determination* may raise the utilitarian issue, the patient is by no way instrumentalized since the primary aim of the withdrawal of futile therapies is to ensure the best interests of the patient.

4.2.3. Accompanying patients in their end of life

Ventilator switch off is a difficult moment for caregivers, particularly if circulatory arrest is not fast enough and hence impedes the adequate timing for optimal preservation of organs, which is essential for the survival of other patients.
In the context of organ donation after circulatory death determination – as in any end-of-life situation occurring in the ICU – the dying process has to be medically accompanied with humanity and dignity. It is during this period that the concept of "utilitarian euthanasia" may be suggested[8].
However, as stated above, the decision to withdraw futile therapies is taken first; organ recruitment after the circulatory death determination is being considered only after this decision.
Switching off ventilator and adequately accompanying the dying process may be considered as responsibility abuse by healthcare professionals. Death could indeed be mistakenly viewed as the consequence of the caregivers' action since it occurs after their intervention. This subjective position would not consider the fact that the patient "holds" his own death and that his incurable illness legitimates the decision to withdraw treatments and to provide comfort therapies.
Lack of understanding the context and the decisional algorithm may lead physicians who are not involved in the end-of-life process to decline their implication in treatment withdrawal on the basis of *conscientious objection*[9]. This could preclude other patients from having their life saved thanks to an organ transplant.

4.2.4. Conclusions

Although ventilator switch off associated with human medical assistance leads to circulatory arrest and hence patient's death, **this is in no way euthanasia**.
Donation after Circulatory Death (DCD) determination of Maastricht category 3 is only considered once the decision to withdraw futile treatments has been taken; the later being in accordance with the respect of patient's dignity.
It may be of interest to distinguish the place where ventilator switch off occurs from the place where the withdrawal decision is taken.
Horizontal sharing of information related to treatment withdrawal and organ recruitment with all actors will allow them to shoulder their own ethical responsibilities.

5. Identification of potential uncontrolled DCD donors - Categories 1 and 2

Franck Verschuren and Hervé Lebbinck

5.1. Definition and scope

The interest for organ Donation after Circulatory Death (DCD) as a potential alternative for increasing the number of transplanted organs has emerged in the early nineties. In 1995, Pr Koostra proposed a classification of 4 DCD categories, called the "Maastricht categories" since they were created during an international DCD meeting in Maastricht. It is easy to separate Maastricht categories 1 and 2 according to the fact that the cardiac arrest of the patient happens *outside* the hospital (category 1) or *inside* the hospital (category 2).Those two categories are clearly different than the other Maastricht categories 3 and 4, since categories 1 and 2 represent a clinical *uncontrolled* situation where the cardiac arrest has occurred, as opposed to the controlled situation of an awaited cardiac arrest after therapeutical withdrawal. Categories 1 and 2 are therefore similar in many points, the most important reason for classifying them into two categories being the potential difference in the duration of the organ ischemia (called warm ischemia) which is supposed to be longer in case of a cardiac arrest outside the hospital necessitating a longer transport time. In the practice, categories 1 and 2 are often mixed and interrelated, with typical situations of a patient presenting a cardiac arrest outside the hospital with no initial consideration for organ donation, who will be transported to the hospital where the death will be certified in the emergency department before an organ procedure.
It is important to notice that the accurate definition of a DCD Maastricht category 1 was initially called "death on arrival", which is not compatible with potential organ donation in Belgium, since the law prevents transporting a death patient to the hospital. It is therefore more appropriate to speak of "cardiac arrest on arrival" which more clearly corresponds to the uncontrolled situation of a patient being reanimated outside the hospital, and then transported to the hospital under reanimation, and finally being considered as dead after a medical decision inside the emergency department.
In conclusion, the scope of this chapter will focus on "uncontrolled DCD from Maastricht categories 1 and 2"

5.2. Importance of warm ischemia

The final interest of creating Maastricht categories was probably related to the need for an international language for appreciating the quality of the future transplanted organs. The definition of warm ischemia for uncontrolled DCD is the time in minutes between the first cardiac arrest and the start of the cold perfusion for organs preservation after the death. This warm

ischemia time is of crucial importance for appreciating the quality of the organs. It is therefore easy to understand that this warm ischemia time might be much shorter when the death occurred inside the hospital (category 2) than outside (category 1). But many other aspects will interfere with this too simple way of considering organs quality for transplantation: (1) the time between cardiac arrest and the start of a cardio-pulmonary reanimation (CPR); (2) the time of a low blood pressure before the occurrence of the cardiac arrest; (3) the quality of the cardio-pulmonary reanimation and the occurrence of several return of spontaneously circulation before the final death; (4) the location of the death inside the hospital either the emergency department or the intensive care unit; (5) the presence of witnesses after the cardiac arrest outside the hospital. While waiting for future research on the influence of all those factors on the quality of the transplanted organs, and in absence of current clear consensus, the definition and the criteria for warm ischemia in DCD categories 1 and 2 may be proposed as the following:

1. The "total warm ischemia time", which is the time between the first cardiac arrest until the start of the cold flush after the death, must be lower than 2 hours
2. The lap between the first cardiac arrest and the start of a first CPR must be lower than 15 minutes. Therefore, the "absolute warm ischemia time", which is the time between starting CPR and the cold flush, must be lower than 1h 45 min.

5.3. Current situation in Belgium

If DCD donation has progressively increased in Belgium for achieving more than 20% of the deceased donation potential and more than 50 transplanted kidneys in 2010, the number of organs from categories 1 and 2 were only 5 kidneys during the same year, coming from 2 or 3 centers in the country. The experience of DCD from category 2 has started in 2000 in the Cliniques Universitaires Saint-Luc and in 2008 at Hospital Sint-Augustinus Veurne, with an average of 1 to 2 successful kidney donations every year. The current practice of uncontrolled DCD from Maastricht categories 1 and 2 allows recovering only kidneys as organs, as well as bones or valvular tissues, which are beyond the scope of this chapter. Many reasons explain why uncontrolled DCD is less expanded than controlled DCD from Maastricht category 3: (1) the uncontrolled occurrence of cardiac death happens in any time over day, night or week-ends; (2) the need for a short warm ischemia time is demanding for the transplantation teams; (3) the multi-organ procurement is difficult to achieve; (4) the risk of family refusal because of a too short reflexion time may be higher; (5) the literature for expanding local experiences is poor.

5.4. Protocols around the world

The recourse to DCD as a potential source of transplanted organs has now emerged in many countries over the world, like USA, UK, Australia, the Netherlands, France, Spain or Canada. But the experience in categories 1 and 2 is restricted to a few of them, France and Spain sharing with Belgium this particularity. France has started a national uncontrolled DCD program in 2007, with two specific aspects: (1) the cornerstone of a well-developed pre-hospital medical intervention teams and (2) the refusal of practising any controlled DCD from Maastricht category 3. They transplanted 60 kidneys in 2010 from this uncontrolled DCD approach, which represent 4% of their deceased donors. In Spain, particular aspects of uncontrolled DCD from categories 1 and 2 are related to (1) the placement of ECMO outside the hospital and (2) the multiorgan procurement with liver and kidneys donation.

5.5. Typical procedure

Let us summarize and explain a typical presentation:

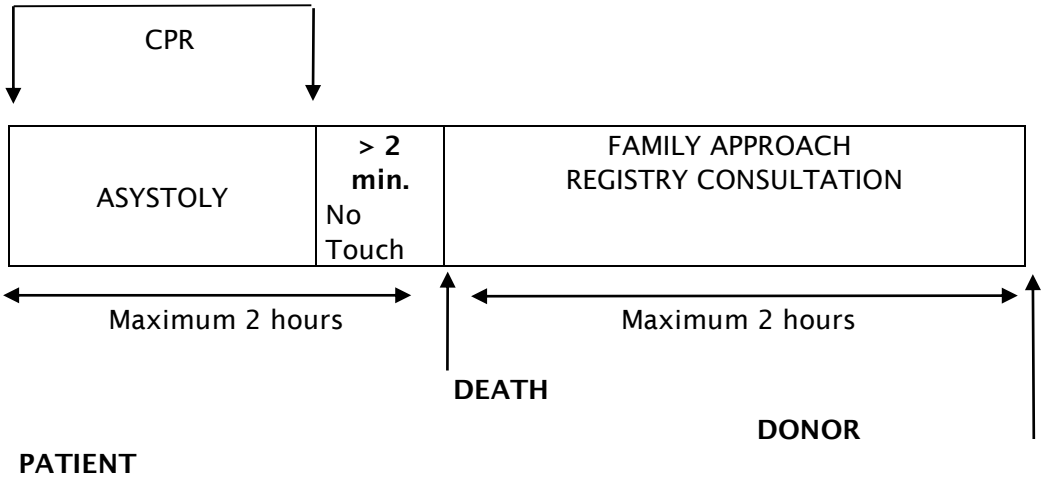
19 years old patient
• **17h00**: faints at home, without prodromes • **17h10 – 18h30**: pre-hospital intervention team discovers asystoly and starts CPR and advanced life support, but without any return to spontaneous circulation • **18h30**: the patient is admitted in the emergency department while CPR is maintained during transport, ideally with an auto-pulse compression • **18h56**: CPR is considered as futile; death is considered • **19h01**: CPR and ventilation are stopped ; start of the « no-touch » period • **19h06**: femoral canulation by the surgical team • **19h20**: canulation performed • **20h00**: admission in operating room

NB: in this example, the "total warm ischemia time", which is the time between the first cardiac arrest until the start of the cold flush, is 2h and 20 minutes (17h to 19h20), which is longer than the recommended maximum time of two hours.

5.6. General criteria and contra-indications

Four hospitals in Belgium currently have a local written protocol for a potential DCD from Maastricht category 2. If most of the items are similar, the few discrepancies will be explained and discussed.

- The "total warm ischemia time", which is the time between the first cardiac arrest until the start of the cold flush after the death, must be lower than 2 hours
- The lap between the first cardiac arrest and the start of a first CPR must be lower than 15 minutes. Therefore, the "absolute warm ischemia time", which is the time between starting CPR and the cold flush, must be lower than 1h 45 min.
- The total time of reanimation must be lower than 1h30
- As DBD there is no age limit but usually limited to 60 years. In practice, most patients considered for this procedure are young and healthy patients with trauma or cardiac ischemia as aetiology of the death.
- There is no ruptured abdominal aneurysm or any major abdominal vascular or renal injury
- The traditional contra-indications for DBD transplantation are respected: neoplasm (<5 years of remission), septicaemia, intravenous drug abuse
- Finally, contra-indications may be discussed case-by-case according to the patient's status before the cardiac arrest, the interpretation of the warm ischemia time, the availability of the transplant team



5.7. Medico-legal considerations

These are the same as for DCD Maastricht category 3, in terms of need for a certified death by 3 independent doctors, the consultation of the national registry, the information to the prosecutor of the king, respect of the corpse, and approach of the family

5.7.1 No-touch period

Most of the time, the surgical transplant team is not yet available when the medical team considers the futility of the CPR. In these cases, CPR and ventilation are maintained until the arrival of the transplant team. At that moment, all medical intervention on the patient is stopped, which corresponds to the start of the "no-touch period". The end of the no-touch period corresponds with the accurate time of the certified death, since this no-touch period certifies the irreversible status of the cardiac arrest. This "no-touch period" must be seen as a "red line" between the status of patient becoming a status of potential donor. The respect of this time is crucial. The duration of this period is a point of debate in the literature, and must be "at least 2 minutes". It is reasonable to propose a duration of at least 2 minutes but not more than 5 minutes for this "no-touch period" in Belgium. The surgical team should never be physically present inside the reanimation room before the death of the patient.

5.7.2. Family approach

The discussion on organ donation must start after the information on the death. Most of the time, this discussion happens during the time the surgical team is busy with the femoral cannulation, which is ethically acceptable since the cannulation happens after the death. When the cannulation is finished, it is still possible for the family to see their death relative in the emergency room. Except if the deceased person previously registered the explicite wish to donate, the discussion on organ donation with the family must respect the Belgian law and avoid putting too much pressure on the decision: the main idea is asking to the nearest relative if the deceased one had previously pronounced any opposition or wish to organ donation. If the relatives are not present after 2 hours of death, the procedure is stopped. The quality of the information concerning organ donation is probably made easier if the relatives were clearly aware of the catastrophic clinical situation during the CPR. The relationship between the care givers and the family must be of high quality, so that the family can trust the physician when he will speak over donation. The presence of the family inside the reanimating room during the CPR may facilitate this trust, and must be encouraged.

5.7.3. Family consent

Differences exist in Belgian protocols on the need for a written consent by the family. There is no legal obligation for such a written consent, and the spontaneous acceptation or refusal by the nearest relative of the deceased person is most of the time so evident that any written consent is of limited interest.

5.7.4. Ethical and psychological considerations

The "dead donor rule" legally imposes that any donation follows the death, and never precedes it. But in the practice, the senior physician in charge of a difficult reanimation may think of potential donation during this phase. He may also inform the transplant coordination team during this phase. It is therefore mandatory for the physician in charge to be conscious that the evocation of donation cannot modify the quality of the reanimation. Other aspects concern the potential interest of separating the medical and/or nursing team from one to the other side of the "no-touch" period line, so that other care givers take care of two aspects of the same person: the patient and the donor. Finally, any DCD procedure should be followed by a systematic psychological debriefing.

5.8. Surgical perfusion techniques

The surgical perfusion technique is the responsibility of the surgeon on duty. The abdominal organs preservation is performed by cannulation of the femoral artery using a double balloon triple lumen catheter and insertion of a catheter in the femoral vein for venous decompression (figure 3). The thoracic organ preservation is performed with topical cooling via chest drains. Another possibility for in situ preservation –albeit only done in very few centers and currently not in Belgium- is the normothermic preservation by means of extra-corporeal membrane oxygenation. (see Preservation chapter)

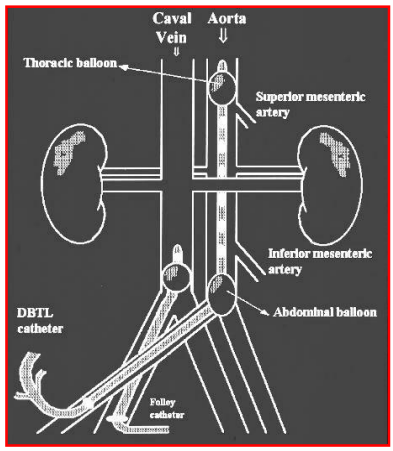


Figure 3

5.9. Interruption of the CPR

The decision of stopping CPR does not currently answer to strict and undiscussed criteria, and remains a medical and responsible decision. Such a decision must be taken independently of any organ donation procedure of course.

- An accurate aetiology of the cardiac arrest will have to be established
- Particular cautions must be taken for children or young adults in terms of establishment of a normal core temperature (at least 34°5 C) and biological parameters (pH > 7.20; PaO2 >60 mmHg; PaCO2 < 45 mmHg). Those criteria applies in case of intoxication or hypothermia
- In the absence of univocal criteria, the interruption of CPR will be considered when the aetiology of the cardiac arrest is classical (unrelated to intoxication or hypothermia), with the absence of return to any cardiac rhythm since more than 20 minutes, and with an end-tidal expired CO2 of less than 10 mmHg
- The definition of a "**refractory cardiac arrest**" must be well known and taken into consideration by the physician, since a patient answering its definition will be a candidate for an extracorporeal circulation rather than organ donation. A refractory cardiac arrest concerns a cardiac arrest of more than 30 minutes in normothermia. In this case, if the "no-flow period" which is the time before the start of CPR is less than 5 minutes, and if the "low-flow period" which is the time of the CPR is lower than 100 minutes, and if EtCO2 remains higher than 10 mmHg, then the placement of an extra-corporeal membrane oxygenator (ECMO) must be discussed instead of any organ donation. Those recommendation have been proposed in 2010 by a French expert consensus

5.10. Reasons for unsuccessful procedures

The success of a Maastricht category 1 or 2 DCD procedure depends on a well-structured organisation with an appropriate collaboration between the pre-hospital team, the emergency department, the transplant coordinators and the transplant surgeons. Moreover, the family refusal rate is around 50% in our experience, due to the dramatic and unattended situation they are just facing. But this refusal rate is inferior to the absence of consideration for a potential DCD procedure due to any reluctance by the medical team. Finally, the cannulation procedure may be unsuccessful.

5.11. The future of Maastricht category 1 and 2 DCD procedure in Belgium

Expanding the procedure in more emergency departments and pre-hospital teams. The Belgian scientific society of Emergency Medicine is currently busy in informing its physicians about this procedure.
Expanding the technical procedure so that livers and lungs may be part of the organ donation.
Informing the population about this procedure.

6. Identification of potential controlled DCD donors - category 3

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6.1. Definition

Every potential DCD donor is a patient with a catastrophic (=non-recoverable) injury or illness who is dependent on life-sustaining therapy. These conditions include severe brain injury of diverse etiology, end-stage musculoskeletal disease, and end-stage organ failure.
In these patients, criteria for brain death are not likely to be met ***and*** an evolution towards brain death with maintenance of circulatory function is not likely to take place.
Consequently, there is an intention in these patients to withdraw life-sustaining therapy because no meaningful recovery or survival is anticipated and therefore continuing medical care may be considered futile. After withdrawal of life-sustaining therapy, imminent death is anticipated.

The decision to withdraw life-sustaining therapy is first taken in consensus by the patient's treating medical team and other caregivers, followed by informing and discussion with the patient which is rarely possible (e.g. end stage neuromuscular disease, euthanasia) or with his legal representative(s) the patient's relatives.
It is mandatory that the decision to withdraw life-sustaining therapy is taken *prior to* and *completely independent* from the option of organ donation.
The decision to stop life support therapies is the responsibility of treating intensive care physician(s). They are responsible for their patient's care; hence it is their duty to create a consensus between doctors, nurses and relatives. They may ask other physicians' opinion to help them making the most appropriate decision.
Similarly to the DBD procedure, no written consent is required. However there must be a written motivation of withdrawal decision (WD) in the patient's record and information has to be communicated to trusted person(s), if any.
It is reported that DCD donors did not express hastened withdrawal decision (time from ICU admission to WD) nor shortened end-of-life (time from WD to death).

For successful DCD donation, cardio-circulatory arrest should occur within an expected time frame to limit the damage during the agonal phase that donor organs are exposed to (e.g. ~30 min for the liver and ~60 for the kidneys/lungs). Currently, there is only one clinical tool available that established a correlation between a numerical score (from 7 to 21) score and the time to expire after extubation, the so-called University of Wisconsin scoring tool[10] (table 5). The higher this score, the less time it takes for the patient to expire. The criteria utilized in this evaluation tool are derived from weaning protocols and evaluate patients who have been disconnected from the ventilator for a period of up to 10 minutes. After this 10 min period, ventilatory rate, tidal volume, negative inspiratory force and oxygen saturation are measured. During this assessment patients may become rapidly unstable (systolic blood pressure <80mmHg or oxygen saturation <70%) intrinsically indicating to be a suitable candidate for DCD. This tool assumes that respiratory tidal volume and airway pressure can be measured bedside. This score was developed for adults, has not yet been validated prospectively and does not take into account the potential effect of comfort therapy given during or before the withdrawal of life-sustaining therapy.

Table 5. Criteria of the UW DCD evaluation tool. The final score reflects an assessment of the patient's eligibility as a potential DCD donor.

CRITERIA	*Assigned Points*
Spontaneous respirations 10 min after disconnection from ventilator	
Rate >12	*1*
Rate <12	*3*
Tidal volume >200 cc	*1*
Tidal volume <200 cc	*3*
Negative inspiratory force (NIF) < -20 cm H_2O	*3*
Negative inspiratory force (NIF) >-20 cm H_2O	*1*
No spontaneous respirations	*9*
Vasopressors/inotropes	
No vasopressors/inotropes	*1*
Single vasopressors/inotropes	*2*
Multiple vasopressors/inotropes	*9*
Patient age	
0-30	*1*
31-50	*2*
51+	*3*
Intubation	
Endotracheal tube	*3*
Tracheostomy	*1*
Oxygenation after 10 minutes	
O_2 sat > 90%	*1*
O_2 sat 80- 89 %	*2*
O_2 sat <79 %	*3*
FINAL SCORE	

6.2. Medical management

Every potential DCD donor is a patient awaiting withdrawal of futile life sustaining therapy and thereafter death has been declared using cardiopulmonary or cardio-circulatory criteria.
Consequently any intervention that aims at optimizing perfusion and oxygenation will therefore be beneficial for the patient, the potential donor and donor organs. However prior to withdrawal support, drugs that aim to improve or preserve donor organ function may be administered (e.g. heparin). Of primary importance is to assure maximal patient comfort during the agonal phase. The administration of such drugs (sedatives, analgesics) is ethically acceptable as long as administration does not hasten death intentionally. Comfort therapy may however shorten the agonal phase referred as the " act with double consequence" (doing good=comfort for the patient with unintended negative side effects= shorter agonal phase).

Recommendations

- *A clear and transparent DNR (do not resuscitate) protocol is instituted in every center participating in DCD donation*
- *The decision to withdrawal life-sustaining therapy is the responsibility of treating intensive care physician(s) and is the result of a consensus between doctors, nurses and relatives.*
- *The organ transplant team is not involved in the decision making of withdrawal of life-sustaining therapies and later in the withdrawal itself*

- *Drugs administered to improve outcome after DCD organ transplantation are ethically accepted when not administered with the only aim to hasten death (also see comfort therapy)*
- *All caregivers involved in the procedure should be fully informed and volunteering to be part of the procedure .*
- *All maneuvers that may maintain or restore cerebral circulation after declaration of death should be forbidden as they may interfere with the natural process of progressive irreversible brain death .*

6.3. Sequential stages during controlled DCD procedures

Different consequent stages should be respected during every DCD procedure in a stringent way (figure 4).
Most importantly, the first step is always the independent decision making process to withdraw life sustaining therapy in the light of an irreversible catastrophic illness without any means of recovery for the patient. This decision has to be taken completely independently from the "organ donation option". This independency should be transparent and its implementation can be facilitated by the development of a clear and written "end of life care" or DNR ("do not resuscitate") protocol in every unit willing to participate in DCD organ donation.
After the decision to withdrawal life sustaining therapy has been made the following steps should be taken:

- Care for the potential donor and donor family
- Notification of a transplant center and planning of the procedure
- The phase of withdrawal of life sustaining support, followed by the declaration of death and stand-off or no-touch procedure
- Surgical procedure or procurement

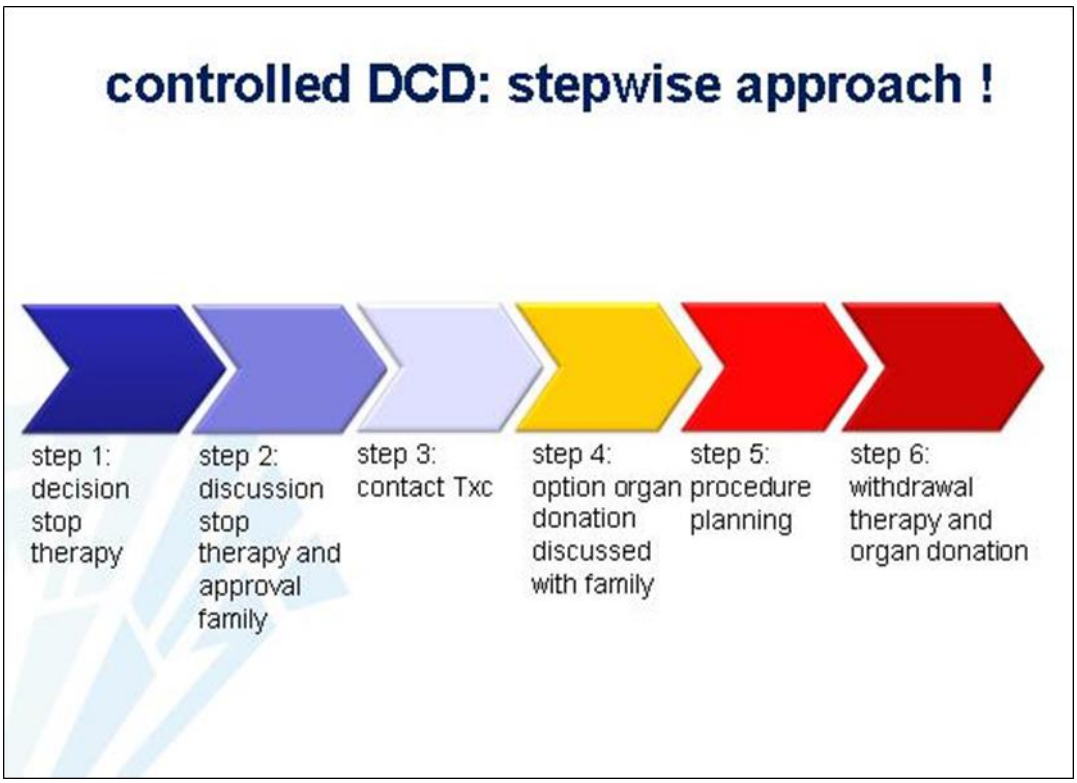

Figure 4. Every DCD procedure should follow and respect a stringent order of stages

Recommendations

A stringent stepwise approach is followed during an uncontrolled DCD procedure:

- *Step 1: decision to withdraw life sustaining therapy in the light of an irreversible catastrophic illness without any means of recovery for the patient. This decision is always taken completely independent from the "organ donation option"*
- *Step 2: discussion withdrawal life sustaining therapy with family*
- *Step 3: eligibility for organ donation discussed with transplant center prior to offer opportunity to donate*
- *Step 4: option organ donation discussed and agreement with family. Implications should be discussed: where, what time scheduled , place to say goodbye, organ and/or tissue retrieval, end of life procedure, pain and comfort therapy during agonal phase, preferences, possible abortion of donation and consequences.*
- *Step 5: planning of withdrawal of life sustaining therapy*
- *Step 6: withdrawal of life sustaining therapy, determination of death on circulatory criteria followed by organ donation and procurement.*

6.4. Communication aspects

6.4.1. Communication with family

First the decision to withdraw life sustaining support is discussed with the family in the light of the hopeless prognosis in the absence of further therapeutic options. Secondly, and ideally in a separate communication, the opportunity to donate after death as diagnosed by cardio circulatory criteria and not by brain death criteria are discussed. An informed consent may or may not have to be signed by the family members depending on the local protocol.

Recommendation

- *Similarly to the DBD procedure, no written consent is required*

6.4.2. Communication with all teams involved

The nature of a DCD procedure remains very different from a DBD procedure (where the patient has been declared dead before arrival in the OR) and should therefore be clearly and thoroughly discussed with all members of the transplantation team as well as all members of the local hospital staff (including all medical and nursing staff, patient's treating physicians, social workers and anyone who might be involved in this procedure). Importantly a detailed and hospital approved protocol should be available and thoroughly be discussed prior to the procedures. It is recommended to document the decision to withdraw therapy as well as the informed consent/ response of the patient/representative in the patient's file.

6.5. Eligibility criteria for DCD

In general, eligibility criteria for DCD are similar as for organ donation after brain death depending on age, comorbid disease states, organ function. The final decision for DCD eligibility should always be determined by individual transplant centers.
Briefly, patients with a history of intravenous drug abuse, active sepsis or systemic infection, active malignancies and high-grade brain tumors are usually excluded. In contrast, patients with e.g. non-melanoma skin malignancies and some primary non-metastatic brain tumors may be eligible and hepatic B or C, HIV positive organs can be transplanted in recipients already infected with these viruses. Other rare contra-indications include prion-related diseases, some systemic viral infections (e.g. rabies) or infection with HTLV.
However, in contrast to DBD, criteria for DCD tend to be more stringent compared to DBD. One example is age which does seem to have a largely negative impact on longer-term DCD allograft

survival. Because organs from DCD donors have higher delayed graft function rates, the combination of older age and DCD may jeopardize outcome in terms as incidence of delayed graft function and allograft survival. This has been consistently reported in larger registry data analyses[11]. However, excellent outcomes (similar to DBD) have been reported by dedicated single center. Interestingly some of these centers reporting excellent outcome apply *very* strict criteria for DCD organ transplantation (e.g. very brief donor warm ischemia and cold ischemia times for liver transplantation[12].
Eligibility criteria should be determined by the individual transplant programs (which might differ amongst each other depending on the individual experience and the potential transplant benefit the recipient candidates might have).
Whether recipient candidates should be informed on the possibility that they receive a potentially inferior DCD graft is left to the discretion of the transplanting center.

6.6. Withdrawal of life-sustaining therapy

6.6.1. Planning

Withdrawal of life-sustaining therapy ideally takes place in the operating room. Most importantly all aspects of withdrawal of life-sustaining therapy need to be discussed in detail with all healthcare takers involved in the procedure and with the donor's family. The opportunity should be offered to the family to spend time with the patient or to be present prior to or during the withdrawal of life support. Clear agreements should be made in advance with the family and the medical team on all aspects of the donation including the possibility in case a patient does not expire within a well-defined time frame of acceptable warm ischemia time which might preclude acceptable graft function post-transplant. Another important issue of the withdrawal of support phase is to ensure that adequate "comfort" therapy will be given during the dying process by the patient's treating physicians.

6.6.2. Comfort therapy

During withdrawal of life sustaining therapy, adequate comfort therapy should be given to minimize all discomfort that may occur during the phase of dying and there is some evidence of such discomfort in DCD donors[13]. This comfort therapy should basically not differ from comfort therapy without organ donation.
Comfort therapy should be provided according to local institutional and/or personal standards.
The family should be informed that the procedure does not include or will not lead to any enhanced discomfort during the dying process. The transplant team should not participate in any of the decisions regarding comfort therapy during the withdrawal of the support phase.

Recommendations

- *Comfort therapy should be offered to all patients in whom life sustaining therapy is withdrawn*
- *Type and dose of comfort therapy is left at the discretion of the patient's treating physicians*
- *No participation of transplant team is allowed regarding comfort therapy*

6.7. End of life care management in the operating room

6.7.1. Involvement of anesthesiologists

The involvement of intensivists, not familiar with material and personnel of the operating room (OR), to provide the end of life care in the OR is not always optimal and welcome to create a required climate of confidence and serenity in the OR due to ethical issues. In these conditions, involvement of anaesthesiologists familiar with the local OR may be recommended.

Since anesthesiologists of the OR do not know the donor medical history and do not participate to the decision of treatment withdrawal, they should not be obliged to manage the end of life care of the patient for donation after circulatory death (DCD). Their involvement should nevertheless be favored and be considered on a voluntary basis. In this case, the presence of the intensivist until the death of patient remains welcome.
The willing anesthesiologists should solicit information about donor's medical history and provide these information to OR personnel. They are not supposed to question the decision of treatment withdrawal taken by intensivists. They are also responsible for maintenance of respectful and serene atmosphere in the OR.
To meet all these prerequisites DCD organs procurements should be ideally scheduled during daytime with personnel familiar to this procedure.

6.7.2. Analgo-sedation
When the decisions of no further benefit of therapy and treatment withdrawal is taken, the need for analgo-sedation is acknowledged, and the patient is transferred to the OR where the procedure leading to organs/tissues recovery is started. The comfort therapy should not be interrupted and the patient should not be returned to the ICU for further care. In case of no organ procurement took place within the preset time limit a room may be accessible for the dying process. Nevertheless the intensivists must provide the family with sufficient time to mourn the end of life of the patient. When the patient is in the OR, the duration of the terminal phase may become irrelevant for the donor. In contrast keeping warm ischemia as short as possible is important for the receiver(s). Accordingly the donor is draped and the surgeons are ready for organs retrieval before the declaration of death. The need and the choice of analgo-sedation are left to the medical judgment of physicians but should be maintained until the death declaration.

6.7.3. Other medication
It is considered as ethically acceptable to give medications and use interventions such as heparine, glucocorticoids, pharmacologic preconditioning that will not benefit the patient, but will protect the viability of the organs and benefit the recipient(s).

6.7.4. Circulatory arrest
The circulatory arrest will be defined as a persistent lack of arterial pulsation determined with an artery catheter. To better define "Warm Ischemia Time (WIT)" it is recommended to equip patient with a femoral line since radial artery pressure monitoring underestimates central arterial pressure in critically ill patients. Residual electrical cardiac activity is not taken into account for circulatory death and electrocardiogram should not be monitored to avoid any confusion and misinterpretation by OR personnel.

6.7.5. No-touch period
The period of no-touch starts when the criteria for circulatory arrest are met. The period of no-touch lasts at least 2 minutes and no more than 5 minutes. This interval is sufficient since we use the femoral artery pressure, because DCD donors are already brain damaged, and then this circulatory arrest is preceded by a prolonged period of brain hypoperfusion and hypoxia.

6.7.6. Diagnosis of death
At the end of this no-touch period and in respect for the Belgian law on organ donation, the death of the donor is diagnosed by three physicians independent from the procurement/transplant team.

Recommendations

- *Circulatory arrest is defined as a persistent lack of arterial pulsation determined with an artery catheter.*

- *A no touch period of at least 2 minutes but no more than 5 minutes will always be respected.*
- *Death is certified at the end of the no-touch period that begins at the moment of the circulatory arrest.*
- *Death is diagnosed by three physicians independent from the procurement/transplant team.*

7. Identification of potential controlled DCD donors - category 4

Includes patients who suffer a cardiac arrest in the process of the determination of death by neurologic criteria or after such determination has been performed (DBD), but before the transfer to the operating theater or during the procurement procedure. It is likely that restoration of cardiac activity is first attempted, with a switch to the surgical protocol of donation, if this fails.

8. Euthanasia

D. Monbaliu, D. Ysebaert, P. Evrard.

With the legal acceptance of euthanasia as a suitable end of life pathway in Belgium and the Netherlands, it is becoming evident that euthanasia can be followed by successful organ donation[14]. This process involves the establishment of irreversible circulatory arrest as in a controlled DCD which is then followed by laparotomy, perfusion and organ donation. Such an approach is perhaps the ultimate DCD donor as the potential donor gives full consent himself rather than being the responsibility of a relative.
Needless to say and similar to other DCD types, the decision of end of life is taken independently of a possible organ donation. Teams in charge of performing the euthanasia are independent of transplant teams and the determination of death must be established by three physicians, excluding the physicians who are treating the recipient or who will perform the recovery or the transplantation.
In addition their blood group and tissue type can be established before death and the potential recipients admitted before death. Such an approach - though strange to the extent of making the donor surgeon very uncomfortable - is the logical sequence after the legalisation of euthanasia.

Eurotransplant recommendation 01.08.
Following the Belgian experience Eurotransplant (ET) established (2008) and implemented (2010) recommendation on organ donation after euthanasia:
Euthanasia has to be an accepted procedure in the legal framework of the donor country.
The euthanasia procedure and the determination of death after the euthanasia procedure have to be in line with national law and national practices.
The euthanasia procedure itself and the explantation should follow a clear protocol.
The euthanasia procedure and the organ recovery as well as the organ allocation should be kept as separate as possible.
All donors have to be reported to ET, the allocation should follow the NHBD allocation rules in the donor resp. recipient country.
Organs from donors after a euthanasia procedure shall only be allocated to patients registered on the waiting list for organ transplantation in ET, and within ET, in countries that accept the transplantation of this type of donor organ. In addition the possibility to indicate the acceptance of organs from donors after a euthanasia procedure should be added to the center- and patient-specific donor profiles in ENIS (Eurotransplant database).

Recommendations

- *Euthanasia decision is taken independently of a possible organ donation*
- *Blood group and tissue type are established before death and the potential recipients admitted before death*
- *Teams in charge of performing the euthanasia are independent of transplant teams*
- *The euthanasia procedure and the organ recovery as well as the organ allocation should be kept as separate as possible.*

9. Procurement

D. Monbaliu, O. Detry

After declaration of irreversible circulatory arrest, the transplantation team ideally reenters the operating room. They preferably may have prepared and draped the donor-patient prior to the withdrawal of life sustaining therapy, and set-up all necessary instruments, preservation solutions, inflow tubing and outflow tubing.

Ideally heparin is administered IV before withdrawal of life sustaining therapy. To avoid any every (potential) conflict of interest and "external" pressure, members of the procurement may leave the operating theatre prior to the withdrawal of therapy and reenter after the cardio circulatory arrest has occurred or at the end of the no touch period just before declaration of death. However if not required by the local ethical committee, the procurement teams can be present during the withdrawal of life sustaining therapy.

The aim of organ procurement in DCD donation is to stop as rapidly as possible the ongoing progressive organ damage occurring during the donor warm ischemia. Until now there are no other techniques than those similar to the DBD procurement. Nevertheless, there are some clear and distinctive differences. Most importantly there is no blood flow (unless ECMO is installed, see below). Dissection takes thus place under hypothermic asystolic conditions. There is a particular concern about the possibility of aberrant arterial vasculature.

9.1. For the abdominal organs

Three procurement techniques have been described:

1. super rapid technique

2. hypothermic in situ preservation with the double-balloon triple-lumen catheter

3. normothermic in situ perfusion

9.1.1. Super rapid laparotomy

Worldwide the most often used technique is the modified super-rapid technique as described by the Pittsburgh group[15]. This consists of a midline laparotomy followed by a rapid cannulation of the aorta to start the cold flush (figure 5). Some centers advocate to first perform a caval venting to reverse venous congestion invariably present in the abdominal / thoracic organs prior to the start of inflow. For the abdominal organs, venous venting can be easily achieved by opening the inferior caval vein in the pericardium. After installing the aortic flush and venous outflow, an additional portal vein flush can be installed with topical cooling of the abdominal organs. This topical cooling is facilitated using abundant volumes of sludged ice and is mandatory followed by decompression and flushing of the common bile duct and gall bladder.

The importance of the intraoperative flushing of the bile duct besides the gall bladder is increasingly recognized as a crucial step in particularly for DCD liver procurement. To avoid any damage of hepatic hilar structures (bile duct, artery, capsular tears…), extensive dissection at the liver hilum and cholecystectomy is avoided.
To minimize the aortic cannulation to perfusion time, different techniques have been described to quickly secure the aorta before the inflush e.g. using a babcock clamp[16] or a strap b[17] although this might cause a narrowing of the inflow tube as observed by Ray et al[18].

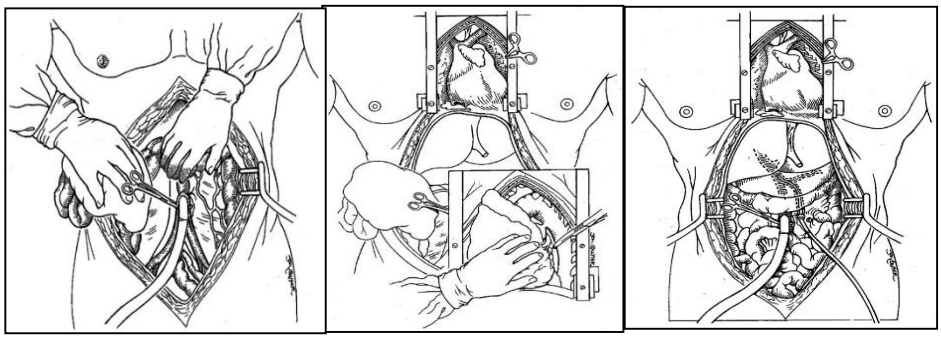

Figure 5. Super rapid laparotomy.

First the infra renal abdominal aorta is cannulated (left), then a clamp is placed on the thoracic aorta through the pericard (middle) and finally, additional portal flush is installed via the vena mesenterica superior or inferior.

9.1.2. Hypothermic in situ preservation with the double-balloon triple-lumen catheter

9.1.2.1. Post-mortem in situ preservation for uncontrolled DCD donors

Hypothermic in situ preservation with a double-balloon triple-lumen catheter (figure 6) is in many centers the method of choice for uncontrolled DCD donors. This catheter is placed into the aorta through the femoral artery. After partial inflation of the distal, abdominal balloon, the catheter is pulled back onto the aorto-iliac bifurcation. Blood is then taken for screening (e.g. blood, HLA typing). Thereafter, the proximal or thoracic balloon is inflated at the level of the diaphragm, well above the level of the renal arteries. Next a large sized catheter (e.g. Foley catheter) is placed in the femoral vein allowing the outflow of the cold (4°C) preservation solution which is infused via the double-balloon triple-lumen catheter to cool the kidneys. Usually, heparine and streptokinase are administered through the catheter before starting the cold flush. In situ preservation preserves organ viability and gives opportunities to meet the legal and logistical requirements of the organ donation that ensues. Donor nephrectomy is performed as soon as possible, usually within 2 hrs after in situ preservation has started.
Post-mortem placement of this double-balloon triple-lumen catheter can be done in the emergency room after failed resuscitation and declaration of death.

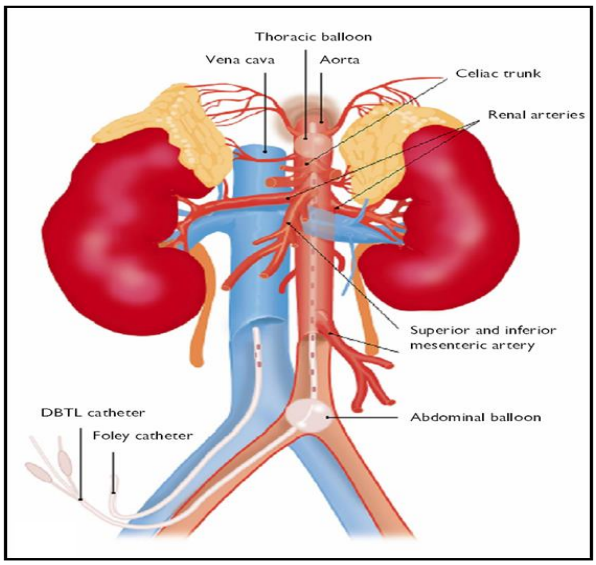

Figure 6. In situ preservation technique with the double-balloon triple-lumen catheter[19]

9.1.2.2. Pre mortem in situ preservation for controlled DCD donors

An alternative to the super rapid laparotomy for controlled DCD donors is the pre mortem cannulation of the femoral artery using a double balloon triple lumen catheter and insertion of a catheter in the femoral vein for venous decompression. This can be done prior to withdrawal of life-sustaining support as described by the Wisconsin group[20].

After declaration of death immediate flushing the abdominal organs with cold preservation solution can be initiated prior to transport the donor to the theatre where organ procurement takes place.

9.1.3. Normothermic in situ preservation

A third possibility for in situ preservation –albeit only done in very few centers and currently not in Belgium- is normothermic preservation by means of extra-corporeal membrane oxygenation allowing to control the temperature of the organ and to add oxygen.

Extra-corporeal membrane oxygenation can be done in DCD donors following pre-mortem cannulation prior to or after withdrawal of life-sustaining therapy in controlled and declaration of death in uncontrolled DCD donors, respectively. Cannulas are introduced into the femoral vessels and connected to the circuit. Importantly, recirculation of blood to the brain should be avoided by means of a balloon inserted via the contralateral femoral artery and inflated at the level of the diaphragm. This also excludes the perfusion of the thoracic organs. ECMO is initiated and normothermic preservation installed; some groups maintain temperatures a~37˚C, others leave the temperature to decrease around 32˚C. During normothermic perfusion, biochemical adjustments regarding ph, acid-base and hematological parameters can be done

For controlled DCD donors, this approach increases the family's access to the donor during the withdrawal therapy. It consequently allows much more flexible timing. ECMO allows preservation of 78 min in a range of 66 versus 99 min. Following ECMO the donor is wheeled to the theatre where a conventional laparotomy organ procurement and cold storage are initiated[21, 22].

In uncontrolled DCD donors, normothermic in situ preservation has been shown to successfully recover and transplant kidneys and livers from such donors. Preliminary reports – albeit in small

cohorts - suggest better kidney function of uncontrolled DCD kidney grafts compared to hypothermic in situ preservation besides the feasibility as well as feasibility for liver transplantation with acceptable outcome[23, 24].

9.2. Rapid laparotomy or pre-mortem cannulation?

The Maastricht-group observed that rapid laparotomy published data from that direct aortic perfusion through a rapid laparotomy leads to less kidney discard rate, decreased warm ischemia time, decreased cold ischemia time and finally improved kidney graft survival at 1 year compared to the double balloon triple lumen catheter approach[25]. Moreover only 42 % of procedures where DBTL perfusion was used were successful[26]. In addition, prolonged double-balloon triple-lumen catheter insertion time is an independent predictor of graft failure[26, 27].

Importantly, DCD transplantation procurement has been a risk factor to damage organs during procurement and in the UK it was observed that more kidneys were injured during the procurement from DCD donors versus DBD donors (11.4% for DCD versus 6.8% for DBD donors). These injuries include capsular tears, ureteric injuries and vascular injuries resulting in a higher discard because of kidney injury. Therefore DCD procurement should ideally be done by experienced surgeons[28].

9.3. Lung procurement from DCD donors

Since DCD are considered multiple organ donors, lung procurement from these donors should not been forgotten. After confirmation of death the sternum is opened and the pulmonary artery is identified, cannulated and flushed. Venous venting is done through the left atrial appendage. Meanwhile the both pleura are opened and the topical cooling of the lungs is achieved by redundant amounts of melting ice water. After the flushing has been completed the lungs are on bloc removed with the heart leaving the lungs moderately inflated. After removal of the heart on the back table the right and left lung are separated from each other and the retrograde flush through pulmonary veins is performed to remove possible blood clots[29].

10. Definitions of warm ischemia time

D. Monbaliu

During the whole transplantation process, organs are exposed to normothermic or near-to-normothermic ischemia in the donor or during the implantation in the recipient, respectively.
During implantation in the recipient, warm ischemia is well defined: the period between the removal of the organ from the ice water until the reperfusion with warm blood in the recipient, also referred to as anastomosis time. In the donor and during procurement, organs can be exposed to “pure” warm ischemia (e.g. during cardiac arrest) prior to the organ procurement and cold perfusion, after applying a clamp to the artery during live donor retrieval or inevitably during DCD organ procurement.
During the whole transplantation process, organs are exposed to normothermic or near-to-normothermic ischemia in the donor or during the implantation in the recipient, respectively. .
During implantation in the recipient, warm ischemia is well defined: the period between the removal of the organ from the ice water until the reperfusion with warm blood in the recipient, also referred to as anastomosis time.
In the donor and during the procurement, organs can be exposed to “pure” warm ischemia (e.g. during cardiac arrest) prior to the organ procurement and cold perfusion, after applying a clamp to the artery during live donor retrieval or inevitably during DCD organ procurement.

Currently, there is no accurate nor uniform definition on warm ischemia for DCD organs. Different definitions have been suggested and mostly vary from the time when the warm ischemia is thought to start (figure 7, new figure to be made!).
In controlled DCD, the start of warm ischemia may include at the moment of withdrawal, a systolic or mean arterial pressure below a certain value (referred to as onset of hemodynamic instability or organ hypoperfusion), or cardio circulatory arrest and ends with the start of cold perfusion (figure 7). Also in controlled DCD donors, there is also variable period of hypotension and hypoxia between withdrawal of life-sustaining therapy and circulatory arrest, known as the agonal phase. Moreover, the method utilized to determine cardio circulatory arrest may or may not substantially prolong the warm ischemia (e.g. absence of blood circulation or complete electrical standstill on ecg may result in a largely different length of warm ischemia). Interestingly experimental models have shown that e.g. splanchnic hypoperfusion began at the moment of withdrawal[30]. Others demonstrated an association between the incidence of ischemic cholangiopathy in DCD liver transplantation and the time between arterial pulseness to aortic cross clamping[31]. Therefore, an accurate definition of donor warm ischemia in DCD is important because the injury associated is known to be deleterious to subsequent graft function. In order to estimate the length of DCD warm ischemic times as accurate as possible, a transplantation coordinator is preferably present during the withdrawal of life sustaining therapy to observe and meticulously record the decrease of blood pressure and saturation over time and to provide this detailed information to the recipient centers. Whether to accept or discard a DCD organ for transplantation, taking into account the length of warm ischemia, should always be left to the discretion of the transplantation team in charge of the recipient.

Therefore, for controlled DCD, a more accurate definition of warm ischemia is proposed as follows (table 6)[32] :

- total warm ischemic time: interval between the withdrawal of life sustaining therapy and start of in-situ cold perfusion
- functional warm ischemic time: interval between inadequate organ perfusion and start of in-situ cold perfusion
- withdrawal (agonal) period: interval between withdrawal of life sustaining therapy and circulatory arrest
- asystolic warm ischemic time: interval between circulatory arrest and start of in-situ cold perfusion.

Of note, evidence of a specific blood pressure or oxygen saturation levels is poor at which functional warm ischemia begins and different countries and transplant organizations have chosen different values (e.g. MAP < 60 mmHg or SAP < 35 mmHg…).

*other references [33-36]

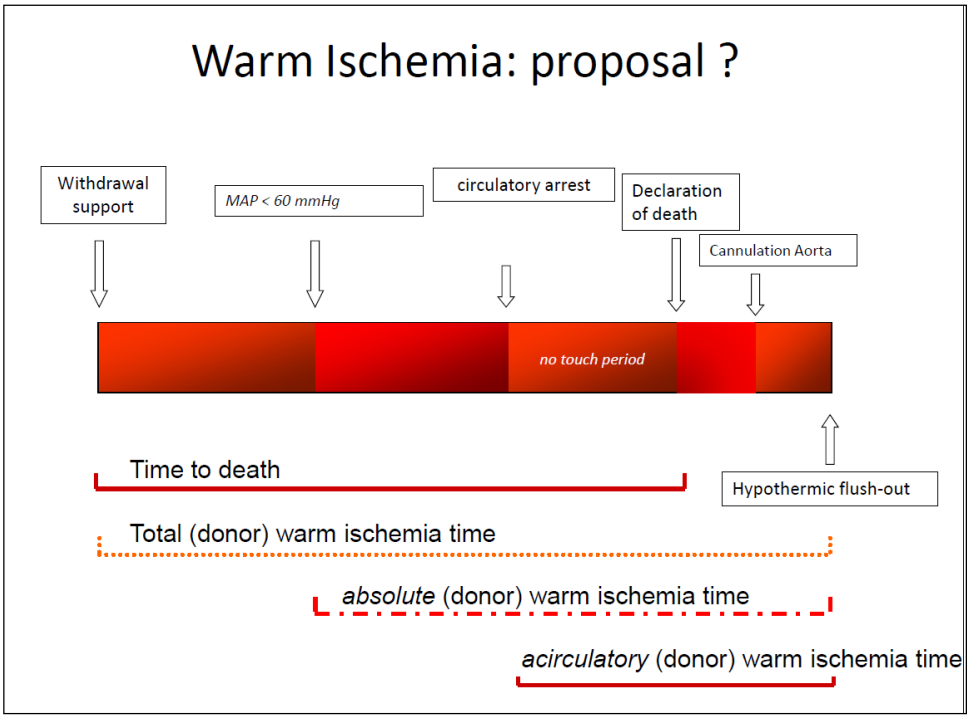

Figure 7. Different definitions of warm ischemia during DCD are possible, starting from the moment of withdrawal of life sustaining therapy or a systolic/mean arterial pressure under a certain value or circulatory arrest and ends with the start of cold perfusion.

Warm Ischemia definitions can apply for uncontrolled/controlled DCD:

	uncontrolled DCD	Controlled DCD
Time to death	Start moment of cardiac arrest until declaration of death	Start withdrawal until declaration of death
Total (donor) warm ischemia time	Start moment of cardiac arrest until cold flush	Start withdrawal until cold flush
absolute (donor) warm ischemia time	Start CPR until cold flush	MAP < 60 mmHg during agonal phase until cold flush (~ASTS)
A-circulatory (donor) warm ischemia time	Certification circulatory death until cold flush	Certification circulatory death until cold flush

Table 6

11. Allocation procedure within Eurotransplant

Coordinators, L. Colenbie

The organs procured from DCD donors are only allocated to countries where retrieval of organ from DCD is allowed. DCD donors are only made in Belgium, the Netherlands, Austria and Luxembourg (patients in Germany, Slovenia and Croatia can't be transplanted with organs from DCD donors).

11.1. Kidneys

Kidneys DCD donors are allocated to the same allocation algorithm as for post-mortem heart-beating kidney donors.
Point Scoring system:

- HLA-typing : Number of HLA-A, -B, -DR mismatches Number of points
  0 MM = 400.00
  1 MM = 333.33
  2 MM = 266.67
  3 MM = 200.00
  4 MM = 133.33
  5 MM = 66.67
  6 MM = 0.00
- Pediatric Bonus 1. dialysis started before the 16th birthday
- registration on the waiting list was before the 16th birthday and dialysis started before the 17th birthday or recipient is proven to be in maturation
- Each pediatric transplant candidate is assigned a pediatric bonus of 100 points: for pediatric transplant candidates the points for HLA-antigen MM are doubled.
- Mismatch Probability (MMP): frequency of HLA- antigen x 100
- Waiting time: upon registration on the kidney waiting list, the recipient's date of onset of maintenance dialysis or date of re-institution of maintenance dialysis after previous kidney transplantation is counted as first day for the calculation of the waiting time. The points for waiting time 0,091 points per day (33,3 per year)
- Distance between donor center and transplant center:

	BELGIUM
LOCAL	200 POINTS
REGIONAL	
NATIONAL	100 POINTS

- National Kidney Exchange Balance: Once every day, for the period of the immediate previous 365 days, the difference between the number of kidneys procured, exchanged between each ET country and transplanted, is calculated.

  Export, i.e. a negative balance, is defined as: kidneys procured in a country > kidneys transplanted in that country.

  Import, i.e. a positive balance, is defined as: kidneys procured in a country < kidneys transplanted in that country.

  National Balance Points = (highest import balance – recipient country balance) x 10

- (ESP/ESDP) The Eurotransplant Senior Program (ESP) allocates kidneys from post-mortem donors ≥ 65 years old to recipients ≥ 65 years without the use of a donor HLA typing.

The ESP aims at a cold ischaemic period (CIP) that is as short as possible. Kidneys from ESP donors are allocated to ESP recipients from the reporting center's local waiting list.

11.2. Liver, lungs and pancreas

Liver, lungs or pancreas from a DCD are regarded as an extended criteria donation (ECD). They are offered in a center-based fashion, allowing the center to choose a suitable recipient from its own waiting list. In case of any suitable recipients are found, the organs are offered to the other Belgian transplant centers before the international allocation following the Eurotransplant rules.

12. Outcome after DCD organ transplantation

D. Monbaliu, P. Ferdinande

12.1. Outcome after DCD kidney transplantation

In general, DCD grafts undergo higher rates of DGF and PNF however for functioning grafts, long term graft and patient survival are similar compared to grafts from brain dead donors[37].

12.2. Outcome after DCD liver transplantation

Initially, in the early 2000's, there was a concern about an increased incident of primary graft non-function which was mainly contributed to prolonged cold ischemia time[38]. Nowadays, primary graft non-function is no longer a big issue but inferior graft survival is related to the higher incidents of ischemic biliary types strictures. Indeed most databases, including the Belgian liver database and registers show inferior graft survival after liver transplantation from DCD donors[39-40]. Nevertheless, excellent outcome, similar to DBD liver transplantation has been reported by single center studies[41]. After DCD liver transplantation the risk on biliary complications is 2.4 times higher than compared to DBD liver transplantation and the risk of ischemic cholangiopathy or ischemic biliary strictures is 10.8 times as high as compared to DBD donors. In addition to the higher graft loss and retransplantation rates an important but often untold story of DCD liver transplantation is the increased number of endoscopic and surgical interventions to treat ischemic type biliary strictures together with the increased morbidity these recipients suffer. Indeed these patients experience more biliary sepsis and growth of multi-resistant organisms, generally experiencing a deteriorated health status. In case of the need for a retransplantation, no priority - based on lab MELD allocation - can be given because of the well-maintained liver function.
Overall, DCD transplantation is leading to increased utilization of resources due to repeated and prolonged hospital admissions, more endoscopic interventions such as ERCP and PTC and more erosion of DBD donors in the donor pool. One possible intervention to reduce the incidence of the ischemic cholangiopathy may the use of Heparin or tissue plasminogen activator but so far conflicting data have been generated. Different phases can be distinguished after the withdrawal of life sustaining therapy usually followed by an agonal phase during which the blood pressure and also the organ perfusion decreases and finally stops. This is than followed by a circulatory arrest which precedes the electrical standstill of the heart. After circulatory arrest or a no-touch period is installed and at the end of the no-touch period the patient can be declared death after which the aorta can be cannulated. Finally the hypothermic flush-out takes place. We propose the following definitions for warm ischemia time.
It is important to realize that depending on the way cardiac arrest or cardiac death is being used, different warm ischemia times will result[42]. After stop of the life sustaining therapy hepatic and renal flow ceases before circulatory arrest and when using circulatory versus electrical standstill

as definition of death imposes a significantly different additional ischemia time on the organs of interest. Some authors reported that a prolonged hypotension below SBP of 50 mmHg is leading to increase the number of adverse effects on ischemia cholangiopathy and an unfavorable graft and recipient survival[43]. In general warm ischemia in DCD liver transplantation is found a risk factor for inferior graft survival and therefore the warm ischemia time is recommended to be less than 30 minutes[35] in accordance with previous preclinical data[44].

12.3. Outcome after DCD lung transplantation

So far similar patient survival and freedom of BOS have been equal comparing DCD vs DBD lung transplantation. In addition there were no differences in acute rejection rates, inflammatory markers and immediate (post)operative outcome[45, 46].

12.4. Heart transplantation

It should not be forgotten that the first heart transplantation was done from a DCD donor[47]. Recently 3 pediatric hearts have been transplanted with hearts from DCD donors with good results. The warm ischemia time was limited to a real minimum and this included the minimization of the no-touch time[48].

13. Expansion or erosion into DBD donor pool by the use of DCD donors

Over the last decennia it has been clear that in some countries with rapidly growing number of DCD donors the number of DBD donors has been decreasing suggesting that the DCD donor pool is not an additional pool but in fact eroding into the DBD donor pool. This leads to less heart transplantations, less pancreas transplantations and more use of resources for liver transplantations. Finally DCD transplantation procurement has been a risk factor to damage organs during procurement and in the UK it was observed that more kidneys were injured during the procurement from DCD donors versus DBD donors (11.4% for DCD versus 6.8% for DBD donors). These injuries include capsular tears, ureteric injuries and vascular injuries resulting in a higher discard because of kidney injury. Therefore the DCD procurement should ideally be done by experienced surgeons[28].

14. Conclusion

It is important to realize that DCD is only one of the strategies to expand the donor pool and each transplant program should focus on expanding all potential donor pools including living donors deceased donation after brain death and expanded criteria donors and not DCD donors alone.
DCD organ transplantation should not be viewed as an equally acceptable alternative to DBD because it yields fewer organs and therefore if brain death is eminent, it might be better to pursue DBD instead of DCD.
Moreover using DCD donors to expand the donor pool has challenged the transplant community on several grounds. First of all the definition of circulatory death is lacking and is not routinely used in daily practice for clinicians. The circulatory death is defined as the permanent lack of arterial pulsation. Organ transplantation from DCD donors has challenged the current way of preservation techniques. The use of DCD donors has challenged the ethical discussion on the end of life treatment and death. DCD donation has also demonstrated the different legal frameworks between different countries since DCD donation is not accepted in every country. And some countries are not even allowed to accept DCD donor organs for transplantation that are recovered elsewhere.

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DCD- Report Centre : Coordinator : Hospital : ..... ET Donor #:..... Date: ..../..../..... DCD Category I ☐ II ☐ III ☐ IV ☐ V (Euthanasia) ☐	*Label* Technique: ☐ DBTL catheter Time : ... h ... ☐ rapid sterno-laparatomy + direct canulation			
Start resuscitation procedure (only for NHBD I and II)	... h ...			
Stop resuscitation procedure (only for NHBD I and II)	... h ...			
Stop ventilation and supportive therapy Extubation: YES /NO Time : Ré-intubation : YES/NO Time :	... h ...	***Acirculatory*** (donor) WIT = ET = ... min	***Absolute*** (donor) WIT = ...min	***Total*** (donor) WIT =...min
Mean Arterial Pressure < 60 mmHg	... h ...			
Asystoly or circulatory arrest (= start "no touch")	... h ...			
Incision time (= end "no touch")	... h ...			
Start of aortic flush	... h ...			

Time of RIGHT pneumectomy : ... h ...
Time of hepatectomy : ... h ...
Time of RIGHT nephrectomy : ... h ...

Time of LEFT pneumectomy : ... h ...
Time of pancreatectomy : ... h ...
Time of LEFT nephrectomy : ... h ...

Remarks :

Donation after Cardiac Death (DCD)
Monitoring of Withdrawal of treatment

Name :
DOB :
Date of procedure :
ET Donor Number :

Time	H. Rate	Mean A.P.	SpO2	Comments

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