Transplant International

REVIEW

New classification of donation after circulatory death donors definitions and terminology†

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SUMMARY

In the face of a crisis in organ donation, the transplant community are increasingly utilizing donation after circulatory death (DCD) donors. Over the last 10 years, with the increasing usage of DCD donors, we have seen the introduction in a number of new terms and definitions. We report the results of the 6th International Conference in Organ Donation held in Paris in 2013 and report a consensus agreement of an established expert European Working Group on the definitions and terminology regarding DCD donation, including refinement of the Maastricht definitions. This document forms part of a special series where recommendations are presented for uncontrolled and controlled DCD donation and organ specific guidelines for kidney, pancreas, liver and lung transplantation. An expert panel formed a consensus on definitions and terms aiming to establish consistent usage of terms in DCD donation.

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Introduction

The aim of the European Working Group, which was established one year prior to the *6th International Conference on Organ Donation after Circulatory Death* held in Paris in 2013, was to clarify the Maastricht classification, definitions and terminology used in the growing field of deceased organ donation particularly with regards to donation after circulatory death (DCD). The findings were discussed and revealed at the Conference. The Working Group reviewing these definitions included members from the UK, France, Spain and from the Eurotransplant zone. Political and logistical support for the Working Group was provided by the European Society for Organ Transplantation (ESOT) and the national component authorities (including UK, France,

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Spain and Euro-transplant zones) and the European Commission.

Since the 90's, in parallel with the evolution of the medical concept of the determination of death, new terms, criteria and recommendations have arisen from across Europe and North America. This has resulted in an ever-changing landscape of emerging terms and definitions being used within the literature and at conferences, between countries, regions and institutions. The purpose of this manuscript, as part of this special edition, was to provide a consensus on terminology in DCD transplantation, attempting to be as accurate as possible to avoid confusion and misconception in the medical community as well as in the civil society. We report the results of this initiative which has focused on revised DCD Maastricht Classification and terminology discussed during the *6th International Conference on Organ Donation after Circulatory Death* held in Paris.

Donation after circulatory death

The opportunities offered by assisted ventilation technologies and other advanced developments such as extra-corporeal life support have led to the introduction of new criteria to define two approaches adopted for the determination of death: *brain death or circulatory death*. In Europe, the term *Nonheart-Beating Donor* (NHBD) was used initially to describe an organ donor after cardio-respiratory arrest. This term was adopted in 1995 during the first International Workshop on Nonheart-Beating donors in Maastricht (Netherlands), leading to the so-called Maastricht Classification [1]. Nonheart beating or cardiac death in case of circulatory death, and the term of heart-beating, in case of brain death have been commonly used interchangeably over the two last decades.

Limitations of these terms arose however, as the terms resulted in misunderstandings about the definition of death being based on a single organ (e.g.. brain or heart) rather than a whole person. Thus the Institute of Medicine – American National Academy of Sciences [2] proposed a clarification of the terms to specify that death can be declared or determined by a physician by the use of either *neurologic* criteria or by *circulatory* criteria. Donation after cardiac death was re-named *Donation after Circulatory Determination of Death* and donation after brain death re-named Donation after Neurologic Determination of Death. This concept of *Donation or Donor after Circulatory Death* (DCD), to define organ donors after circulatory arrest (CA), has now been adopted by the World Health Organization (WHO) [3]. In recent years, the term Donation after Circulatory Determination of Death (DCDD) has been suggested as a more precise term. However, at the recent consensus meeting DCD was preferred term over DCDD for its simplicity and already widespread use.

The accepted standard for determining circulatory death, in these circumstances, is the *permanent absence of respiration and circulation* as advances in technology allows maintenance of sustainable respiration and circulation when the capacity to breathe spontaneously and maintain circulatory function have been irretrievably lost. *Electrical asystole*, *i.e.* the inability to generate any spontaneous heartbeat or circulation - signifies *mechanical asystole* and circulatory death. The shift to a circulatory concept means that death in this condition can be declared in a pulseless patient without any spontaneous circulation (mechanical asystole), even if a cardiac electrical activity is still present. Therefore, both cardiac electrical rhythm and arterial pressure should be assessed, using electro-physiology as well as measurement of central arterial blood pressure and pulse, echocardiography or Doppler ultrasonography.

Maastricht classification revisited: categories of donation after circulatory death

The *NHBD Maastricht classification* (Table 1) was agreed as the growing experience in DCD led up to the need to distinguish several categories of potential donor in different end-of-life situations [1]. This classification has been used worldwide over the last 20 years. It has the advantage of characterizing the different DCD situations and the different categories of donors, considering technical and medical aspects (organ viability, preservation modalities, graft survival) and ethical aspects. Another advantage is its simplicity and usefulness. Attempts to improve the Maastricht classification have focused on adding more categories, with the objective of distinguishing the different ischaemic insults to the organ and consequently different outcomes.

The original Maastricht classification

In Table 1, the original Maastricht Classification of DCD - then called NHBD (Maastricht 1995) is shown,

Table 1. The Maastricht categories of NHBD [1].

Category I. Dead on arrival at hospital
Category II. Death with Unsuccessful resuscitation
Category III. Awaiting cardiac death
Category IV. Cardiac arrest while brain dead

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reflecting the most important categories of donation after circulatory arrest. Each category is explained subsequently

Category I

Dead on arrival includes victims of out-of-hospital (OH) accidents who are not resuscitated for clear reasons such as death due to a broken neck or successful suicide. These deceased patients could be transported to the emergency department and become a donor if the organs are deemed appropriate for donation. One of the criteria for acceptance for donation is a warm ischaemia time (WIT- time between the circulatory arrest and the start of the cooling, as defined later) of less than 45 min. To date, there are few examples of successful organ donation in this category, mainly because of the uncertainty about the duration of WIT.

Category II

Unsuccessful resuscitation includes patients brought to the emergency room while being resuscitated by the emergency medical services (EMS) but if cardiopulmonary resuscitation (CPR) is unsuccessful, the patient may be declared dead (Fig. 1). At the Maastricht workshop, a 10-min period of "no-touch" after cardio-circulatory arrest (CA) to ensure a situation equivalent to brain death was proposed as 10 min of absent blood circulation to the brain at normothermia. In the past years, in most countries a period of 5 min has been adopted by medical societies and authorities, although depending on the jurisdiction a range from 2 min (USA) to 20 min (Italy) still exists. Countries with presumed consent (opting-out) can immediately proceed to the cooling preservation, while countries with opting-in legislation might have to bridge the time until consent for organ donation has been given. Legislation in The Netherlands was introduced where "preparatory handlings" could be allowed in order to preserve the organs for transplantation, before the person's or the family's wish was known.

In some countries (Spain, France), two subcategories have been added due to different logistic conditions according to the site where CA occurs: IIa for out-of-hospital (OH) and IIb for in-hospital (IH) [4,5]. Although most of the cases of CA in category II occur in the OH setting, clinicians have argued that the two situations should be considered separately because of logistical aspects involved [6–8] and consequently different WITs that could impact significantly on outcomes after transplantation. Besides the impact of WIT, the prearrest clinical and functional conditions of the patient could be relevant factors [9,10].

In case of IH circulatory arrest, some have suggested to further differentiate whether CA occurs in the Emergency or ICU department [11–13].

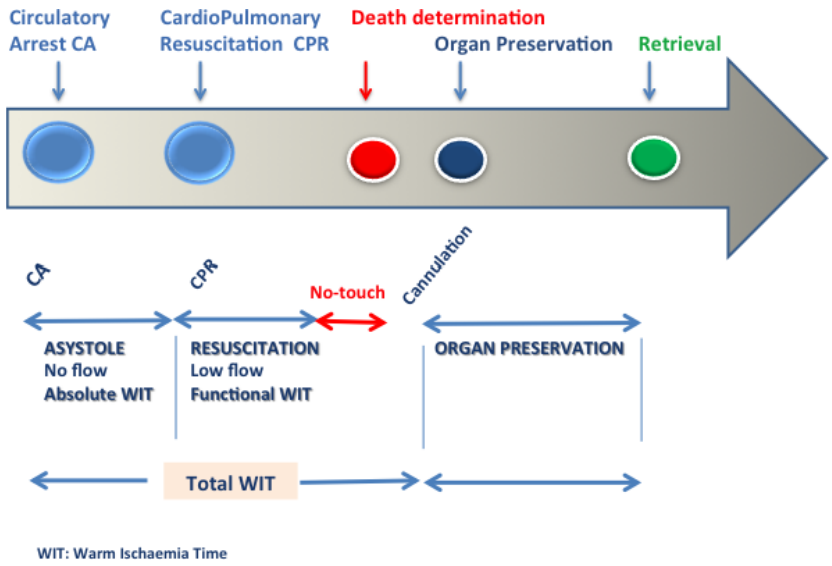

Figure 1 Uncontrolled DCD process.
1 No flow: Kidney ≤30 min; Liver ≤ 15 min
2 CPR duration: ≥30 min
3 No-touch period: 2 min to 20 min
4 Total WIT: 120 min to 150 min

Category III

Awaiting cardiac or circulatory death includes those patients for whom circulatory death occurs after a planned withdrawal of life-sustaining therapies (WLST), mainly cardiorespiratory support (Fig. 2). CA is expected and the medical decision of WLST is taken in a defined and multi-disciplinary approach, consistent with local/national legal requirements, by the clinical team together with the family, where further treatment is considered futile. In the initial description, the term "controlled" meant that the ischaemia time was short enough to consider recovery of liver, kidneys, pancreas and lungs. This category, which was defined in the 90s, does not include euthanasia or medical-assisted CA, an end-of-life practice authorized in some European countries (Belgium, Netherlands, Luxemburg).

Category IV

Cardiac arrest in a brain-dead donor includes patients who suffer an unexpected CA after diagnosis of brain death and during donor management but prior to the planned organ recovery. In this case, it is likely that health care professionals will try first to restore adequate circulation and perfusion of organs, but when unsuccessful, the patient can be considered for DCD donation (uncontrolled CA).

In some countries, where the legislation does not accept brain death criteria (i.e. Japan) or when the patient will never meet the neurological criteria for the diagnosis of BD, the procedure for this potential DBD can be converted to a DCD one (controlled CA).

Other possible classifications

During its review the Working Group discussed other National classifications in pursuit of a common denominator allowing a certain level of uniformity.

One example is a form of classification proposed by the Spanish National consensus to adjust the Maastricht Classification for DCD (Madrid 2011) including a number of subcategories as mentioned above (Table 2) [4]. Another adjustment was related to the fact that the Eurotransplant organization including eight different countries formally recognized the possibility of organ donation after euthanasia in The Netherlands, Belgium and Luxemburg. This modified and more complete categorization by Detry *et al.* defines the different situations (expected CA or not, precise CA location, witnessed or not, resuscitation or not) encountered in the different groups and countries with active DCD program. Also, a fifth category, which consists of euthanasia or medically assisted cardiocirculatory death is included (Table 3) [13].

In addition, the WHO Critical Pathway for deceased organ donors describes the different sequential phases of the donation process as possible, potential, eligible, actual and utilized donor (Fig. 3) [14]. It allows, on the basis of clear definitions, a comprehensive analysis of the real potential for donation and of the effectiveness at each step of the process.

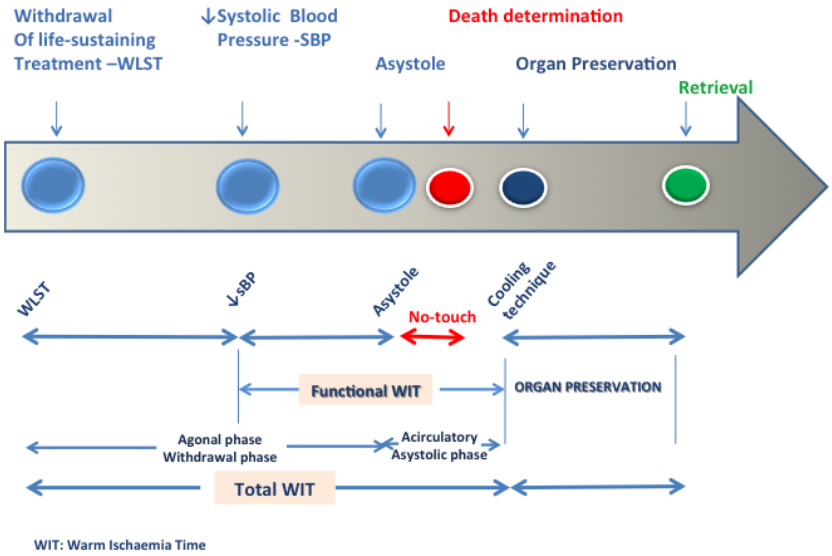

Figure 2 Controlled DCD process.
1 Functional WIT starts when SBP is ≤ 50 mmHg or ≤ 60 mmHg
2 No-touch period: 2 min to 20 min

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Table 2. Modified Maastricht Classification for Donors after Circulatory Death (Madrid 2011) [4].

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	Unsuccessful 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	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 neurological criteria or after such determination has been performed, but before the transfer to the operating theatre. 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 donors after circulatory death (Detry, 2012) [13].

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	Unsuccessful resuscitation	2A. Unexpected cardiocirculatory death in ICU. Uncontrolled 2B. Unexpected cardiocirculatory death in hospital (ER or ward), with witnesses and rapid resuscitation attempt. Uncontrolled
ControlledDCD	III	Awaiting cardiac arrest	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

The modified Maastricht classification of DCD in Paris 2013

Following extensive discussion in the Working Group as well as during the DCD Conference in Paris in 2013 it was agreed to modify the original Maastricht Classification and update according to new developments but attempt to keep its relatively simplicity and straightforwardness intact. The result of this discussion is shown in Table 4.

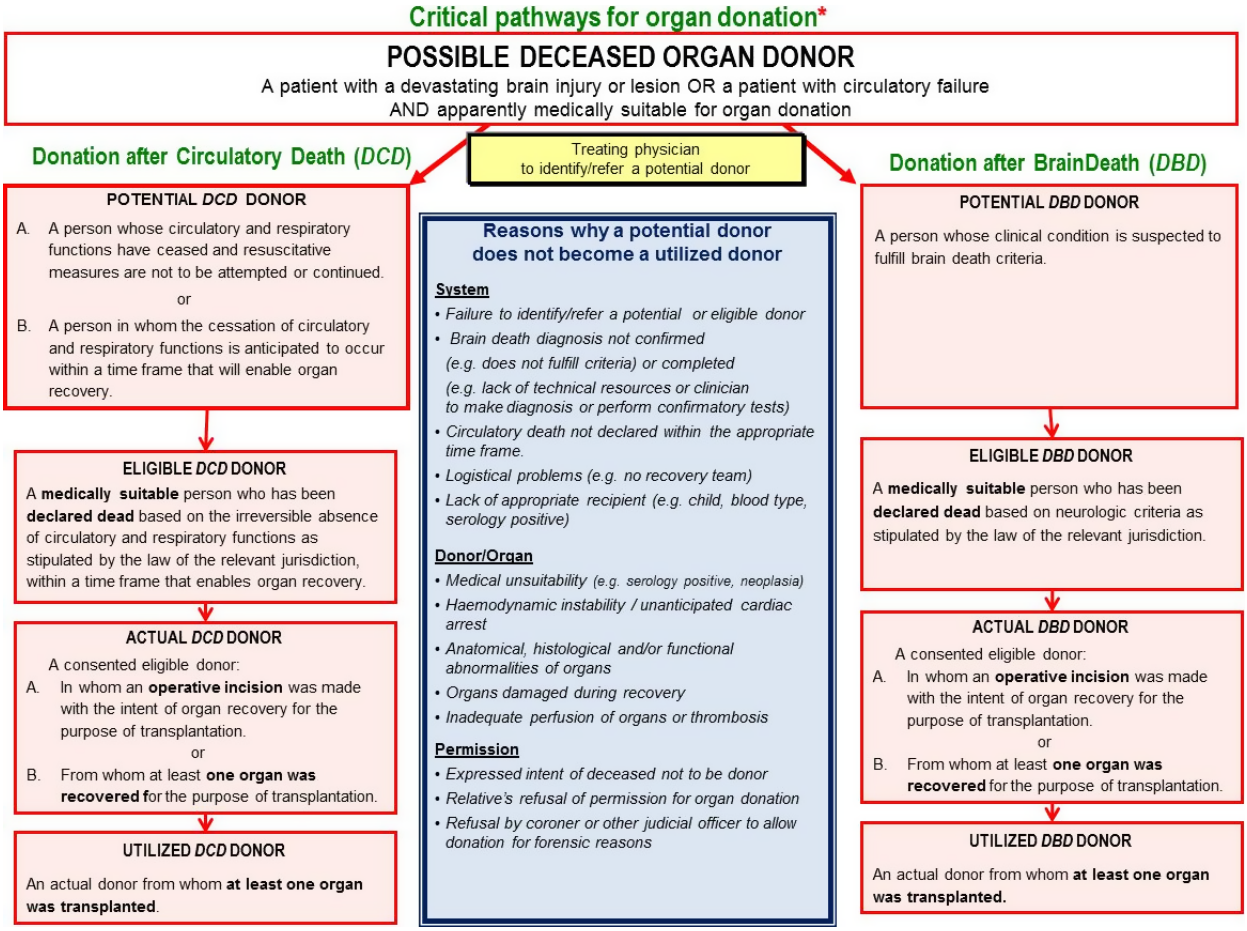

Figure 3 WHO Critical Pathway for deceased donation [15].

Table 4. The Modified Maastricht Classification of DCD.

Category I. Uncontrolled	*Found dead* IA. Out-of-hospital IB. In-hospital	*Sudden unexpected CA without any* attempt of resuscitation by a life-medical team; *WIT to be considered according to National life-recommendations in place; reference to in- or out-of-hospital life-(IH-OH) setting*
Category II. Uncontrolled	*Witnessed cardiac arrest* IIA. Out-of- hospital IIB. In-hospital	Sudden unexpected irreversible CA with *unsuccessful resuscitation life-by a life-medical team*; reference to in- or out-of-hospital (IH-OH) life-setting
Category III. Controlled	*Withdrawal of life-sustaining therapy*	Planned withdrawal of life-sustaining therapy*; expected CA
Category IV. Uncontrolled Controlled	*Cardiac arrest while life-brain dead*	Sudden CA after brain death diagnosis during donor life-management but prior to planes organ recovery.

CA, circulatory arrest.

*This category mainly refers to the decision to withdraw life-sustaining therapies. Legislation in some countries allows euthanasia (medically assisted CA) and subsequent organ donation described as the fifth category.

This modified classification preserves the essential skeleton for further clarification, as it is simple and clear. It gives a new insight by providing more detail and describes the different DCD types by process. This may help not only the healthcare professional in donation and transplantation but also those involved in

Table 5. Terminology – definitions.

Acronym and full name	Other terms	Definition
Agonal phase	Agonic, Withdrawal phase	Time elapsed from withdrawal of life-support therapy– WLST (dying patient) to asystole (dead patient) [16].
Ante-mortem Interventions	Premortem	Interventions to support organ donation and transplantation that start in the period before death is declared
Asystole		Cardiac standstill and complete cessation of circulation, with no cardiac contractility or ventricular depolarization
Asystolic phase	Acirculatory phase	Time elapsed from circulatory arrest to initiation of organ perfusion procedure [17,18].
Autoresuscitation	Return Of Spontaneous Circulation (ROSC)	ROSC phenomenon that can be observed when CPR procedure is stopped [19]
Brain death (BD)		Severe and irreversible brain injury leading to death. Diagnosis of death is based on neurological criteria.
Cardiopulmonary resuscitation (CPR)		Group of cardiopulmonary manoeuvres undertaken with the therapeutic goal of restoration of circulation in case of circulatory arrest (CA) (international guidelines produced by the American or European Heart Association [20,21]). Confirmation of death certification is done after a usual 30-min period of a well-conducted but unsuccessful CPR without any ROSC (except in case of severe hypothermia or cardiotoxic poisoning).
No flow period		The asystolic period without any attempt of CPR (*i.e.* uDCD – category 1). This is the most critical issue in terms of ischaemic injury; A maximum of 45-min of no flow was first recommended in initial classification of NHBD [1]. The Spanish and French uDCD programs limit the no flow period to less than 30 min for kidney transplantation and 15 min for liver transplantation [4,5].
Low flow period		The asystolic period when CPR is attempted (*i.e.* uDCD-category 2)
Circulatory arrest (CA)	Cardiac arrest	Cessation of cardiac function leading to the loss of effective circulation
Donation after brain death (DBD)	Heart Beating Donation(HBD)	Organ donation after confirmation of brain death diagnosis by neurological criteria
Donation after circulatory death	Nonheart Beating Donation (NHBD)	Organ donation after confirmation of cessation of circulation and any legally mandatory no touch period
Controlled DCD (cDCD) (Fig. 2)	Maastricht type III/IV donors	DCD donors where cessation of circulation is expected. Circulatory death is diagnosed in terms of "permanency" (do not resuscitate order).
Uncontrolled DCD (uDCD) (Fig. 1)	Maastricht type I/II/IV donors	DCD donors after unexpected cessation of circulation. Circulatory death is diagnosed in terms of "irreversibility" (failure of resuscitation).
Delayed graft function (DGF)	–	Failure of renal graft function so there is a need for dialysis in the 1st week after kidney transplantation

Table 5. Continued.

Acronym and full name	Other terms	Definition
Early allograft dysfunction (EAD)		One or more of the following: (i) Bilirubin ≥10 mg/dl on post operative day 7; (ii) INR ≥ 1.6 on post operative day 7; (iii) aminotransferase l evel (alanine aminotransferase [ALT] or aspartate aminotransferase [AST]) >2000 IU/ml within the first 7 postoperative days [22].
Ex vivo lung perfusion (EVLP)	*Ex situ* Lung Perfusion (ESLP) Normothermic-Hypothermic lung perfusion (nMP-hMP)	Perfusion of lungs *ex situ* for the purposes of transplantation. The term *ex-vivo* tends is missleading as in donation after brain death or circulatory death, there is no *ex-vivo condition* as with normal patients. The Working Group prefers nMP or hMP that is by definition always *ex situ*.
Expanded criteria donor		DBD Donor aged > 60 years or > 50 with 2 of the following: hypertension, terminal creatinine >1.5 g/dl or cerebrovascular cause of death with no risk factor (such as recent drug use etc) [23].
Functional delayed kidney graft function (fDGF)	–	Failure for serum creatinine to improve by 10% on three consecutive days post-transplant
Irreversible condition		Pertaining to a condition that will not or cannot return or resume. In the context of death determination, there are variable definitions including: 1. Loss of function or a condition that cannot be restored by anyone under any circumstances at a time now or in the future. 2. Loss of function or a condition that cannot be restored by those present at the time. 3. Loss of function or a condition that will not resume and will not be restored.
Permanent condition		Pertaining to a situation or condition that will not return to its previous state. In the context of death determination, refers to loss of function that will not resume spontaneously and will not be restored through intervention.
Postmortem interventions		Interventions in actual or potential organ donors after the declaration of death
Primary non function (PNF) (Kidney)		Non- and never functioning transplant, return to dialysis.
Primary non function (PNF) (Liver)	-	Death or retransplantation within 7 days post-transplant
Normothermic regional perfusion (nRP)	ECMO: Extra-corporeal membrane oxygenation nECMO: Normothermic ECMO	Circulating *in situ* machine perfusion of organs using a device applied at normothermic temperatures in the donor
Hypothermic regional perfusion (hRP)	hECMO: Hypothermic ECMO	Circulating *in situ* perfusion of organs using a device applied at hypothermic temperature (usually between 10-20 °C) in the donor
Sub-normothermic regional perfusion (snRP)	–	Circulating in-situ perfusion of organs with a device at temperatures between 10 °C and normal body temperatures in the donor

Table 5. Continued.

Acronym and full name	Other terms	Definition
Double balloon triple lumen (DBTL)	–	Vascular balloon catheter, typically used for the isolation of abdominal organs for the purposes of RP, using cold preservation solution
Machine perfusion (MP)	–	Using a pump to perfuse an organ *ex-situ*
Hypothermic machine perfusion (hMP)		Using a pump to perfuse an organ *ex-situ* (machine perfusion) at hypothermic temperatures (usually between 5 and 10 °C)
Normothermic machine perfusion (nMP)		Using a pump to perfuse an organ *ex situ* (machine perfusion) at normothermic temperatures
Sub-normothermic machine perfusion (snMP)		Using a pump to perfuse an organ *exsitu* (machine perfusion) at temperatures between 10 °C and normothermic temperatures
Hypothermia	–	<10 °C (for cold storage this is normally 0-5 °C)
Normothermia	–	36-37 °C, the normal core body temperature
Warm ischaemia time (WIT)	–	The time without perfusion and oxygen elapsed from the beginning of circulatory arrest (DCD category II and III) to the start of organ preservation (cold flush/ nRP). Depending on whether it is in an uncontrolled [11, 24–26] or controlled [4, 18, 27] situation, the acceptable time may vary according to local protocol.
Functional warm ischaemia (*f*WIT) [4–18]	True WIT (tWIT)[27]	Functional WIT (*f*WIT) is the time from when the systolic blood pressure drops below 50 mmHg (irrespective of oxygen saturation) for at least 2 min after Withdrawal of Life Sustaining Treatment (WLST) until organ preservation (cold flush/nRP).
No touch period	Hands off period	Observation period without any intervention to confirm circulatory death [1]. In most countries a period of 5 min is recommended, however some centres (such as in the US) have shorter periods, and other centres may have longer periods (such as in Italy).
Donation professional	Donor co-ordinator Specialist nurse in Organ Donation (SNOD)	A health care professional with expertise to support the donation process
Transplant professional	–	Health care professional with expertise to support the transplant procedure

ethical, psychological and legal issues as well as the non-medical reader interested in this field.

The two main discriminant factors are retained in the modified Maastricht Classification: the circumstances of CA (sudden or planned, uncontrolled or controlled) and the initial therapeutic procedure engaged (resuscitation or not). We have added the 'location' where the sudden CA occurs [outside (a) or inside (b) the hospital]. One of the objectives of the modified classification is to point out logistics (uncontrolled activity in uDCD and controlled activity in cDCD), including delays and subsequent WIT, that are usually much longer in uDCD [15].

The Working Group considers it very important that all data should be defined and precisely recorded, including the relevant times, to allow for determination of the duration of ischaemia together with other factors such as demographics, co-morbidities, all conditions to ensure a comprehensive analysis.

Definitions of terms

Table 5. Describes a list of definitions and terms discussed by the Working Group. The associated terms and their abbreviations are used throughout this special issue. A description of alternative terms are described.

Conclusion

The terms and definitions described in this overview and revisiting of the Maastricht criteria aim to provide the transplant community with concise and consistent definitions for commonly described terms in transplantation. The wide variety of definitions and terms currently in use has lead to inconsistencies in descriptions in the past. This document will provide consistent definitions for the use of these terms in the literature, during presentations and other scenarios reducing confusion.

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Conflicts of interest

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