

REVIEW

Ethical, legal, and societal issues and recommendations for controlled and uncontrolled DCD

Bernadette Haase¹, Michael Bos², Catherine Boffa³, Penney Lewis⁴, Chris Rudge⁵, Ricard Valero⁶, Tineke Wind⁷ & Linda Wright⁸

1 Dutch Transplant Foundation, The Hague, The Netherlands

2 Health Council of the Netherlands, The Hague, The Netherlands

3 Nuffield Department of Surgery, Oxford Transplant Center, University of Oxford, Oxford, UK

4 King's College London, London, UK

5 Former Clinical Director for transplantation DoH, London, UK

6 Hospital Clinic de Barcelona, Barcelona, Spain

7 Maastricht University Medical Centre, Maastricht, The Netherlands

8 Toronto General Hospital, Toronto, ON, Canada

Correspondence

Catherine Boffa, Nuffield Department of Surgical Sciences, University of Oxford, Oxford, UK.

Tel.: 01865 228686;

fax: 01865 225773;

e-mail: catherine.boffa@nds.ox.ac.uk

SUMMARY

This report deals with organ retrieval procedures in both controlled and uncontrolled DCD, looking at the ethical, legal, and psychosocial aspects during the different phases of the process. A recently published report by the UK Donation Ethics Committee (UKDEC) has served as an important reference document to outline the steps in the controlled DCD patient–donor pathway (Academy of Medical Royal Colleges. UK Donation Ethics Committee. An ethical framework for controlled donation after circulatory death. December 2011). For uncontrolled DCD, the UKDEC pathway description was adapted. At the 6th International Conference in Organ Donation held in Paris in 2013, an established expert European Working Group reviewed the UKDEC reports, which were then considered along with the available published literature. Along this pathway, the crucial ethical, legal, and psychosocial aspects have been flagged, and relevant recommendations have been formulated based on a consensus of the working group.

Transplant International 2016; 29: 771–779

Key words

donation after cardiac death, donation after circulatory death, ethical, guidelines, legal, nonheart beating donation, recommendations, review, societal

Received: 28 July 2015; Revision requested: 4 September 2015; Accepted: 11 November 2015;

Published online: 13 January 2016

The overall DCD process and context

Although DCD donation is not available in all countries, in those where it is allowed, in order for hospitals to implement an ethically acceptable DCD program, a number of preconditions should be met. A key prerequisite is the availability of a national protocol or set of (inter)national best practice guidelines for DCD, on which a local program can be based. A second important prerequisite is that all decisions concerning the treatment of the patient, including the decision to withdraw or limit life-sustaining treatment in a controlled DCD setting, or

the cessation of cardiopulmonary resuscitation (CPR) in an uncontrolled DCD procedure, should be based on the patient's best interests [1] (see Fig. 1).

Avoiding conflicts of interest

Conflicts of interest may arise if a medical professional involved in treating a potential uncontrolled DCD donor (cardiac arrest donor) has a vested interest in this person becoming a donor, since this may (intentionally or unintentionally) influence his actions and decisions to focus on securing a successful donation rather than

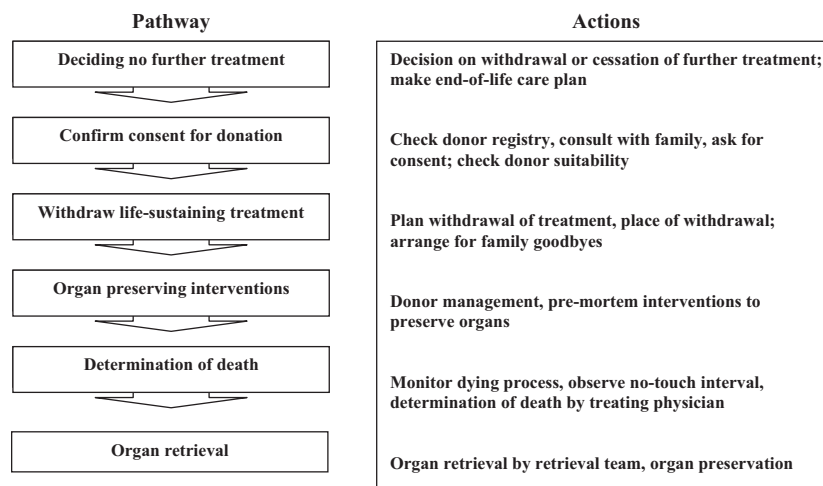


Figure 1 DCD pathway (controlled).

performing adequate resuscitation, and facilitating a comfortable and peaceful end-of-life care of the patient. On the other hand – considering that donation could be the last will of a patient – the treating professional should offer this possibility to their patient (Figs 2 and 3).

Consulting the Donor Register during the CPR procedure, and before death has been declared, may be seen by some to constitute a conflict of interest, since it means that one is considering the possibility of organ donation while the patient is still being treated. However, no actual steps toward donation will be performed until the treating team has declared the patient dead, and valid consent for donation has been obtained. The decision to stop the treatment (CPR) must be made strictly on medical judgement and be independent of the possibility of donation. If there is no evidence available of what the patient wanted, the option to perform organ donation will be open to the family to decide.

Further conflicts may arise as a result of staffing or other logistical issues. The working group has considered the position of three professional groups involved and distinguishes the following division of roles and responsibilities:

1. The treatment team in the intensive care unit or emergency department (intensivist, anesthetist, nurse, or cardiologist resp.). The treatment team is fully responsible for the treatment of the patient, including the decision to withdraw or withhold treatment or to end CPR, and for the determination of death.

2. The donor team (e.g. transplant coordinator, specialist nurse – SNOD). Their task is to coordinate the donation process, to communicate with the potential donor's family, and – once consent for donation is obtained – for liaising between the treatment team, the retrieval team

and with the organ transplant center. The working group considers there would be a conflict of interest if the transplant coordinator or SNOD were to be involved in providing medical care to the patient while he/she is still alive and being treated.

3. The retrieval team is the surgical team that – with the help of the donor team – carries out the preservation of the organs after death has been confirmed and retrieves the organs. The potential donor is handed over into the care of the retrieval team after death has been determined by the treating team. The working group considers there would be a conflict of interest if the retrieval team were to play any part in the care of the patient before death has been confirmed.

Once the death of the patient has been officially determined and declared, the donor team, as well as members of the emergency department/ICU team, may assist in caring for the donor if their particular skills are required (e.g. re-intubation to facilitate lung retrieval may be carried out by a member of the treatment team if necessary).

In certain situations, staffing problems may compromise the DCD donation procedure. It is advised that hospitals should have protocols setting out solutions for managing staff shortages in order to achieve a potential donor's wish, and for identifying circumstances when such difficulties render donation inappropriate. The working group is of the opinion that the treating physician and nurse in charge are responsible for ensuring that staffing arrangements are sufficient to provide appropriately skilled care that meets the necessary ethical standards to the potential donor.

Taking into account the above considerations, the following recommendations are relevant when implementing a DCD program:

Timelines and responsibilities

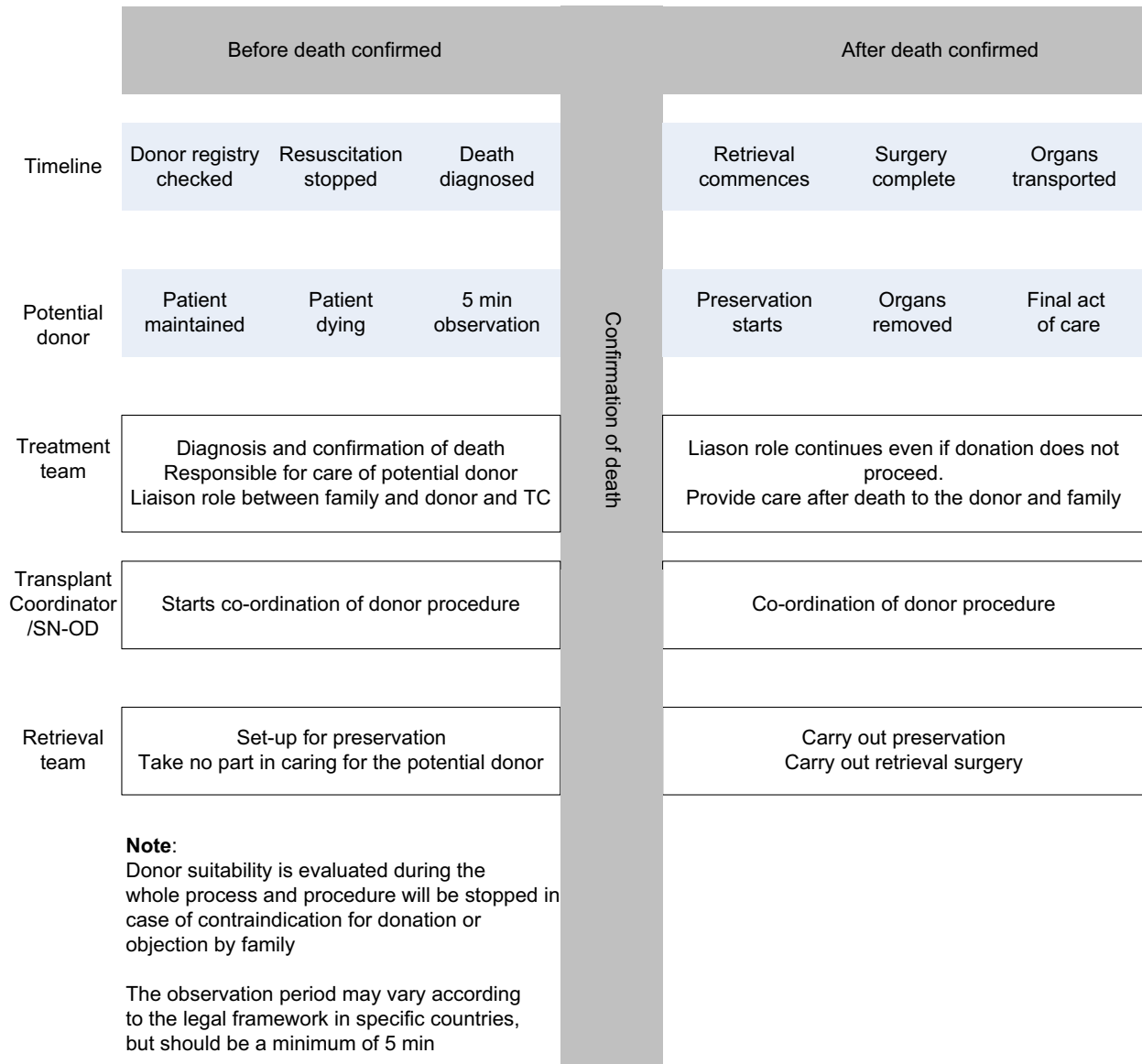


Figure 2 Time line and responsibilities in Uncontrolled DCD.

Recommendation 1:

Hospitals, planning to implement a DCD program (controlled and/or uncontrolled) should develop a clear and approved protocol, preferably based on (inter)national guidance, describing the roles and responsibilities of all staff and teams involved, as well as the range of possible outcomes in a (potential) DCD case.

Recommendation 2:

As the basis of any DCD program, there should be a clear medical, ethical and legal framework outlining

when and how to decide on withdrawing or withholding life-sustaining treatment, or on the cessation of CPR. This should be based on the patient’s best interests. In making these decisions each action involving that patient is justified by balancing the potential benefits and harms to that patient, also taking into account his or her wish to donate.

End-of-life care

The decision to start a DCD procedure evolves from the fact that the patient is approaching the end of life. In the context of the provision of end-of-life care,

Determining whether organ donation is of overall benefit : uncontrolled DCD

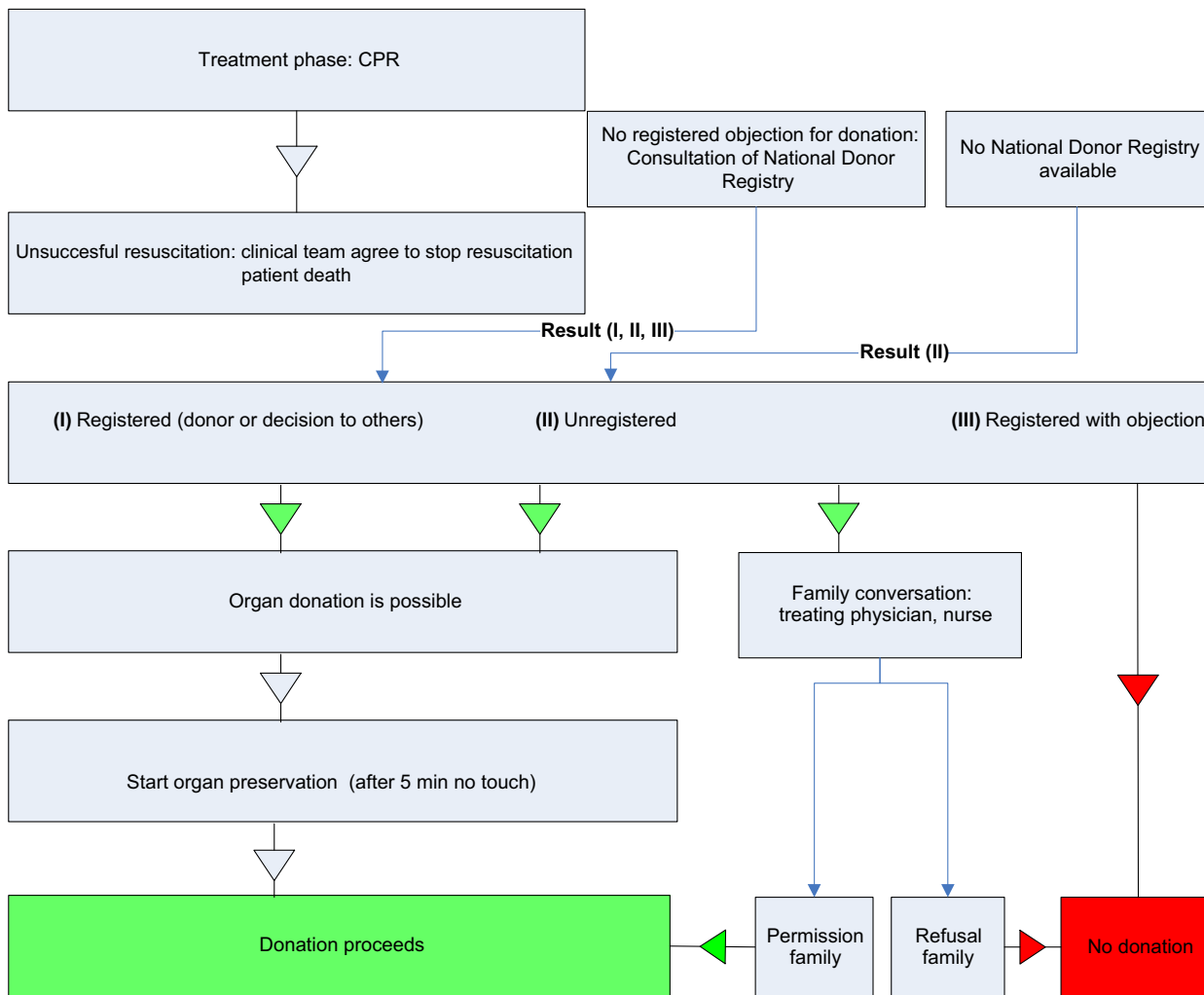


Figure 3 Decision-making tree in uncontrolled DCD.

decisions have to be taken concerning the different pathways for that particular patient (controlled or uncontrolled DCD) (Table 1) [2]. The roles and responsibilities of those treating the patient, and those performing the retrieval procedure, should be clearly defined and separated [3]. Consideration should be given to the possibility of carrying out interventions to optimize donation, prior to death. These considerations lead to the following recommendations:

Recommendation 3:

In order to avoid any conflict of interest, there must be a clear separation between the team treating the patient, including taking care of donor management, and the team responsible for retrieving the organs. Responsibility

for deciding to withdraw, limit or end further treatment in a patient, as well as determining and declaring his death, lies solely with the treatment team.

Recommendation 4:

In all patients (including children) approaching the end of life, the option to donate organs should be considered and discussed with the next-of-kin, depending on the known will of the patient, the existence of medical contra-indications, and the possibility of obtaining consent for donation. It is acceptable to consult a National Donor Registry (or similar source), at the time when withdrawal, limitation of treatment, or cessation of CPR in a patient is considered (and before death is declared), in order to know the registered will of the patient concern-

Table 1. Key differences between uncontrolled and controlled DCD.

Issue	Uncontrolled DCD	Controlled DCD
CPR	CPR attempted following standard criteria and algorithms is unsuccessful, and death is declared	CPR is not attempted, life-sustaining treatment is withdrawn, and cardiac arrest awaited
Irreversibility	Irreversibility is demonstrated: all attempts at resuscitation, under established medical standard, have failed	Permanent absence of circulation ultimately leads to irreversible circulatory arrest: there is no intention to attempt CPR to recover cardiac function
Auto-resuscitation	Evidence of auto-resuscitation at 7 min	No reported auto-resuscitation after 1 min following cardiac arrest
Demonstrating cardio-circulatory arrest	Asystole on ECG must be confirmed	In general, absence of pulse (by arterial blood pressure monitoring) will be confirmed
No-touch time (standard observation time)	Time elapsed between demonstration of unsuccessful CPR until declaration of death and beginning of preservation measures	Time elapsed between demonstration of circulatory arrest until declaration of death, and beginning of preservation measures
Premortem interventions	No interventions to optimize organ quality during attempts to recover cardiac function	According to protocols, ethical consideration, etc.
Postmortem interventions	According to protocols, ethical considerations, etc.	According to protocols, ethical considerations, etc.
Preservation techniques	Irreversible circulatory arrest after failed CPR (irreversible brain damage) and no risk of recovery of brain perfusion. Circulation isolation during normothermic recirculation may be done to improve splanchnic perfusion	Potential recovery of circulation to the brain and heart must be prevented (CPR, normothermic regional perfusion without circulation isolation)

ing organ donation. For each patient a plan for end-of-life care should be made that addresses these issues.

Determination of death

In organ donation, death should be diagnosed and confirmed by the treatment team, by strictly following the

schedule laid out in a national protocol for the determination of death that is approved by the medical profession (and in some countries prescribed by legislation) [4]. Most countries already have such a protocol for determining death on neurological criteria (brain death), but protocols based on cardio-circulatory criteria (circulatory death) are often lacking. Onset of death in a potential DCD donor is to be determined by the irreversible loss of the capacity for consciousness and the irreversible loss of the capacity for spontaneous respiration in that patient, in order to comply with the dead donor rule [5]. These considerations lead to the following recommendations:

Recommendation 5:

A hospital implementing a DCD program should have a clear and approved local protocol – consistent with national protocol – for determining and declaring death in a DCD context (controlled/uncontrolled).

Recommendation 6:

After the onset of circulatory arrest or the cessation of CPR, an observation period (no-touch interval) of at least 5 minutes must be observed before death shall be declared. In controlled DCD (withdrawal or limitation of life-sustaining treatment), the requirement of ‘irreversibility’ of respiratory–circulatory function is (ethically) met because a deliberate decision has been taken not to take any action to resuscitate the patient, in his or her best interests.

Pre (ante)-mortem and postmortem interventions

In controlled DCD, transplantation of the organs is facilitated, and the outcome of the transplantation improved, if certain measures are taken in the period after consent to become a donor has been given (withdrawal of treatment) and before the death of the patient is declared [6]. These pre (ante)-mortem measures are intended to optimize the viability of the organs and should be consistent with the wish of the patient to become a donor. Interventions to preserve and improve organ quality *in situ* can be taken after death has been declared, thereby facilitating the wish of the patient to be a donor, but care should be taken not to compromise the determination of death (e.g., the risk of restarting cerebral or cardiac circulation when applying normothermic regional perfusion) [7].

A strategy for implementing pre (ante)-mortem interventions

When preparing pre (ante)-mortem interventions in controlled DCD, with the aim to improve the quality of transplantable organs, the following considerations and ethical framework should be taken into account.

1. The question whether interventions to improve donation are acceptable and relevant will arise at the end of a three-stage decision-making process:

- i. It should have been decided that the continuation of life-sustaining treatment is no longer in the best interests of the patient;
- ii. It should have been decided that organ donation would be in the best interests of the patient;
- iii. A balancing process for deciding whether particular interventions to optimize donor organ quality and improve transplant outcomes would be in the best interests of the patient, should be undertaken in a manner that is both ethical, and lawful.

2. Before the balancing process is undertaken in relation to a particular intervention, a clear justification for the intervention in terms of its potential to improve the transplant outcomes from the patient's donation(s) should be identified. If an intervention is routinely undertaken but the evidence for its potential to improve transplant outcomes is weak, then the potential for the patient to benefit from the intervention will be proportionately reduced. The absolute minimum level of intervention should be used consistent with facilitating the success of the transplant.

3. In order to assess whether an intervention designed to optimize donor organ quality and improve transplant outcomes would be in the best interests of the patient, the potential benefits to the patient must be balanced against the potential harm or distress (or risk of harm and distress) that may be caused by the intervention.

4. In the assessment of the balance of benefits and harms for any such intervention, the patient's wishes and feelings, beliefs, and values must all be considered. A person's interests are wider than simply their clinical interests. A person's social, emotional, cultural, and religious interests should be considered in determining what course of action may be in his or her best interests.

5. The strength of the patient's decision or wish to donate will play an important role in assessing the balance of benefits and harms for any such intervention. Further information from the patient's family and friends about their wishes, feelings, beliefs, and values about organ donation and (if available) any procedures

designed to optimize donor organ quality and improve transplant outcomes may also be valuable in building up a picture of the strength of the patient's wishes.

Potential benefits

Not being able to fulfill the patient's wish to be an organ donor may potentially harm the patient's best interests. This concept can be made more positive by considering the potential benefits, which may accrue to the patient by facilitating their wish to be an organ donor. These encompass both the prospective benefit of knowing their wishes will be facilitated, and the future benefit it will attach to their legacy. In most cases, the patients will have an interest in the well being of their family and so may also be benefitted indirectly if the donation helps family and friends to come to terms with their loss and promotes positive memories of the patient after death.

Potential harm

An intervention designed to optimize donor organ quality and improve transplant outcomes may potentially cause harm or distress (or risk causing harm or distress) to the patient. Examples of potential harm include pain or discomfort; examples of potential distress include anxiety or gasping.

Thought should be given to the extent to which symptoms of pain, discomfort, or distress might be caused so they can be alleviated using appropriate symptom control.

The risk of causing distress to the patient's family should also be considered a potential risk of harm to the patient. Ways of avoiding this should be explored through careful explanation of both the need for particular interventions in order to facilitate the patient's wish to be a donor and what is involved in those interventions. Those caring for the patient must also ensure that interventions are carried out in a way that is as respectful as possible of the patient and their family and friends.

For each patient and each proposed intervention, the clinical team will need to assess whether the potential benefits of the intervention outweigh any potential harm that cannot be prevented by using appropriate symptom control. If so, the proposed intervention may not be in the best interests of the patient. A wide range of relatively minor interventions are likely to meet this threshold for all patients who want to become organ donors. A few interventions carry risks of serious harm, and very

Recommendation	Grade	References
Hospitals, planning to implement a DCD program (controlled and/or uncontrolled), should develop a clear and approved protocol, preferably based on (inter)national guidance, describing the roles and responsibilities of all staff and teams involved, as well as the range of possible outcomes in a (potential) DCD case	D	
As the basis of any DC program, there should be a clear medical, ethical, and legal framework outlining when and how to decide on withdrawing or withholding life-sustaining treatment, or on the cessation of CPR. This should be based on the patient's best interests. In making these decisions, each action involving that patient is justified by balancing the potential benefits and harms to that patient, also taking into account his or her wish to donate	D	[1]
In order to avoid any conflict of interest, there must be a clear separation between the team treating the patient, including taking care of donor management, and the team responsible for retrieving the organs. Responsibility for deciding to withdraw, limit, or end further treatment in a patient, as well as determining and declaring his death, lies solely with the treatment team	D	[2,3]
In all patients (including children) approaching the end of life, the option to donate organs should be considered and discussed with the next of kin, depending on the known will of the patient, the existence of medical contraindications, and the possibility of obtaining consent for donation. It is acceptable to consult a National Donor Registry (or similar source), at the time when withdrawal, limitation of treatment, or cessation of CPR in a patient are considered (and before death is declared), in order to know the registered will of the patient concerning organ donation. For each patient, a plan for end-of-life care should be made that addresses these issues	D	
A hospital implementing a DCD program should have a clear and approved local protocol – consistent with national protocol – for determining and declaring death in a DCD context (controlled/uncontrolled)	D	[4]
After the onset of circulatory arrest or the cessation of CPR, an observation period (no-touch interval) of at least 5 min must be observed before death shall be declared. In controlled DCD (withdrawal or limitation of life-sustaining treatment), the requirement of 'irreversibility' of respiratory–circulatory function is (ethically) met because a deliberate decision has been taken not to take any action to resuscitate the patient, in his or her best interests	D	[5]
When it has been established that a) further treatment is no longer in the best interests of the patient, and b) organ donation is in accordance with the will of the patient and/or the next of kin, it is medically and ethically appropriate to take certain measures before the death of the patient is declared, to ensure the best possible quality of organs to improve the outcome of the transplanted organ. For each specific intervention, the potential to optimize the organ quality, and thereby facilitate the patient's wish to be a donor, should be balanced against the potential for harm and distress in that patient (and also his next of kin)	D	[6]
Interventions in the uncontrolled DCD donor, that are carried out (or continued) after the death of the patient has been declared, should be applied in such a way that the determination of death is not compromised in any way	D	[7]
The option of organ donation should not be discussed with the next of kin before the decision to withdraw or limit treatment or cease CPR has been made, and the family has been informed and consulted on this issue. Consent from the next of kin should be sought after efforts have been made to establish the own will of the patient. If the family objects to donation, or if donation is abandoned in case of a contraindication, the family should still receive full support and bereavement care	D	[8]
Communication with the family should preferably be the responsibility of a single designated liaison (member of treatment staff or trained nurse) throughout the DCD procedure. At an early stage in the donation process, this communication should address any particular religious observances that need to be fulfilled or cultural traditions to be taken into account during the dying phase and period following the death of the patient	D	[8]
At the time of being waitlisted, potential recipients of DCD organs should be informed about the possibility of receiving and accepting such an organ. Allocation of DCD organs should be based on the agreed national allocation policy	D	
There is a need for information, education, and guidance to the general public, as well as stakeholders involved, on the issue of DCD	D	[9,10]

strong evidence of potential benefits would be needed in order for them to be in the best interests of the patient. The evidence relating to the risk of harm associated with particular interventions is likely to change over time and should be regularly revisited by a suitable body in order to ensure that clinicians are able to make evidence-based assessments of those risks, if they exist.

The above considerations lead to the following recommendations:

Recommendation 7:

When it has been established that a) further treatment is no longer in the best interests of the patient, and b) organ donation is in accordance with the will of the patient and/or the next of kin, it is medically and ethically appropriate to take certain measures before the death of the patient is declared, to ensure the best possible quality of organs to improve the outcome of the transplanted organ. For each specific intervention, the potential to optimize the organ quality, and thereby facilitate the patient's wish to be a donor, should be balanced against the potential for harm and distress in that patient (and also his next of kin).

Recommendation 8:

Interventions in the donor that are carried out (or continued) after the death of the patient has been declared should be applied in such a way that the determination of death is not compromised in any way.

Family communication and guidance

Good communication with and guidance of the family throughout the end-of-life care and donation procedure is of utmost importance for their acceptance of donation and bereavement care [8]. Following the wishes of the next of kin is of paramount importance for a good outcome of a DCD procedure and this may have a bearing on the way the procedure is arranged and implemented. These considerations lead to the following recommendations:

Recommendation 9:

The option of organ donation should not be discussed with the next of kin before the decision to withdraw or

limit treatment or cease CPR has been made, and the family has been informed and consulted on this issue. Consent from the next-of-kin should be sought after efforts have been made to establish the own will of the patient. If the family objects to donation, or if donation is abandoned in case of a contra-indication, the family should still receive full support and bereavement care.

Recommendation 10:

Communication with the family should preferably be the responsibility of a single designated liaison (member of treatment staff or trained nurse) throughout the DCD procedure. At an early stage in the donation process, this communication should address any particular religious observances that need to be fulfilled or cultural traditions to be taken into account during the dying phase and period following the death of the patient.

Allocation of DCD organs

The allocation of retrieved DCD organs should follow the current national allocation system, taking into account the characteristics of both the donor and the potential recipient, and the potential for a good outcome of the transplant, as well as equity of access. DCD organs can also be offered for cross-border exchange, between countries where DCD is accepted. These considerations lead to the following recommendation:

Recommendation 11:

At the time of being waitlisted, potential recipients of DCD organs should be informed about the possibility of receiving and accepting such an organ. Allocation of DCD organs should be based on the agreed national allocation policy.

General policy for implementing DCD

When considering starting a DCD program, hospitals should make efforts to inform the general public and other stakeholders involved, by setting up and implementing an outreach education program [9,10]. This does not need to be done by the hospital itself and could be undertaken by the transplantation organization, such as Eurotransplant or NHS Blood and Trans-

plant. This should focus on preparing all parties for the occurrence of DCD, and growing and maintaining trust and confidence. This leads to the following recommendation.

Recommendation 12:

There is a need for information, education, and guidance to the general public, as well as stakeholders involved, on the issue of DCD.

Funding

The authors have declared no funding.

Conflicts of interest

The authors declare no conflict of interest.

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