Original article

Donation after circulatory determination of death: What information to whom?

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Abstract

Donation after circulatory determination of death (DCDD), developed in several countries as a means to increase the organ pool, includes controlled DCDD, i.e., after a withdrawal of life-sustaining therapy, and uncontrolled DCDD, i.e., after an unexpected cardiac arrest. Controlled and uncontrolled DCDD protocols differ substantially from donation after brain determination of death (DBDD) protocols and raise several ethical issues. However, the public has often not been well informed about these differences.

In this paper, we analyze what information on DCDD is necessary to provide to permit first-person consent to organ donation, surrogate consent to organ donation and recipient consent to DCDD organs reception. This information should include relevant steps of DCDD protocols, and disclosure around main ethical controversies. Pre-mortem procedures require a specific informed consent. Furthermore, the development of advance directives, national registry, or donor cards that specifically separate information and consent of DBDD and DCDD would be welcome. Recipients have to be given the opportunity to refuse an organ from DCDD if there exists a risk of inferior outcome.

We are confident that transparency will lead to greater respect for ethical standards, will enhance public trust in transplantation, and as a consequence, will increase the organ donation rate.

Key words: transplantation, ethics, controlled and uncontrolled donation after circulatory determination of death (DCDD), information, advance directives, informed consent.

Abbreviations: controlled and uncontrolled donation after circulatory determination of death (DCDD); cardio-pulmonary resuscitation (CPR); intensive care unit (ICU); withdrawal of life-sustaining therapy (W-LST); life-sustaining therapy (LST); extracorporeal membrane oxygenation (ECMO); operating room (OR); the dead donor rule (DDR); donation after brain determination of death (DBDD); extracorporeal-CPR (E-CPR).

I Introduction

In opt-in countries, consent to deceased organ donation is obligatory and happens at two levels: 1) The *first-person consent to organ donation (or first-person consent)*, where the person herself/himself consents to organ donation while still alive, either by registering in a national registry for organ donation, by registering through the driving license, by signing an organ donor card, by writing advance directives or by simply telling family members of his/her wish to donate; 2) The *surrogate consent to organ donation (or surrogate consent)*, which is done by the next-of-kin once the patient is dead or nearly dead. Ideally, the surrogate consent should be on behalf of the donor, i.e., it should represent, as for any medical surrogate consents, the patient's wishes and best interest. In practice, the surrogate consent may be based instead on what the family wants.

Informed consent is the person's authorization of diagnostic and therapeutic procedures [1, 2], based on 1) sufficient and comprehensible information ([3], 2) the patient's competence to make a decision [4], and 3) a voluntary and free choice, with the absence of manipulation or coercion [5].

This paper will analyze what information is necessary to provide in order to permit first-person and surrogate consent to donation after circulatory determination of death (DCDD), as well as recipient consent to DCDD organs reception.

DCDD programs have been developed in several countries as a means to increase the organ pool for transplantation, in addition to donation after brain determination of death (DBDD), living donation and the use of expanded criteria donors, i.e., the use of less optimal donors, such as those with comorbidities. Uncontrolled DCDD, which is also termed Maastricht category II [6], concerns patients sustaining a sudden refractory cardiac arrest [7, 8]. Controlled DCDD, also known as Maastricht category III [6], concerns donation after withdrawal of life-sustaining therapy (W-LST), once health professionals and family members have agreed that there was no further benefit to continue life-sustaining therapy (LST) [9, 10].

DCDD protocols differ substantially from DBDD protocols, have generally inferior future graft outcome compared with DBDD [9], and raise many ethical issues. However, several of these elements of DCDD are often not disclosed to the general public, influencing *first-person consent to organ donation*, to the concerned families, influencing *the surrogate consent to organ donation*, or to the recipients, influencing their *willingness to receive such DCDD organs*.

We propose here some suggestions to improve the information provided to people regarding DCDD in order to permit an informed choice.

II What should be disclosed?

II.1 The relevant elements and steps of DCDD protocols

To permit an informed choice, necessary information has to be given, such as the circumstances and relevant steps of DCDD programs, and the key differences from DBDD programs. Such information will be the foundation of the information concerning the ethical issues raised by DCDD programs (see point II.3), with understanding of the latter issues depending on knowledge of the practical aspects.

Uncontrolled DCDD protocols

As uncontrolled DCDD programs have mainly been developed in France and Spain, the elements and steps described here are based on French [7, 11] and Spanish [8, 12] uncontrolled DCDD protocols. The information regarding uncontrolled DCDD programs may include the following:

Uncontrolled DCDD programs concern unexpected cardiac arrest, usually in the out-of-hospital setting, when all efforts of cardio-pulmonary resuscitation (CPR) have failed. If the patient is then included in an uncontrolled DCDD protocol, CPR maneuvers will be continued (or resumed) in order to maintain some organ perfusion for future donation. Once at the DCDD center, death will be declared, if the cessation of circulatory and respiratory functions (sometimes also of brain functions) is confirmed after a no touch period (defined as the time between the termination of CPR efforts and the declaration of death), which varies among uDCDD protocols between 5 and 10 minutes. After the declaration of death, organ preserving maneuvers such as extracorporeal membrane oxygenation (ECMO) [7] or cold renal perfusion [12] will be introduced. Information concerning ECMO may include what it is (an extracorporeal device that oxygenates and decarbonates the blood), why it is used (i.e., to preserve organs for future organ donation), how it will be implemented (by the insertion of large catheter in vessels), and its associated risks. Finally, once consent to organ donation is confirmed, organs will be procured.

Controlled DCDD protocols

Controlled DCDD programs have been developed in several countries, including the US, the UK, and Australia. The elements of information here described are based on several DCDD protocols [9, 10, 13]. Controlled DCDD protocols concern patients in severe clinical conditions, whose life is sustained by LST. If there is no more benefit to continue LST, W-LST may be decided conjointly by family and health professionals. The process of W-LST may be explained, particularly the differences with standard W-LST (i.e., outside the context of organ donation) and their reasons [14]. For instance, many controlled DCDD programs perform W-LST in the operating room (OR), while the standard of care is to withdraw LST in the intensive care unit. Once LST has been withdrawn, cardio-circulatory functions will gradually decrease, before finally ceasing. If this takes too long, DCDD may not be possible. When circulatory functions cease, death is declared after a stand-off period (i.e., the time between the cessation of circulatory function and the determination of death) varying between 75 seconds and 20 minutes. After the determination of death, if organ-preserving maneuvers are used (such as ECMO), information may include what it is, why it will be used, how it will be implemented, and its associated risks (see previously).

II.2 Inferior future graft outcome

DCDD has generally inferior outcomes compared with DBDD [9]. Studies on kidney DCDD reveal that long-term patients' survival and graft function are similar to kidney DBDD, but have an increased rate of kidney-delayed graft function [15, 16]. Studies on liver DCDD reveal a decreased rate of patient and graft survival, with more biliary complication, graft dysfunction and ischemic cholangiopathy, compared with DBDD [16, 17]. Studies on lung DCDD reveal comparable patient survival [4, 16], some studies having shown a tendency of higher rates of bronchiolitis obliterans syndrome [18]. The evidence regarding heart DCDD remains anecdotal [19]. Furthermore, studies with bad outcomes may not have been published.

Such information regarding the outcome of DCDD programs may be disclosed as it might influence first person consent and surrogate consent to organ donation, as well as the recipient's consent to organ reception. From the perspective of the recipient, it may be argued that an inferior organ is better than no organ at all. However, as for any other medical procedures, information regarding outcomes, risks of complications and the outcomes of existing alternatives (living donation depending of the organs, or DBDD) has to be provided to recipients, in order to permit them to make an informed decision.

Furthermore, it is up to the donor (or surrogate) to choose whether they want to donate organs that might be of sub-optimal quality. Thus such information may be relevant, because some persons may refuse to become organ donors if they judge that the burdens imposed on them are not outweighed by the benefits for future recipients.

II.3 The ethical issues raised by DCDD programs

DCDD programs raise major ethical controversies that we summarize here below. It may be necessary to disclose some of these issues to lay persons, in order to help them to make an enlightened and informed choice about organ donation. However, this might be difficult to achieve in practice.

Uncontrolled DCDD

One of the major concerns of uncontrolled DCDD programs is the risk of conflict of interest that exists in

case of unexpected cardiac arrest while choosing between the pursuit of resuscitation maneuvers, including the use of lifesaving procedures such as extracorporeal-CPR (E-CPR) [20], or uncontrolled DCDD programs. Because the inclusion criteria for extracorporeal-CPR and uncontrolled DCDD protocols are very similar, there is a risk of wrongly including a saveable patient into an uncontrolled DCDD protocol, converting him/her into an organ donor, instead of having included him/her into an E-CPR protocol in order to try to save his/her life [20]. As such a risk is not just theoretical [21], it might be thus advocated that the risk of being prematurely included in an uncontrolled DCDD protocol should be disclosed to the public. Indeed, doing so would give everyone the possibility to refuse to consent specifically to uncontrolled DCDD, if they judge that they do not want to take such a risk. However, there are risks of conflicts of interest in many areas of medicine, and the fact that a few isolated cases have been identified does not in itself mean that the risk of conflict of interest should be disclosed. Only if there were evidence of widespread instances of conflict of interest, would disclosure to the public, surrogates and families be routinely necessary.

Another ethical issue raised by uncontrolled DCDD programs concerns the principle of autonomy. Indeed, CPR and ECMO (or cold renal perfusion) are usually performed before any consent to organ donation has been obtained [22]. Such procedures permit preservation of organs for transplantation purposes, until consent to organ donation has been confirmed or obtained by the family. Without the use of organ-preserving maneuvers (CPR, ECMO), uncontrolled DCDD programs may not be possible, potential organ donors may be lost, and patients' wish to donate may not be respected. The benefits that the use of organ-preserving maneuvers offer, have to be balanced with the potential harm of using such maneuvers without knowing whether the person consented to organ donation. In opt-out countries, such as France and Spain, the implementation of ECMO or the pursuit of CPR in DCDD programs occur before having obtained surrogate consent to organ donation, without legal issues, as anyone is considered an organ donor unless having opted out. In the US, the pilot study on uncontrolled DCDD that took place in NYC failed to recruit any patients because of such consent issues [23].

Controlled DCDD programs

Controlled DCDD programs raise several ethical issues, some of which may be necessary to be disclosed to the public.

First, when controlled DCDD protocols involve pre-mortem procedures [24], such as cannulation or/and the injection of heparin or phentolamine, this requires a specific informed consent because these are more than minimally invasive procedures performed on a living patient [14].

Second, as discussed in a previous paper, controlled DCDD programs present risks of conflict of interests in the W-LST decision and process [14]. In the W-LST decision, the risk is that therapy will be withdrawn not because the continuation of LST presents no benefit, but because of organ donation purposes. In the W-LST process, there is a risk of hastening death in order to favor future graft function outcome. Though these risks exist, they are usually acknowledged by health professionals, and proper procedures are in place to minimize such risks of conflict of interest. We think that there is no need to disclose these risks, as disclosing them to potential donors and their families when there is little risk of this occurring would be tantamount to scaremongering.

Controlled and uncontrolled DCDD programs

The main ethical issue raised by DCDD programs is the concern that the donor might not be dead when organs are procured and thus that the dead donor rule (DDR) might not be respected [20–27]. The DDR states that no one should be killed by organ procurement.

There has been substantial debate concerning the fact that DCDD programs may not respect the DDR, and the issue is still not resolved. Some authors acknowledge that DCDD programs do not respect the DDR and propose abandoning the DDR [28], while others called for a moratorium on DCDD [29]. The main argument concerning the fact that the DDR may not be respected in DCDD programs states that a stand-off period as short as 5 to 10 minutes (or even 20 minutes in the Italian DCDD programs) is not enough to reach a state of irreversible death, whatever criteria of death are used to determine death (circulatory or brain death criteria) [30–32]. The word *irreversible* implies that no technology or action can restore heart, circulatory or brain function [30]. First, the simple possibility of heart donation in DCDD programs [19] invalidates a determination of death based on the irreversible cessation of heart function [30]. Second, the possibility of restoring circulation after death by the use of ECMO, as foreseen in some DCDD programs [33], invalidates a determination of death based on the circulatory criteria [32]. Third, as stated in a previous paper [31]:

"Studies on the outcomes of out-of-hospital cardiac arrest patients suggest that some neurons in the human brain may survive a deprivation of circulation of at least 20 minutes and animal studies suggest that some brain functions may be restored after a deprivation of circulation of 30 to 50 minutes. Therefore, DCDD donors at the time they are declared dead do not satisfy the irreversibility requirement of brain death."

Because DCDD donors are not irreversibly dead, as just discussed, James Bernat has proposed the adoption of "permanent" rather than "irreversible" in the definition of death; thus respecting the DDR in the context of DCDD. The main justification for this is that in practice, outside the context of organ donation, death is often

determined before a state of irreversible death and thus during a state of permanent death [34]. Permanent death means that death cannot be reversed spontaneously (the possibility of auto-resuscitation has vanished), but can be reversed by some actions or techniques, which will not be used because doing so would be futile and/or not in the patient's best interests.

The public could be transparently informed that, in the context of DCDD, death is declared before a state of irreversibility and thus is a state of permanency. Indeed, it may be important to provide such information, as usually lay people associate deceased organ donation with the concept of irreversible death. However, the concept of brain death in the context of DBDD is often misunderstood, so it is not clear how the concept of permanency in the context of DCDD will be understood by the population. Overall, it may be disproportionate to disclose controversies around the DDR.

Another ethical issue concerns the use of ECMO after the declaration of death, as foreseen in some DCDD programs [33]. As discussed in another paper, the use of ECMO raises particular ethical issues, such as the interference with end-of-life care, the damage of bodily integrity, and the risk of "invalidating the preceding declaration of death" [32]. In our opinion, these ethical issues have to be disclosed if the use of ECMO is foreseen.

III To whom information should be disclosed

In order to permit first person and surrogate consent to DCDD organ donation, as well as recipient consent to DCDD reception, information has to be provided at different levels: 1) public information by media, 2) information given when signing the donor card, advanced directives, in a national registry, 3) when discussion with the next-of-kin to obtain the surrogate consent to organ donation, and 4) when discussion with future recipients to obtain their consent to DCDD reception.

III.1 Public information via media

The provision of public information on DCDD programs has been relatively sparse in countries with such programs, which remains problematic.

Transplantation potentially concerns any of us. In order to permit each citizen to make an informed choice regarding either consent for future organ donation or reception, comprehensive and transparent public information is necessary. Via TV, radio, newspapers, leaflets in hospitals and the Internet, this information should explain the differences in procedure between DBDD, uncontrolled DCDD, and controlled DCDD (inasmuch as these mediums allow such complex information to be conveyed accurately).

We think that respect for transparency will oblige DCDD programs to meet better ethical standards and as a consequence will increase public trust in transplantation in general.

We thus recommend improving public information on both DCDD and DBDD, and to ensure that future donors have understood the option to indicate whether they are happy with both types of donation, or only one of them.

III.2 Advance directives – national registry – donor cards

As stated by Childress et al., "The most ethically appropriate manner to obtain consent for organ donation is directly from the individual" [13]. Thus, in order to enable first-person consent to DCDD, the information has to be improved at this level, i.e., when the persons will sign in organ donation registries, driving licenses, organ donor cards, or advance directives.

Making decisions about organ donation in advance and communicating them to our families and friends enables reflection before any period of crisis [13]. It also discharges next-of-kin from the responsibility of making a decision regarding what a deceased relative would have wanted, and decreases the risk that families will overrule a deceased patient's registered intention to donate [35]. Whatever type of advance directive is chosen, whether simply registering for an organ donor card or creating a personalized organ donation directive (PODD) [36], the point at which the directive is created offers a good opportunity to inform citizens adequately and accurately about DBDD and DCDD. The option to consent only to DBDD or to DCDD, while opting out from DBDD or DCDD should be offered clearly to each citizen, as a general consent for organ donation (as it is mostly the case) does not offer this option, and can have a counterproductive effect if consent mechanisms are not sufficiently sensitive. This proposal could be accommodated in countries operating a presumed consent system by informing citizens that they have the option of refusing both DCDD and DBDD.

In Zürich, the Interdisciplinary Health Institute for Ethics (Dialog Ethik) has published an online advance directive form that includes, among other things, a separate consent for DBDD and DCDD [37] that could be followed as example. Specifically it states:

- *For DBDD:* "In the state of irreversible brain death, I would like to donate the following organs, tissues and cells." "This consent includes all medical measures to preserve the function of affected organs such as: continuation of initiated therapy despite terminal prognosis, administration of medication to maintain cardiovascular function."
- *For DCDD:* "In the case of death from cardiac arrest after unsuccessful resuscitation or after the decision of the treatment team to end-life-sustaining measures as futile, I would like to donate the following organs, tissues and cells." "This consent includes all medical measures to preserve the function of affected organs such as: blood tests and other examinations, drug injections, heart massage, probe

insertion to keep organs cooled and supplied with oxygen, and similar."

Again, as for public health disclosure, during the completion of advance directives, individuals should be informed of the differences between DBDD and DCDD protocols, in order to be able to give informed consent. Indeed, an informed consent is valid only if individuals are transparently informed of the incurred risks.

III.3 Information to surrogates

If there is no evidence of first-person consent, health professionals will seek surrogate consent to organ donation. This time, the information will be provided directly from health professionals to family members. The elements discussed under the point II should be discussed carefully, in order that the family understands the relevant steps of the foreseen procedures.
As previously mentioned, the discussion about DCDD with the family should in most cases be limited to discussion of the practicalities and technical measures involved. Although disclosing the aforementioned ethical issues would increase transparency, this may be counterproductive for several reasons. First, the risks of conflict of interest and of patients not being dead are very small, and perhaps non-existent, depending on the context. Second, ethical issues may be difficult to understand, and their disclosure may bring a risk of misunderstanding. Third, a discussion around the ethical issues previously mentioned may increase the refusal rate to organ donation. And fourth, it may induce family mistrust toward the health professionals that took care of their relative, and toward the medical community.

III.4 Information to recipients

Information regarding an inferior graft outcome
In France [7], the UK [10] and the US [13], informed consent is required from recipients concerning the risks and benefits of receiving a DCDD organ. In the UK [10], it is specifically mentioned that receivers are offered the possibility to refuse such organs, while in the Netherlands this possibility is denied [38].
Receivers should be honestly informed of any risks and benefits related to DCDD. They should be given a completely free choice to refuse organs from DCDD, with the conditions that they have understood the risks involved in doing so and are willing to stay on the waiting list. Furthermore, any refusal should not be "punished" by a displacement on the waiting list and health professionals should be extremely careful to respect the choice of the patient, not to influence his/her choice because of conflict of interest, and not to discriminate against them because of refusal. Because the "next" patient on the waiting list will normally be offered an organ when the first in line rejects it due to concerns about graft outcomes following DCDD, organs will not usually be wasted by such refusals.

Information regarding the ethical issues surrounding DCDD
We think that recipients should be honestly informed about ethical issues raised by DCDD in order to allow them to provide informed consent. Indeed, organ donors exist because of the need of others. Furthermore, many receivers do not see transplantation as a right but more as a gift and they are often concerned about how the organ donors are managed.
Recipients share a moral responsibility regarding how donors are managed and deserve the right to be informed and to consent. We quite understand that ethical issues surrounding donors' management might not seem relevant to recipients. However, they have a right to make an informed choice.

IV Conclusion

DCDD is substantially different from DBDD and living donation, may have inferior future graft outcomes (depending of the organs) and raises ethical issues. Therefore, we think that transparent and comprehensive information should be provided to the public, to the next-of-kin and to recipients.
Ad minima, first, DCDD procedures should be explained, particularly in the way they differ from DBDD procedures. Second, the eventual inferior graft outcome should be disclosed (particularly to recipients). Third, if ECMO is used, the associated risks should be disclosed (interference with end-of-life care, damage of bodily integrity and risk of patient revival).
Fourth, pre-mortem procedures require a specific informed consent because they are performed on a living patient for the benefit of future graft function.
Furthermore, the development of advance directives, national registry, or donor cards that specifically separate information and consent of DBDD and DCDD is welcomed and offers a good opportunity to inform citizens adequately and accurately about DBDD and DCDD, as well as an opportunity to consent only to uncontrolled or controlled DCDD.
Recipients have to be given the opportunity to refuse an organ from DCDD if there exists a risk of inferior outcome, as this could have serious consequences for them.
DCDD, whether uncontrolled or controlled, raises ethical issues that cannot be ignored and that certainly cannot continue to be hidden from prospective organ donors. We are confident that transparency will lead to greater respect for ethical standards, will enhance public trust in transplantation, and as a consequence, will increase the organ donation rate.

Conflict of interest: None to declare.

Zusammenfassung

Die Organspende nach Herz-Kreislauf-Stillstand (DCDD), die sich in mehreren Ländern zur Erhöhung der Anzahl von Organen etablierte, schliesst sowohl die kontrollierte DCDD (nach Abbruch der lebenserhaltenden Massnahmen) als auch die unkontrollierte DCDD (nach unerwartetem Herzstillstand) ein. Kontrollierte und unkontrollierte DCDD-Protokolle unterscheiden sich wesentlich von der Spende nach Hirntod und werfen verschiedene ethische Fragen auf. Die Bevölkerung ist oft nicht gut genug informiert.

In diesem Beitrag analysieren wir, welche Informationen über DCDD erforderlich sind, damit der Spender oder sein Vertreter der Organentnahme sowie der Empfänger der Transplantation zustimmen können. Die Aufklärung sollte den Ablauf gemäss DCDD-Protokoll sowie die zentralen ethischen Aspekte beinhalten. Vorbereitende Massnahmen, die im Hinblick auf eine Organentnahme durchgeführt werden, setzen zudem eine spezifische Zustimmung voraus. Der Beitrag widmet sich deshalb auch der Entwicklung von Patientenverfügungen, nationalen Registern und Spendekarten; die Trennung zwischen Aufklärung und Einwilligung bei DBDD und DCDD wird befürwortet. Die Empfänger sollten die Möglichkeit haben, ein Organ nach DCDD zu verweigern, wenn die Gefahr besteht, dass deshalb die Erfolgsaussichten der Transplantation geringer sind.

Wir sind überzeugt, dass eine solche Transparenz zu einer verbesserten Einhaltung der ethischen Standards führt, das Vertrauen der Öffentlichkeit in die Transplantationsmedizin und letztlich die Spendebereitschaft erhöht.

Résumé

Le don d'organes après la détermination de la mort circulatoire (DCDD) a été développé dans plusieurs pays afin d'augmenter le pool d'organes. Il comprend le DCDD contrôlé, i.e. après un retrait de mesures thérapeutiques, et le DCDDD non contrôlé, i.e. après un arrêt cardiaque réfractaire. Les protocoles DCDD contrôlés et non contrôlés diffèrent du don après mort cérébrale et soulèvent plusieurs enjeux éthiques. Cependant, le public n'en a été généralement que peu ou pas informé.

Dans ce papier, nous analysons quelle information sur le DCDD est nécessaire pour permettre le consentement de la personne elle-même ou de son représentant au don d'organes et le consentement du receveur à la transplantation. Cette information devrait inclure les différentes étapes des protocoles DCDD et la description des enjeux éthiques principaux. Les procédures ayant lieu avant le décès requièrent un consentement informé spécifique. De plus, le développement de directives anticipées, d'un registre national ou de cartes de donneur, qui sépareraient spécifiquement l'information et le consentement du DCDD et du don après mort cérébrale, serait bienvenu. Les receveurs devraient avoir la possibilité de refuser un organe issu de DCDD s'il était avéré qu'il y ait un risque d'un moins bon pronostic.

Une stratégie d'information transparente concernant les DCDD, par son respect de standards éthiques, pourrait augmenter la confiance du public et éventuellement avoir un impact positif sur le taux de dons d'organes.

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