Donation after uncontrolled Cardiac Death (uDCD): A review of the debate from a European perspective

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In the early days of organ transplantation from deceased donors (mid-1950's), the surgical team would bring the donor into the operating room with the recipient, the respirator would be stopped and the team would wait for the donor's heart to cease beating. This type of organ donation has been defined as donation after cardiac death (DCD), also referred to as non-heart-beating donation (NHBD). These donors were not declared dead using neurological criteria, but rather using conventional cardiorespiratory criteria. In 1959, Molaret and Goulon coined the term "coma dépassé" (beyond coma) for the patients with an irreversible state of coma and apnea.¹ Jean Morelle and Guy Alexandre of the Catholic University of Louvain, Belgium, were the first to introduce a set of brain death criteria based on the description of coma dépassé, and carried out, in 1963, the first transplants from a brain dead donor in their country and in the world.² Although heavily criticized at that time by other transplant pioneers such as Sir Roy Calne and Thomas Starzl³, organ donation from donors pronounced dead by neurological criteria (also referred to as 'heart-beating donation') has become the gold standard and main source of organs for transplantation since. In these cases, organs are removed from patients in whom irreversible cessation of all brain and brainstem function has occurred. Whereas cardiocirculatory functions remain supported by mechanical ventilation, death is diagnosed based on neurological criteria in this category of potential donors.

However, transplantation has become the victim of its own success and the number of potential brain dead donors seems to be insufficient to answer the growing demand for organs. As a result, interest in DCD has grown, beginning in the mid 1990s and steadily increasing over the years.

This article will review some of the medical and ethical issues surrounding the procurement of so-called "uncontrolled" DCD (uDCD organs), with an emphasis on the European situation. Inevitably, and in the context of DCD, this review will address the system of presumed consent for organ donation that is in use in most European countries. This article will also discuss the recent position of the Institute of Medicine

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Table 1

Maastricht Categories for Non-Heart-Beating Donors

Category I	Dead on arrival
Category II	Failed resuscitation following cardiac arrest
Category III	Withdrawal of life support from a ventilator-dependent patient
Category IV	Unexpected cardiac arrest following brain death

on uDCD organs and argue that it should have gone further in pursuing a presumed consent system.

Classification of DCD

In 1995, during the First International Workshop on Non-heart-beating Donation hosted by Gauke Kootstra in Maastricht, four categories of DCD were defined as the ‘Maastricht categories’⁴ to distinguish between several types of DCD (Table 1). Category I, II, and IV are patients in whom cardiac death occurs suddenly. Because in these cases the cardiopulmonary functions cease spontaneously this is called “uncontrolled.” Subjects in category III are considered “controlled donors” because the potential donor is identified after a decision has been made to withdraw life-sustaining therapy, usually in an intensive care unit environment. In this context, the patient is withdrawn from life support because of a terminal illness and the medical futility of further medical therapy, and organs are procured after death is diagnosed based on cardiopulmonary criteria.

Controlled vs. Uncontrolled DCD

Since the mid 1990s, several transplant centers in Europe have started expanding their donor pools by including DCD donors. While initially most European centres predominantly relied on uDCD donors, significantly more controlled than uncontrolled DCD procedures have occurred in recent years.⁵ Organ donation in Japan has relied almost exclusively on DCD of the controlled

type.⁶ In the United States, the practice of DCD has been steadily increasing and constituted of 5.5% of all deceased donors in 2004 and 7.4% in 2005.⁷ This group is mainly composed of controlled DCD donors: only in exceptional cases are organs procured from

Figure 1

Overview of DCD donation rates per million in 7 European Countries with a DCD program

Data collected by the Council of Europe Expert Committee on Transplantation- 2006

uDCD donors.⁸

Of all the European countries with active DCD programs, Spain has by far the largest experience with uDCD. For example, more than 70% of Madrid's Hospital Clinico San Carlos' current donation population are type I or II (uncontrolled) donors. From 1989 until

Table 2

DCD Organ Donation (2002-2006), based on Eurotransplant Annual Reports 2002-2006

	2002	2003	2004	2005	2006
Belgium	3	14	5	9	34
Category I	1 (33%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Category II	1 (33%)	1 (7%)	0 (0%)	3 (33%)	3 (9%)
Category III	1 (33%)	11 (79%)	5 (100%)	5 (55%)	30 (88%)
Category IV	0 (0%)	2 (14%)	0 (0%)	1 (11%)	1 (3%)
The Netherlands	65	110	129	112	116
Category I	2 (3%)	2 (1%)	2 (1%)	0 (0%)	0 (0%)
Category II	6 (9%)	15 (14%)	21 (16%)	15 (13%)	11 (9%)
Category III	57 (88%)	94 (85%)	106 (82%)	95 (85%)	105 (90%)
Category IV	0 (0%)	0 (0%)	1 (1%)	2 (2%)	1 (1%)

2006, this center transplanted 342 DCD kidneys: 273 (79.8%) of the type I variety, and 47 (13.7%) of the type II uncontrolled donors.⁹

Table 2 provides an overview of DCD organ donation in Belgium and the Netherlands for the period of 2002-2006. This overview shows that in Belgium (where individuals opt-out of organ donation) and the Netherlands (where individuals opt-in to organ donation) most cases of DCD are type III. Nevertheless, although limited, the practice of uDCD is done throughout Europe. In these cases, organs are perfused using a double-balloon-triple-lumen catheter placed in the aorta or using a cardiopulmonary bypass. These procedures occur during the period when the legal requirements for organ donation are being taken care of, including a family interview.¹⁰ Currently, preservation strategies have been developed to reduce the warm ischemia time, including situ organ flushing and cooling immediately following uncontrolled death while waiting for formal consent.¹¹

professionals that are responsible for making decisions regarding discontinuation of cardiopulmonary resuscitation should be completely distinct from the healthcare professionals responsible for the assessment of the patient as a potential donor and responsible for approaching families.¹³ It is crucial that both decisions are made independently from each other. This separation in roles is extremely important in ensuring that the care of the patient is not compromised by conflicting roles. Secondly, to ensure a separation between the resuscitation and the transplant teams, it is reported that a "hands-off" period should be observed.¹⁴ Thirdly, decisions to discontinue resuscitation should be in accordance with international guidelines regarding that topic (e.g., standards of the European Resuscitation Council). Hereby, the issue of medical futility will be relevant. Fourthly, transplant centers that proceed with uDCD should only do so after the elaboration of a protocol.

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Resuscitation

In uncontrolled settings, an issue at stake is at what moment resuscitative efforts should be discontinued. The recent report by the Institute of Medicine¹² summarized some recommendations that are commonly found in active protocols in Europe. Firstly, it was underscored that in this context the healthcare pro-

Postmortem Interventions

The performance of postmortem interventions on the recently dead without consent has often been rejected.¹⁵ It has been argued that preservation techniques themselves are invasive procedures, and that consent should be obtained before initiating them.¹⁵ In situations where an individual has signed a donor card or joined a donor registry, the intention and con-

Figure 2

The relation between the legal system and donor rates

sent of the individual to donate his organs is documented. Therefore, the procedures needed to preserve his organs are clearly acceptable. But, can we say the same when the individual did not express his or her wishes or when this is (still) unknown? In the situations of controlled DCD, potential donors have been maintained on artificial ventilation, allowing time to contact families and obtain their permission. However, in the case of uDCD, potential donors are not maintained on artificial ventilation and families are not always available. Interestingly, the Institute of Medi-

vation interventions are a component of proper medical practice.”¹⁶ In its report, the Institute of Medicine underlines that there is some evidence that the use of preservation techniques enhances rather than limits autonomy. Indeed, the possibility of organ donation would be completely lost if the use of preservation techniques was not initiated when the wishes of the patient are unknown.¹⁷ In addition, the Institute of Medicine reaffirms that this is not in opposition with an opt-in system of consent for donation.

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cine regards “the use of preservation techniques while families are contacted — for the purpose of preserving the family’s opportunity to make their own informed decision regarding donation — to be ethically acceptable in principle. In cases in which the family will be making the decision regarding donation, organ preser-

Legislation Concerning DCD

The legislation regarding DCD differs greatly throughout Europe. In some countries (e.g., the Netherlands¹⁸ and the United Kingdom¹⁹), DCD donation is encouraged by the government and laws have been passed that allow invasive procedures of potential DCD

Figure 3

Ranking of countries according to their refusal rates towards organ donation

donors to preserve organs before consent has been sought from the relatives. Conversely, German law forbids the procurement of organs from deceased donors that have not been formally declared brain dead.²⁰ As a consequence, this essentially rules out the option for DCD of any kind.²¹

as head traumas from traffic accidents and cerebrovascular diseases have been considered important determinants of organ donation rates.²³

For many years, there has been debate over whether legislative systems have an impact on the rate of deceased donor organ donation. Two main systems are in place, with several adaptations in various coun-

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Between Opting In or Opting Out

Numerous factors have been hypothesized to affect the variability between hospitals, regions and countries with regard to their deceased donor rates. Among those the level of wealth expressed as per capita income, public health expenditures, religious beliefs, the level of public and medical education have been described as factors which influence positively cadaveric organ donation rates.²² In addition, between-country variability in mortality rates of eligible death causes such

tries. On the one hand, some countries have chosen an opting-in system. This is based on the assumption that the donor should be able to express his explicit consent for organ donation. This is generally achieved by inviting the public to complete donor cards or register their intentions in a donor registry. On the other hand, some countries have chosen an opting-out system. This system is based on the assumption that all persons are potential donors, unless they have expressed their explicit objection during life.-

A Council of Europe Recommendation²⁴ dating from 1978 has been instrumental in paving the way for almost all EU Member States to enact an opting-out system.²⁵ Only four of them (Germany, The Netherlands, the United Kingdom and Denmark) have chosen an explicit consent system. Various adaptations have also been made with regard to the level of decisional authority of the family members. In the opting-out model in France, for example, family members have the right to consent or refuse post mortem organ removal.²⁶ However, the opting-in systems currently in use are not pure opting-in systems because this would require rejecting any involvement of family members regarding organ donation. For instance, in Germany, when the potential donor has not made a decision, the next of kin may consent to post mortem removal, and this is in accordance with the presumed consent of the deceased person.²⁷ In the Netherlands and the United Kingdom, the next of kin may provide consent if the

When ranking countries according to their refusal rates towards organ donation (Fig. 3), a clear relationship can be demonstrated between countries' legal system and the percentage of objections against donation. Data were compiled from Council of Europe statistics³⁵ the Donor Action Database,³⁶ and AOPO data.³⁷

Despite compelling evidence of the opposite, several authors have questioned whether systems of opting-out do ensure higher rates of donation compared to opting-in systems. Some have argued that:

the effect of presumed consent is hard to evaluate as it is implemented in different ways in different contexts, with different results. More organs may be available for transplantation because of the number of intensive care beds, transplant surgeons, coordinators, and specialized units or because of which organs are needed and the predominant cause of death.³⁸

The Institute of Medicine should consider moving one step further and introducing an overall system of opting out for organ donation. Presumed consent alone will of course not solve the organ shortage, but it will create an ethical and legal context that supports organ donation, respects individuals who object to organ donation, relieves families from the burden of decision making, and can save lives.

deceased did not do so.²⁸ Moreover, in the opt-out system, even when organ removal can be carried out by law without the consent of the family, transplant coordinators in charge of the donation process will always inform the family and proceed only when the family does not object.²⁹

There is good evidence of opting-out systems improving organ supplies.³⁰ National reports from Belgium³¹ and Austria,³² two countries which have passed presumed-consent legislation, for example, showed a spectacular increase in the number of organ donors after the introduction of these laws.³³ A good example of the impact of this type of legislation is illustrated in Fig. 2. Of the four largest Eurotransplant countries (Austria, Belgium, Germany and the Netherlands), each with a comparable socio-economic status (Gross National Product, health expenditures), Austria and Belgium have a presumed consent law, and Germany and The Netherlands an explicit consent system. It is clear that donation rates and organ availability in the two presumed consent countries are about twice as high compared with the two other countries.³⁴

It is clear that only statistically solid multivariate analyses which takes into account all determinants of donation will be able to put an end to this controversy.

In one such contribution, Abadie et al. covered 22 countries over a 10-year period.³⁹ They conclude that a presumed consent legislation not only "has a positive and sizeable effect" but that "cadaveric donation rates are 25-30% higher on average in presumed consent countries". A survey among individuals from more than 15 different transplant-related medical professionals from 15 different countries concluded that the "single most effective way to increase organ donation was presumed consent."⁴⁰ Seventy-five percent of the respondents in the survey supported presumed consent legislation, and 39% identified this type of legislation as the most effective way to increase donation rates.⁴¹ The study also notes that mandated choice, a less extreme option than presumed consent, would increase awareness of organ donation among the entire population and would likely lead to an increased donation rate.⁴²

uDCD and Opting Out

The recommendation of the Institute of Medicine to accept the use of preservation techniques can be considered an opting out system at the level of organ preservation. As long as the wishes of the potential donor are unknown, preservation techniques are allowed until the family has been consulted and consent sought. Why not go a step further? In addition to the introduction of an opting out system at the level of organ preservation, the U.S. would gain by introducing an opting out system at the level of organ donation. Even if most European countries have presumed consent legislation, it should be clear that "organs or tissues shall not be removed from the body of a deceased person unless consent or authorization required by law has been obtained. The removal shall not be carried out if the deceased person has objected to it."⁴³ As a consequence, the right of the individual to refuse to donate organs is guaranteed and it becomes essential to ensure that simple mechanisms for registering an objection are easily available. In cases where no will has been registered (whether for or against organ donation), the primary role of the relatives becomes to report whether or not the dead person objected to organ donation when he was alive. If the answer is no, organ donation becomes more and more an option, but will not be initiated if this causes severe distress to the relatives. The most opposition to opt-out policies are directed toward opt-out legislation that does not stipulate notification of the family. It should be clear that such policies are also viewed critically in Europe. Families are always contacted and the process of organ donation is discussed with them.

A move to presumed consent is the way forward. It would be (a) good for those who support donation — because they have to make no effort to ensure their wishes are followed; (b) good for those who oppose donation — because their wishes will be formally recorded and must be followed; (c) good for families — because they are relieved of the burden of decision making when they have just been told their relative has died or is dying; (d) good for those who need a transplant — because with more organs available more lives can be saved.⁴⁴

Conclusion

Support for increasing the rates of DCD organ donors in the United States and in Europe is in an effort to expand the donor pool. In its report, the Institute of Medicine regards the practice of preservation techniques in the case of uDCD organ donors while families are contacted to be ethically acceptable. By doing so, the Institute of Medicine introduces an opting out

system at the level of organ preservation. The Institute of Medicine should consider moving one step further and introducing an overall system of opting out for organ donation. Presumed consent alone will of course not solve the organ shortage, but it will create an ethical and legal context that supports organ donation, respects individuals who object to organ donation, relieves families from the burden of decision making, and can save lives.

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