

Not for the Faint of Heart: Organ Donation after Cardiocirculatory Death

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“Know thyself means this, that you get acquainted with what you know, and what you can do”

-Menander

Organ donation is often referred to as the “gift of life,” but a discrepancy exists between the number of organ donors and of individuals needing transplantation. In the U.S., there were 99,111 candidates on the organ waiting list as of June 2008, but only 6,623 transplantations took place between January and March of 2008 (Campbell, 2009, p. 34). Price (2009) suggested that the number on the waiting list is increasing; the number reached 111,000 in August 2009. Registered donors in 2008 amounted to about 3,374, of whom 1,401 were living donors (Campbell, 2009, p. 34). This data indicates that more than half of these donors were deceased. Deceased donors make up a large percentage of the donation pool, and the two standards of death currently followed are the neurological and cardiocirculatory standards of death. However, the cardiocirculatory method of declaring death before organ donation is problematic. Some complications include ambiguity in the definition of death, controversy in the processes used to maintain organ viability before procurement, and the efficiency of the transplantation of these organs. In addition, problems arise with donation if the wishes of the deceased are not known, which is very common. Therefore, the consent system in the United States allows for decisions regarding donation to be put into the hands of the deceased's relatives. This report explores issues with the cardiocirculatory method of determining death before donation and explains various forms of consent systems in order to raise awareness and urge a decision about donation to be made. This way, the “gift of life” does not entail the loss of life for the donor.

In order for donation to take place after death, death must first be defined by medical standards. McGregor, Rady, and Verheijde (2008) explained that the Uniform Determination of Death Act (UDDA) defines two standards of death. One is the “irreversible cessation of

circulatory and respiratory functions” and the second is the “irreversible cessation of all functions of the entire brain, including the brain stem”(p. 305). McGregor et al. (2008) addressed a statement by the President's Commission that stated the neurological standard of death must also be met if the cardiocirculatory standard is used to determine death. Glannon (2005) noted that criteria for death based on the neurological standard was achieved by the Harvard Medical School ad hoc committee in 1968. Before this, death was primarily defined by the end of “cardiopulmonary function,” (p. 120) in which brain function was lost when heart and lung functions were lost.

According to Glannon (2005), the transition of focus to the neurological standard of death was based on the introduction of life-sustaining mechanisms, like the ventilator, that could artificially maintain heart and lung function. According to the Institute of Medicine (1997), those who met the neurological criteria for death and had circulatory functions upheld through a ventilator were “heart beating cadavers” (p. 21). Organs that could be retained from these patients “were viable and more likely to function well immediately and to yield good long term results” (p. 21). The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research stated that “permanent loss of all brain functions should be the main criterion for determining death, because these functions are necessary for the integrated functioning of the organism as a whole” (Glannon, 2005, p. 121). Therefore, the Institute of Medicine and the President's Commission suggest that the heart-beating donor is preferred.

Due to this great advance, previous organ transplantations that focused on donors who met the circulatory standard of death, classified as non-heart-beating donors (NHBD), became much less prominent in the U.S. (IOM, 1997, p. 21). However, the high demand for organ donors led to a protocol issued by the University of Pittsburgh Medical Center (UPMC) in 1992

allowing organ donation after cardiac death (DCD) (McGregor et al., 2008, p. 303). Humar (2009) portrayed this as a method “to successfully boost the number of deceased donors and decrease the dire shortage of transplantable organs” (p. 23).

A person who can be considered a NHBD, and is consistent with DCD protocols, has suffered “irreversible cessation of circulatory and respiratory functions” (IOM, 1997, p. 23). Bernat (2010 b) defined the permanent cessation of circulation as “once it stops, it will neither restart spontaneously-'auto-resuscitate'- nor will it be restarted by medical resuscitation” (p. 3). The Institute of Medicine (1997) lists the following two forms of DCD: controlled and uncontrolled. Controlled DCD involves a patient who has suffered detrimental neurological injury and is supported by a ventilator but is not brain dead according to official standards. With the consent of the patient, or a surrogate decision maker, life support is withdrawn (p. 24). Resuscitative methods are withheld, and the patient undergoes the procurement process upon announcement of death (McGregor et al., 2008, p. 304). In contrast, uncontrolled CDC contains three categories. This includes donors who undergo cardiac arrest before being hospitalized, those who undergo cardiac arrest while hospitalized but fail to be resuscitated, and those who have been declared brain dead before undergoing cardiac arrest (IOM, 1997, p. 25). However, the most common NHBD falls under the controlled DCD category (IOM, 1997, p. 24).

The ambiguity in the definition of death under DCD protocol is emphasized by the different interpretations of cardiocirculatory. Price (2000) noted that there is disagreement whether cardiocirculatory cessation can be regarded as “criteria” used as “indicia of brain death,” where loss of circulation leads to brain death, or if it can be an “independent standard” of death itself (p. 73). Price argued that cardiocirculatory cessation is considered a standard rather than a criterion of death in many jurisdictions such as the U.S. and Denmark. Price's point suggests that

defining cardiocirculatory death as an “independent standard” violates the requirement made by the President's Commission that neurological death must follow cessation of circulation.

Therefore, the authenticity of this standard can be questioned. Furthermore, some inconsistency present in defining cardiocirculatory involves the inter-changeability of cardiac and circulatory to define the cause of death. Veatch (2011) indicated that some protocols announce death based on the irreversibility of cardiac function, although circulatory function may be restored. This is commonly the case with uncontrolled DCD since resuscitative methods may be employed after cardiac arrest. Other protocols determine death based on the irreversibility of circulation, even though cardiac function may be restored (p. 4). Based on this uncertainty, Veatch's point questions the validity of DCD.

Ambiguity is also present in the variation of time constraints used for declaration of death in order to ensure irreversibility of circulatory cessation. This is often considered controversial with respect to the irreversibility guidelines of the UDDA. Joffe (2007) has claimed that in the cardiocirculatory standard of death, “irreversible” is defined as “will not be reversed” (p. 30), specifically in the case of controlled DCD, since the patient consents to have resuscitation withheld. Joffe further argued that since the cessation of circulation is in fact reversible, the person cannot be considered dead. This is supported by evidence that, with resuscitation, circulation that has stopped for longer than ten minutes can be restored (Joffe, 2007, p. 31). In addition, protocols in the U.S. differ regarding the time necessary to declare irreversibility of circulatory cessation after the last heartbeat (IOM, 1997, p. 58). Usually, the “time from the onset of asystole,” or circulatory cessation, to the formal “declaration of death” ranges anywhere from two to five minutes, regardless of any electric activity on the electrocardiogram (Steinbrook, 2007, p. 210). According to the Institute of Medicine (1997), an individual

physician, in accordance with the law, can determine when cessation is irreversible, allowing for great variability between different Organ Procurement Organization (OPO) protocols.

In addition to ambiguity about irreversibility, variation also exists in protocols regarding the amount of time after the last heartbeat necessary to ensure auto-resuscitation is not possible (IOM, 1997, p. 58). For example, the Society of Critical Care Medicine recommends a waiting time of two minutes, while the Institute of Medicine recommends a waiting time of five minutes (Reich et al., 2009, p. 2008). Although patients have requested to withhold resuscitation upon the removal of life support in controlled DCD, auto-resuscitation, or the “spontaneous return of circulation and cerebral perfusion” has been claimed to be possible in the time frame currently practiced in DCD protocol (McGregor et al., 2008, p. 304). McGregor, Rady, and Verheijde (2007) reported that auto-resuscitation in humans can occur after ten minutes of stagnant circulatory and respiratory functions. Joffe (2007) also supported the idea that auto-resuscitation is possible by reporting cases in which it even occurred five to eight minutes following circulatory cessation, including the cessation of circulation to the brain. These points emphasize the uncertainty in determining the possibility of auto-resuscitation in deceased donors.

The controversial processes used to maintain organ viability for procurement also highlight some of the complications with DCD and may raise questions about the authenticity of the patient's death. According to the Institute of Medicine (1997), one of the few agreements between different organ procurement protocols lies in the “discussion of organ donation with families and informed consent” (p. 44). This discussion must only take place after the decision to withdraw life support and with assurance that the physician who announces the time of death after withdrawal cannot be “affiliated in any way with the OPO, procurement team, or transplant team” (p. 44). However, Humar (2009) indicated that surgical procedure is “demanding and

rushed” (p. 24). As a consequence, most times the family is not asked to consent to organ preservation methods (Price, 2000, p. 159). In addition, Price (2000) pointed out that if a patient has the capacity to make a decision regarding these methods, then it is his or her right to authorize it. When a patient becomes classified as a DCD donor, the President's Council on Bioethics (2008) indicated that in controlled DCD the “final cardiac contractions must be controlled” in order for the body to be ready for prompt removal of organs “following asystole” to maintain viability (p. 80).

One of the controversial and problematic methods used to preserve organs before procurement includes the administration of certain medications. At the Institute of Medicine conference held in 2005, the administration of heparin, a medication that increases blood flow, upon withdrawal of life support was stated to be “the current standard of care” (as cited in Steinbrook, 2007, p. 211). However, consent for this must be obtained from a surrogate decision maker before life support is removed (Reich et al., 2009, p. 2007). This administration is most commonly performed in the operating room, where donors are brought prior to the removal of the life support system (Steinbrook, 2007, p. 211). One problematic aspect of the administration of heparin is that there is no clear indication of exactly when in the donation process it should be used. This lack of clarity is portrayed by the Institute of Medicine (1997), in which these medications are noted as being administered at “some point during the death and donation process” (p. 39). Some protocols allow heparin to be used before withdrawal of life support, some once life support is withdrawn but before death is announced, and some shortly after the determination of death in which heparin is circulated throughout the body with “chest compression” (IOM, 1997, p. 39). On the other hand, some protocols do not allow the use of medications for preservation purposes and postulate that it may “hasten death” (IOM, 1997, p.

40). Price (2000) stated that “drugs are in fact routinely used to maintain organ quality and viability under all forms of transplant protocols” (p.177). Price's point may lead to questions regarding what adverse effects these drugs can have on the patient other than those intended, and, if administered before formal death, whether they can expedite the process of death.

Preserving organs through various interventions “during the time needed to confirm death, and possibly before death has occurred” may lead to inaccurate pronouncement of death (IOM, 1997, p. 176).

Another problematic method of organ preservation in the procurement process regarding the authenticity of patient death is the support of circulatory and respiratory functions after death. In 2007, the United Network for Organ Sharing (UNOS) indicated the use of “artificial support of circulation” and “lung ventilation” (p. 305) through extracorporeal membrane oxygenation (ECMO) and bronchoscopy, respectively, as a way to preserve organs after cardiocirculatory death (McGregor et al., 2008, p. 305). When these resuscitative methods are implemented, they can possibly revive some heart and brain function that may, as a consequence, require medications for their suppression (McGregor et al., 2007; Price, 2000). This point by Price and McGregor et al. emphasizes the idea that the authenticity of patient death can be questioned. Because “artificial ventilation” is used under many DCD protocols to maintain organs after death, Price (2000) argued that the criteria of “irreversible” is not met since circulation can be restored (p. 75). However, the claim that supports this process of preservation states that brain death has already been met prior to the initiation of any external circulatory support (Price, 2000, p. 78). Bernat (2010 a) argued that if these types of resuscitative medical interventions occur before brain death, then the person is not dead (p. 245). Cooling using cold preservation solution and cannulation to uphold organ viability is yet another method common in most protocols

(Price, 2000, p. 159). Cold preservation techniques are usually initiated before death and are used to decrease the effect of warm ischemia, the time in which organs are not receiving oxygenated blood (Reich et al., 2009, p. 2008). These methods are used in conjunction with post-mortem practices that also restore oxygenated blood to organs after death before procurement begins (Reich et al., 2009, p. 2008). This method can be controversial since this preservation technique begins before the patient is declared dead, and it is debated whether procurement processes should take place while the patient is still alive.

Although cases of DCD have increased, the effectiveness of these transplantations is questionable. This is due to the lower rate of success of these transplantations than those after brain death, which results from the difficulty of maintaining organ viability. The President's Council on Bioethics (2008) noted that from 1997 to 2007 the cases of organ donation from DCD donors increased from 78 to 793. In addition, there was an increase of about 24% in the DCD category between 2006 and 2007 (Krishnan, 2009, p. 880). This increase was due in part to requirements from UNOS and the Joint Commission that “hospitals either institute controlled DCD protocols or, at the very least, address the practice in their statement of hospital policy” (President's Council on Bioethics, 2008, p. 83). An interesting point made by the Institute of Medicine (1997) is that “transplantation literature” regards the use of DCD as a response to “the intense pressure to increase supply [of organs]” (p. 24). This implies that this method may be a desperate attempt to meet the demand affiliated with organ donation. However, due to warm ischemia issues associated with NHBD and the problem of maintaining organ viability, heart-beating donors are usually the preferred candidates for donation (President's Council on Bioethics, 2008, p. 72). In UPMC protocol, the time between the discontinuation of life support and the removal of organs should be as brief as possible (McGregor et al., 2008, p. 304). This

serves to minimize organ damage that is caused by the lack of oxygenated blood flow to the organs (McGregor et al., 2008, p. 304). Even if the wait time to declare death exceeds five minutes, the quality of organs can be severely impacted (McGregor et al., 2007, p. 2). According to the Institute of Medicine (1997), due to the high chance that this crucial time interval is surpassed in uncontrolled DCD donors, the recovery of organs in this case is the most problematic. In controlled DCD donors, if death after withdrawal of life support does not occur for an hour or two, then organs will not be recovered because of the damage caused to them (p. 24). In such cases, if a patient does not die within the allotted time frame, then the patient is returned to the intensive care unit (ICU) (Reich et al., 2009, p. 2008). As a result, donation is canceled, which has been reported to happen in about 20% of DCD cases (Steinbrook, 2007, p. 210). The average time that was noted for DCD donors to die after the withdrawal of life support was 4.8 hours, which surpasses the maximum allowable warm ischemia time of 1.5 hours (McGregor et al., 2008, p. 307). Controlled DCD donors may not be an effective source for organ transplantation since the maximum warm ischemia time is often exceeded after the withdrawal of life-support. For example, in Phoenix, Arizona patients admitted to the ICU between January 1999 and December 2004 had a 53% survival rate after life support was withdrawn (McGregor et al., 2008, p. 307).

In addition to the frailty of sustaining organ viability in DCD donors prior to transplantation, the functionality of organs from these donors after transplantation may also be problematic. According to the 2009 Annual Report of the U.S. Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR), a nearly tenfold increase in kidney donors was accounted for by DCD donors between 1999 and 2008 (HRSA). In addition, 33% of all kidneys recovered are from DCD and expanded criteria

deceased donors (ECD), but these kidneys are also known to have the “higher rates of discard” (Krishnan, 2009, p. 882). Renz (2008) pointed out that biliary complications are common in kidney and liver transplantations from DCD donors. These have been reported in 15-37% of recipients and usually occur within the first few months of transplantation (p. 486). Data from the Scientific Registry of Liver Transplant Recipients also reports “higher incidence of graft failure and subsequent morbidity and mortality of recipients of DCD livers” than those livers recovered from donation after brain death (DBD) (as cited in McGregor et al., 2008, p. 309). Furthermore, “delayed graft function and primary graft non-function” for kidneys is also much higher for those retrieved from DCD donors than DBD donors, which may be a result of damage caused to them by warm ischemia (Bartlett, 2010, p. 1365). Humar (2009) further supported this claim by revealing that 43% of those who received renal transplants from NHBD experienced delayed graft function compared to 23% of those who received the same transplants from heart-beating donors. According to Bartlett (2010), the majority of organs from DCD donors are kidneys because poor graft function can be aided with therapies such as dialysis. Bartlett's point suggests that the majority of organs received from DCD donors usually do not function well on their own.

Furthermore, in addition to understanding issues relevant to donation after cardiocirculatory death, understanding consent is also vital to the potential donor. Price (2009) revealed that “the language of consent has come to dominate the contemporary transplant and research policy scenes” (p. 119). McGregor et al. (2007) indicated that before the withdrawal of life support, hospitals must notify OPOs “of all imminent deaths” (p. 4) in order for consent to be discussed between OPO representatives and surrogate decision makers. Organ procurement organizations have access to the donor registry, which is an “electronic database” (p. 4)

containing information about a donor's consent. Methods of consent for organ donation include state registration accessed through an OPO website, or obtaining a donor card or driver's license. If a decision has not been made upon death, and a patient is not capable of making the decision, a surrogate decision maker has authority (p. 4).

Although donation after cardiocirculatory death is similar to that of donation after brain death, DCD contains certain uncertainties that may confuse people in regards to consent. Donation websites tend to focus on persuading individuals to donate whenever possible (McGregor et al., 2007, p. 4). This point stresses that consent may be misleading. For example, the U.S. Department of Health and Human Services website includes the following statement above a link to donor registration: "By deciding to be a donor, you give the gift of hope...hope for the thousands of individuals awaiting organ transplants and hope for the millions of individuals whose lives could be enhanced through tissue transplants" (U.S. HHS). This indicates persuasion to donate rather than an unbiased representation of information regarding donation.

The various consent systems regarding donation allow for different methods of informed consent. These consent systems include explicit consent, presumed consent, mandated choice, and conscription (McGregor et al., 2007, p. 4).

According to Price (2000), explicit consent is expressing the wish to donate after death. On the other hand, presumed consent, common in most European countries, is the presumed "willingness to donate" if the potential donor did not indicate a wish regarding donation (p. 112). The donor is therefore placed in a "default position of donation," unless his or her wishes are clearly indicated (McGregor et al., 2007, p. 5). On the other hand, in express consent systems, if the deceased made no decision regarding donation, then it is often taken as an objection to

donation, or a wish for the matter to be left up to relatives (Price, 2000, p. 112).

A mandated choice system requires that all adults make a decision regarding donation, either to consent or to opt out, and the decision must be documented (McGregor et al., 2007, p. 6). Some issues that arise with this system could be a high refusal to donation, as was the case when Texas implemented mandated choice in driver license renewal forms. The result was an 80% refusal to donation, which could be an indication of the lack of education about donation (McGregor et al., 2007, p. 6). Price (2009) argued that mandated choice would limit the decision-making power of relatives, which would therefore not affect the actual wishes of the deceased. However, when mandated choice systems were implemented in Texas and Virginia, relatively low numbers of people registered as pro-donation. The IOM recommended that these systems do not take place due to the possible reduction of transplantable organs (as cited in Price, 2009, p. 86). IOM's recommendation indicates that maintaining higher rates of transplantation may be more important than guaranteeing the protection of a patient's wishes for donation through mandated choice. One final aspect of the mandated choice system is conscription, or "mandatory donation," which requires all persons to allow organ donation after death if necessary (McGregor et al., 2007, p. 5). McGregor et al. suggests that this means society, not the deceased individual, has the right to make the decision about organ donation.

Explicit consent is the current policy in the U.S. The explicit consent system allows for relatives or a surrogate decision maker to have a say in the donation process (Price, 2009, p. 95). Thus, the failure of many to indicate their wishes regarding donation before death leaves the decision making to a relative or a surrogate, which may impact donation rates. It is implied that if a decision is not made prior to death, then it is delegated to be made after death (Price, 2009, p. 83). However, surveys expose the fact that most relatives are not aware of the deceased's

intentions regarding organ donation, yet they are “nevertheless invariably afforded the pivotal role as the conduit for the wishes of the deceased” (Price, 2009, p. 95). According to Price (2000), although the explicit wishes of the deceased to donate cannot be overridden (p. 93) by relatives, the family is able to consent to donation even if the deceased did not express a desire to donate, unless a wish to be excluded from donation was indicated. Therefore, if the deceased is not registered as a donor or a donor card is absent, the family can make any wishes related to donation known and may even partake in the decision if the deceased's wish is already known (Price, 2009, p. 72). Under the Human Tissue Act of 2004, nominated representatives, those who were previously nominated by the deceased to make the decision about donation, can also take part in the decision making process (as cited in Price, 2009, p. 92). In addition to the possibility that the deceased's wishes are not known, if relatives are to take part in the decision, then “the amount of information provided to the family during or after informed consent is not clear in many protocols” (IOM, 1997, p. 37). About only half of protocols describe an informing process including information about procedural methods that will be taken following cardiocirculatory arrest (IOM, 1997, p. 37). Therefore, a truly informed decision cannot be made by relatives, and the protection of the deceased's autonomy may be questioned if their wish regarding donation is not known.

The fine line between life and death is evident in organ donation after cardiocirculatory death. It is vital to understand that the cardiocirculatory method of determining death before organ donation is an imperfect process riddled with ambiguities and complications. In addition, the effectiveness of these transplantations may be hindered by organ viability. This means that donation after cardiocirculatory death not only effects the donor, but also the recipient as well. Placing consent into the hands of the potential donor, rather than into the hands of someone else,

guarantees that the body will be treated according to the donor's wishes. This indicates a need for individuals to make a decision regarding donation if they wish to avoid the complications of consent after their death. This matter may require additional research by the potential donor and must be investigated in order for a knowledgeable decision to be made. The potential donor should protect his or her life and consider the consequences of donation not only for themselves, but also for the potential recipient.

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