

RABBI YONAH BARDOS, M.B.E.

Donation after Cardiac Death: Myth or Reality? A Secular and Ethical Analysis¹

The demand for transplantable organs significantly outpaces their availability from both living and brain dead donors. In searching for ways to increase the potential donor pool, various suggestions have been proposed, including allowing donation after cardiac death. The following pair of articles will attempt to explore this particular transplant technology. The first will describe the protocol and its medical basis as well as analyze the ethics behind it and its potential ramifications. The second article will present a halakhic discussion and analysis of donation after cardiac death.

Claire, a 35 year old mother of three, was diagnosed three years ago with renal failure. At that time, she was told

¹ I would like to thank my father, Richard Bardos JD, for his advice and crucial editorial contributions. His time and effort are greatly appreciated. Additionally, I would like to thank R. Dr. Edward Reichman for his continued mentorship and guidance in the research for this and other articles.

R. Yonah Bardos is a fourth year medical student at Albert Einstein College of Medicine and a fourth year student at RIETS. He holds a masters in bioethics (MBE) from Einstein-Cardozo and semikhah from R. Zalman Nechemiah Goldberg.

that dialysis would not be a permanent cure; at some point, she would either have to receive a kidney transplant or die. That day came last Tuesday, when doctors told her that dialysis was failing and that a kidney transplant was crucial. Unfortunately, Claire shares her need for a transplant with 90,000 other patients in the same situation.

Last Tuesday was also a bad day for John Q. Early that morning, John was walking with his friend just three blocks from where Claire lay waiting and worrying. Despite being otherwise healthy, John suddenly suffered a massive heart attack and collapsed. His friend immediately called 911 and started CPR. Paramedics arrived within minutes and began advanced cardiac life support measures to try to restart John's heart, but after 30 minutes of vigorous efforts, drugs, and shocks, John's heart could not be restarted. John was a registered organ donor and even after this resuscitation, his kidneys would have remained viable for donation had they been immediately preserved by keeping oxygenated blood flowing to his kidneys. Sadly, however, because there is no protocol for quickly preserving ones organs after cardiac arrest, his kidneys were not available to save Claire's life.²

If the same John Q. had instead been hit by a car, brought to the hospital, placed on a ventilator,³ and found to be brain dead, his kidneys would have been able to save Claire's life. Since the heart of a brain dead patient still beats and the ventilator oxygenates the blood, John's kidneys would have

2 There are a few protocol trials such as the Bellevue trial that will be addressed later in the paper.

3 Quick summary of cardio-respiratory physiology: Breathing is controlled by the brain, however the heart beats independently of the brain and will continue to beat as long as oxygenated blood supplies the hearts muscle. The heart is the mechanical pump that moves oxygenated blood to the organs (and itself). If a person is brain dead, they will not continue to breathe on their own therefore they need to be on a ventilator to keep their blood oxygenated. If a person meets cardiac criteria for death (meaning their heart no longer pumps) not only do they need a ventilator for oxygen, but they need a machine to pump their blood for them.

been preserved. However, John suffered his heart attack outside the controlled environment of a hospital, and there are currently no protocols in the United States that would allow the immediate preservation of John's organs outside that setting⁴. His viable organs thus rapidly deteriorated and were unsuitable for donation.

This paper addresses the underpinnings of possible preservation protocols, examines alternate successful practices that accept otherwise healthy organs from "uncontrolled" cardiac deaths, and proposes changes that could save tens of thousands of lives a year.

Introduction

Over the past fifty years, modern medicine and medical technology have made enormous strides in patient care, creating formerly unimaginable situations. Probably the most significant medical technological advances center around our ability to maintain and extend lives artificially and advances in organ donation. The scientific community continues to explore new frontiers to enlarge the donor pool, with many national conferences dedicated to increasing the organ supply. Organ donation has similarly been discussed at length in the halakhic literature due to its sensitive nature and complexity, and many *Poskim* have weighed in on the matter, providing a plethora of opinions.⁵ In this series, we will discuss the ethical and halakhic implications of the possible expansion of the pool of possible donors.

The body's organs are kept alive due to the consistent flow of blood and oxygen to those organs. When that flow ceases, an organ will begin to die; at a certain point, the organ will no longer be viable or usable either in its current body or in a new body. In order to keep an organ alive after death and enable donation to a recipient's body, blood flow and oxygen

⁴ See supra n.2

⁵ See Avraham Steinberg, "Transplantation," in *Encyclopedia of Jewish Medical Ethics* (Brooklyn, 2003), Feldheim 1088-1106.

must be maintained to the organs (perfused) to keep the organ alive. The amount of time an organ remains without blood and oxygen is called “warm ischemic time;” the longer the warm ischemic time, the less likely the organ will function properly after donation.

When organ transplantation first developed, donations were taken either from live donors or from donors declared dead after their heart had stopped (“donation after cardiac or circulatory death,” or DCD). Many of these transplants were not successful, often owing to the extended time the organs were maintained without oxygen and blood flow once the heart had stopped.

Currently, most organs are transplanted from brain-dead donors. A patient diagnosed with brain death is maintained on a respirator, which provides oxygen to the blood, and, importantly, his heart is still beating, circulating the oxygenated blood to his organs⁶. Thus, a brain-dead patient’s organs are kept viable and the warm ischemic time remains at a minimum.

The remainder of organs available today come from either live or DCD donors. DCD donors by definition do not have a beating heart and therefore have no way to naturally circulate blood. The warm ischemic time is minimized by cooling the patient’s body immediately after death and/or artificially circulating oxygenated blood.

The medically accepted “Maastricht classification” divides DCD donors into two distinct categories based on the circumstances of the patient’s death – controlled and uncontrolled. In controlled donation, the patient’s cardiac arrest is orchestrated in a hospital setting via the withdrawal of life sustaining treatment, with the intention of organ donation. In these situations, pre-mortem steps are in place to preserve the organs upon the patient’s death. Thus, the length of time the organs are without blood and oxygen is controlled by the medical team and the viability of the organs is therefore readily

⁶ See *supra* n.2.

known. Controlled donors fall under the Maastricht classification III and IV.⁷

Uncontrolled deaths can occur inside or outside the hospital. In either case, death occurs when “no prior plans had been made to procure organs from these individuals, and therefore, the warm ischemia time (during which organs deteriorate) was unpredictable and uncontrolled.”⁸

Uncontrolled DCD is divided into two categories. Category I includes patients who are dead upon arrival of EMS, such as “victims of an accident outside the hospital who are for obvious reasons not resuscitated. An example is a victim of a car accident who dies on the spot due to a broken neck, or a victim of successful suicide.”⁹ This patient’s organs could potentially be used for donation through rapid initiation of artificial circulation and ventilation, along with prompt transportation to the hospital.

Category II includes patients for whom attempts of resuscitation outside the hospital were unsuccessful. In the

7 See G. Kootstra, *Categories of Non-Heart-Beating Donors* (Transplantation Proceedings, October 1995), 27(5) 2893-2894.

Category III is termed “Awaiting cardiac arrest.” This includes patients dying in an intensive care unit (ICU) in cases in which the patient or his family have agreed to organ donation. Once treatment is withheld, the team waits for cardiac arrest, and after a certain amount of time has elapsed (as discussed below), organ donation procedures can begin. Patients in this category include those who have sustained severe brain trauma but do not meet brain death criteria and patients with end-stage neurologic disease (brain tumor and in a coma) who are not considered brain dead.

Category IV is termed “Cardiac Arrest after Brain Death.” Patients who fall under this category have experienced an unexpected cardiac arrest in the ICU after being diagnosed as brain dead. Generally, the medical team first attempts to restore the heart beat; if this attempt proves unsuccessful, they then continue with organ donation procedures.

A final category, Category V, termed “In Hospital Cardiac Arrest,” was instituted in 2000 to include all patients in the ICU who have an unexpected cardiac arrest with failed resuscitation after multiple manipulations. They can also be considered for a non-heart beating organ donation.

8 Koostra, *Categories*, 2893-2894.

9 *Ibid.*, 2893-4.

United States, since there is no way to rapidly obtain consent to preserve the organs, warm ischemic time rises and the organs swiftly begin to die; such patients are therefore not candidates for donation.

Thus, thousands of potential organ donors, like John Q., are currently unable to donate their organs. The American Heart Association estimates that each year in the United States, about 335,000 deaths are due to sudden cardiac arrest. Although reports of the rates of survival vary among EMS systems, around 95% of sudden cardiac arrest victims die before they reach the hospital. At present, virtually all of these individuals are denied the opportunity to be organ donors. Of those 335,000 patients, many are not candidates due to criteria unrelated to where their deaths occurred, but of those remaining, there are potentially 35,000 donors (70,000 kidneys!) who have are not able to donate.¹⁰ Despite the increase of organ availability due to donations after brain death, there are still not enough organs for the over 113,000 on the waiting list in the United States; every day, 19 people in the United States die while waiting for a donated organ.¹¹ Even if donors who die outside of a hospital could provide only kidneys for transplant, their donations would make an enormous impact on the current deficit; over 91,000 people currently on the transplant list are waiting for kidneys.¹²

Is there a way to change these statistics by enabling organ donation in uncontrolled DCD situations? In these cases, if there were a way to know that the patient consented to organ donation (via a donor card, for example) and the proper equipment were available, doctors could immediately begin organ preservation to maintain the organs' viability after death via

10 James Childress and Catherine T. Liverman, *Organ Donation: Opportunities for Action* (National Academies of Science, Washington DC, 2006), 156.

11 See www.unos.org and <http://www.thenationalnetworkoforgandonors.org/about.html> for the most current figures.

12 <http://optn.transplant.hrsa.gov/data/> (retrieved April 3, 2012).

cardiac massage and artificial ventilation.¹³ In Spain, for example, there is presumed consent, which means that emergency personnel can legally begin preserving the body immediately upon death, without obtaining explicit consent. Patients in Spain are brought to the emergency room via mobile ICU, which provides mechanical ventilation, external cardiac massage, and fluid perfusion. Upon arrival at the hospital, the emergency department staff takes over and begins full ACLS (Advanced Cardiac Life Support) resuscitative measures. After some length of time, the resuscitative measures are deemed futile and are terminated. If the donor meets DCD criteria,¹⁴ the hospital staff can then begin cooling and preserving the organs. Such preservation measures extend organ viability for up to an additional 240 minutes, allowing more time to obtain consent for donation from the next of kin.¹⁵¹⁶

Numerous ethical questions are raised by the possibility of both controlled and uncontrolled DCD. Those pertaining to controlled DCD relate to both the pre-mortem context – what can and cannot be done, even with prior consent, to preserve

13 See H. Myron Kauffman, “Non–heart-beating donors (then) and donation after cardiac death (now),” *Transplantation Review* 21 (2007): 237–48: “Categories 1 and 2 were defined as uncontrolled because no prior plans had been made to procure organs from these individuals, and therefore, the warm ischemia time was unpredictable and uncontrolled. In countries that have presumed consent, immediate insertion of femoral catheters for either flush cooling or extracorporeal perfusion for category 1 and 2 donors is possible. However, where presumed consent does not exist, cardiac massage with artificial ventilation is the only available method of bridging the time until consent can be obtained.”

14 There is no uniform DCD criteria, as different protocols have different requirements.

15 See A. I. Sanchez-Fructuoso et. al, *Transplantation Reviews* 21 (2007) 249-254; J. R. Nunez, “Non-heart beating donors: An excellent choice to increase the donor pool,” *Transplantation Proceedings* (2005): 3652. Cf. S. P. Wall, “Derivation of the uncontrolled donation after circulatory determination of death protocol for New York City,” *American Journal of Transplantation* 11 (2011): 1417-1426.

16 It is important to note that Spain’s policy *does not* allow organ *donation* without consent, just organ *preservation* without consent.

the organs without either harming the patient while alive or hastening his death – as well as how long to wait after asystole (cessation of heartbeat) before initiating organ retrieval. Since cardiac arrest in uncontrolled DCD occurs in the absence of medical personnel and necessary equipment, the ethical issues in that context are all related to post-mortem questions, such as what steps can be taken after death without consent to preserve organs and buy time for the hospital to seek consent from the next of kin.

In this article, we relate to these questions from both a secular ethical and halakhic perspective. According to almost all opinions, Halakhah sanctions organ donation *provided that the patient is dead*.¹⁷ While the halakhic definition of death is subject to debate, when cardiac death has occurred – as in DCD – all opinions concur that the patient is dead. The halakhic issues are therefore related in this context to the same general ethical questions outlined above.

Controlled DCD

Controlled DCD candidates usually suffer from profound loss of cognitive capacity, but they are not brain-dead. They are therefore considered alive according to all secular and religious perspectives. These patients are often supported by a host of machines and medications that maintain adequate perfusion to the organs. In order for their heart to stop, their care must be withdrawn.

17 While *Binyan Tzion* (1:270) and others do not condone organ donation, most *Poskim*, including R. Moshe Feinstein, R. Shlomo Z. Auerbach, and *Hatam Sofer*, do. According to those who maintain that brain death is indeed halakhic death, organ donation faces far fewer challenges. The majority of *Poskim*, however, maintain that such patients are halakhically alive, posing grave difficulties, as viable critical organs (heart, lung) are currently only harvested from brain dead patients. For a detailed analysis of brain-death in Halakhah, see David Shabtai, *Defining the Moment: Understanding Brain Death in Halakhah* (New York, 2012) and Mordechai Halperin *Rega Ha-Mavet* (The Dr. Falk Schlesinger Institute for Medical-Halachic Research, Jerusalem 2007) (Hebrew).

In 2007, the New York State Department of Health produced an analysis of and guidelines for controlled donation after cardiac death.¹⁸ The paper identified five steps that occur during the DCD donor process: the decision (and obtaining of consent) to withdraw treatment, assessment for DCD, pre-mortem interventions, the actual withdrawal of treatment, and cardiac arrest and declaration of death.¹⁹

According to US law, the patient or his legal representative has the right to decide whether to continue or withdraw life-sustaining treatment.²⁰ As part of the decision to withdraw care, the patient must have an order not to resuscitate (DNR). Without such an order, the physicians attending the dying patient are obligated to reinsert the breathing tube and attempt resuscitation. With a DNR in place, however, health professionals may not attempt any resuscitation or intervention after a breathing tube has been removed.²¹

Pre-mortem interventions, which increase organ viability, are crucial to successful organ donations however the protocols for pre-mortem interventions vary greatly. Some hos-

18 *Donation After Cardiac Death: Analysis and Recommendations from the New York State Task Force on Life & the Law* (April 2007). This report can be found online at

http://www.health.state.ny.us/regulations/task_force/donation_after_cardiac_death/.

19 The assessment for DCD is beyond the scope of the present article and will not be discussed here.

20 The New York Family Health Care Act (NYFHCA), passed in 2010, delineates how a surrogate decision maker should make this decision when the patient did not make his wishes known through a living will – either based on the wishes of the patient or substituted judgment (an attempt by the surrogate decision maker to establish with as much accuracy as possible what decision the patient would have made if the patient were competent to do so). See 2010 N.Y. Laws ch. 8, A.7729-D (Gottfried et al.) and S.3164-B. (Duane et al.). Section 2 of Chapter 8 amends N.Y. Public Health Law (PHL) to create “Article 29-CC Family Health Care Decisions Act.” cf. R. Swidler, “New York’s Family Health Care Decisions Act: The Legal and Political Background, Key Provisions and Emerging Issues,” *NYSBA* (2010): 18-27.

21 *Donation After Cardiac Death*, (April 2007) 1-16.

pitals, consistent with the 2000 Institute of Medicine report (“IOM report”),²² allow the insertion of a large catheter into the patient’s leg before death in order to rapidly supply cooling and preservative fluids upon death. To preserve the viability of the donor’s organs, other hospitals go even further and allow the use of various medications that help increase blood flow to vital organs but which may lower the patient’s blood pressure (vasodilators), as well as the intravenous administration of heparin, which helps prevent the formation of blood clots in the donor’s organs. From a bioethical perspective, interventions performed after death do not pose any ethical problems, as the patient consented to organ donation, but these types of pre-mortem interventions pose a series of ethical dilemmas. Thus, the New York State Health Task Force analysis suggests that “hospital policies should support the use of heparin, but should not currently support the insertion of additional catheters pre-mortem or the addition of medications solely for the purposes of...organ donation,” since these may hasten the patient’s death.²³

After the decision to withdraw care and donate organs has been made and pre-mortem interventions have been implemented, the patient is extubated (their breathing tube is removed) and the ventilator is shut off. After the declaration of death, organs can be harvested for transplantation. Declaring the patient dead, however, is far from a simple process.

A. The Dead Donor Rule and Declaration of Death

The “Dead Donor Rule” (DDR), which states that the patient must be declared dead prior to the removal of organs, is

22 *Non-Heart-Beating Organ Transplantation: Practice and Protocols Committee on Non-Heart-Beating Transplantation II: The Scientific and Ethical Basis for Practice and Protocols* (Washington DC: National Academy Press, 2000), 51.

23 *Donation After Cardiac Death*, 13. For a detailed discussion of the risks of heparin administration, see also Elizabeth D. Motta, “The Ethics of Heparin Administration to the Potential Non-Heart-Beating Organ Donor,” *Journal of Professional Nursing* 21:2 (March–April 2005): 97–102.

accepted as authoritative by the transplant and bioethical communities. The precise definition of death is extremely important in organ donation, as it is crucial to minimize the time that the organs go without oxygen without violating the dead donor rule.

While death can be medically defined by many different criteria, the legally accepted criteria require either cardiac or brain death. According to the UDDA (Uniform Determination of Death Act), once there is irreversible cessation of circulatory and respiratory functions, the patient can be declared dead.²⁴ Brain-death was defined by the Ad Hoc Committee of Harvard Medical School in 1968 as the irreversible cessation of brain and respiratory functions,²⁵ and this has been accepted in the United States and many other countries as legal death.²⁶ Both definitions of death demand irreversibility, that the current state cannot be changed – the heart will not begin to beat again or the brain will not function anymore. As the current discussion surrounds donation after cardiac death, we will presently consider only the declaration of death following cessation of heartbeat.²⁷ At what point can irreversible cessation of heart function be declared, paving the way for organ donation in compliance with the DDR?

B. The Definition of Irreversibility

With regard to cardiac death, three stages of the dying process present potential points for declaring the patient dead. At Point A, the heart stops. Even if resuscitation is not attempted at this point, the heart may begin to pump again on its own (autoresuscitation). At some later point after the cardiac arrest,

24 Uniform Anatomical Gift Act (UAGA 2006).

25 “Report of the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death: A Definition of Irreversible Coma,” *JAMA* 205 (1968): 337-40.

26 This definition was confirmed by the President’s Bioethics Council in 1981.

27 As noted above, the acceptability of brain-death in Halakhah is subject to much debate and will not be discussed here. See *supra* n.11.

the patient reaches Point B, when the heart can no longer start on its own, but resuscitative efforts may cause it to restart. At an even later point after the arrest, Point C, the heart cannot be restarted even with resuscitative efforts.²⁸

If the patient could potentially recover with resuscitative efforts, is he considered dead in their absence? When a patient's heart stops at Point A, is he "dead"? If we were to effectively resuscitate the patient or if his heart started to beat on its own, it would seem to indicate that the patient was not dead at Point A, even though his heart was no longer beating. Similarly, at Point B, the heart may no longer restart on its own, but it may be possible to restart it through resuscitative efforts. Can he be said to be "dead"? Essentially, at what point in the dying process has the heart irreversibly ceased functioning?

This question is particularly pertinent in a case of DCD, as in such situations, a DNR must be in place and no attempt will be made to restart the heart. If no attempts to resuscitate will be made, can the patient be declared dead at Point A, Point B or Point C? The answer to this question is critical, as the time difference between Point A and Point C may greatly affect the possibility of a successful organ transplant.

While providing a legal definition of death, the New York State Task Force does not define irreversible or specify when irreversible cessation of cardiac activity occurs.²⁹ Traditionally, death was declared only after resuscitative measures failed to restart – meaning, at Point C. The IOM 2000 report, however, greatly broadens the definition of cardiac death, suggesting several possible meanings of the word "irreversible:" "1) Will not resume spontaneously (autoresuscitate); 2) Cannot be started with resuscitation measures; 3) Will not be restarted on morally justifiable grounds"³⁰ (e.g., if patient has a DNR

28 See K. Hornby, et al, A systematic review of autoresuscitation after cardiac arrest, *Critical Care Med* 2 38, 5 (2010):1246-1253. Some papers have noted that autoresuscitation can occur even after failed resuscitation, but this does not appear to be the norm.

29 *Donation After Cardiac Death*, pp1-16.

30 Non-Heart-Beating Organ Transplantation, 2000, p24.

order). The IOM, and the transplant community as a whole, chose a hybrid definition of the first and third meanings, rejecting the second, thus concluding that death occurs when cardiopulmonary function will not resume spontaneously and will not be restarted on moral grounds. This is a modified version of Point B, at which point the heart will not restart on its own and will not be restarted with external measures. Accordingly, the definition of cardiac death is broadened to people whose hearts **could** be restarted but practically **will not** be.

This broader definition has been called by one ethicist “moral irreversibility”³¹ and has been decried by others as effectively killing the patient, as organ retrieval procedures begin before the patient is truly dead.³²

Regardless of the ethical acceptability of the IOM’s conclusion, even the time it designates as cardiac death – Point B – is difficult to determine conclusively. A recent paper concluded that it remains unclear at which point the heart will no longer restart on its own.³³ S. Dhanani et. al and the IOM report mention certain protocols that permit declaration of death as short a time as two minutes after cardiac arrest, while other hospitals required ten minutes of absent heartbeat before declaration.³⁴ The New York State Health Task Force and the

31 J. Menikoff, *Law and Bioethics* (Georgetown University Press, 2001), 464.

32 See Robert M. Veatch, “Donating hearts after cardiac death – reversing the irreversible,” *New England Journal of Medicine* (2008): 672-673, who writes that removing organs from a patient whose heart not only can be restarted but also has been or will be restarted in another body is ending a life by organ removal. See also idem., “Transplanting hearts after death measured by cardiac criteria: The challenge to the Dead Donor Rule,” *Journal of Medicine and Philosophy* 35 (2010): 313–29; J. Bernat, “How the distinction between ‘irreversible’ and ‘permanent’ illuminates circulatory–respiratory death determination,” *Journal of Medicine and Philosophy* 35 (2010): 242–55.

33 K. Hornby, “A systematic review of autoresuscitation after cardiac arrest,” *Critical Care Medicine* 38 (2010): 1246 –53.

34 S. Dhanani et. al, “Variability in the Determination of Death After Cardiac Arrest : A Review of Guidelines and Statements,” *Journal of Intensive*

Institute of Medicine have recommended a period of five minutes of cardiac arrest as an “appropriate pause” before beginning organ donation.³⁵

Uncontrolled DCD

Having addressed the issues raised by controlled DCD, we will now examine the uncontrolled DCD (uDCD) process. In these cases, patients experience cardiac arrest outside the hospital and undergo full cardiac resuscitative measures. After resuscitative measures have been exhausted, the patient is dead, as he meets the criteria for irreversible cessation of cardiac and respiratory functions. For the purposes of our present discussion, we will not differentiate between Maastricht categories I and II.³⁶

As noted above, with rare exceptions, uDCD is not permitted in the United States.³⁷ No protocols exist for preserving even young, healthy organs that become available through accidents or other causes unrelated to the overall health of the donor. Without such protocols, the equipment and training necessary for immediate organ preservation, including mobile ICU's and ECMO (*Extracorporeal membrane oxygenation*³⁸) are simply not available for most uDCD patients. As a result, thousands of potentially life-saving organs are lost.

Care Medicine 27(4) (2012): 238-252; Non-Heart-Beating Organ Transplantation, 40.

35 *Donation After Cardiac Death*, p13.

36 We similarly do not discuss Category V, which was instituted in 2000 and refers to patients in the ICU who experience unexpected cardiac arrest.

37 There has been limited practice in the United States, such as from 1993-1997 through the Washington DC Hospital Center's Rapid Organ Recovery Program and as per the New York City 2011 protocol, which will be discussed below.

38 Extracorporeal membrane oxygenation (ECMO) is a treatment that uses a pump to circulate blood through an artificial lung back into the bloodstream. This system provides heart-lung bypass support outside of the body. <http://www.nlm.nih.gov/medlineplus/ency/article/007234.htm> accessed September 12 2012.

In general, there are four major reasons why uncontrolled DCD protocols are not commonplace in the United States: 1) The assumption that uDCD organs are of inferior quality; 2) EMS response times; 3) lack of patient and family trust in the health care system; and 4) the legality of beginning preservative measures before obtaining consent from the next of kin.

Current scientific research indicates that uDCD programs not only can work, they also have a significant impact on organ donation as a whole, and the authors of the 2006 paper “Organ Donation: Opportunities for Action” call upon the American medical-legal community to implement more uDCD programs.³⁹ UDCD has been practiced successfully for over 20 years across Europe, and research published in Spain delineates the procedures, protocols, and success rates of uDCD,⁴⁰ refuting the American medical community’s perception that uDCD organs are of inferior quality or pose an increased risk to the recipient. In fact, some papers have shown that uDCD organs are actually preferred over brain-dead organs because the organs are generally younger and healthier.⁴¹ About two years ago, the New York Fire Department and Bellevue Hospital in New York City created a pilot uDCD program focused on retrieving kidneys. While to date it does not

39 Childress and Liverman, *Organ Donation: Opportunities for Action*, Committee on Increasing Rates of Organ Donation (National Academies Press, Washington DC, 2006).

40 Some of the successful studies from Spain include M. Gomez, et al., Liver Transplantation with Organs from Non-Heart-Beating Donors, *Transplantation Proceedings* 29 (1997) 3478-3479; Gomez M, et al. The use of kidneys from non-heart-beating donors for transplantation. *Transplantation Proceedings* 25(1) 1993:1501-1502; J. Alvarez et al. Type I non-heart-beating donors: Policy and results. *Transplantation Proceedings* 29(8) 1997:3552. J. Alvarez et. al , Non-heart-beating donors from the streets: An increasing donor pool source. *Transplantation* 70(2):2000 314-317; J. Alvarez et al, Five years of experience with non-heart-beating donors coming from the streets. *Transplantation Proceedings* 34(7): 2002 2589-2590.

41 J. R. Nunez et al, “Non-heart beating donors,” *Transplantation Proceedings*, 37 (2005) 3651-3654.

appear that the program has recovered any organs, the Bellevue protocol directly addresses the concerns of the American medical community regarding uDCD. The first major hurdle was to change the medical communities assumption regarding the quality of uDCD organs. The transplant community in America, has been under the impression that organs from uncontrolled DCD donors are of inferior quality and therefore have not significantly explored the possibility of using these organs. However, the data from Spain shows that this impression is incorrect.⁴² Next, we will address the other concerns preventing widespread uDCD protocols.

42 Wall, "Derivation of the uncontrolled donation after circulatory determination of death protocol for New York City,," 1417-26. The Bellevue protocol, as cited by Wall, reads as follows:

The NYC UDCDD protocol commissions a dedicated organ preservation unit (OPU) staffed with a family services specialist, two organ preservation technicians, and an emergency medicine physician. After vigorous attempts at resuscitation fail, EMS responders, blinded to OPU availability, may announce termination of resuscitation (TOR) if established criteria are met. OPU staff will arrive at the arrest location within 2 min of termination and determine whether there is evidence of prior first person consent for organ donation (by searching the NYS Registry of Consent or for duly executed documentation). Staff will conduct pre-hospital screening examinations, including brain stem assessment, and if eligible, will commence preservation only if an AP affirms the deceased's wish.

Heparin (and thrombolytics for liver preservation) will be infused followed by 1 min of manual chest compressions and transfer of the deceased to the organ preservation vehicle (OPV). In the OPV, technicians will continue preservation using mechanical ventilation and an automated chest compression device. At the hospital, OPU staff will repeat the screening examinations to ensure preservation procedures do not impede "natural progression to irreversible brain death." Once confirmed, nECMO will be established, standard NYODN screening procedures will be followed, and if the deceased is eligible and the AP affirms the deceased's prior wish, organ procurement will ensue according to standard protocols. Warm ischemic time, defined as time from EMS initiating resuscitation to establishing nECMO, will not exceed 120 min. This definition was chosen as a proxy for true warm ischemic time, as time of cardiac arrest is often unreliable or undocumented.

A. Response Time

The issue of EMS response time is indeed an important one. For kidneys to remain viable, resuscitative measures must begin within 15 minutes of witnessed cardiac arrest,⁴³ and many rural areas lack the personnel and equipment to allow arrival within this time frame and to maintain the organs during transport to the hospital. Thus, a uDCD program would not be feasible in most rural areas in the United States. In urban areas, however – such as the one served by Bellevue Hospital – extensive trauma and emergency care operations exist, making a uDCD program plausible.⁴⁴ The Bellevue protocol requires that cardiac arrest occur within a 10 minute ambulance ride of the hospital. This distance limit was created because the preservation methods to maintain perfusion used in the field do not allow optimal organ support. Such time and distance limits should satisfy the second major concern.

B. Trust in the Health Care System

Proponents of uDCD also address the issue of patient and family trust in the health care system. The necessary legislation and money will only be committed to an uncontrolled DCD program once patients and families have complete confidence “that all emergency and resuscitative efforts will be made and that organ donation will be considered only in the event of a loss of life after every appropriate measure has been attempted.”⁴⁵ The community must fully believe that the healthcare workers’ decisions are made in the best interest of their dying patient, and not controlled by a desire to maximize organ donors.

The Bellevue study recognized the importance of these concerns and therefore had a team of bioethicists review the pro-

43 Witnessed cardiac arrest is necessary in order to determine how much time has passed without circulating oxygenated blood.

44 Childress and Liverman, *Organ Donation: Opportunities for Action*, 139 (Modified Madrid Criteria).

45 *Ibid.*, 156.

tol to ensure that it would not violate the Dead Donor Rule. To make sure that every patient receives the optimal care, this team reviewed the research and determined that termination of resuscitation should only occur after a full 30-minute resuscitative attempt.⁴⁶ To ensure that the responders would provide a full resuscitative attempt rather than try simply to maximize organ availability, responders are kept unaware of the patient's organ donor status as well as the availability of the organ preservation unit (OPU). The OPU is a "shadow unit" assigned to certain types of calls without the knowledge of the paramedics; the unit parks nearby and is available to move in should the EMTs terminate resuscitation. The rescuers thus give their best

46 During resuscitative efforts, the patient is connected to an EKG monitor to detect if any heart activity resumes. If there is no heart activity after a certain period of time, those efforts will be terminated. Although emergency medical technicians have developed a method for deciding when to stop these efforts, there is no universal protocol defining "Point C," when resuscitative efforts will no longer be effective. The American Heart Association (AHA), among others, gives no specific time and leaves the decision for the treating team to determine; see "Management of Cardiac Arrest," *Circulation* 112 (2005): IV-58-IV-66 and reiterated in the updated version, Part 8: "Adult Advanced Cardiovascular Life Support: American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care," *Circulation* 122 (2010): S729-S767. European protocols suggest that the patient must remain in asystole, without any spontaneous return of circulation, for times ranging from two to thirty minutes despite all resuscitative attempts. See, for example, *A Code of Practice for the Diagnosis and Confirmation of Death* (Academy of Medical Royal Colleges, UK, 2008); *Recognition of Life Extinct (ROLE) by Ambulance Staff* (The Joint Royal Colleges Ambulance Liaison Committee [JRCALC], 2003), an update P. Baskett, J. Fisher, A. Marsden, "Recognition of death by ambulance personnel," Joint Colleges Ambulance Liaison Committee Newsletter (1996): 1. For discussion of in hospital cardiac arrest, see Carl van Walraven, "Derivation of a Clinical Decision Rule for the Discontinuation of In-Hospital Cardiac Arrest Resuscitations," *Arch Internal Medicine* 159 (1999): 129-34 among others. According to the Madrid Protocol, the patient may be pronounced dead by a physician not associated in any way with the transplant team only after (1) At least 30 minutes of unsuccessful CPR has been attempted and (2) 10 minutes of an absent heartbeat after termination of resuscitative efforts. Only at that point can perfusion or organ retrieval proceed.

efforts to resuscitate. Only after a vigorous attempt has failed and the patient has met the criteria for terminating resuscitation will the responder call medical control for permission to terminate resuscitative efforts.⁴⁷

Even with a full resuscitative attempt, how long after the heart stops would one have to wait before determining that the heart can no longer be restarted? A recent study reported that when no CPR was given (for e.g. with a controlled DCD patient) there were no reported cases of autoresuscitation (heart did not restart). Various American protocols suggest waiting between two and ten minutes after asystole in controlled DCD before declaring death. (Some reports have even waited 75 seconds after the heart stopped in a pediatric patient before declaring death.⁴⁸) Therefore, it would seem that same time or even shorter should be applied where there is a full failed resuscitative effort as is the case of uDCD. The time to autoresuscitation is important to determine as that is the time that one would have to wait after terminating resuscitation before beginning any post mortem steps.

C. Organ Preservation After Death

From a strictly ethical-legal perspective, the fourth issue – beginning preservative measures before obtaining consent from the next of kin – is significantly more complicated. To best preserve the organs, preservation measures must begin immediately after the declaration of death, before informed consent is obtained.⁴⁹ Can post-mortem procedures such as in-

47 All terminations of resuscitation (TOR) require contacting medical control. The TOR criteria in the NYC UDCCD protocol (supplemental table 2) require at least 30 minutes of EMS resuscitation, including at least 20 minutes of advanced life support; effective airway management; a non-shockable rhythm (asystole or flat line); and no return of spontaneous circulation at TOR.

48 M. Boucek, et al., "Pediatric heart transplants after declaration of cardio-circulatory death," *New England Journal of Medicine* 359 (2008): 709-14.

49 See Childress and Liverman, *Organ Donation: Opportunities for Action*, 2006 p 158.

sersion of a femoral catheter or administration of cooling fluids or heparin, be initiated without the consent of the family?

In the Washington, DC 1993 Rapid Organ Recovery Program, legislation stipulated that post-mortem preservation could be performed without requiring consent; the actual harvesting of organs would have to wait until it could be determined to be the patient's or family's wishes.⁵⁰ Alternatively, in Spain, where much of the research has been done, there is an opt-out protocol whereby all Spaniards are considered to consent to postmortem preservation methods unless they expressly state otherwise. Some ethicists maintain that it is not only ethically permissible, but possibly obligatory to preserve the body until the wishes of the patient and family can be determined.⁵¹ Rather than go through a prohibitive legislative process to change the law in New York City, Bellevue administrators asked various legal agencies whether the Bellevue protocol violated the law.⁵² After much discussion among the various

50 By the time the IOM report was published, legislation that allowing immediate preservation without consent existed in several Western democratic countries and in three jurisdictions in the United States (Washington, D.C., Virginia, and Florida).

51 See J. Childress, "Organ donation after circulatory determination of death: Lessons and unresolved controversies," *Journal of Law, Medicine, and Ethics* 36 (2008): 766-771. See R. Bonnie, S. Wright, K. Dineen, "Legal authority to preserve organs in cases of uncontrolled cardiac death: Preserving family choice," *Journal of Law Medicine and Ethics* (Winter 2008): 36(4):741-751. The authors are surprised by the common practice in which we "initiate and preserve mechanical ventilation and other preservation procedures after patients have been declared dead according to neurological criteria while families are notified of the patients death and approached about donation. In other words, hospitals and organ procurement organizations apparently assume that they now have the necessary authority to preserve organs after death had been declared according to neurologic criteria." I would argue, however, that the cases they describe are very different than DCD cases, as neurologically dead patients are by definition attached to machinery; their doctors merely continue these measures while awaiting consent. This is not comparable to initiating preservation measures in dead patients, such as a thumper, large bore femoral catheters, and intubation.

52 See R. Bonnie, et al, "Legal Authority," 610, 741-51. See also HRSA, Organ Procurement and Transplant Network, National Organ Transplant

city departments, it was determined that the hospital could legally preserve patients' organs post-mortem without any need for consent. The commission concluded that placing a catheter is "no more intrusive than that which morticians typically perform;"⁵³ therefore, preservation efforts without consent would be acceptable provided the community does not oppose such efforts. The "mortician analogy" appears debatable, as a mortician usually prepares the body for burial at the request of the deceased family, while the question at hand is whether intrusive methods may be used on a dead body without family consent.⁵⁴ It is possible that the Bellevue report meant that inserting a catheter and pumping fluids through the body is thought to be so unobtrusive that it is permitted.

The Bellevue report identified additional concerns that must be addressed. First, it was recognized that various religious traditions regarding dead bodies would make institution of this protocol difficult, if not impossible. Furthermore, societal perception of performing any non-consensual actions on a dead body might pose a problem. For example, the Bellevue program was labeled "unethical" by the media, which claimed that "crews would swoop in and perform procedures on corpses without consent," and calling the OPU a "meat wagon."⁵⁵ In response, the protocol was changed to require first person consent for organ donation (such as a driver's license making an anatomical gift, an organ donor card, or membership in the NYS organ donor registry) before allowing immediate preservation activities. Furthermore, although the wishes of the de-

Act, 2008, available at <http://optn.transplant.hrsa.gov/policiesAndBylaws/nota.asp.29>; and Laws NCoCo US. Revised Uniform Anatomical Gift Act. 2006, available at <http://www.anatomicalgiftact.org/DesktopDefault.aspx?tabindex=1&tabid=63>.

53 Wall, "Derivation of the uncontrolled donation after circulatory determination of death protocol for New York City," 1419.

54 The Bureau of Labor Statistics Handbook, <http://www.bls.gov/ooh/Personal-Care-and-Service/Funeral-directors.htm>, retrieved April 5, 2012.

55 Ibid.

ceased legally supersede those of his family,⁵⁶ if anyone at the scene objected to the preservation activities, they would be discontinued.

As a result of all of these safeguards, the Bellevue program ultimately did not obtain any organs. Nevertheless, it was an important valiant effort and a good start towards changing America's uDCD protocols.

Conclusion

Uncontrolled donation after cardiac death holds much potential for saving lives, and programs of this nature should continue to improve their protocols within appropriate ethical boundaries. At the same time, we must remain sensitive to the practical and emotional aspects of such a program. For example, when a death occurs in the field, it would be quite difficult for a family member, immediately following a frantic resuscitative attempt and the discovery that their loved one is dead, to properly understand and deliberate on such a decision. From a Jewish perspective, it seems that organ preservation efforts would be permitted without necessitation of first person consent. One possible solution may be something like an opt-in or uDCD checkbox on a driver's license for those who, for religious or other reasons, would not otherwise donate organs. An opt-out program that would allow only temporary organ preservation would also be helpful. Clearly, further research must be done to determine a system that will accommodate both American law and religious traditions.

56 Uniform Anatomical Gift Act (UAGA 2006).