# Preserving Totality and Integrity in Donation after Circulatory Determination of Death

Thomas J. Driscoll Jr.

Abstract. The permissibility of circulatory determination of death (CDD) preceding organ procurement remains controversial. This paper discusses the controversy and the liceity of irreversible circulatory cessation as a determinant of death. When specific protocols have been satisfied, including a waiting period of five minutes of asystole, CDD licitly signals the disintegration of the unitary and integrated whole that was the living human person. The author contends that after terminating disproportionate care, a surrogate may rely on irreversible circulatory cessation thus determined and may authorize organ donation, including limited pre-death procedures that are consonant with the dignity and well-being of the dying patient-donor. National Catholic Bioethics Quarterly 12.1 (Spring 2012): 69–84.

Catholic moral tradition exults in the dignity of each human being as the gift of a loving God, a dignity that endows human life with a sacred character. This dignity does not require the preservation of human life against all odds, but in recognition of death as the passage to life eternal, it does require the use of ordinary or proportionate means to maintain health and life. Heroic measures are not obligatory, and the magisterium teaches that medical measures that are futile or excessively burdensome may be avoided or discontinued without violating the sanctity of human life.

Thomas J. Driscoll Jr., JD, is a general civil practice attorney who lives and works in Lodi, California. He and his wife serve the sick and dying in St. Anne's Parish. He obtained certification in health care ethics from The National Catholic Bioethics Center, and is preparing for the permanent diaconate in the Diocese of Stockton.

When a person dies, the Church recognizes not only the moral liceity but the "generosity and altruism" of organ donation, which provides vital organs on which recipients' lives depend, but such donation is licit only so long as vital organs are removed only after the donor is dead. This is known as the "dead donor rule." For centuries, death was confirmed on the cessation of circulation, but in more recent times, confirmation of death has been based on the irreversible cessation of brain function.<sup>2</sup>

Cardiac death or, more precisely, irreversible circulatory cessation—on which the circulatory determination of death, or CDD, is based<sup>3</sup>—is again attracting interest as a standard for determining death because of the increasing demand for organs for transplantation, a morally problematic rationale.<sup>4</sup> Many more deaths are determined on the basis of cardiac criteria (due to cardiac arrest from various causes) than brain criteria (due to cessation of total brain activity, usually in a patient on life support in an intensive care unit).<sup>5</sup> Acceptance of CDD after a relatively short period of circulatory cessation potentially provides more, and more viable, organs for transplantation. Controversies in the medical profession concern the waiting period from circulatory cessation to organ donation and the propriety of pre-death, nontherapeutic procedures that are concerned with organ viability and transplantation, not with the well-being of the donor, which appear to violate the principle of totality and integrity.

<sup>&</sup>lt;sup>1</sup>Benedict XVI, Address to an International Congress Organized by the Pontifical Academy of Life (November 7, 2008).

<sup>&</sup>lt;sup>2</sup> John Paul II, Address to the Eighteenth International Congress of the Transplantation Society (August 29, 2000), n. 5; and Pius XII, Address to an International Congress of Anesthesiologists (November 24, 1957), reprinted in *Catholic Health Care Ethics: A Manual for Practitioners*, 2nd ed., ed. Edward J. Furton (Philadelphia: National Catholic Bioethics Center, 2009), 299–301. See also William E. May, *Catholic Bioethics and the Gift of Human Life*, 2nd ed. (Huntington, IN: Our Sunday Visitor, 2008), 317, regarding ongoing discussions in ethical–medical communities as to whether functions of the entire brain must have ceased.

<sup>&</sup>lt;sup>3</sup>Institute of Medicine (IOM), Committee on Increasing Rates of Organ Donation, *Organ Donation: Opportunities for Action*, ed. James F. Childress and Catharyn T. Liverman (Washington, DC: National Academies Press, 2006), 31; and James L. Bernat et al., "The Circulatory–Respiratory Determination of Death in Organ Donation," *Critical Care Medicine* 38.3 (March 2010): 964.

<sup>&</sup>lt;sup>4</sup>See James L. Bernat, "The Boundaries of Organ Donation after Circulatory Death," *New England Journal of Medicine* 359.7 (August 14, 2008): 669–671, http://www.nejm.org/doi/pdf/10.1056/NEJMp0804161; K. Hornby, L. Hornby, and S.D. Shemie, "Systematic Review of Autoresuscitation after Cardiac Arrest," *Critical Care Medicine* 38.5 (May 2010): 1246–1253; and Robert N. Sladen and R. Joseph Shonkwiler, "Donation after Cardiocirculatory Death: Back to the Future?" *Canadian Journal of Anesthesia* 58.7 (May 28, 2011): 591–598. The IOM notes that the demand for organs "far exceeds the current supply of available organs" (*Organ Donation*, 2). Current supply and demand statistics are available from OPTN, http://optn.transplant.hrsa.gov.

<sup>&</sup>lt;sup>5</sup> Joseph F. Magliocca et al., "Extracorporeal Support for Organ Donation after Cardiac Death Effectively Expands the Donor Pool," *Journal of Trauma Injury, Infection and Critical Care* 58.6 (June 2005): 1095–1101; and IOM, *Organ Donation*, 22.

These questions give rise to ethical quandaries for a surrogate who must make decisions on the basis of an advance directive stating that the patient does not want his life prolonged artificially and does want to donate his organs after death. Following a CDD protocol, can the surrogate be sure the patient is dead so that organ donation may occur? Does CDD subjugate our duty of care to the dying patient to the needs of patients who want organs to delay death or avoid disability? Without violating the principle of totality and integrity, may a surrogate authorize procedures that will be performed before death on a dying patient to preserve the patient's organs for transplantation?

This paper discusses these questions and shows the moral liceity of terminating disproportionate life support, donating vital organs after CDD with confirmed asystole of five minutes, and consenting to limited preparatory procedures performed on the dying patient so long as certain protocols are followed.

We take as a hypothetical example a patient with amyotrophic lateral sclerosis (ALS), whose condition has recently deteriorated, moving from ventilator support to ventilator dependence. The patient is worn physically, emotionally, and psychologically from the rigors of the disease and the severe limitations on his circumstances, including his current reliance on ventilation for respiration. He now lacks the competence to make medical decisions. The patient executed an advance health care directive many years ago, stating in very general terms that he does not want his life prolonged artificially but does want his organs donated to others upon his death.

## Licit Discontinuance of Life Support

Life is a precious gift. As Pope John Paul II wrote in *Evangelium vitae*, "Man has been given a sublime dignity, based on the intimate bond which unites him to his Creator: in man there shines forth a reflection of God himself." <sup>6</sup> Created by God, the author of biological generation, in his image, and infused with a soul, each human being is of inestimable dignity. <sup>7</sup> This dignity is consecrated by the Savior's incarnation as a human being and his free, loving choice to suffer crucifixion for our salvation, and is confirmed by "our common destiny to share a life with God beyond all corruption." <sup>8</sup> From beginning to end, the life of every human being "is part of God's plan, . . . in whom 'we live and move and have our being' (Acts 17:28)." <sup>9</sup>

<sup>&</sup>lt;sup>6</sup> John Paul II, Evangelium vitae (March 25, 1995), n. 34.

<sup>&</sup>lt;sup>7</sup> Ibid., n. 43.

<sup>&</sup>lt;sup>8</sup> U. S. Conference of Catholic Bishops (USCCB), *Ethical and Religious Directives for Catholic Health Care Services*, 5th ed. (Washington, DC: USCCB, 2009), part II introduction, hereafter cited as *ERDs*. See also USCCB, "To Live Each Day with Dignity: A Statement on Assisted Suicide" (June 16, 2011), 4, http://www.usccb.org/issues-and-action/human-life-and-dignity/assisted-suicide/to-live-each-day/.

<sup>&</sup>lt;sup>9</sup> John Paul II, Evangelium vitae, nn. 44 and 47.

Such dignity calls forth the responsibility of stewardship.<sup>10</sup> We do not own our lives.<sup>11</sup> We have been given life bought at the greatest price (1 Cor. 6:20) and therefore "do not have absolute power over life." <sup>12</sup> We have the obligation to preserve the gifts of life and health. <sup>13</sup> But this obligation is not absolute: death is inevitable, and life "finds its full perfection only in eternal life." <sup>14</sup> Thus understood, the obligation of stewardship imposes a requirement to utilize ordinary or proportionate means to preserve health and life. <sup>15</sup> As Pope Pius XII explained in his address to an international congress of anesthesiologists on November 24, 1957, "Normally one is held to use only ordinary means—according to circumstances of persons, places, times, and culture—that is to say, means that do not involve any grave burden for oneself or another. A more strict obligation would be too burdensome for most men and would render the attainment of the higher, more important good too difficult. Life, health, all temporal activities are in fact subordinated to spiritual ends." <sup>16</sup>

We determine whether a particular treatment is ordinary and proportionate or extraordinary and disproportionate by assessing "the type of treatment to be used, its degree of complexity or risk, its cost and the possibilities of using it, and comparing these elements with the result that can be expected, taking into account the state of the sick person and his or her physical and moral resources." Treatment that offers reasonable likelihood of benefit and is not too burdensome, considering the patient's personal, financial, and social circumstances, is ordinary, or proportionate, and obligatory. Treatment that offers no reasonable hope of benefit or is too burdensome, considering a patient's circumstances, is understood as extraordinary or disproportionate care and is therefore not morally obligatory. This does not mean that medical measures originally determined ordinary must continue once begun. If ordinary means become extraordinary, because they have proved to be futile or disproportionately burdensome, they may be discontinued, as there is no difference between forgoing extraordinary or disproportionate means initially and terminating them once so determined. On the proportionate means initially and terminating them once so determined.

<sup>&</sup>lt;sup>10</sup> Ibid., n. 48; *Catechism of the Catholic Church*, n. 2280; and Congregation for the Doctrine of the Faith (CDF), *Declaration on Euthanasia* (May 5, 1980), I, http://www.vatican.va/roman\_curia/congregations/cfaith/documents/rc\_con\_cfaith\_doc\_19800505\_euthanasia\_en.html. The selection of a surrogate and implementation of the surrogate's authority are also components of the responsibility of stewardship; see *ERDs*, n. 25.

<sup>&</sup>lt;sup>11</sup> John Paul II, Evangelium vitae, n. 40.

<sup>&</sup>lt;sup>12</sup> ERDs, part V, introduction.

<sup>&</sup>lt;sup>13</sup>CDF, Declaration on Euthanasia, I; and ERDs, n. 32.

<sup>&</sup>lt;sup>14</sup>CDF, Declaration on Euthanasia, I.2.

<sup>&</sup>lt;sup>15</sup>*ERDs*, nn. 32 and 56.

<sup>&</sup>lt;sup>16</sup>Pius XII, Address to Anesthesiologists, 300.

<sup>&</sup>lt;sup>17</sup>CDF, Declaration on Euthanasia, IV.

<sup>18</sup> ERDs, n. 56.

<sup>&</sup>lt;sup>19</sup> Ibid., n. 57.

<sup>&</sup>lt;sup>20</sup> John Paul II, *Evangelium vitae*, n. 65; see also *ERDs*, n. 57; and Pius XII, Address to Anesthesiologists, 301.

A death resulting from the withdrawal of extraordinary or disproportionate medical procedures is not a case of euthanasia or assisted suicide. The decision to forgo or terminate extraordinary or disproportionate means of preserving life is an acknowledgment that the means have begun to prolong life artificially.<sup>21</sup> It is not a decision based on the assertion of an independent, autonomous right of self-determination or on a subjective assessment of an insufficient quality of life. Nor is a surrogate's decision to withdraw treatment an expression of disregard for a neighbor's need (Luke 10:25–37, Lev. 19:16). Instead, it shows an acceptance of the reality of the inevitable end of human life by the forgoing of extraordinary or futile procedures that artificially prolong it, and the withdrawal of treatment is permissible "so long as the normal care due to the sick person in similar cases is not interrupted."<sup>22</sup>

Both civil law and the *Ethical and Religious Directives* (*ERDs*) recognize the validity and benefit of appointing a health care surrogate to make decisions for a patient who is temporarily or permanently unable to make health care decisions for himself.<sup>23</sup> In California, for example, the lawful scope of the surrogate's authority is identical to that of the patient: the surrogate may make health decisions to the same extent as the principal during capacity.<sup>24</sup> A Catholic surrogate who exercises such authority must be faithful to Catholic moral principles and to the patient's intentions and values or, if the latter are unknown, to the patient's best interests.<sup>25</sup> Assuming that the advance directive contains the provisions laid out in the hypothetical case mentioned above, the surrogate's authority legally and morally is coextensive in scope to that of the patient.

In the example of the patient with ALS, these principles present the surrogate with the moral and legal authority to terminate life support licitly. The surrogate possesses the written authorization in the advance directive, but he or she must also obtain all reasonable information regarding the patient's condition, the patient's prognosis, and the procedure for discontinuing ventilation so that he may make a free and informed judgment in authorizing withdrawal from the ventilator.<sup>26</sup>

In the example, the patient's ALS has progressed to the point of complete deprivation of respiratory function: the patient cannot breathe on his own. A machine has replaced the vital function of his inoperative respiration, and the patient's respiratory function will never return. Because the ventilator is not a temporary response to a transient circumstance but a permanent, mechanical replacement of the patient's respiratory function, it is not ordinary or proportionate care.<sup>27</sup> The patient's life is being artificially prolonged by a machine despite his permanent inability to breathe. By withdrawing ventilator support, the surrogate does not offend Catholic moral

<sup>&</sup>lt;sup>21</sup> See Catechism of the Catholic Church, n. 2278.

<sup>&</sup>lt;sup>22</sup>CDF, Declaration on Euthanasia, IV; see also John Paul II, Evangelium vitae, n. 65.

<sup>&</sup>lt;sup>23</sup> See *ERDs*, n. 25.

<sup>&</sup>lt;sup>24</sup> California Probate Code § 4683(a).

<sup>&</sup>lt;sup>25</sup> *ERDs*, n. 25.

<sup>&</sup>lt;sup>26</sup> Ibid., nn. 26–28 and 57.

<sup>&</sup>lt;sup>27</sup> Ibid., n. 56.

principles regarding the sanctity of life, because the ventilator cannot restore respiration and its use is excessively burdensome.<sup>28</sup>

#### Cardiac Death as a Morally Licit Criterion

Vital organ donation is laudable but permissible only after the death of the patient.<sup>29</sup> As John Paul II states, organ donation, "performed in an ethically acceptable manner," proclaims the Gospel of Life as "offering a chance of health and even life itself to the sick who sometimes have no hope," and constitutes "a gesture which is a genuine act of love ... by giving something of ourselves." <sup>30</sup> But does CDD provide a morally licit criterion for the determination of death?

Since the 1980s, death has typically been defined as brain death. In 1980, the National Conference of Commissioners on Uniform State Laws approved and recommended adoption by all the states of the Uniform Determination of Death Act. As the commissioners explained, the UDDA became necessary because of advances in life-saving medical technology, which resulted in a medical, legal, and moral challenge of great significance. This was the specter of the living dead—a person whose entire brain function had ceased but whose circulation and respiration were continued by mechanical means.<sup>31</sup> Since the common law standard for the determination of death was cessation of circulatory and respiratory functions, these medical developments sparked a decade-long interdisciplinary reassessment of death, resulting in the UDDA standard: a person is dead "who has sustained either (1) irreversible cessation of circulatory and respiratory functions or (2) irreversible cessation of all functions of the entire brain, including the brain stem." The UDDA has been adopted, in some form, in almost every state.<sup>33</sup>

The Church has recognized each of the criteria set forth in the UDDA as evidence that death has occurred. While the magisterium teaches that death occurs when the soul leaves the body, it recognizes that there is no method to specifically identify that event.<sup>34</sup> The Church also has long understood that it is not the Church's prerogative to define death and its occurrence scientifically; this decision is within

<sup>&</sup>lt;sup>28</sup> Ibid., nn. 32 and 57; John Paul II, Evangelium vitae, n. 65.

<sup>&</sup>lt;sup>29</sup> Ibid., n. 64; John Paul II, Address to Transplantation Society, n. 4; and Benedict XVI, Address to Congress Organized by the Pontifical Academy of Life.

<sup>&</sup>lt;sup>30</sup> John Paul II, Address to Transplantation Society, nn. 1 and 3, and *Evangelium vitae*, n. 86; see also John Paul II, Address to First International Congress of the Society for Organ Sharing (June 20, 1991).

<sup>&</sup>lt;sup>31</sup> National Conference of Commissioners on Uniform State Laws, *Uniform Determination of Death Act*, (1980), prefatory note, http://www.law.upenn.edu/bll/archives/ulc/fnact99/1980s/udda80.htm.

<sup>&</sup>lt;sup>32</sup> Ibid., prefatory note and sec. 1.

<sup>&</sup>lt;sup>33</sup>Maxine M. Harrington, "The Thin Flat Line: Redefining Who Is Legally Dead in Organ Donation after Cardiac Death," 86 Denv. U.L. Rev. 335 (2009), 342; and Uniform Law Commission, "Legislative Fact Sheet—Determination of Death Act," 2012, http://uniformlaws.org/LegislativeFactSheet.aspx?title=Determination%20of%20Death%20Act.

<sup>&</sup>lt;sup>34</sup>Pius XII, Address to Anesthesiologists, 300; and John Paul II, Address to the Transplantation Society, n. 4.

the competence of medicine.<sup>35</sup> Pius XII accepted that circulatory cessation would bring about death "in a few minutes."<sup>36</sup> In his 2000 address to the Transplantation Society, John Paul II recognized the traditional "cardio-respiratory signs" of death and acknowledged the liceity of health workers' reliance on "complete and irreversible cessation of all brain activity (in the cerebrum, cerebellum, and brain stem)" as "a scientifically secure means of identifying the biological signs that a person has indeed died."<sup>37</sup> While John Paul II addressed the neurological determination of death, he did not preclude reliance upon the circulatory determination of death. Both John Paul II and Pius XII recognized irreversible circulatory cessation as an indicator of death in modern medical science.

When does circulatory death occur? The response from medical science is more complicated than the elementary assessment of no heartbeat and no pulse. The standard for the determination of circulatory death has developed in the United States over the past three decades in tandem with developments in transplantation and the concomitant increase in demand for transplantable organs. In 1984, the National Organ Transplant Act created the Organ Procurement Transplantation Network, which maintains a list of persons requiring transplants, matches organs to patients, operates a procurement and allocation system, provides information to physicians and other professionals on organ donation, and maintains an extensive database. The network includes regional organ procurement organizations, which are responsible for procuring, testing and distributing organs in their regions.

The use of brain death criteria allows organ procurement to proceed without ischemic damage to vital organs, which are maintained by the use of life support preceding death; this makes organs procured from donors declared dead by brain death criteria vastly preferable to organs procured after CDD, which "invariably incur some ischemic damage following donor circulatory and respiratory arrest." <sup>40</sup> But because the number of brain-dead organ donors remains insufficient to meet transplantation needs, manifold efforts are being made to increase the supply of donors, and interest in CDD to increase possible organ sources has been renewed, owing to favorable developments in "donor preparation and organ preservation methods." <sup>41</sup>

Cardiac deaths are divided into two categories: controlled and uncontrolled.<sup>42</sup> The controlled CDD (expected death) category pertains to patients who, because of

<sup>&</sup>lt;sup>35</sup>Pius XII, Address to Anesthesiologists, 301, n. 3; see also *ERDs*, n. 62.

<sup>&</sup>lt;sup>36</sup>Pius XII, Address to Anesthesiologists, 299 and 300.

<sup>&</sup>lt;sup>37</sup> John Paul II, Address to Transplantation Society, nn. 4 and 5.

<sup>&</sup>lt;sup>38</sup> National Organ Transplant Act of 1984, Pub. L. 98–507, 98 Stat. 2339, sec. 372(b)(2); IOM, *Organ Donation*, 20.

<sup>&</sup>lt;sup>39</sup> Harrington, "Thin Flat Line," 343.

<sup>&</sup>lt;sup>40</sup> Sladen and Shonkwiler, "Donation after Cardiocirculatory Death," 592.

<sup>&</sup>lt;sup>41</sup> IOM, *Organ Donation*, 1–2. OPTN provides current supply and demand statistics, http://optn.transplant.hrsa.gov. Harrington, "Thin Flat Line," 343–345.

<sup>&</sup>lt;sup>42</sup>Bernat et al., "Circulatory–Respiratory Determination of Death," 964. The IOM suggests that a change in nomenclature from *controlled* to *expected* and from *uncontrolled* to *unexpected* may make the meanings less "subject to misinterpretation." *Organ Donation*, 130.

the futility of care, have decided themselves or through surrogates that life support will be removed and resuscitation will not be performed, with death resulting. The uncontrolled CDD category pertains to those who suffer cardiac arrest outside the hospital or unexpectedly during hospitalization and for whom resuscitation is unsuccessful. Most organ donation programs in the United States exclude organs from donors who were "unsuccessfully resuscitated from in- or out-of-hospital cardiac arrest" 44—in other words, from uncontrolled CDD patients.

Since patients in the uncontrolled category have no cardiac activity and resuscitation has failed, the fact that death has occurred is certain, as evidenced by irreversible circulatory cessation; it is therefore not necessary to determine whether irreversible cessation of all functions of the entire brain has occurred. For patients in the controlled category, however, resuscitation will not be attempted after life support is removed. This raises a question regarding irreversibility, because a failed attempt at resuscitation customarily provides confirmatory evidence of irreversible cessation of circulation, but such evidence is not available in controlled deaths.

Without a failed resuscitation effort, how do we know circulatory cessation is irreversible? The response of the medical community has been that we know cessation is irreversible when "cardiopulmonary function *will not resume spontaneously*" during a specified observation period.<sup>46</sup> This "death watch" following the loss of heartbeat and breathing (asystole and apnea) is to rule out autoresuscitation (the return of circulation).<sup>47</sup>

The medical literature reports cases of autoresuscitation after cardiac arrest following failed cardiopulmonary resuscitation (CPR).<sup>48</sup> However, "autoresuscitation has never been reported after sixty-five seconds of asystole" (absence of heartbeat, or cardiac electrical activity) and, therefore, absence of blood circulation.<sup>49</sup> Absent cardiac activity is determined by electrocardiography and absent pulse by arterial catheter.<sup>50</sup>

<sup>&</sup>lt;sup>43</sup> Bernat et al., "Circulatory–Respiratory Determination of Death," 964; and Harrington, "Thin Flat Line," 345–346.

<sup>&</sup>lt;sup>44</sup>Bernat et al., "Circulatory–Respiratory Determination of Death," 964.

<sup>45</sup> Ibid., 965.

<sup>&</sup>lt;sup>46</sup> James L. Bernat et al., "Report of a National Conference on Donation after Cardiac Death," *American Journal of Transplantation* 6.2 (February 2006), 282, original emphasis. This is a second period of observation. The first is the time from the removal of life support until death. If that period lasts longer than one hour, the patient cannot be a donor, as organ quality diminishes during the dying process. Magliocca, "Extracorporeal Support for Organ Donation," 1097. The second period, and the one discussed here, is the time from loss of heartbeat (asystole) to formal declaration of death—that is, "the period necessary to determine that circulation will not recur spontaneously" (Bernat et al., 282). After this period, organ recovery can begin.

<sup>&</sup>lt;sup>47</sup>Bernat et al., "Circulatory–Respiratory Determination of Death," 964.

<sup>&</sup>lt;sup>48</sup> Sladen and Shonkwiler, "Donation after Cardiocirculatory Death," 593.

<sup>&</sup>lt;sup>49</sup>Bernat, "Boundaries of Organ Donation," 670.

<sup>&</sup>lt;sup>50</sup>Bernat et al., "Circulatory–Respiratory Determination of Death," 966.

The Institute of Medicine has recommended an asystolic period of five minutes, but the Society of Critical Care Medicine and the American Society of Transplant Surgeons advocate a two-minute period.<sup>51</sup> In 2005, an interdisciplinary National Conference on Donation after Cardiac Death supported the recommendation of the Society of Critical Care Medicine that "at least two minutes of observation is required, and more than five minutes is not recommended."<sup>52</sup>

However, the actual practices of organ procurement organizations cast doubt on the general acceptance in the medical community of a waiting period of two to five minutes of asystole, and indicate the need for adherence to the five-minute protocol, the original standard reported by the Institute of Medicine. Karen Hornby, Laura Hornby, and Sam Shemie note that there "is a lack of consensus on how long circulation must cease for death to be determined after cardiac arrest." This conclusion is confirmed by Jennifer Fugate and colleagues in their assessment of sixty-four cardiac-death protocols from organ procurement organizations (OPOs) throughout the United States. Of these OPOs, forty-nine require confirmation of circulation cessation by observation for five minutes, ten specify no particular observation period, one specifies three minutes, and three specify two minutes. In other words, 75 percent of OPOs follow a five-minute protocol and only 0.5 percent follow a two-minute protocol.

The principle of totality and integrity demands that no harm accrue to the patient unless the harm is necessary to preserve the patient's life or health. Very short asystole protocols may cause harm to patients solely for the benefit of others. The two-minute standard, which was proposed by the Society of Critical Care Medicine and the Transplantation Society, appears tainted by conflict of interest, a suspicion that the waiting interval has been minimized to avoid damage to transplantable organs, not to protect the patient-donor. As Pope Benedict XVI counsels, "There cannot be the slightest suspicion of arbitration, and where certainty has not been attained the principle of precaution must prevail." Since no one suggests that transplantation occur after only sixty-five seconds of asystole, there is evident doubt about the immediacy of circulatory cessation following asystole. Two minutes is a very short time. Reducing the waiting period to this extent disregards the principle of totality and integrity and taints confidence in the integrity of the standard.

Some contend that CDD is a legally or morally sufficient standard only because the irreversible cessation of circulation and respiration leads to brain death.<sup>56</sup> The

<sup>&</sup>lt;sup>51</sup> IOM, *Organ Donation*, 145–146; and Sladen and Shonkwiler, "Donation after Cardiocirculatory Death," 592–593.

<sup>&</sup>lt;sup>52</sup> Bernat et al., "Report of National Conference," 282.

<sup>&</sup>lt;sup>53</sup>Hornby, "Autoresuscitation after Cardiac Arrest," 1246.

<sup>&</sup>lt;sup>54</sup> Jennifer E. Fugate et al., "Variability in Donation after Cardiac Death Protocols: A National Survey," Transplantation 91.4 (February 27, 2011): 386–389.

<sup>&</sup>lt;sup>55</sup>Benedict XVI, Address to International Congress Organized by PAL.

<sup>&</sup>lt;sup>56</sup>Bernat, "Boundaries of Organ Donation," 670; and Francis L. Delmonico, "The Concept of Death and Deceased Organ Donation," *National Catholic Bioethics Quarterly* 10.3 (Autumn 2010): 452, 454.

argument, whether put forth secularly as a construction of the UDDA or morally as an interpretation of John Paul II's 2000 address to the transplantation society, is that the neurological standard of death of the entire brain was adopted as the exclusive standard for the determination of death. The contention finds no support in either the UDDA or John Paul II's address. The UDDA's disjunctive phraseology clearly indicates that *either* irreversible cessation of circulation *or* irreversible cessation of function of the entire brain suffices for a legal declaration of death.<sup>57</sup> And while John Paul II acknowledges specifically that the neurological criterion appears morally licit as providing "that degree of assurance in ethical judgment which moral teaching describes as 'moral certainty,'" he definitively refuses to identify either criterion as the only morally licit one for the determination of death: "With regard to the parameters used today for ascertaining death—whether the 'encephalic' signs or the more traditional cardio-respiratory signs—the Church does not make technical decisions." <sup>58</sup>

The contention that CDD is insufficient alone also confuses the fundamental issue, which is whether *death* has occurred, not whether brain death or cardiac death has occurred. Each system is a *sine qua non* of life: "Once circulation is permanently lost, so too is neurologic function permanently lost. Consciousness is lost and brain function ceases approximately 15 seconds after circulation to the brain ceases." <sup>59</sup> When either circulation or brain function ceases, the human being ceases to be alive. Consequently, irreversible cessation of circulation is a legal and morally sufficient basis for the determination of death.

Others contend that even five minutes does not establish irreversible circulatory cessation. For example, James Bernat notes that the five-minute standard establishes permanent, not irreversible, cessation of circulation. The distinction has semantic allure, because in controlled or expected CDD resuscitation will not be attempted, suggesting that the issue of irreversibility remains unresolved, but this contention misses the point. Autoresuscitation becomes impossible after sixty-five seconds of asystole: once the period of circulatory cessation has passed the point of autoresuscitation by almost four minutes, it is impossible (to the certainty of current medical science) for the patient's circulation to resume on its own. Such a patient has suffered irreversible cessation of circulation. Historically, and by the standard of natural reason, a human being ceases to live within a few minutes after circulation ceases, as Pius XII noted. Since the standard of five minutes of asystole confirms to the satisfaction of medical science that the cessation of circulation is irreversible, the human being has finished his earthly life. Without circulation, life has left the body, and the person has ceased to be a unified and integrated whole.

<sup>&</sup>lt;sup>57</sup>ULC, Uniform Determination of Death Act, sec. 1; and IOM, Organ Donation, 82.

<sup>&</sup>lt;sup>58</sup> John Paul II, Address to Transplantation Society, n. 5.

<sup>&</sup>lt;sup>59</sup>IOM, Organ Donation, 146.

<sup>&</sup>lt;sup>60</sup>Bernat et al., "Circulatory–Respiratory Determination of Death," 965–966. In permanent cessation, circulation will not return; in irreversible cessation, it cannot return (964–965).

<sup>61</sup> Ibid., 965.

<sup>&</sup>lt;sup>62</sup> Pius XII, Address to Anesthesiologists, 300.

Francis Delmonico notes that both Robert Truog and Robert Veach contend that CDD is not irreversible if a patient's heart is subsequently transplanted successfully into another person. <sup>63</sup> However, the fact that a heart stops performing its integrating circulatory function in the circumstances of one patient, but with surgical and chemical interventions resumes it in the circumstances of another, does not bring into question the irreversible cessation of circulation in the original patient. With or without the heart, the original patient's integrating circulatory function ceased irreversibly; it could not resume on its own. That the same heart might later beat in another person is irrelevant to the determination of death in the original patient. <sup>64</sup>

The five-minute protocol establishes a criterion for the determination of death that is consonant with the dignity of the human person. As John Paul II declared in his address to the transplantation society, death is an event consisting of "the total disintegration of that unitary and integrated whole that is the personal self. It results from the separation of the life-principle (or soul) from the corporal reality of the person." <sup>65</sup> Following withdrawal of life support, the patient in controlled CDD circumstances experiences the process of death until heart function ceases. At that point—like a patient with advanced metastatic carcinoma who has breathed his last, or a patient in intensive care who has "flatlined" (with constant asystole), or a patient after failed CPR—the patient undergoing controlled CDD may be declared dead on the basis of the absence of heartbeat and circulation as appropriately determined. <sup>66</sup> In each of these cases, the total disintegration of the person as a unitary self is evident because the circulatory function, essential for life, has ceased and lacks the ability to resume. So too with the patient undergoing controlled CDD. A patient whose circulation stops, without the ability to resume, is dead.

#### **Avoiding Rushed Cardiac Death Determinations**

Adoption of a Five-Minute Period of Asystole

The issue for a potential CDD donor is ascertainment of death. None of the transplantation addresses of the papal magisterium, no recognized Catholic moral principles, and no provision of the UDDA permits a change in the standards for determining death because of transplantation: the fact of death must be established without regard to transplantation concerns. The human dignity of the dying patient requires no less.<sup>67</sup>

<sup>63</sup> Delmonico, "Concept of Death," 454.

<sup>&</sup>lt;sup>64</sup>My argument is similar to that of Delmonico in reliance upon Bernat et al., except that my explanation contends irreversibility while Delmonico and Bernat et al. contend permanence.

<sup>&</sup>lt;sup>65</sup> John Paul II, Address to Transplantation Society, n. 4.

<sup>&</sup>lt;sup>66</sup>Bernat et al., "Circulatory–Respiratory Determination of Death," 964.

<sup>&</sup>lt;sup>67</sup>May, *Catholic Bioethics*, 316–317. As May and Paul Ramsey contend, the separation of the care physician from the transplant physician in the practical realm (to guard against conflicts of interest) parallels the separation in the intellectual realm between the determination of death and the use of organs for transplantation (to protect the dignity of the dying patient).

As both John Paul II and Benedict XVI agree in their transplantation society addresses, "Moral certainty is ... the necessary and sufficient basis for an ethically correct course of action" in this area. 68 Moral certainty requires the establishment of a medical standard that provides reliable evidence that death has occurred. The persistence of asystole over five minutes establishes such certainty. The medical community overwhelmingly agrees that five minutes of asystole confirms irreversible cessation of circulation, demonstrating that death has occurred. The pressure for shorter periods appears to emanate from the transplantation community, with its bias in favor of best organ viability. Until studies confirm the irreversible cessation of circulation after two minutes of asystole, the five-minute standard should be followed.

Confirmation of Circulatory Cessation by Electrocardiography and Arterial Catheterization

Bernat contends that circulatory cessation can be determined by pulse and arterial catheter alone; ineffectual heartbeats do not affect circulation.<sup>69</sup> Yet a beating heart, however weak, is still beating, and while a patient's heart beats without assistance, the integrative capacity remains, and the life source cannot be said to be absent or the soul departed. Consequently, until asystole has been confirmed by electrocardiography and the cessation of circulation has been confirmed by arterial catheterization, death cannot be said to have occurred and the five-minute observation period cannot begin.

Limits on Contact between the Patient or Surrogate and the Transplant Team

The question of whether to discontinue ventilation that has become excessively burdensome must be decided without regard to the issue of transplantation. The human dignity of the patient demands such respect. His life is not subordinate to the life of any other person, and for him to permit his own life to be terminated through organ donation is as morally repugnant as it would be for a surrogate to permit it. While organ donation is licit, it is licit only if the patient is "not placing his/her own health and identity in serious danger, and only for a morally valid and proportional reason." Donation of vital organs cannot occur until after death. Otherwise, vital organ donation constitutes euthanasia or assisted suicide.

To avoid confusion of the issues, as well as implicit coercion—since awareness of another patient's need for a transplant may affect a dying patient's decision to terminate extraordinary care—the subject of transplantation should not be addressed until after the decision about terminating ventilator support has been made. An

<sup>&</sup>lt;sup>68</sup> John Paul II, Address to Transplantation Society, n. 5; see also Benedict XVI, Address to International Congress Organized by PAL.

<sup>&</sup>lt;sup>69</sup> Bernat et al., "Circulatory–Respiratory Determination of Death," 966.

<sup>&</sup>lt;sup>70</sup> *ERDs*, n. 23.

<sup>&</sup>lt;sup>71</sup>Benedict XVI, Address to International Congress Organized by PAL; and *ERDs*, n. 30.

<sup>&</sup>lt;sup>72</sup> John Paul II, Address to Transplantation Society, n. 4; see also Benedict XVI, Address to International Congress Organized by PAL, and *ERDs*, n. 64.

inherent part of a proper protocol, of course, is the complete separation of the care team from the transplant team.<sup>73</sup>

#### Uninterrupted Care of the Patient

Patient care should continue uninterrupted. The patient undergoing controlled CDD should receive all indicated care and comfort measures without regard to potential transplantation. Care should never be compromised. The utmost care of each patient, inherent in the dignity of the human person, is the moral commitment of health care workers. The patient has entrusted his care to them, s and it would be a betrayal of that trust to change his care in any way because of a decision about transplantation. Moreover, if the donation of organs is to be encouraged generally, changes in care due to donation decisions will be inherently counterproductive and can only fuel mistrust. The Institute of Medicine has reported that the major objection to organ donation is fear that if a patient's donor status is known, his care will be compromised. Countering such mistrust requires that the care continuum for dying patients is clearly not affected by their donation decisions.

Appropriate care includes access to, if not provision for, religious resources as the dying patient prepares to meet Christ, in keeping with the traditions of the religion the patient practices or esteems.<sup>77</sup> For Catholic patients, the hospital and the surrogate should make sure the sacraments are available, particularly Anointing of the Sick, Reconciliation, and Viaticum, and under no circumstances should ventilation be discontinued until the higher obligations have been satisfied.<sup>78</sup>

#### Informed Consent of the Surrogate

Informed consent of the surrogate is mandatory.<sup>79</sup> Termination of ventilation requires a decision on the cessation of medical treatment and procedures, and all "reasonable information about the essential nature of the procedure" <sup>80</sup> must be provided, including information regarding the process of stopping ventilation, the use of palliative antispasmodics and relaxants to ease the deprivation of ventilation for the patient, and the process of determining death, including the five-minute period of observation to confirm circulatory cessation. In addition, all the surrogate's questions, including moral ones, should be answered and requests for information or counseling should be honored.<sup>81</sup> While perfectly informed consent is unlikely, "adequately informed and free consent" in accordance with the Golden Rule suffices.<sup>82</sup>

<sup>&</sup>lt;sup>73</sup> *ERDs*, n. 64.

<sup>&</sup>lt;sup>74</sup> Ibid., n. 23.

<sup>&</sup>lt;sup>75</sup> Pontifical Council for Pastoral Assistance to Health Care Workers, *Charter for Health Care Workers* (Vatican City: Libreria Editrice Vaticana, 1995), n. 2.

<sup>&</sup>lt;sup>76</sup>IOM, Organ Donation, 69 and 82.

<sup>&</sup>lt;sup>77</sup> John Paul II, Evangelium vitae, n. 65; and CDF, Declaration on Euthanasia, III.

<sup>&</sup>lt;sup>78</sup> ERDs, nn. 10-13, 15 and 16.

<sup>&</sup>lt;sup>79</sup> Ibid., n. 26.

<sup>80</sup> Ibid., n. 27.

<sup>81</sup> Ibid., n. 28.

<sup>82</sup> May, Catholic Bioethics, 220.

### Preparations to Facilitate Transplantation and Preserve Organ Viability

Assuming that the previous protocols have been followed and the surrogate has decided to terminate ventilation as unduly burdensome, then and only then may the issue of organ transplantation be raised. Transplantation requires informed consent, which means that information and counseling appropriate to its separate and distinct issues must be provided. These issues include how and when transplantation will occur in relation to the processes of stopping ventilation and confirming the cessation of circulation; what pre-death procedures will be used to facilitate organ transplantation and viability; and specifically whether intravenous heparin will be administered before death to impair coagulation, whether balloon catheterization will be performed before death, and whether solutions to reduce body temperature or extracorporeal membrane oxygenation (ECMO) will be performed after death.<sup>83</sup>

Utilization of any pre-death transplant preparation procedures must comply with the principle of totality and integrity. Such procedures must respect the dignity of the patient through natural death, without regard to health conditions or circumstances. 84 The well-being of the whole person—spiritual, physical, mental, and emotional—must be taken into account when considering pre-death transplant preparation procedures. 85

Neither directive 31 nor directive 33 of the *ERDs* is directly applicable to predeath transplant-preparation procedures, which are not experimental or therapeutic. <sup>86</sup> However, directive 31 is instructive because of the dying patient's vulnerability and because the pre-death procedures are nontherapeutic for the patient: by inhibiting damage to the donor's organs from coagulation and warm ischemia, these procedures benefit the organ recipients, not the donor. Thus understood, the procedures are licit only if they pose no significant risk to the dying patient's well-being considered in its entirety—spiritual, physical, mental, and emotional. In our hypothetical case, since the patient lacks competence, there must be a substantial need for these non-therapeutic procedures.

Directive 33 is instructive in that, if therapeutic procedures that cause harm or undesirable side-effects may be performed only if they confer a proportionate

<sup>83</sup> *ERDs*, n. 26.

<sup>84</sup> Ibid., nn. 23 and 60.

<sup>85</sup> Ibid., nn. 29, 31, and 33.

<sup>86</sup> Directive 31 states that "no one should be the subject of medical or genetic experimentation, even if it is therapeutic, unless the person or surrogate first has given free and informed consent. In instances of nontherapeutic experimentation, the surrogate can give this consent only if the experiment entails no significant risk to the person's well-being. Moreover, the greater the person's incompetency and vulnerability, the greater the reasons must be to perform any medical experimentation, especially nontherapeutic." Directive 33 states, "The well-being of the whole person must be taken into account in deciding about any therapeutic intervention or use of technology. Therapeutic procedures that are likely to cause harm or undesirable side-effects can be justified only by a proportionate benefit to the patient."

benefit to the patient, then nontherapeutic procedures must satisfy no less stringent a requirement. Consequently, pre-death transplant-preparation procedures may be used licitly only if they pose no significant risk to the patient, his dignity, or his integral well-being. Procedures that are harmful or produce undesirable side effects may be performed only if they produce a benefit to the dying patient that is proportional to the harm.

Heparin may be administered intravenously before death to impair coagulation and maintain organ viability. The available medical literature indicates that its use in this way does not endanger the donor or cause undesirable side effects.<sup>87</sup> Since heparin is dispensed intravenously through a peripheral venous cannula that is likely to have been inserted previously for medications and other substances, the dignity and integral well-being of the patient are not disturbed. The pre-death administration of heparin in these circumstances, assuming informed consent, is licit.

The placement of a cannula in the femoral artery and an occluding balloon in the aorta before death, in preparation for the use of ECMO after death, are an entirely different matter. In ECMO, a cardiopulmonary bypass machine is used to provide artificial circulation to the organs after death to preserve them for transplantation. The cannula is a necessary part of this perfusion. The occluding balloon is placed in the aorta and its placement confirmed by temporary inflation before death, but it is permanently inflated after death to prevent the artificial circulation from re-animating the patient's heart.<sup>88</sup>

These two procedures are each problematic morally. The insertion of the cannula and the occluding balloon are nontherapeutic procedures that affect the patient without providing benefit, and they may be uncomfortable and frightening in the moments before death, particularly for incompetent patients. In addition, use of the occluding balloon to prevent ECMO from re-animating the heart raises serious questions about the irreversibility of circulatory cessation.<sup>89</sup>

The provision of relaxants and analgesics during pre-death procedures may minimize a dying patient's discomfort and anxiety, but these procedures are not without the risks that accompany all invasive procedures, they do nothing to ensure the well-being of the dying patient, and they disrupt the dignity of the patient's final moments of life and prayerful preparation for meeting Christ. These considerations are all the more pressing because our hypothetical patient is incompetent and vulnerable, circumstances for which directive 31 mandates greater care.

It may be argued that a patient's charitable desire to donate organs is evident in his written directive. However, that directive is likely to indicate only the patient's desire to donate his organs after death, not during life. Without further information about the dying patient's intentions, a vaguely written directive is not persuasive evidence of the donor's intention to authorize painful, risky, and disruptive procedures in the last minutes of life. Of course, if a donor has explicitly authorized pre-death

<sup>87</sup> IOM, Organ Donation, 146-147.

 $<sup>^{88}\</sup>mbox{Details}$  of these procedures are based on Magliocca, "Extracorporeal Support for Organ Donation," 1095–1097.

<sup>89</sup> Bernat, "Boundaries of Organ Donation," 671.

transplant-preparation procedures such as arterial cannulation and placement of an occluding balloon for ECMO, these procedures would be considered a proportionate harm to which the donor has consented, and directive 30 would allow them. In that case, since the procedures involve impairment not of an essential bodily function but of the patient's dignity and integral well-being, and since the patient consented to them as part of the charitable gift of his organs after death, his voluntary participation in pre-death transplant-preparation procedures would be licit.

In our hypothetical case, however, if we assume that the surrogate has no further knowledge of the dying patient's intentions, the patient's written authorization does not provide explicit consent to arterial cannulation and ECMO procedures. Therefore, the surrogate cannot authorize these procedures, since they are illicit because of the patient's vulnerability (directive 31), the imposition of harm without patient benefit (directive 33) and the lack of informed consent (directive 27).

#### **Assessing Totality and Integrity**

The magisterium of the Church provides reassuring guidance for Catholic patients and surrogates who must make decisions about declining or discontinuing extraordinary or disproportionate care, using circulatory determination of death, donating organs, and authorizing pre-death transplantation procedures:

- Extraordinary or disproportionate care may be discontinued after informed consent has been given for the process, procedures, the circumstances of death determination and after the spiritual and sacramental needs and desires of the patient have been met.
- Death may be declared after five minutes of confirmed circulatory cessation, so long as a period of five minutes of confirmed asystole is observed, circulatory cessation is confirmed by electrocardiography and arterial catheterization, assessment for transplantation is not done until after the decision to discontinue ventilation has been made, and continuing care for the patient is not interrupted.
- Organs may be donated after death has been declared following the protocols discussed here, including the obtaining of informed consent for the process and for pre-death transplant-preparation procedures such as the administration of intravenous heparin, arterial cannulation, and placement of an occluding balloon for use in ECMO.
- As to intravenous administration of heparin, the absence of harm to the patient
  indicates its liceity. However, the invasive arterial cannulation and balloon
  catheterization procedures offend the principle of totality and integrity and
  expose dying patients, especially those who are incompetent, to risky and
  painful procedures without proportionate benefit during the most vulnerable
  moments of life.

If a patient has given more detailed and explicit instructions regarding donation and has authorized such procedures, a different decision would be licit. In the absence of these, however, arterial cannulation and ECMO must be considered illicit and should not be permitted.