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An Examination of the Bio-Philosophical Literature on the Definition and Criteria of Death: When is Dead Dead and Why Some Donation After Cardiac Death Donors Are Not

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An Examination of the Bio-Philosophical Literature on the Definition and Criteria of Death: When is Dead Dead and Why Some Donation After Cardiac Death Donors Are Not

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For my grandparents,
Marguerite and Joseph Tantalo

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Preface

Human fascination with transplantation has been portrayed in mythology and legend as well as in art and literature throughout history. It has both horrified and captivated our collective conscience and has progressed, in a relatively short time period, from science fiction to a modern accomplishment that can improve longevity and enhance quality of life.

The primary obstacle for transplantation is no longer scientific in nature but is predominantly one of supply and demand and carries with it attendant ethical concerns. Specific to this work is the question of whether a particular method of organ procurement known as Donation After Cardiac Death procures organs from the newly dead or from the imminently dying. Since the normative rules that guide transplantation require that one may not be killed for or by the removal of one's organs determining the nature of death is of paramount importance.

Accordingly, the primary question concerned herein is whether Donation After Cardiac Death donors are dead at the moment of organ recovery. This work focuses on the conceptual underpinnings of why a person is said to be dead according to particular definitions and when specific criteria and tests are fulfilled. Much attention is devoted to exploring why the irreversible loss of cardio-respiratory functions or the irreversible cessation of all functions of the entire brain signifies death and whether these two criteria represent distinct types of death or if they instantiate the same overarching definition.

The first two chapters of this work are structured as a chronology demonstrating how our conception of death was intimately tied to the ability to test for certain bodily functions. These notions would quickly change when medicine developed technologies that could substitute for such functions and when transplantation demonstrated that the brain, not the heart, was of primary importance in determining life from death.

The third chapter focuses on clinical and theoretical arguments with the discussion of the traditional biological definition of death and the whole brain death criterion. Chapter four continues by challenging the biological definition of death as internally inconsistent and advances an ontological position while retaining the neurologic criterion. The dissertation concludes by drawing on the arguments established throughout to ultimately claim that some Donation After Cardiac Death Donors are not yet dead at organ procurement according to either a traditional or an ontological definition of death.

Transplantation saves lives and is a social good that society ought to continue to support. The aim of this dissertation is not to denigrate the field. On the contrary, if donation is to thrive we must ensure that our definition and criteria for death are coherent and that the methods for procurement operate accordingly.

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Chapter 1
The History of the Definition(s) of Death
18th century to the 20th century

A person is dead when a physician says so.[1]

This dissertation will argue that some Donation After Cardiac Death (DCD) donors are not dead at the moment of organ recovery because the practice uses a criterion of death that prognosticates death rather than diagnoses it. The analysis of DCD is reserved for the final chapter, with each prior chapter addressing a particular issue that contributes to the foundation of that claim.

This first chapter is not concerned with a conceptual exploration of what death "is" but focuses instead on when death occurs (determination of death) and the operational criteria used to confirm it (tests). The question of why death is said to occur when particular criteria are met will be more fully examined in chapter three during the discussion of cardio-respiratory death versus brain death. The purpose here is to chronicle when and how death has been determined beginning in the 18th century until the mid 20th century.

An interesting dynamic will be shown across these time periods. Physicians in the 18th century were certain that death occurred when the heart and lungs ceased but lacked adequate tests to certify it. In the 20th century the moment of death became less clear, and for that reason the tests physicians had finally perfected proved insufficient. This chapter lays the foundation for this dissertation

[1] Kenneth V. Iserson, *Death to Dust* (Tuscon: Galen Press Ltd., 1994) 19.

by examining when an individual is said to be dead and discusses it in an historical sequence.

To this end, this chapter will examine the history of the determination of death from the 18th century until the mid 20th century, focusing on the ways in which death has been diagnosed and misdiagnosed, the problem of premature burial, and the cultural shift that occurred when the brain death criterion was introduced.

Historically, until the early 20th century, physicians' inexperience in human anatomy and physiology left them poorly equipped to accurately test for death. Despite the fact that death could not be assessed with precision instruments, the moment when an individual was considered dead was simple and absent substantial disagreement: from the 18th through mid 20th centuries a person was declared dead when her heart stopped beating and her lungs ceased to function; this was also known as the cardio-respiratory standard of death. A consensus emerged that once the heart and lungs ceased to function the person was dead, although the empirical criteria to test for death were suspect, depending more on folklore, wives' tales, and superstition than on medical expertise. Because of this critical divide between theory and practice, instances of premature burial occurred.

Refined tests with enhanced sensitivity to measure somatic functions would come about later, in the early part of the 20th century. However, in this time period, while the criteria to test death were by now well established, the understanding of when death occurred became the subject of great debate. The fear of premature burial was replaced by the fear of suspended animation regulated by life support systems. These issues culminated in the latter part of the 20th century when the cardio- respiratory standard of death was reevaluated and a new notion of brain death was introduced. In addition to raising new questions as to the moment of death, the brain death criterion further necessitated that empirical tests be revised.

It is necessary to establish a working definition of death in order to explore the topics presented above. The nature of death, however, does not lend itself to one discipline; it cannot be defined without considering metaphysics, sociology, theology, and medicine. Death evades an immutable objective definition and instead is understood in subjective terms that are culturally and historically regulated.[2] Karen Gervais argues that a “decision of significance” must be established before criteria to test for the definition of death can be imposed. Such a decision identifies specific features that are necessary to differentiate a living person from a dead person and the conceptual reasons why such features are significant.[3]

Historically, the permanent cessation of heart and lung activity constituted death because the absence of heart and lung function quickly resulted in the failure of the entire organism. Thus consensus emerged that cardiac and respiratory activities were significant for distinguishing the living from the dead. The moment of death was firmly established but the task of creating criteria to

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[2] Martin S. Pernick, "Back From the Grave: Recurring Controversies Over Defining and Diagnosing Death in History," *Death: Beyond Whole-Brain Criteria*, ed. Richard M. Zaner (Boston: Kluwer Academic Publishers, 1988):17.

[3] Karen Grandstrand Gervais, *Redefining Death* (New Haven: Yale University Press, 1986) 2.

test for the permanent quiescence of these functions proved more challenging and often had devastating results.

Safeguards to prevent premature burial date back to antiquity with the Thracians, Romans, and Greeks who each waited three days for putrefaction to begin before burying their dead.[4] The Romans took a more extreme approach by cutting off a finger to see if the stump bled (spilling blood would imply circulation) in addition to calling out the person's name three times while on the funeral pyre.[5] It is clear that premature burial was a concern, although it did not reach a fevered pitch until the 18th century; this was largely facilitated by the intellectual climate.

The Enlightenment and Scientific Revolution catalyzed a radical change in perceptions of life and death. Secularization, together with a mechanistic interpretation of the body and new burial practices, encouraged a sense of isolation by individualizing the person, and subsequently, personalizing their death.[6] Belief in the afterlife was no longer as important as life in the "here and now" due in part to the works of Bacon, Descartes, and Galileo, which focused on the notion that life could be improved if not perfected by scientific manipulation. Galileo compared mastering nature with mastering mathematics. Once the patterns and rules were discovered the argument followed that outcomes could be accurately predicted and ultimate understanding of the body

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[4] Iserson, *Death to Dust* 25.

[5] Iserson, *Death to Dust* 25.

[6] Marc Alexander, "The Rigid Embrace of the Narrow House: Premature Burial and the Signs of Death," *Hastings Center Report* 10(1980): 27.

could be achieved. Accordingly, there was little practical need to concern oneself with an afterlife if this life could be manipulated by the art of medicine.[7] This engendered the notion of a vitalist perspective where every second of life was intrinsically valuable and immeasurable. Bruhier D'Ablaincourt wrote, "As the Life of man is priceless, one should be instructed how to bring back to life, or better, to a long life, those returned from the tomb. This is proper even if after a century or more, only one life will be saved, indeed, even if only one life can be prolonged for a few hours."[8]

The revulsion against cadaveric dissection found in the 16th and 17th centuries dissipated as the study of human anatomy revealed the secrets of the "belle mécanique" or the beautiful machine.[9] Man was no longer an enigma but could be deconstructed and dutifully examined. Such knowledge revealed the unique vulnerabilities of the human body and served to heighten an awareness of oneself and one's mortality as understood within the new mechanistic paradigm. Illness could now be directly related to a particular malfunction within the individual rather than a curse or punishment for wrongdoing; sickness was no longer capricious but traced directly to one's own body.

Changes in 18th century tombstone iconography also had a profound impact on the perception on death. Effigies and plaques now adorned individual graves

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[7] Alexander, "The Rigid Embrace" 27.

[8] Alexander, "The Rigid Embrace" 28.

[9] Alexander, "The Rigid Embrace" 27.

that accurately depicted the deceased individual.[10] Further, the introduction of the coffin meant burial was no longer a communal experience where bodies were commingled in catacombs or mausoleums, but was an isolated event, effectively sealing off the body from any other.[11] Fear of "subterraneous seclusion" and premature interment became endemic due to ideological changes coupled with the uncertainty of the signs of death.[12]

The anxiety of premature burial was not simply a literary device found in the legendary works of Edgar Allen Poe, but it permeated the collective conscience as scientists began to study the phenomena of suspended animation and resuscitation. The horror of science gone awry illustrated in Mary Shelly's *Frankenstein* was based on the work of Giovanni Aldini, a physics professor in Bologna who pioneered electrical cardiac resuscitation.[13] Reality was becoming as bizarre as fiction while the line between them grew less distinct through each new medical discovery.

Knowledge of artificial ventilation was well documented by the 1740s, though the first recorded incident dates back to 1627 when William Harvey maintained a decapitated rooster's lungs and circulation with a bellows.[14] Giovanni Bianchi is known for resuscitating a canine in 1755 using electricity; this technique was

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[10] Alexander, "The Rigid Embrace" 27.

[11] Alexander, "The Rigid Embrace" 27.

[12] John Snart, *Thesaurus of Horror* (London, 1817) 145.

[13] Pernick, "Back From the Grave" 23.

[14] Stuart Youngner, Robert Arnold, and Renie Schapiro eds. *The Definition of Death Contemporary Controversies* (Baltimore: Johns Hopkins Press, 1999) 5.

applied to the first human nineteen years later. By the early 19th century electro resuscitation and artificial respiration helped increase public fears of the inability to distinguish life from death and with that the hysteria of premature burial gained momentum.

It is a fact that premature burial occurred; its frequency however, is debated. Physicians had an obvious self-interest in downplaying such instances but a near universal distrust of the medical establishment bred communal hysteria. Disagreement in the medical field itself over the uncertainty of the signs of death in addition to professional insecurity further eroded the public confidence. Further challenging physicians' credibility were the abundance of charlatans and quacks, which were difficult to distinguish from physicians, especially in rural areas.[15]

Despite the sensationalist headlines run by the press that "many ugly secrets are locked up underground," some physicians in the 18th and 19th centuries collected data in order to better understand the phenomenon of premature burial to prevent further occurrences as well as to bolster their status in society.[16] Jean Bruhier-d'Ablaincourt, a Paris physician, attested that seventy-two people were mistakenly declared dead in 1742.[17] In 1842 J. de Fontenelle reported forty-six incidences of misdiagnosis of death or actual premature interment and just three years later Carré recorded an additional forty-six cases

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[15] Alexander, "The Rigid Embrace" 26.

[16] Iserson, *Death to Dust* 32.

[17] Iserson, *Death to Dust* 29.

of persons who revived before burial.[18] In 1896 T.M. Montgomery oversaw the disinterment of the Fort Randall Cemetery. He speculated from the exhumed remains that nearly two percent of persons had been buried alive, the unfortunate victims of suspended animation.[19]

M. Josat, a 19th century French physician, studied 'apparent death' by chronicling how long it took for persons who were declared dead to revive. According to Josat's records, thirty persons recovered in two to eight hours; fifty-eight recovered in eight to fifteen hours; forty-seven recovered in fifteen to twenty hours; twenty persons recovered in twenty to thirty-six hours; and in seven cases thirty-six to forty-two hours elapsed before recovery.[20] The causes of apparent death included lack of oxygen, apoplexy, hysteria, overdose, and concussion, with concussed victims reviving in the shortest amount of time.[21]

Women may have been especially vulnerable to being misdiagnosed as dead since they suffered bouts of fainting and fits of hysteria that accurately feigned death. William Tebb observed the following:

> Nervous and highly hysterical females, who are subject to fainting fits are the most frequent subjects of this kind of apparent death, in which the person seems in a state very nearly resembling that of

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[18] Iserson, *Death to Dust* 29.

[19] Iserson, *Death to Dust* 33.

[20] Iserson, *Death to Dust* 29.

[21] Iserson, *Death to Dust* 29.

> hibernating animals, such as the dormouse, bat, toad, frog, etc. which annually become insensible, motionless and apparently dead, on the setting in the winter's cold, but spontaneously revive on the returning warmth of spring. Here by some peculiar and as yet unknown circumstance, the vital principle has its action suspended, but neither its existence destroyed, nor its organs injured, so as absolutely to prevent recovery, if not too long neglected.[22]

Also, a Roman law still imposed in some areas of 18th century Europe required physicians to perform a Caesarian section on females who died in labor. If a female were hastily declared dead but in fact was not, the procedure would be deadly given the lack of antiseptics and antibiotics.[23] Advances in bacteriology would not come until the works of Pasteur and Koch in the 1860's and sulfa drugs and antibiotics would not revolutionize the pharmacopoeia until the 20th century.[24]

There is an extensive literature on instances of premature burial ranging from ancient to contemporary times, although for the purpose at hand a brief

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[22] William Tebb and Edward Perry Vollum, *Premature Burial and How it May be Prevented with Special Reference to Trance, Catalepsy, and other forms of Suspended Animation* (London, 1896) 121.

[23] Iserson, *Death to Dust* 29.

[24] Roy Porter, *The Greatest Benefit to Mankind* (New York: W.W. Norton & Company, 1997) 10-11.

summary of the more infamous cases will suffice. In a New York hospital in May 1864, a male patient unexpectedly died. In order to determine the cause of death a post mortem examination was ordered. When the first incision was made however, the 'dead man' lunged at the physician and grasped his throat. The physician promptly died of apoplexy while the 'dead man' went on to make a full recovery.[25]

Two renowned cases occurred in 17th century Scotland. Marjorie Elphinstone was declared dead and subsequently buried without incident. She revived while grave robbers attempted to steal her jewelry, and according to records, she ultimately walked home. In a similar event Margaret Halcrow Erksime was purposely buried in a shallow grave in order for the sexton to steal her jewels. Having difficulty in obtaining a ring from her finger, the sexton began to cut the finger off, at which point the dead woman awoke and eventually recovered.[26]

Another case, which is frequently cited in the literature, concerns a young girl who was visiting Edisto Island, South Carolina. During her holiday she had fallen ill from diphtheria and was immediately entombed in a local family's mausoleum in order to prevent further spread of the disease. The mausoleum was reopened after the family's son was killed in the Civil War where the small skeleton was found lying next to the door.[27] The following is an excerpt from a

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[25] Iserson, *Death to Dust* 28.

[26] Iserson, *Death to Dust* 32.

letter published by Dr. Brouardel, the director of the Paris morgue on October 1, 1867:

> I exhumed at eight p.m. Philomèle Jonetre, aged twenty-four, buried at five p.m. in a grave six feet deep. Several persons heard her tap distinctly against the lid of the coffin. These blows appeared to me to have left visible marks, but I did not hear them myself…Ammonia and other restoratives were applied…She was not dead, but like a candle, the flames of which had been extinguished, though the wick continues to glow. No definite sounds of the heart, but the eyelids moved in my presence. [28]

Perhaps the greatest risk of being buried alive occurred in times of epidemic and civil unrest. During the outbreaks of cholera, plague, and smallpox, the deceased were interred quickly for infection control. Both renowned British medical periodicals, *The Lancet* and *The British Medical Journal* (BMJ), addressed the problem of hasty interment in the late 19th century. *The Lancet* exposed a rash of premature burials resultant from the cholera outbreak. The article stressed the need to ascertain the cause and fact of death

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[27] Margaret M. Coffin, *Death in Early America* (New York: Thomas Nelson Inc., 1976) 106.

[28] Iserson, *Death to Dust* 33.

before burial and compared such “inexcusable carelessness” akin to manslaughter.[29]

The *BMJ* recounted a case of premature burial occurring in Naples where a female was interred while being in a state of suspended animation. The article concluded with a description of the court’s penalty for the physician who signed the death certificate and the Major who authorized her burial. Each was sentenced to three months in prison for involuntary manslaughter.[30]

Many of the foremost graphic accounts of premature interment can be found in *Premature Burial and How it May be Prevented*. In it, William Tebb declares that narrow escapes from premature burial numbered in the thousands and that evidence of such occurrences could be found wherever cemeteries were removed due to overpopulation.[31] Such evidence usually involved the following: bodies flipped on their faces, the limbs broken or badly dislocated, the hair and clothing torn, and the body mutilated from the torture of entombment.[32] Tebb concluded that premature interment was vastly underreported in order to spare the family such a horrifying image of their loved one and in order for physicians to maintain public trust.[33]

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[29] “Burying Cholera Patients Alive," *The Lancet* 2(1884): 329-330.

[30] "Buried Alive," *British Medical Journal* 2(1877): 819.

[31] Tebb,*Premature Burial* 64, 105.

[32] Tebb, *Premature Burial* 105.

[33] Tebb, *Premature Burial* 105.

Horace Welby addressed the unthinkable in his work *Mysteries of Life, Death, and Futurity* in 1861. In his chapter on trance, he concludes that suspended animation does not always lead to the suspension of consciousness; thus a person could be well aware that he or she is about to be buried alive. He supports this premise from a case where a young woman who appeared to be dead was prepared for burial. Before the coffin lid was nailed shut, however, she was observed to perspire profusely. She soon revived and retold her terrifying experience of being unable to speak or move but being able to clearly hear and feel others around her.[34]

Safeguards to prevent premature burial were creative though impractical and often bordered on the macabre. One 1790 practice in England involved laying a corpse out and painting the words “I am dead” above it in silver nitrate on a pane of glass. The silver nitrate words remained invisible until they were converted to a visible sulfide form by a surplus of hydrogen sulfide gas emitted from the corpse.[35] Once the declaration was apparent, the body was buried, though it could take some time for enough sulfide gas to accumulate.

In the early 20th century, Anthony de Chionski invented an apparatus that functioned as a vacuum chamber in which to assure death.[36] The body was placed within the chamber while air was incrementally removed; any movement of the body during the process would be cause to stop and check for signs of life.

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[34] Horace Welby, *Mysteries of Life, Death, and Futurity* (London, 1861) 119.

[35] Iserson, *Death to Dust* 25.

[36] Iserson, *Death to Dust* 27.

Absence of movement after undergoing the process signified that the corpse was in fact dead.

Christian Eisnebrandt invented the prototype of the “life preserving coffin” in 1843.[37] It was fashioned with wires and pins, which facilitated the lid to spring open if any movement was detected within the coffin. In 1897 Count Karnicé-Karnicki invented a similar “life signaling” coffin that would alert the outside world if the inhabitant revived.[38] The coffin was hermetically sealed and equipped with a tube that extended from the coffin to the surface approximately three and one half inches in diameter. The tube was affixed to a spring-loaded ball, which rested upon the body’s chest and would release at the slightest movement causing the lid of the box to open to allow for the passage of air and light inside. At the surface, a flag would raise while a bell would sound for thirty minutes. If the body should revive during the night, a lantern would burn as well.

A “torpedo coffin” was suggested to deter grave robbers who frequented new burial sites to pilfer corpses for jewels or other valuables. If disturbed, the torpedo coffin would emit an explosive current. Less violent means to discourage grave robbers involved sprinkling ashes over the tops of graves, which would reveal footprints.[39] A “preserver” or “corpse cooler” was favored in the later half of the 18th century, which allowed the body to putrefy while packed

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[37] Coffin, *Death in Early America* 106.

[38] Iserson, *Death to Dust* 36.

[39] Coffin, *Death in Early America* 107.

on ice.[40] The corpse cooler was constructed out of a wooden box with a galvanized liner. It allowed for ice to be stocked up to the body's shoulders while a glass pane allowed the face to be viewed. Openings were drilled into the cooler to facilitate a continuous ice supply while a hose aided in drainage (both for water and bodily fluid) into a bucket beneath the cooler.[41] If a corpse cooler was not on hand, the body could be placed in sod instead.[42]

The question that arises thus far is what methods were physicians using to determine death that caused such ghastly mistakes and required such extreme measures be taken? Not surprisingly, there was little agreement in the 18th and 19th centuries on which methods could accurately confirm death and the dubious process of testing could take hours. In fact, simply waiting, referred to as the Death Watch, was standard practice before accurate tests were established.[43]

Thierry pioneered the concept of waiting mortuaries, which were large rooms with glass doors where corpses were left to decay in sanitary isolation before burial.[44] The bodies were arranged in rows on sarcophagi, each one tilting downward with the deceased in a supine position.[45] An additional safeguard consisted of a ring fitted for each corpse with a string attached to it

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[40] Coffin, *Death in Early America* 108.

[41] Coffin, *Death in Early America* 108.

[42] Coffin, *Death in Early America* 108.

[43] Michael DeVita, "The Death Watch: Certifying Death Using Cardiac Criteria," *Prog Transplant* 11.1(2001): 58.

[44] Alexander, "The Rigid Embrace" 29.

[45] Iserson, *Death to Dust* 34.

that was tied to a set of bells affixed above the head. Any movement of the body would stir the bells, which in turn alerted a caretaker, staffed twenty four hours a day, to check for signs of life. Usually however, any movement was due to the build up of gasses within the body rather than revival.

The mortuary rooms were separated between the rich and poor, although aside from the types of flowers adorning the bodies, no practical difference between them existed.[46] Humane Societies to resuscitate the apparently dead were established in the 1760's and spread throughout England, the United States, the West Indies, South America, and North Africa.[47]

The London Society claimed to have resuscitated over two thousand people by 1796, although what level of functionality these individuals were returned to is not documented.[48] One of the primary problems with Humane Societies was that a person was only declared dead after failure to resuscitate. Ostensibly, this meant that there was no longer a 'natural death,' but death could only be declared after every medical restorative had been applied. This mentality is a precursor to the medicalization of death seen in 20th century, which will be addressed in the following chapter.

In addition to waiting mortuaries and Humane Societies, there were many notable methods used to determine death. Johannes Creve postulated that life may not be absent if the application of a sulfer and zinc arc (used to create an

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[46] Iserson, *Death to Dust* 34.

[47] Alexander, "The Rigid Embrace" 29.

[48] Pernick, "Back From the Grave" 22.

electrical current) caused a contraction in an exposed muscle. Dr. Josat, whom we have noted for his studies in apparent death, won first prize from the Académie de France for his invention of the nipple pincher, whose implementation certainly would rouse one from an apparent state of death.[49] In 1813, F.E. Foderé, a Paris physician, suggested drawing an incision in the left chest to manually feel if the heart was still beating.[50]

Many individuals specifically requested such tests or others like them in order to alleviate the fear of premature interment, especially since the medical community could not adopt a single authoritative test. In response to the need for a definitive test for death, the French anatomist Jean-Jaques Winslow published *The Uncertainty of the Signs of Death and the Danger of Precipitate Interments and Dissections* in 1740. Winslow favored thrusting a long needle deep under one's toenail and was also partial to burning the apparently dead through the application of a hot iron to the feet or crown of the head.[51]

Pinpricks, blood letting, or incisions were proposed but ultimately could not be relied on with absolute certainty. Winslow's student, Bruhier d'Ablaincourt, carried Winslow's ideas further and championed the Uncertainty Thesis, that is, that all signs of death were inconclusive save for putrefaction.[52]

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[49] Iserson, *Death to Dust* 26.

[50] Iserson, *Death to Dust* 35.

[51] Jean-Jacques Winslow, *The Uncertainty of the Signs of Death and the Danger of Precipitate Interment* (London, 1746) 24.

[52] Alexander, "The Rigid Embrace" 26.

Putrefaction was endorsed by Diderot's Encyclopédie and gained rapid acceptance by the medical and lay communities.[53] Though putrefaction did obviate the possibility of premature burial, it was not without its drawbacks. Since waiting for a body to putrefy did not require medical expertise, this further decreased confidence in physicians' abilities. Further, waiting for decomposition posed a serious health threat to the living and was not only aesthetically displeasing but also emotionally draining on families who had to bear witness to the process. Waiting for the onset of putrefaction also hindered human dissection as anatomists preferred to study the newly dead rather than decomposed bodies.[54]

The French surgeon Antoine Louis criticized the theory that putrefaction was the only certain means to determine death. His opposition was likely due to the fact that the practice fundamentally undermined the authority of physicians. Louis emphasized the need for education, especially on the 'apparent' signs of death, which could include syncopy (fainting) and lethargy among others. In an effort to prove the necessity of well-trained physicians, Louis maintained that putrefaction was not an absolute sign of death since it could be confused with gangrene, which preyed on the living.[55] Louis recommended documenting changes in the eye and rigor mortis as a more accurate measure of determining death.

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[53] Pernick, "Back From the Grave" 21.

[54] Alexander, "The Rigid Embrace" 26.

[55] Alexander, "The Rigid Embrace" 26.

The infamous *Thesaurus of Horror* authored by John Snart in 1817 catalogues other methods used to assure death including: placing a mirror to the mouth; keeping the body warm for one week during the Death Watch; applying acid, electricity, or warm water to the soles of the feet; placing tissue paper over the nose and mouth; pumping scotch snuff up the nose; funneling ammonia down the throat; severing the jugulars; separating the carotid arteries; cutting the medulla in half; and piercing the heart.[56] Obviously if one was not dead before these tests were performed, one was assuredly dead afterward.

By the mid 19th century, physicians were well acquainted with thanatomeisis, or death feigning.[57] Such conditions that mimicked death included alcoholic stupor, extreme cold, opiates, hemorrhage, apoplexy (stroke), suffocation, fever, head injury, lightening strike, diabetic ketoacidosis, epilepsy, drowning and hysterical fainting.[58] Inhalation anesthesia was introduced in 1846, which also mimicked death.

Suspended animation was problematic, and occupied much of the scientific debate over the signs of death.[59] Research on animals provided perplexing data. Scientists found that the most primitive single celled organisms could return to life after months of apparent death and worms had the stunning

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[56] Snart, *Thesaurus of Horror* 145.

[57] Iserson, *Death to Dust* 26.

[58] Pernick, "Back From the Grave" 23; DeVita, "The Death Watch" 58.

[59] Snart, *Thesaurus of Horror* 76.

ability to revive even decades after apparent death.[60] Tebb cited other instances of suspended animation in animals including pond trout and snails. The former could be frozen in snow for days but regain life when brought back to body temperature while the latter could be dry and in a state of dormancy for fifteen years but easily revived by cold water. [61]

It was not a far leap to speculate whether human beings could possess this power of 'hibernation' or suspended animation similar to the states found in animals.[62] Instances of human torpor can be found in the literature concerning Indian fakirs. An Indian Sanskrit scholar was renowned for his ability for self-induced trance. Skepticism and rumors of a hoax were put to rest in 1889 when the fakir submitted to a medical exam upon entering his trance.[63] The physician reported that the fakir's heartbeat and pulse slowly decreased until it could no longer be detected by auscultation or palpation. The fakir was wrapped in a shroud and entombed in an underground cell for a period of thirty-three days.[64] He was in rigor mortis when the tomb was opened and appeared on all levels to be dead. Three days later, however, the fakir was fully recovered.[65] This experiment was chilling, for it forced the question of how many other individuals

[60] Pernick, "Back From the Grave" 23.

[61] Tebb, *Premature Burial* 41,42.

[62] Tebb, *Premature Burial* 43.

[63] Tebb, *Premature Burial* 44.

[64] Tebb, *Premature Burial* 44.

[65] For further reading on the Indian fakirs see also James Braid, *Observations on Trance, or Human Hibernation*, (Churchill, 1850); *India Journal of Medical and Physical Science* 1(1836): 389.

could be in a similar state of life-in-death but would not be as fortunate to be exhumed?

Most 18th century physicians skilled in resuscitation believed that suspended animation was the result of a true suspension of circulation and respiration.[66] Others in the medical establishment however denied such a condition existed. They rejected the notion that circulation and respiration had in fact ceased and insisted that such functions were merely undetectable by standard devices.[67] The debate was settled by the late 19th century discovery of open chest cardiac massage, which could restart a heart that had ceased beating.[68]

Such discoveries allowed 19th century physicians to shed their previous image and propelled them into a secure status. Instead of developing a single test for death as Winslow attempted, physicians now relied on a variety of tests and incorporated newer ones with traditional ones.[69] In 1819 Rene Laennec had a serendipitous encounter with a portly young female patient, which lead to the invention of the crude stethescope. Laennec, not wanting to place his ear to his patient's breast, rolled up his notebook and used it to amplify her heart sounds.[70]

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[66] Pernick, "Back From the Grave" 25.

[67] Pernick, "Back From the Grave" 39.

[68] Pernick, "Back From the Grave" 40.

[69] Alexander, "The Rigid Embrace" 29.

[70] Guenter B. Risse, *Mending Bodies, Saving Souls: A History of Hospitals* (New York: Oxford University Press, 1999) 316.

It was not until 1846, however, that Eugene Bouchut used it as a diagnostic tool to test for death.[71]

The 19th century fascination with suspended animation launched the search for more sensitive tests to determine the presence of heartbeat and circulation while traditional tests were employed as well. Tests for respiration in the 19th century included the following: a mirror held to the mouth; a feather placed under the nose; submerging the body in water for the presence of bubbles; auscultation with a stethescope; and a hygrometer held to the nose. Tests for circulation included palpating for a pulse manually or cutting open an artery to detect the presence of flowing blood. The following empirical signs indicated circulatory failure: livid spots; pallid skin; depressed loins; sunken eyeballs; relaxed sphincter; and a cold body.[72] Carl Wunderlich was the first to measure body temperature in the 1860's and thermometers were employed from 1868-1880 in order to ascertain a person's "vital fire."[73]

Newer tests were more technical but also proved to be more destructive to the body. High intensity heat lamps were used in order to view circulation through the webbing between fingers. Microphones were used in order to clearly detect chest sounds and x-ray fluoroscopy was used in order to determine movement of internal organs.[74] The ophthalmoscope was used to examine

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[71] Pernick, "Back From the Grave" 38.

[72] Pernick, "Back From the Grave" 24.

[73] Pernick, "Back From the Grave" 38.

[74] Pernick, "Back From the Grave" 38.

changes in the vessels of the eyes. The presence of boxcars, or stationary segments in the eye, indicated a lack of circulation and loss of cardiac activity.[75] The hypodermic syringe, having been recently improved, was used to inject ammonia into the body in order to elicit an inflammatory response. Dr.'s Cloquet and Laborde invented a technique where a new steel needle was inserted deep into a muscle. Their theory maintained that when inserted into living muscle the steel needle would be metabolized and rust but when inserted into a dead muscle the needle would remain shiny and without corrosion.[76]

Other tests to check for inflammatory response were widely used. These included burning the skin over an open flame, pouring boiling water over the body, or inserting a heated cautery deep into the flesh. Dr. A.T. Middledorpf was known for inserting a needle directly into the heart with a flag attached to the other end that would ceremoniously wave if the heart were still beating.[77] The complexity of these tests elevated the status of physicians, and the fact that most of these tests would kill those who were still living did not curtail the practice.

Arterial embalming was introduced in the 1880's and 1890's and effectively squelched the fear of premature burial.[78] Embalming has been used by various cultures throughout history, but in its original form it meant to anoint

[75] Iserson, *Death to Dust* 27.

[76] Pernick, "Back From the Grave" 39.

[77] Pernick, "Back From the Grave" 39.

[78] Iserson, *Death to Dust* 36.

with balm or natural sap.[79] Embalmment was an ancient practice that involved removing the internal organs, packing the cavities with chemical solution, and allowing the body to dehydrate, as evidenced by the ancient Egyptian mummies.

Modern arterial embalming involves replacing a body's fluids with chemicals in order to disinfect the body and slow the rate of decomposition by inhibiting the growth of microorganisms.[80] The fear of premature burial may have been the initial impetus to accept the practice since embalming is not necessary unless a body is transported over some distance. [81] Today, embalming is mainly used to prepare the body for viewing, a custom mainly practiced in the United States and Canada.

The early part of the 20th century was a somewhat awkward transition stage for medicine, however, as it enjoyed monumental successes but still retained some of its primitive roots in folklore and superstition with regard to determining death. As late as 1926 a primary text, *Medical Diagnosis for the Student and Practitioner*, shows this dichotomy:

> Signs of Life in Persons Apparently Dead.
>
> 1. A deep red or purple color in the fingertips will become evident gradually if a firm ligature be applied to the digit.
> 2. Several hours after a supposed death blood will flow persistently from a cut artery.

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[79] Iserson, *Death to Dust* 185.

[80] Iserson, *Death to Dust* 185.

[81] Iserson, *Death to Dust* 185,187.

3. If a needle thrust into the tissues and left for a time becomes oxidized, life is present.
4. If any cloud repeatedly appears upon an ice-cold mirror held close to the mouth, there is respiration, but its absence does not alone suffice to prove death.
5. If a powerful vesicant produces redness or blisters, there is life.
6. If a body fails to take approximately the temperature of its environment forty-eight hours after apparent death there is life.
7. Pupillary response to light shows life, its absence does not prove death. Several hours after death it is affected neither by atropin nor eserin.
8. Persistence of the red in, and visibility of the arteries of the optic disc are signs of life, as is also persistent clearness of the media, six to eight hours after death.
9. A sensitive cornea is a sign of life, absence of the corneal reflex is not a sign of death.
10. Presence of electric excitability in all muscles twenty-four hours after apparent death indicates life.[82]

Like their forefathers, 20th century physicians incorporated newfound sophisticated technology with traditional diagnostic tools. Fears of premature burial became but a historical remnant of centuries past, however, as interest in

[82] Charles Lyman Greene, *Medical Diagnosis and the Student Practitioner* (Philadelphia: P. Blakiston's Son & Co., 1926) 1302.

deconstructing the individual at the organ and cellular level occupied scientific inquiry. Carl Ludwig and Sydney Ringer developed perfusion techniques between 1910 and 1920.[83] Using these techniques, Alexis Carrel, the United State's first Nobel Laureate, effectively cultured cells, tissues, and organ systems outside the human body.[84] Doubtless, this epochal discovery was cause to reevaluate traditional notions of life and death. At this juncture we see a fundamental change from being unable to determine death due to medical inadequacy to being unable to determine death because of scientific advancement.

By 1920 kidney transplantation had been attempted and had limited success in animals. The idea that organs could be procured from one body and function in another was previously conjured only within the realm of science fiction. Organ transplantation continued to fascinate, although it would not reach its zenith until 1968, with Christiaan Barnard, the ramifications of which will be discussed at length in the following chapter.

The principles of organ transplantation led neurologists to conclude that the brain, not the heart, was the primary seat of integrative functioning.[85] Scientists were now primed to experience a veritable renaissance within their field. Rather than pour boiling water over the patient's body to test for life, which

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[83] Youngner, *The Definition of Death* 5.

[84] Pernick, "Back From the Grave" 53.

[85] Pernick, "Back From the Grave" 53.

they had done just years before, physicians now used complex devices like the Electroencephalogram (EEG) to measure the brain directly.[86]

Advances in resuscitation proved to further blur the lines between life and death as the introduction of effective cardiopulmonary resuscitation (CPR) proved that death—as it had been traditionally understood—was not always irreversible.[87] Complicating conceptual matters further, by 1927 electric shock was able to reverse ventricular fibrillation and in 1940 Carrel's perfusion techniques facilitated life to be maintained in the head and body of a decapitated dog.[88]

Such progress in such a short amount of time was not without its problems. As Poe and Shelley's prose captured the climate of the 18th century, Huxley and Orwell's vision of medical progress gone awry echo contemporary concerns. 20th century society was now primed to embrace their newfound knowledge and equally quick to dissociate itself from the atrocities of premature burial and other follies perpetrated by medical ignorance. However, as we shall see in the following chapter, science does not exist in a vacuum; the boundaries imposed by ethics, the law, and social policy will necessarily dictate its course.

To briefly summarize, this chapter examined the typical methods used to determine death from the 18th through mid 20th centuries in order to frame the fundamental question of this dissertation: when is dead 'dead,' and how is the

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[86] Pernick, "Back From the Grave" 53.

[87] Pernick, "Back From the Grave" 54.

[88] Pernick, "Back From the Grave" 53.

practice of Donation After Cardiac Death consonant with our conceptual definition. It is clear that the cardio-respiratory standard of death had been agreed upon, but the methods used to determine it were questionable. The medical community's lack of consensus lead to distrust and societal instability, which was furthered by the discovery that sometimes the dead were not truly dead upon burial.

Extravagant life-saving coffins were thus conceived and physicians performed an array of grisly tests to confirm death. The fear of premature burial abated as embalming was introduced and medicine approached a secure status. Medical advance exploded with the discoveries of perfusion techniques, organ transplantation, and resuscitation. However, these new technologies forced a unique problem that was foreshadowed by the institution of Humane Societies in the 18th century: if the dead can be resuscitated, when are they ever "really" dead? This question opens many more; yet before they can be explored, the history of whole organ transplantation and the attendant problems it introduced must be examined in the following chapter.

Chapter 2
The History of Organ Donation

> A Person is dead when he has undergone irreversible changes of a type that make it impossible for him to seek to litigate.[89]

We will now explore the history of organ donation from its mythological roots, to its parallels with science fiction literature, to its current trend as a successful treatment for organ failure. The medical and surgical aspects of transplantation will be discussed including the discovery of anastomosis, the phenomenon of rejection, and the problem of immunosuppression and anti-rejection drugs. This chapter will also explore how advances in resuscitation and the diagnosis of brain death impacted organ transplantation, raising questions that would have to be answered by sound public policies. To this end, this chapter will use a timeline approach that is built around the major developments in transplantation in order to chronicle the progression of organ donation and demonstrate how we have arrived full circle back to Donation After Cardiac Death candidates, who served as the first cadaveric organ donors.

I. Mythology and Legend

The mythical Chimera hails as the ultimate expression of success within transplantation medicine. The Chimera was a fire-breathing hybridization composed of a lion's head, goat's body, and serpent's tail. This beast, and other chimeric gods and heroes like it, was not regarded as a monstrosity, but as a

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[89] Peter Brian Medawar

figure of potency derived from its various acquired parts.[90] This notion has a longstanding tradition in myth and folklore but also plays a prominent role in the current goals of transplantation, at least metaphorically. To attain chimerism is to succeed in incorporating genetically foreign tissue into a host body seamlessly, in order to make the recipient stronger.[91]

Interestingly, even the complex notion of clinical organ rejection can be traced back to classical mythology. In the *Metamorphosis*, Ovid recounts the story of the hunter Actaeon who is caught spying on the Goddess Artemis while she bathes. Artemis punishes Actaeon by transforming him into a stag but his new identity comes to an early demise when his own dogs fail to recognize their owner and subsequently devour him.[92] The dogs' inability to recognize the new composite creature as their master and their violent reaction to destroy it mirrors the immunologic struggle that ensues whenever an organ is transplanted, as will be discussed later in this chapter.

Transplantation surgery is a modern accomplishment but the notion of transplantation has a rich and impressive history. Evidence of prehistoric tissue transplantation dating back to the Bronze Age can be found in the form of a practice known as trephination, which was used to relieve intracranial pressure

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[90] Hossein Shayan, "Organ Transplantation: From Myth to Reality," *Journal of Investigative Surgery* 14(2001): 135.

[91] Michael Federle, "Milestones and Future Trends in Solid Organ Transplantation," *Radiologic Clinics of North America* 33.3(1995): 430.

[92] Judit Nagy, "History of Dialysis and Transplantation," *American Journal of Nephrology* 19(1999): 346.

following a head injury.[93] Trephination involved the removal of a circular piece of bone taken from the calvarium that was later replaced after brain swelling subsided. This crude procedure represents one of the first known orthotopic autografts that is, when tissue is removed from an individual and is later re-implanted in its proper positioning in the same individual.

The New Testament recounts several miracles in the form of autografting. In one account Jesus reattaches a servant's ear that Simon Peter had sliced off with his sword. Similarly other biblical stories recount St. Peter restoring St. Agatha's breasts, which had been torn off through torture, and St. Mark reattaching a soldier's hand that had been lost in combat.[94] But perhaps the most pervasive myth surrounding transplantation concerns two brothers, Cosmas and Damian, the patron saints of surgery.

According to legend, Cosmas and Damian were twins born in Arabia during the reign of Diocletian. They studied medicine in Syria, Cilicia, and Asia Minor and were renowned for their medical skill and piety. The Roman Empire, however, found the brothers' faith in and encouragement of Christianity scandalous and made several attempts to assassinate them though they miraculously survived each attack.[95] The Empire finally succeeded by decapitating Cosmas and Damian in 287 C.E.[96]

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[93] Shayan, "Organ Transplantation: From Myth to Reality" 135.

[94] Shayan, "Organ Transplantation: From Myth to Reality" 135.

[95] Eric B. Loucks, "The Origin and Future of Transplantation Surgery," *Journal of Investigative Surgery* 2.11(1998): iii.

The brothers had developed a strong following that persisted after their deaths as evidenced by the many loyalists who made pilgrimages to their burial tomb in Ciro. After visiting their tomb, Emperor Giustiniano claimed to have been healed of his maladies and subsequently erected a basilica in their honor.[97] In 348 C.E. the deacon Justinian visited the basilica to pray for relief from his gangrenous leg. According to legend, while Justinian slept in the basilica Cosmas and Damian appeared to him that night and replaced his leg with the leg from a recently deceased Moor.[98]

This represents the first cadaveric allograft, that is, the transplantation of tissue or organ from an individual who is genetically distinct but belonging to the same species.[99] This scenario has been recreated in art and literature and is represented most prominently by Beato Angelico's painting, The Miracle of Transplantation.[100] These types of myths and legends whether found in Greco-Roman mythology, Ovid's *Metamorphosis* or the Bible, demonstrate how the notion of transplantation has been firmly rooted within the collective conscience over the millennia.

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[96] Loucks, "The Origin and Future of Transplantation Surgery" iii.

[97] Loucks, "The Origin and Future of Transplantation Surgery" iii.

[98] Patricia Barozzi, Mario Luppi, and Guiseppe Torelli, "Mysticism to Medicine," *Nature Medicine* 9.5(2003): 507.

[99] G.E.W. Wolstenholme and Maeve O'Connor, eds., *Ethics in Medical Progress: With Special Reference to Transplantation Ciba Foundation Symposium* (Boston: Little, Brown and Company, 1966): 8.

[100] Barozzi, "Mysticism to Medicine" 507.

II. Early Experimentation

It is not until the 18th century that we depart from the realm of myth and legend for the first recorded scientific experiments with transplantation. In 1749 Henri-Louis Duhamel du Monceau performed the bizarre experiment of transplanting a chicken's spurs into its comb.[101] John Hunter, known as the British father of Scientific Surgery, implanted teeth into this chicken's comb as well, and in 1767 procured teeth from a human cadaver and transplanted them into a living patient.[102]

Skin grafts were attempted in the 19th century but were generally unsuccessful. Two milestones that helped pave the way for future success in all types of transplantation came with the discovery of ether in 1846 by William Morton and the use of antisepsis endorsed by Joseph Lister in 1865.[103] Of note, ether was thought to induce a state of "artificial death" by many and was not endorsed by the American Medical Association (AMA) until 1848.[104]

Organ transplantation would remain within the realm of science fiction until the early 20th century when life imitated art by way of animal experimentation. In 1902 Emerich Ullman reprised the role of Mary Shelly's Dr. Frankenstein by

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[101] "Organ Transplantation," *Encyclopedia of Human Biology,* 1997: 476.

[102] "Organ Transplantation," *Encyclopedia of Human Biology,* 1997: 476.

[103] Shayan, "Organ Transplantation: From Myth to Reality" *136*.

[104] Robert P. Baker and Victoria Hargreaves, "Organ Donation and Transplantation: A Brief History of Technological and Ethical Developments," *The Ethics of Organ Transplantation*, eds. Wayne Shelton and John Balint (Oxford: Elsevier Science Ltd., 2001) 10.

transplanting a dog's kidney into another dog's neck. The ureter was sewn through the neck and produced urine in front of an astonished crowd for five days.[105] Six years later Charles C. Guthrie grafted the entire head of a dog onto the neck of a larger dog creating a stunning similarity to the mythological Cerberus. Though the dog(s) only survived for one day, this same experiment would be recreated in the 1950's by Vladimir Demikhov who grafted the upper body of a puppy, including it's forepaws, onto its mother's body. This transplant was successful for twenty-six days.

The same year Guthrie presented his two headed dog, he and his colleague Alexis Carrel published a technique for joining blood vessels together in a leak-proof manner, known as vascular anastomosis (literally meaning mouth to mouth), which revolutionized the field of transplantation medicine.[106] The primary surgical problem inhibiting organ transplantation had not been in excising the organs for transplant, but in reattaching them into the host since the blood vessels had to be rejoined seamlessly.[107] Carrel and Guthrie's technique of anastomosis was seminal for future trends in transplantation and cardiovascular surgery by overcoming the problem of unstable sutures but it was only one part of the complicated equation.[108]

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[105] Nagy, "History of Dialysis and Transplantation" 349.

[106] R.M. Langer and B.D. Kahan, "Alexis Carrel's Legacy: Visionary of Vascular Surgery and Organ Transplantation," *Transplantation Proceedings* 34(2002): 1061.

[107] Baker *"Organ Donation and Transplantation: A Brief History of Technological and Ethical Developments"* 11.

Despite this contribution, progress in transplantation continued to yield poor results for the next two decades. In 1936 Y.Y. Voronoy, a Russian physician, was the first to transplant a human kidney from a cadaver donor. However, Voronoy had virtually guaranteed failure since the donor had committed suicide from mercury poisoning, thus Voronoy placed the recipient at risk by using potentially tainted organs.[109] Not surprisingly, the kidney only lasted forty-eight hours and failed to produce any urine.

Not long after Voronoy's failed kidney allograft, an unfortunate impetus demanded a renewed interest in skin grafting. The Second World War produced an overwhelming number of burn victims and the scientific armamentarium was ill equipped to treat them effectively. The War Wounds Committee of the British Medical Council solicited a scientist, Peter Brian Medawar, to investigate what was causing the rejection phenomenon associated with skin grafts.[110]

III. Phenomenon of Rejection

Medawar realized early on that burn victims did remarkably better when skin was transferred from other parts of their own body (autologous skin grafting) than from skin donated from a different individual (allogeneic grafts), but he needed to establish why.[111] In 1946 R.D Owen proved that freemartin cattle,

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[108] Langer, "Alexis Carrel's Legacy: Visionary of Vascular Surgery and Organ Transplantation," 1061; Baker, *"Organ Donation and Transplantation: A Brief History of Technological and Ethical Developments"* 11.

[109] Starzl, "History of Clinical Transplantation" 760.

[110] Shayan, "Organ Transplantation: From Myth to Reality" 137.

which are fraternal or dizygotic twins, would permanently accept each other's skin if their placentas had fused during fetal development.[112] Placental fusion would allow for cross-circulation between the calves resulting in a failure to differentiate "self" from "non-self," which would become the cornerstone of the immunologic concept of tolerance.[113]

Medawar was confident that the biology of rejection was an immunologic response and in 1953 he conducted his own experiments using mice that would prove his theory. Medawar injected immunocompetent adult spleen cells, meaning active cells that were not attenuated, into mice while in utero. Because the mice did not have the capability to reject the spleen cells at such an early developmental stage, the foreign cells infiltrated the body at a systemic level and ultimately achieved chimerism, leading to immunologic nonreactivity.[114] When the mice reached maturity they were exposed to skin and tissue from the donor strain but were unable to differentiate it as foreign and as such did not mount a rejection response.[115]

This experiment proved two crucial points, first, that rejection was directly based on immunologic factors, and second that these immunologic factors could

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[111] W. Muller-Rucholtz, "Glances at the History of Transplantation Immunology," *Transplantation Proceedings* 31(1999): 1444.

[112] Starzl, "History of Clinical Transplantation" *759*.

[113] Rebecca Malouin, "Surgeons' Quest for Life: The History and the Future of Xenotransplantation," *Perspectives in Biology and Medicine* 37(1994): 419.

[114] *"*Organ Transplantation*," Encyclopedia of Human Biology,* 476.

[115] Thomas E. Starzl, "Transplantation Milestones Viewed with One-And Two-Way Paradigms of Tolerance," *JAMA* 273.11 (1995): 876.

be manipulated in utero. The second point, while intriguing and perhaps of benefit for future scientists, served little practical value at the time, as injecting human fetuses in utero with donor cells was simply implausible. The first point, however, was directly relevant to clinical medicine as it became apparent that transplantation would be successful only if the recipient's immune system accepted the new tissue or organ as quasi-self.[116] The inverse would not be realized until 1956, that an immunocompetent graft could in fact reject the donor in a response known as Graft-Versus-Host-Disease (GVHD).[117]

Despite some key misapprehensions early on regarding immunogenetics, it was becoming rapidly clear that a transplant would be rejected relative to genetic disparity such that the greater the genetic difference between donor and recipient, the quicker and more aggressive the rejection response.[118] Medawar was further convinced of this as evidenced by other mice experiments where their immune systems appeared to remember or immediately recognize foreign skin when it was grafted a second time. Exposure to the same donor graft strain produced a rejection response much quicker than the first rejection, indicating that the immune system operated under a type of pattern recognition.

Medawar hypothesized that the body's immune system produced an inflammatory response in an attempt to fight off any foreign tissue or organ

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[116] W. Muller-Rucholtz, "Glances at the History of Transplantation Immunology," 1446.

[117] Michael Federle, "Milestones and Future Trends in Solid Organ Transplantation" 430.

[118] Federle, "Milestones and Future Trends in Solid Organ Transplantation" 419.

because it perceived such material as an invader. Once the invader was recognized and the immune system developed means to fight it off, any subsequent interaction with the same invader would produce a prompt and effective immunologic response. This finally explained why the autologous skin gratfs that Medawar observed faired better than allogeneic skin grafts. In skin grafting experiments with rabbits, Medawar noted that the application of cortical steroids or total body irradiation forestalled the rejection response and encouraged longer survival.[119] Medawar concluded that the body would need to be immunosuppressed through the use of drugs in order to counter or delay such a rejection response.[120]

In 1958 Jean Dausset argued that one cause of rejection was due to incompatibility of leukocytes or white blood cells (WBCs) between donor and recipient.[121] Dausset theorized that Human Leukocyte Antigens, (HLA), which are essential to a normal immune system response, could be tissue-typed for compatibility in a similar way that blood had been typed into different classifications.[122] This revelation would ultimately lead to a complex network for organ sharing, which will be discussed later in this chapter.

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[119] Federle, "Milestones and Future Trends in Solid Organ Transplantation" 417.

[120] Baker, "Organ Donation and Transplantation: A Brief History of Technological and Ethical Developments" 12.

[121] Baker, "Organ Donation and Transplantation: A Brief History of Technological and Ethical Developments" 19.

[122] Baker, "Organ Donation and Transplantation: A Brief History of Technological and Ethical Developments"*19*.

IV. Overview of Immune System

The immune system, which is relatively mature at birth, is an elaborate and complex mechanism that plays both offensive and defensive roles in its effort to protect the body.[123] Pathogens in the form of bacteria or viruses produce what are known as antigens. These antigens stimulate an immune response rallied by B Lymphocytes, which are found in WBCs and are the body's first defense against invasion.[124] The B cells react to antigens by dividing and producing antibodies, which then bind to the antigens and ideally destroy the invader.[125] A second arsenal of T Lymphocytes or "killer cells" will be deployed if the B Lymphocytes cannot adequately fight the invader.[126]

In the case of organ transplantation, the immune system immediately sends out B Lymphocytes to determine if the organ is "self" or "non-self." That is, these cells must decide if the organ belongs or if it is an invader and they do this by evaluating the antigens that come part and parcel with the donated organ.[127] The B Lymphocytes can be regarded as the sentries that will only summon the T Lymphocytes if they cannot perform adequate damage control. Once called

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[123] Roy Calne, "The History and Development of Organ Transplantation: Biology and Rejection," *Bailliere's Clinical Gastroenterology* 8.3 (1994): 391.

[124] Lee Gutkind, *Many Sleepless Nights* (Pittsburgh: University of Pittsburgh Press, 1990) 24.

[125] "Organ Transplantation," *Encyclopedia of Human Biology* 475.

[126] Gutkind, *Many Sleepless Nights* 24

[127] Gutkind, *Many Sleepless Nights* 24.

upon however, T Lymphocytes are virtually unremitting and will ultimately be the responsible party for destroying the donor organ.[128]

Rejection can be broken down into three categories: Hyperacute Rejection, Acute Rejection, and Chronic Rejection. Hyperacute Rejection, though rare today, is a swift process that occurs almost immediately after implantation of allogeneic material.[129] This type of reaction is induced when the recipient's immune system already has formed antibodies to the antigens that are introduced by the donor organ; thus destruction of the organ is certain.[130] Acute Rejection typically presents within three months of grafting but can often be effectively reversed through the use of cortical steroids.[131] Chronic Rejection, as the name implies, is a late response that is not fully understood but appears to be the unpredictable result of the immune system overreacting to the donor antigens it seemingly tolerated until that point.[132]

Once Medawar established the basis for rejection, attempts at transplantation surgery burgeoned in the 1950s and 1960s although success was not routine and many lives would be lost in these early years. The first "modern" transplant is credited to Joseph Murray and his colleagues who performed the first renal transplantation in monozygotic (identical) twins at the Peter Bent

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[128] "Organ Transplantation," *Encyclopedia of Human Biology* 476.

[129] "Organ Transplantation," *Encyclopedia of Human Biology* 476.

[130] "Organ Transplantation," *Encyclopedia of Human Biology* 476.

[131] "Organ Transplantation," *Encyclopedia of Human Biology 476*.

[132] "Organ Transplantation," *Encyclopedia of Human Biology* 476.

Bringham Hospital on December 23, 1954.[133] Using Medawar's principles, it was clear that a transplant between identical twins would eliminate the possibility of an immunologic rejection response.

V. Modern Era of Transplantation

Interestingly, the main concern over Murray's historic procedure was not surgical but focused instead on an ethical question: ought a physician jeopardize a healthy person by removing an organ for the sake of another life? This question had never before presented and as such there were no guidelines, policies, or committees from which to seek recourse. Murray and his colleagues were subjected to harsh criticism for merely considering the operation, but ultimately the principles of autonomy and beneficence prevailed.[134] As organ transplantation became mainstream in practice, norms regarding donation and consent would be concomitantly developed.[135]

Murray followed his successful renal isograft that is, a transplant between two genetically identical individuals, with a renal transplant between dizygotic twins on January 24, 1959.[136] The transplantation boom had now

[133] Baker, "Organ Donation and Transplantation: A Brief History of Technological and Ethical Developments" 13.

[134] Baker, "Organ Donation and Transplantation: A Brief History of Technological and Ethical Developments" 14.

[135] Baker, "Organ Donation and Transplantation: A Brief History of Technological and Ethical Developments" *14*.

[136] Thomas E. Starzl, "The Early Days of Transplantation," *JAMA* 272.21 (1994): 1705.

officially swept the USA and parts of Europe. René Kuss in Paris led his team in a number of successful renal transplants between 1959 and 1962 using dizygotic donors, cousins, and in two cases non-relatives. Kuss' success was due to the use of immunosuppression, but these cases turned out to be the exception rather than the rule.

Anti-rejection drugs were a necessity if transplantation medicine was to move forward since most patients in need of a transplant did not have an extra copy of their genetic material found in the form of a twin sibling. Further, vital organs that do not come in pairs such as the heart or liver could not be acquired through living donation for obvious reasons. Thus drugs that could depress the body's immune response to foreign tissue would widen the donor pool and in the process utilize another source—the cadaveric organ donor.[137]

Since Medawar had limited success in the early 1950s using Total Body Irradiation and adrenal cortical steroids to prolong skin grafts in rabbits, these chemotherapeutic agents were administered to human renal recipients in 1959.[138] However, since Total Body Irradiation rendered the patient immunologically defenseless, any benefit of prolonging the renal transplant was subverted by the risk of serious infection.[139] As transplantation immunology progressed, three distinct immunologic patterns became clear. First, that

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[137] Nadey S. Hakim and Vassilios E. Papalois, eds. *History of Organ and Cell Transplantation*, (London: Imperial College Press, 2003) 68.

[138] Federle, "Milestones and Future Trends in Solid Organ Transplantation"*417;* Shayan, "Organ Transplantation: From Myth to Reality" 137.

[139] Shayan, "Organ Transplantation: From Myth to Reality" 137.

rejection could be due to a Host-Versus-Graft (HVG) reaction, second that rejection could also result from the graft rejecting the host (GVHD), and third that tolerance/chimerism could be induced.[140]

Thomas Starzl documented the vivid immunological chimeric change that occurs in an organ recipient by conducting skin tests. Using tuberculin, mumps, and candida, Starzl tested both the recipients and donors preoperatively. He found that when skin reactions were positive in the donor but negative in the recipient 77% of the recipients would exhibit a positive reaction post transplant. In essence, the recipients were conferred with the donor's immunity, which led to chimerism and kidney acceptance. When the recipients failed to convert from negative to positive reactions, the graft failed as a result of rejection.

In the early 1960s alternatives to Total Body Irradiation were introduced. Starzl discovered that cortisone and prednisone could actually reverse an acute rejection response, but the use of high dose steroids alone produced tremendous adverse side effects including depression that could lead to psychosis, as well as catatonia, inability to eat, memory impairment, and facial swelling.[141] Roy Calne endorsed another type of chemical suppression known as azathioprine.[142] On April 5, 1962, Murray successfully transplanted an unrelated kidney that

[140] Carl G. Groth, et al, "Historic Landmarks in Clinical Transplantation: Conclusions from the Consensus Conference at the University of California, Los Angeles," *World Journal of Surgery* 24(2000): 835.

[141] Lee Gutkind, *Many Sleepless Nights* 38.

[142] Shayan, "Organ Transplantation: From Myth to Reality" *1*37.

functioned for a staggering 17 months using azathioprine.[143] Azathioprine was originally used in oncology because it killed replicating cancer cells. It was applied to transplant patients under the assumption that it would kill the lymphocytes that cause rejection but it too produced negative side effects.[144]

Beginning in 1962 Starzl was the first to incorporate steroids with azathioprine creating a type of drug “cocktail.” This cocktail increased survival but at the cost of a diminished quality of life as it caused bone marrow toxicity, anemia, and growth retardation.[145] In 1963 at the University of Colorado Starzl performed the first human liver transplant, but its failure echoed the sentiment of much of the transplantation community at the time—transplantation had reached a plateau.[146] Four years later, however, Starzl would reinvigorate the field by producing long-term liver allograft survivors.[147] 1967 was also the year Christiaan Barnard performed the first human heart transplant using a Donation After Cardiac Death organ donor in Cape Town South Africa. Though the patient, Louis Washkansky, only lived for eighteen days, this procedure resonated not merely with the transplantation community but with the world. Barnard claimed to have waited three minutes before excising the heart from the donor, who had been in a motor vehicle accident, though an undercurrent of skepticism was

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[143] Starzl, "The Early Days of Transplantation" 1705.

[144] Gutkind, *Many Sleepless Nights* 36.

[145] Gutkind, *Many Sleepless Nights* 37.

[146] Michael Federle, "Milestones and Future Trends in Solid Organ Transplantation" *419.*

[147] Federle, "Milestones and Future Trends in Solid Organ Transplantation" *420.*

palpable and questions of when a person is dead began in earnest. At this point two major medical themes and one conceptual theme converged almost simultaneously, which would challenge the traditional notion of death: the use of Cardio Pulmonary Resuscitation (CPR), the discovery of cyclosporine, and the notion of brain death.

VI. CPR

The reanimation of the apparently dead has been attempted in a variety of ways since ancient times but has not been a medical reality until quite recently. The Ancients identified the body's warmth with its vital fire, such that when the body went cold the vital fire had been extinguished and the person was considered dead.[148] The logical response to this was to apply heat or warmth to a body in order to revitalize it. The methods of choice called for warm ashes, burning excreta, or hot water to be applied to the victim's abdomen either alone or in combination with auditory stimulation such as yelling or crying.[149] Physical abuse consisting of slapping or whipping was also a common practice.[150] Of all of these, physical stimulation would ultimately play a fundamental role in modern day resuscitation.

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[148] Howard P. Liss, "A History of Resuscitation," *Annals of Emergency Medicine* 15.1(1986): 65.

[149] Liss, "A History of Resuscitation" 65.

[150] Kelly Tucker, Michael A. Savitt, Ahamed Idris, and Rita F. Redberg, "Cardiopulmonary Resuscitation: Historical Perspectives, Physiology, and Future Directions," *Archives of Internal Medicine* 154(1994): 2141.

The 19th century saw its share of creative resuscitative methods including stretching the rectum, stretching the tongue, and a process known as fumigation, which called for air to be blown into the patient's mouth and air and tobacco to be forced into the rectum.[151] Whipping the victim took on a more violent and likely destructive aspect when stinging nettles were added in hopes of "waking" those in a "deep sleep."

Though the bellows was popular for artificial ventilation throughout history it became clear by the mid 19th century that a patient could be severely injured or even die from over distension given the bellows' imprecise nature. In response to this problem, Marshall Hall developed a manual method of ventilation where the patient's body was flipped from lying on the stomach, which aided expiration to lying on the side, which aided inspiration sixteen times per minute.[152] Tilting the head back when attempting to resuscitate a patient had apparently been instinctively done for many years but it was Hall who proved why it was a scientific necessity: the patient's tongue and larynx generally fall back and obstruct breathing thereby obviating any chance of successful resuscitation.[153] In 1858 Henry Silvester made modifications to Hall's method, which was used well into the first half of the 20th century. Silvester's method required the patient to be placed in the supine position where the arms would be raised over the head in

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[151] Liss, "A History of Resuscitation" 66.

[152] Liss, "A History of Resuscitation" 67.

[153] Liss, "A History of Resuscitation" *67*.

order to expand the rib cage causing inhalation and then lowered onto the chest with pressure to cause exhalation.[154]

In the mid 20th century, the Consolidated Edison Company (Con-Edison) funded a research project to determine how their employees—electrical linesman—could be effectively treated in the event of electrical injury.[155] To this end W.B. Kouwenhoven was enlisted to study ventricular fibrillation at Johns Hopkins where he and his colleagues made a series of crucial rediscoveries that would lay the foundation for modern resuscitation, which would further be championed by Peter Safar. Kouwenhoven determined that an electrical shock given to a dog in ventricular fibrillation could reset the heart's electrical pattern.[156] This theory, that a fibrillating heart could actually stop fibrillating with the application of another electrical shock, led to the introduction of the first cardiac defibrillator in Johns Hopkins in 1957.[157]

Kouwenhoven and Safar collaborated during the same year to discover a way for lay individuals to aid a victim while awaiting a defibrillator. The following year Kouwenhoven and his research fellow established the efficacy of closed chest cardiac massage, that is, that chest compressions performed on fibrillating

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[154] Liss, "A History of Resuscitation" *67.*

[155] Tucker, "Cardiopulmonary Resuscitation: Historical Perspectives, Physiology, and Future Directions" 2142.

[156] Tucker, "Cardiopulmonary Resuscitation: Historical Perspectives, Physiology, and Future Directions" 2142.

[157] Tucker, "Cardiopulmonary Resuscitation: Historical Perspectives, Physiology, and Future Directions" *2142.*

canines could restore spontaneous circulation.[158] Safar went on to provide the complex fundamentals behind CPR, which are beyond the scope of this paper, but the repercussions of which bear directly on the topic at hand.

In 1958 modern and effective CPR had arrived along with its attendant consequences. Patients who would have otherwise died were now being resuscitated and often required follow-up support in the form of intensive care or rehabilitation, a new concept that required an innovative response. Such patients could not be cared for on general wards; thus in 1958 Safar opened the first Intensive Care Unit (ICU) in the United States at Baltimore.[159] One of the problems, however, was that it was nearly impossible to predict which patients would fully recover after resuscitation and which patients would suffer permanent brain damage of varying degree. ICUs subsequently became in danger of being overwhelmed with moribund patients who were being maintained with new technologies that could promote vital signs or specific organ systems but offered little to no hope of recovery of the individual as a whole. Resuscitation further had serious implications on the traditional notion of death, which was identified by the absence of cardio-respiratory activity. Since machines could now support ventilation and support hemodynamic systems, it became difficult to establish where life ended and death began.

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[158] Peter Safar, "On the History of Modern Resuscitation," *Critical Care Medicine* 24 (2S) Supplement.2S (1996): 9S.

[159] Peter J.F. Baskett, "The Resuscitation Greats: Peter J. Safar, The Early Years 1924-1961, The Birth of CPR," *Resuscitation* 50(2001): 21.

The introduction of mechanical ventilation in the late 1950s furthered the ambiguity between life and death in the presence of technology. The iron lung was the prototype of tank respirators. The term “respirator” has infiltrated the lay public’s vocabulary and is frequently used interchangeably with “mechanical ventilator.” In fact, respiration and mechanical ventilation are not the same activity and ought not be confused. Respiration is a process that occurs at the cellular level within the mitochondria from the exchange of oxygen and carbon dioxide whereas ventilation simply refers to the passage of air through the trachea into the lungs.[160] Respiration is essential to life, whereas ventilation is not, as evidenced by the sustainability of individuals on cardiopulmonary bypass or even a fetus in the womb.[161] The distinction between respiration and ventilation will be explored further in chapter three; it is briefly presented here in order to clarify our language and definitions.

The iron lung was a large tank that engulfed the patient’s entire body, save for the head, which functioned by lowering the atmospheric pressure inside the tank fifteen to twenty times per minute to expand the ribcage to allow for inhalation.[162] Routine nursing care for a patient confined to an iron lung was daunting as nurses only had access to the patient through ports on the sides of

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[160] D. Allen Shewmon, "The Brain and Somatic Integration: Insights into the Standard Biological Rationale for Equating "Brain Death" with Death," *Journal of Medicine and Philosophy* 26(2001): 464.

[161] Shewmon, "The Brain and Somatic Integration” 464.

[162] Gordon L. Snider, "Thirty Years of Mechanical Ventilation," *Archives of Internal Medicine* 143(1983): 745.

the tank, which could only be opened upon exhalation, which occurs naturally without the maintenance of air pressure.[163]

Iron lungs were predominantly used for those suffering from poliomyelitis but as medicine progressed, mechanical ventilators improved, became more accessible, and were applied to a larger population of patients who were critically ill. Anesthesiologists were among the first to understand that a body could be kept alive using life-sustaining treatment in the absence of a functioning brain.[164] This raised troubling questions that were not easily answered within the medical community and would begin a public dialogue that would include religion, philosophy, and the law. Pope Pius XII was asked whether it was appropriate to keep a body alive when the brain has been irreversibly destroyed. In *The Prolongation of Life*, Pius XII did not presume to displace physicians' authority or their expertise in the determination of death. Rather, he stated that such a determination was a medical decision not to be usurped by the Church. However, the Pope concluded that extraordinary means of treatment need not be undertaken when a situation is considered hopeless as life need not be maintained at all costs.[165]

Two years later French neurophysiologists studied patients in deep coma during which they coined the term coma depassé, meaning "beyond coma." These patients lacked spontaneous respiration, requiring the use of mechanical

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[163] Snider, "Thirty Years of Mechanical Ventilation" 745.

[164] Julius Korein, "The Problem of Brain Death: Development and History," *Annals of the New York Academy of Sciences* 315(1978): 28.

[165] Korein, "The Problem of Brain Death: Development and History" 28.

ventilation and demonstrated electrocerebral silence.[166] Upon autopsy the brains showed variations of necrosis with the most extreme presenting as autolysis, or liquification of the brain. It became clear at this point that mechanical ventilation could prolong “life” in a body with a dead brain but the necessary ingredients for a historical shift to determine death by neurologic criteria had yet to coalesce until the late 1960s.

As the 1960s progressed, technology continued to burgeon, raising questions that had never before been entertained while medical advance far outpaced society’s ability to reconcile these new ethical dilemmas. In what follows we shall see that the advancement in organ preservation techniques and immunosuppression through the drug cyclosporine were crowning achievements in the late 1960s and 1970s, although the future of organ transplantation required more than isolated medical accomplishments. In order for transplantation to thrive, it ultimately depended on social and public policies to guide it, as we shall see in the final section.

VII. Logistics of Organ Transplantation

At this time during the late 1960s, medicine focused on improving two fundamentals to successful organ transplantation: organ preservation techniques and anti-rejection drugs. The success of cadaveric organ donation was directly proportional to adequate preservation techniques, as laws concerning heart-beating cadavers declared dead by a brain-based standard had yet to be

[166] Korein, "The Problem of Brain Death: Development and History" *29.*

codified. In the 1960s Starzl developed a process known as core cooling, which remains the initial step in the preservation of organs today.

Core cooling utilizes cannulae, or long thin tubes, to lower the temperature of the organs *in situ* (in their proper position), which allows them to be cooled within the donor's body before excision.[167] Cannulation cools the organs using the vascular route, through the capillaries, arteries, and veins.[168] Organs must be cooled in order to reduce warm ischemia, which begins as soon as circulation stops. By carefully dropping the temperature and cooling the organs, organs can remain viable because they are in a state similar to hibernation and require little nutrients, a concept known as metabolic inhibition.[169] Organs cannot remain in such a state indefinitely, however, as each organ has its own shelf life after being cooled.

Since organs often need to be transported after excision, F.O. Belzer developed a process that would induce hypothermic metabolism outside of the body by perfusing the organ with plasma, which allowed the organ to be supported in its natural substrate.[170] Belzer's method facilitated a large increase in kidney transplants, although cold storage methods continued to be improved. Collin's or Ringer's solution utilized a high amount of potassium in order to counter the loss of intracellular potassium that results from metabolic inhibition,

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[167] Gutkind, *Many Sleepless Nights* 288.

[168] Gutkind, *Many Sleepless Nights* 288.

[169] Hakim, *History of Organ and Cell Transplantation* 69.

[170] Hakim, *History of Organ and Cell Transplantation* 69.

and this remained in practice until the 1980s when Viaspan replaced it.[171] Viaspan was developed at the University of Wisconsin and was responsible for extending the viability of the liver and pancreas from four hours post excision to between thirty and seventy-two hours.[172]

The most significant anti-rejection drug discovery came in the form of a fungus found in the soil of Southern Norway in 1969 known as cyclosporine.[173] Cyclosporine was not officially introduced in clinical practice until 1978 but upon its application it increased the number of successful liver transplants from 18% to 68%.[174] This drug was remarkable not only for its ability to exponentially increase survival but to do so with fewer side effects. The beauty of cyclosporine lay in the fact that it was more discriminating than any anti-rejection drug used previously. Rather than obliterate the immune system as other drugs had done, it sought instead to manage the immune system. Cyclosporine allowed the immune system to function at a normal capacity by inhibiting rather than destroying T Lymphocytes, which were responsible for destroying the new organ.[175]

Cyclosporine was clearly an improvement on previous drugs although it was by no means the perfect solution. Cyclosporine reduced the incidence of

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[171] Hakim, *History of Organ and Cell Transplantation* 70.

[172] Hakim, *History of Organ and Cell Transplantation* 70.

[173] Gutkind, *Many Sleepless Nights* 51.

[174] Shayan, "Organ Transplantation: From Myth to Reality" *137.*

[175] Gutkind, *Many Sleepless Nights* 52.

acute rejection although chronic rejection remains a problem to this day; thus new drugs are continually in development.[176] The current species of anti-rejection drugs, FK506 and sirolimus, have shown promising results in effective immunosuppression although they too are not without side effects. The risk of infection, usually from viral, fungal, or bacterial agents, remains the most common cause of death in immunosuppressed transplant recipients with up to 90% of all kidney recipients at risk of Cytomegalovirus (CMV), which ranges in presentation from flu symptoms to myocarditis to pancreatitis, or immune system collapse.[177]

As better preservation techniques and anti-rejection drugs were implemented, the next problem and still the most formidable one today, became apparent; the supply of organs was insufficient to meet the demand. Many historians attribute this problem as the impetus that led to the proposal of a redefinition of the traditional notion of death.[178]

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[176] Federle, "Milestones and Future Trends in Solid Organ Transplantation" *425.*

[177] Federle, "Milestones and Future Trends in Solid Organ Transplantation" *425.*

[178] By way of a preface to the following section it should be clear that whether the notion of brain death was "constructed" as a means to access a larger donor pool or whether it was merely "discovered" by the concomitant boom in medical acumen is not the focus at hand. It will be clear that organ transplantation obviously played a role in the development of brain death, but this must be viewed within a broader context as no single event caused a new definition of death but it was part of a multi factorial socio-historical shift. Also, it is worth noting in order to frame our perspective that the many ethical tenets that we take for granted today such as removing a patient from life sustaining treatment (LST) when it offers no benefit were foreign concepts at this time. Since removal of LST was akin to homicide, the licit removal of LST may have been an equally compelling reason to redefine notions of life and death. It is accurate to say that society was indelibly shaped by medicine and its new technologies since life does not exist in a vacuum but always reflects a particular culture in relation to a particular place in time. The culture of medicine at this time was undergoing a twentieth century

VIII. Historical Shift

In 1968 The United States National Conference of Commissioners on Uniform State Laws proposed model legislation in the form of the Uniform Anatomical Gift Act (UAGA).[179] The UAGA allowed individuals to direct whether they would like to donate all or part of their bodies to science after death and further allowed a deceased patient's family to authorize donation provided the deceased did not voice a previous objection.[180] By 1971 all fifty states adopted the UAGA in an effort to publicize the practice of organ donation and also to remedy what was quickly becoming the greatest obstacle to transplantation, the organ shortage.

The same year the UAGA was drafted, Henry Beecher chaired the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death that would develop a new concept of death.[181] A new definition of death had been suggested years before this formal Committee convened, however, as we saw in 1959, when French neurophysiologists studied patients on mechanical ventilation whose brains were permanently damaged.

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renaissance. It is therefore impossible to determine what *caused* the definition of brain death; suffice it to say that it came by way of a set of circumstances and factors that contributed to the growth of organ transplantation at a particular point in history. Whether or not brain death is a structurally sound diagnosis for death will be discussed at length in subsequent chapters.

[179] Baker *"Organ Donation and Transplantation: A Brief History of Technological and Ethical Developments*" 13.

[180] Baker, *"Organ Donation and Transplantation: A Brief History of Technological and Ethical Developments"* 13.

Transcripts from a 1966 Symposium on Medical Ethics in London hosted by the Ciba Foundation show that perceptions were radically changing about how and when death ought to be declared.[182] During the Symposium, physicians from Belgium and France discussed a type of “heart-beating cadaver” that was used for organ transplantation. This new type of organ donor was not declared dead based on the traditional cardio-respiratory criterion of death, but by a series of criteria that proved the brain was dead. This revolutionary idea allowed organs to be removed from a corpse with intact circulation, which greatly improved the possibility of a successful transplantation by diminishing the problem of warm ischemic injury.[183]

The Harvard Committee set forth the necessary criteria for diagnosing a dead brain. Unfortunately, their language was imprecise at best, for the original task was to define “irreversible coma.” Perhaps the most glaring criticism is that the Committee failed to prove why the criteria that diagnosed a dead brain proved that the individual was dead. In other words, even if specific criteria may be met to confirm that a brain is dead, where is the justification to prove that a dead brain is the same as a dead person? What is special about the brain per se that death can be declared by neurological criteria even if the heart continues to beat? These questions raise conceptual problems that are appropriate for discussion in the following chapter on whole brain death. For our purposes here

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[182] Groth, "Historic Landmarks in Clinical Transplantation” 835.

[183] Groth, "Historic Landmarks in Clinical Transplantation" 835.

I wish to simply present rather than critique the Harvard Committee's recommendation in order to show its implications on organ transplantation.

The Harvard Committee advanced two primary reasons for a redefinition of death. First, new technologies made it difficult to determine death using traditional criteria, and the application of such technologies could maintain the irreversibly comatose indefinitely, which the Committee concluded, could be emotionally draining on families as well as on hospital resources.[184] Second, since the traditional determination of death was in question, obtaining organs from such patients was mired in controversy. Thus by endorsing a new, modern definition of death as opposed to the obsolete cardio-respiratory standard, death could be determined in the presence of technology and in the process allow for the licit removal of a patient's organs.[185] Certainly it was preferable to procure organs from a well-perfused cadaver that was being maintained by machines than from a cadaver whose circulation had ceased. The question arose, however, of how to consider a breathing person who is pink and warm as one who is actually dead whose organs can be excised? This and many other questions will be fully explored in the following chapter.

The following criteria were endorsed by the Committee to diagnose irreversible coma:

> *1.* Unreceptivity and Unresponsivity*. There is a total unawareness to externally applied stimuli and*

[184] Baker, *"Organ Donation and Transplantation: A Brief History of Technological and Ethical Developments"* 20.

[185] Baker, *"Organ Donation and Transplantation: A Brief History of Technological and Ethical Developments*" 20.

inner need and complete unresponsiveness—our definition of irreversible coma. Even the most intensely painful stimuli evoke no vocal or other response, not even a groan, withdrawal of a limb, or quickening of respiration.

2. No Movements or Breathing*. Observations covering a period of at least one hour by physicians is adequate to satisfy the criteria of no spontaneous muscular movements or spontaneous respiration or response to stimuli such as pain, touch, sound, or light. After the patient is on a mechanical respirator, the total absence of spontaneous breathing may be established by turning off the respirator for three minutes and observing whether there is any effort on the part of the subject to breathe spontaneously.*

3. No Reflexes*. Irreversible coma with abolition of central nervous system activity is evidenced in part by the absence of elicitable reflexes. The pupil will be fixed and dilated and will not respond to a direct source of bright light. Since the establishment of a fixed, dilated pupil is clear-cut*

> *in clinical practice, there should be no uncertainty as to its presence. Ocular movement (to head turning and to irrigation of the ears with ice water) and blinking are absent. There is no evidence of postural activity (decerebrate or other). Swallowing, yawning, vocalization are in abeyance. Corneal and pharyngeal reflexes are absent.*
>
> 4. Flat Electroencephalogram*. Of great confirmatory value is the flat or isoelectric EEG. We must assume that the electrodes have been properly applied, that the apparatus is functioning normally, and that the personnel in charge is competent…*[186]

Contemporary brain death protocols differ somewhat from the above criteria set forth in 1968. For example, most institutions do not require the absence of all reflexes given the potentiality for the "Lazarus Sign." This phenomenon, which ranges from the deceased exhibiting small twitches to sitting upright, is due to residual spinal cord activity and/or muscle reflexes that may persist after death.[187] Since this activity, though certainly unsettling to some

[186] "A Definition of Irreversible Coma: Report of the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death," *JAMA* 252.5(1984): 677.

degree, does not indicate the presence of life, a modern determination of death typically focuses on the quiescence of cephalic reflexes, which indicates a dead brain stem rather than on stretch reflexes.[188]

Despite some other modifications, which shall be discussed in the next chapter, the criteria remain largely unchanged, perhaps explaining how the Committee's fundamental recommendation that a non-functioning brain is equivalent to death was rapidly accepted in the late 1960s and is accepted, though not without criticism, today. A primary problem that resulted, however, was a lack of uniformity, such that a person could be declared dead by brain-based standards in one state but alive in another state that did not recognize brain death.

In 1981 the Uniform Determination of Death Act (UDDA) was enacted to remedy this problem. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research endorsed and presented the UDDA to President Ronald Reagan on July 9, 1981. The UDDA, which stated that an individual who has sustained either 1.irreversible cessation of circulatory functions, or 2.irreversible cessation of all functions of the entire brain, including the brain stem, is dead, was approved by the American Bar Association (ABA), the American Medical Association (AMA), and the National Conference of Commissioners on Uniform State Laws.[189] The UDDA did not

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[187] Robert D. McKay and Pam Duncan Varner, "Brain Death and Ethics of Organ Transplantation," *Anethesia and Organ Transplantation*, ed. Simon Gelman (Philadelphia: W.B. Saunders Company, 1987):16.

[188] Robert J. Joynt, "A New Look at Death," *JAMA* 252.5 (1984): 681.

determine how the above criteria ought to be tested, only that a determination be made in accordance with accepted medical practice.

Upon acceptance of the UDDA, heart-beating cadavers became a potentially large resource for organs, at which point it became clear that organized social policies concerning organ donation were necessary. In 1984 Congress enacted the National Organ Transplant Act, which prohibited buying and selling organs and set up provisions for a national organ sharing system that would later become the United Network for Organ Sharing (UNOS).[190] The following year The Association of Organ Procurement Organizations was created and the Organ Procurement and Transplantation Network (OPTN) established. In 1986 The Omnibus Reconciliation Act required that all transplantation programs be members of the OPTN, which is regulated by UNOS.[191] Also this same year hospitals were bound to perform Required Referral, which entailed that they report all deaths to the local Organ Procurement Organization (OPO), though organs could only be procured with consent.[192]

In 1987 UNOS was established as a national registry for organs and is divided into regions across the United States. Organ shortage was apparent

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[189] Joynt, "A New Look at Death" 681.

[190] Dale H. Cowan, Jo Ann Kantorowitz, Jay Moskowitz, and Peter H. Rheinstein, eds. *Human Organ Transplantation: Societal, Medical-Legal, Regulatory, and Reimbursement Issues* (Ann Arbor: Health Administration Press, 1987): 389.

[191] "How the System Functions: The Roles of the United Network of Organ Sharing, the Organ Procurement and Transplantation Network, and the Organ Procurement Organization in Heart Transplantation," *Critical Care Nursing Clinics of North America* 12.1 (2000): 12.

[192] "How the System Functions" 12.

from UNOS's inception as evidenced by formal waiting lists. Statistics show that from 1987 to 1991 the number of patients in need of transplants increased by 75% from 13,153 to 23,056 but the number of donors remained relatively unchanged, growing only from 4000 to 4357.[193] In theory, heart-beating cadavers were viewed as a solution to the problem of scarcity as up to 200,000 people were declared brain dead annually in the 1980s. However, of the 200,000 brain dead corpses, organs were only retrieved from 2000 each year.[194]

There was and continues to be disagreement as to how organs ought to be allocated and despite the fact that transplantation is a medical procedure it became quickly apparent that values and issues of social justice were at stake. When life hinges on the need for an organ it is often difficult to be dispassionate about allocation. Some groups lobby for the right to purchase organs, though the 19th century Burke and Hare scandal still persists as an historical reminder of the inherent dangers surrounding the commodification of human bodies.[195]

Burke and Hare were originally body snatchers in Edinburgh, that is, they dug up the freshly dead and sold the cadavers to medical schools for dissection lessons.[196] Pilfering graves, however, proved to be laborious and time consuming with unpredictable results, as only corpses in good condition would

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[193] Federle, "Milestones and Future Trends in Solid Organ Transplantation" 428.

[194] Baker, *"Organ Donation and Transplantation: A Brief History of Technological and Ethical Developments" 24.*

[195] Baker, *"Organ Donation and Transplantation: A Brief History of Technological and Ethical Developments" 14*.

[196] Kenneth V. Iserson, *Death to Dust* (Tuscon: Galen Press Ltd., 1994) 343.

elicit a competitive price from anatomists. Since it was impossible to determine a cadaver's condition prospectively, the men sought alternate means to procuring bodies where they could control the amount of bodily injury and/or decomposition in order to ensure payment would be forthcoming. Burke and Hare subsequently developed a strangulation technique, which is still known as Burking, that belied their murderous ways allowing them to kill and sell the bodies of sixteen men, women, and children before their activities were discovered.

Another concept that seems to have arisen directly as a means to safeguard against Burking is the Dead Donor Rule (DDR), which dictates that one may not be killed for or by the removal of organs.[197] Our organ retrieval system is based fundamentally on the idea of donation, and while other means to obtain organs have been attempted such as presumed consent, our normative guidelines rely squarely on the notion of altruism.[198]

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[197] Baker, *"Organ Donation and Transplantation: A Brief History of Technological and Ethical Developments"* 24.

[198] Robert Truog has argued prolifically to abandon the DDR in favor of removing organs from patients who are in PVS or from similarly neurologically devastated patients who he claims are beyond harm and/or from those who can explicitly give consent for organ removal such as the imminently dying. He argues that respect for autonomy and nonmaleficence should guide normative rules for donation rather than relying on the concept of whole brain death, which does not satisfy the DDR given its inherent incoherence, which shall be explored in the following chapter. See Robert D. Truog and Walter Robinson. "Role of Brain Death and the Dead-Donor Rule in the Ethics of Organ Transplantation." *Critical Care Medicine*. 31.9 (2003): 2391-96.

Notwithstanding Truog's often compelling arguments, especially with regard to the problems with whole brain death, the transplantation community is sensitive to public perception and has repeatedly refused to abandon the DDR despite the fact that it would surely expand the donor pool. In 1994 the American Medical Association's Council on Ethical and Judicial Affairs recommended making an exception to the DDR in the case of anencephalic infants. The UNOS Ethics Committee immediately rejected their recommendation despite the fact that some members viewed such infants as appropriate candidates for donation. While some UNOS members agreed with the AMA that such infants could be used as organ sources, they unanimously rejected violating

In the interest of equipoise, UNOS rations organs on a point system that seeks to uphold just allocation. The following criteria are applied to each patient and a number of points is accumulated according to: geographic location, tissue type, compatibility in size of organ, blood type, degree of medical need, and amount of time on the waiting list.[199]

It is however beyond our purposes to further elaborate on the problems and potential solutions to the just allocation of organs.

This chapter has chronicled the major developments in organ transplantation from its fabled beginnings to its current place in medicine as a viable treatment for organ failure. Despite its accomplishments, however, the future of organ transplantation may be inhibited due to the shortage of donor organs. Whether or not it was a solution to this particular problem, this chapter presented the notion of whole brain death proposed in 1968 that in theory would expand the donor pool. What we did not do, which is the task for the following chapter, is to explore in fine detail what is meant by whole brain death and determine whether it is clinically as well as philosophically sound, as well as to

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the DDR, which would sanction killing for their organs. Those who advocated using anecephalics as organ donors argued that such infants should be reclassified as dead using an ontological definition of death as fulfilled by a higher brain death criterion, thereby safeguarding the fundamental tenet of organ transplantation. Ultimately the AMA Council rescinded its position after much criticism. The general consensus is that removing organs prior to death is regarded as homicide even with consent and even when a patient is beyond harm. Thus organ donation remains faithful to the DDR despite a vocal minority opinion. See Robert M. Veatch "The Dead Donor Rule: True By Definition." *ajob*. 3.1 (2003): 10-11.

[199] Baker, *"Organ Donation and Transplantation: A Brief History of Technological and Ethical Developments"* 35.

build our case to argue that cardiac death is not the same as brain death and donation after cardiac death patients are not yet dead.

Chapter 3
The Legitimacy of Whole Brain Death

It isn't that they can't see the solution. It's that they can't see the problem.[200]

This chapter explores the legitimacy of Whole Brain Death (WBD). I will argue that WBD is a theoretically inconsistent criterion and that its main premise, that a functioning brain is required for integrative life, is flawed. I will provide evidence that the bodies of WBD patients continue to integrate at the level of the organism as a whole and therefore fail the classic definition of death. If the ability to maintain integrated functioning is what distinguishes life from death as the current definition of death holds, I will argue that a dead brain does not stop such functions from continuing.

I will also dispute whether the clinical tests used to diagnose WBD are sufficient to prove all critical brain functions have ceased, as well as examine the sets of brain functions that persist in many WBD patients. I will ultimately conclude that the definition of death must be modified if we intend to maintain a WBD criterion. We cannot adequately analyze the practice of non-heart-beating donors (DCD) before we analyze the concept that supports organ procurement from heart-beating (WBD) donors. That is, before we can endeavor to expose the problems with DCD it is necessary to ensure our definition of death is medically and philosophically coherent. This chapter will argue that WBD in fact

[200] Gilbert Keith Chesterton

is neither and must be reformulated in order to legitimately continue to use such patients as organ sources.

The concept that undergirds the WBD criterion avoids the philosophical issue of what is significant to the human and focuses instead on the biological claim that a dead brain proves the organism, as a whole, is dead. I object to WBD in that it fails to prove this biological claim, for while a patient cannot be dead if the brain is alive, the classic definition of death requires more than a dead brain; it requires the permanent cessation of the integrated functioning of the organism as a whole. I will argue that integrated functioning continues in WBD patients and the brain is not the primary integrator of the organism as a whole.

I. The relationship between transplantation and death

There are two misconceptions that must be clarified at the outset of this chapter. First is the belief that the definition of death is distinct from organ recovery efforts, and second is the belief that donors are stone dead at the moment of organ procurement. As pertains to the first issue, it has traditionally been held that a definition of death should remain independent of organ donation and the public has been assured there is such a division.[201] History shows otherwise, however, as one of the primary reasons WBD was introduced was as a means to obtain organs, which was disclosed in the Harvard Committee's Report. Further, Donation After Cardiac Death (DCD) protocols (previously referred to as non heart—beating donation (NHBD) manipulate a declaration of death in order to obtain organs as rapidly as possible for transplantation based

[201] Thomas Russell, "Brain Death," *Intensive Care Medicine* 30(2004): 1697.

on the moral position that the patient will not be resuscitated rather than on clinical data that proves death has occurred.

Therefore, while it may be theoretically safer to separate any definition of death from transplantation in order to avoid the specter of impropriety, they cannot practically be removed from one another. Thus we will be better off to concede that definitions of death are constructed with the efforts of organ transplantation in mind and maintain that this does not necessarily cause problems.

Problems arise when we attempt to obfuscate this truth rather than acknowledge that death is definitional, meaning that human beings decide at what point on the continuum a particular clinical state qualifies as dead. A definition of death is a pronouncement rather than an authentic discovery because the specific biologic moment of human death cannot be readily identified. Thus we agree on the characteristics that all organisms that are dead should share and call that point death.

The point on the continuum is inevitably to some degree a construct. This does not mean, of course, that the determination of death is totally constructed. We do indeed *discover* that death has certainly occurred at some point in the continuum. That death has occurred for Aristotle and for John Kennedy is not simply a construct; it is a fact that we discover. Thus there is a point on the continuum *after which* death has certainly occurred. And there is also a point *before which* death has certainly *not* occurred and that point is the point when revival to a conscious state is still possible. We will deal in chapter five with the problems this poses for Donation After Cardiac Death and with suggestions for dealing with these.

It is not by accident that our definition of death fits nicely with organ transplantation nor should it be a problem provided we deal openly with the issue. Integrity requires that the public understands that our definition of death is a socially constructed agreement that may change. Danger lurks when we attempt to modify it surreptitiously under the false pretense that we have discovered this unknowable truth that coincidentally facilitates organ transplantation.

Concerning the second issue, the clinical requirements of transplantation demand living organs and tissues while the conceptual requirements promise a dead donor. This is where WBD comes to the forefront, specifically whether we can call the WBD patient clinically dead despite the fact that the body continues to cooperate in unison as an integrated unit. If WBD does not fulfill the classic definition of death, then by virtue of the dead donor rule organs ought not to be procured from such patients. If we adhere to this, however, the following repercussions are likely: organ transplantation will collapse until other technologies such as organ cloning are developed and/or DCD will increase in order to balance the loss of WBD donors. Both of these are undesirable outcomes that may pose more societal problems than maintaining WBD as it currently stands, but we must at the very least expose the problems therein.

Conceptual clarity and honesty are at stake. While the public may in fact accept WBD as death, the majority of people cannot articulate why a dead brain is equivalent with a dead human being. This is not surprising given that medical professionals themselves are confused about the concept.[202] This is less surprising still given that with support a WBD body can be maintained for long periods of time and can continue to perform many tasks that corpses cannot, leading to the conclusion that they really are not dead in the traditional sense of the word.

One of the reasons we have difficulty reconciling such patients as dead is that they do not *look* dead; they do not exhibit the characteristics we associate with death.[203] For example, our visceral reaction to a person who is pink and warm and who is breathing is fundamentally different from one who is cold, stiff, and pallid. We do not need to appeal to reason to reach the conclusion that one is alive and the other dead, for we know it at a primitive or intuitive level. But a brain dead patient requires that we suppress this distinction, which sets the stage for an epistemological struggle.

In order fully to examine the conceptual underpinnings of WBD we must go back to the source. WBD was endorsed as a criterion of death in 1968 and was accepted with little public opposition. The Harvard Committee began by stating, “Our primary purpose is to define irreversible coma as a new criterion of death.” As Paul Byrne and Walt Weaver observe, however, the Committee did not set out to establish *if* coma was a new criterion of death, but to *make* it so. In this manner, data could be manipulated to fit an already pre-designed

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[202] Tom Tomlinson, "Misunderstanding Death on a Respirator," *Bioethics* 4.3(1990): 253.

[203] Martyn Evans, "A Plea for the Heart," *Bioethics* 4 (1990): 230.

conclusion. Further, Byrne and Weaver note that the Harvard Committee published its report without patient data or references to scientific reports.[204] While the Harvard Committee outlined criteria to diagnose a dead brain, it would be more than ten years before any justification was offered as to why a dead brain was equivalent with a dead person.[205] Notwithstanding the fact that more than a decade elapsed before a coherent presentation of WBD was offered, what is more puzzling is how WBD, appearing at least on a pre-theoretic level to contradict the traditional notion of death, did not generate more public debate.[206]

In fact, what debate did ensue was isolated mainly within academic circles, perhaps owing to a society that was disinclined to challenge the medical establishment.[207] More than thirty years later, however, our current social climate coupled with ample empirical data regarding the physiology of the brain-dead patient, has enabled spirited debate as to the validity of WBD. Disagreement over the legitimacy of WBD is now widespread in philosophy and medicine, especially with regard to the practice of organ donation and the

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[204]Paul A Byrne, Walt F. Weaver, "Brain Death" Is Not Death" Brain Death and Disorders of Consciousness," *Advances in Experimental Medicine and Biology* (2004): 44.

[205] Stuart J. Youngner, Robert M. Arnold, "Philosophical Debates About the Definition of Death: Who Cares?" *Journal of Medicine and Philosophy* 26 (2001): 529.

[206] It should be noted, however, that the legitimacy of whole brain death as it relates to Halakha has been and continues to be debated in Orthodox Judaism. Daniel Wikler provides reasons for why, despite some organized dissenters, the consensus on brain death nonetheless borders on unanimity and is accepted by all but a handful of countries. He writes, “The array of kinds of expertise and sources of authority now marshaled in support of the whole-brain definition of death constitute a powerful endorsement of the concept for the average citizen. Bound up in the arcane terminology and concepts of modern neurology, perhaps the least familiar of medical specializations, the notion of brain death is intellectually intimidating.” Daniel Wikler, "Brain Death: A Durable Consensus?" *Bioethics* 7.2-3(1993): 239.

question of whether one is “really” dead when organs are recovered from brain-dead donors.

In chapter one we examined the many signs and tests used to diagnose death from the 18th to the mid 20th century. The most reliable indicator among these was the irreversible cessation of breathing and heartbeat. As Bartlett and Youngner note, “When a human being’s heart stopped beating or breathing failed, consciousness, internal integration, and the life of individual organs, tissues, and even cells ceased—quickly, inevitably, and permanently.”[208] As we saw in chapter two, however, advances in artificial life support systems in the latter part of the 20th century made it difficult to determine death accurately using the traditional cardio-respiratory criterion and, subsequently, a whole brain death criterion was introduced. The first question that arises is what is “brain death ”as opposed to “cardiac death?”

II. The Concept of Whole Brain Death

It is generally asserted that there is only one definition of death: *irreversible cessation of the integrated functioning of the organism as a whole*, but that it can be diagnosed in two ways, using a cardio-respiratory criterion or a neurologic criterion. As we saw in the previous chapter, the Uniform Determination of Death Act (UDDA) devised this “separate but equal” status, which established that death could be established by either 1) the irreversible cessation of circulatory functions or 2) the irreversible cessation of the entire brain, including the brain stem. This means in effect that “brain death” or

[208] Edward T. Bartlett, Stuart J. Youngner, "Human Death and the Destruction of the Neocortex" *Death: Beyond Whole-Brain Criteria*, ed. Richard M. Zaner (Boston:Kluwer Academic Publishers, 1988): 199.

"cardiac death" are two ways to diagnose the same condition, not fundamentally different types of death as either criterion signifies the loss of functioning of the organism as a whole. But this requires further examination.

The criterion for death as the irreversible cessation of circulatory and respiratory functions does not require that the brain has ceased functioning. Moreover, it is theoretically possible for the heart and lungs to stop and for the brain to continue to function for a time.[209] James Bernat, a vocal defender of WBD, recognizes the problem with using dual criteria when he notes, "It takes considerably longer than a few minutes for brain and other organs to be destroyed from cessation of circulation and lack of oxygen."[210] This is of grave concern for DCD, which we will explore at length in a subsequent chapter.

Conversely, the criterion for death as the irreversible cessation of all functions of the entire brain does not require cessation of circulation and respiration. We will also pursue this in greater detail in the chapter on DCD, but it appears then that death has a bifurcated rather than a unitary definition that does not require the permanent cessation of the organism as a whole but only of certain parts of it.[211]

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[209] Paul A Byrne, Sean O'Reilly, Paul M. Quay, and Peter W. Salsich, "Brain Death-The Patient, the Physician, and Society", *Beyond Brain Death* eds. M. Potts, Paul A. Byrne and Richard G. Nilges (The Netherlands: Kluwer Academic Publishing, 2000): 61

[210]James L. Bernat, "A Defense of the Whole-Brain Concept of Death," *Hastings Center Report* 28.2 (1998): 20.

[211] Mary R. Hayden, "A philosophical Critique of the Brain Death Movement," *Linacre Quarterly* 49(1982): 245.

Scholars agree that regardless of the criteria used to fulfill the definition of death they should be both necessary and sufficient.[212] The UDDA, however, only requires the neurologic criterion to fulfill both conditions, and even that is arguable according to some WBD critics.[213] For example, loss of consciousness is necessary for death but it is not sufficient; only whole brain death (according to WBD proponents) meets both necessary and sufficient conditions to declare death.

In discussing necessary and sufficient conditions, we must consider the cardio-respiratory criterion of death: loss of heartbeat and breathing are sufficient for death but not necessary in the presence of WBD. Heartbeat and circulation are said to be irrelevant if the patient is clinically brain dead, but as F.M. Kamm observes, "any property empirically correlated with a characteristic or criterion of life can be a sign of it."[214] Interestingly, WBD proponents ascribe significance to heartbeat and respiration when they are spontaneous. WBD advocates criticize a higher-brain criterion that would allow death to be declared in the presence of spontaneous breathing and heartbeat but negate their importance in the WBD patient simply because they are artificially induced.[215] WBD advocates argue that implementing a higher brain death criterion would entail burying patients with

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[212] James L. Bernat, "A Defense of the Whole-Brain Concept of Death," 18.

[213] Jeff McMahan, "The Metaphysics of Brain Death," *Bioethics* 9.2 (1995): 94.

[214] Kamm, "Brain Death and Spontaneous Breathing," *Philosophy and Public Affairs* 30.3 (2001):303

[215]President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research*, Defining Death: A Report on the Medical, Legal, and Ethical issues in the Determination of Death* (Government Printing Office, 1981) 35.

spontaneous breathing and heartbeat, something that would be a profound departure from our traditional practices.[216] This is true, although WBD allows excising a beating heart and/or mining other organs in a WBD patient who exhibits the same signs of life simply because such functions are maintained through technology.[217]

This is an argument we will explore in greater detail, but let us grant for the moment that if certain functions are necessary for the continued functioning of the organism as a whole then the mechanism that performs them, whether it is a brain or a machine, is irrelevant so long as the functions continue.[218] From what has been raised thus far it is clear that we will need to examine further whether it is legitimate to declare brain death when cardio-respiratory functioning continues, albeit with assistance. We will fully address the issue after we give a more detailed account of why WBD is said to be death.

There are two main reasons advanced for why WBD is considered an appropriate criterion for death. The first is the claim that all death is in fact brain death, such that all the signs traditionally used to determine death have always been neurologic in nature.[219] In other words, as we saw above, the cardio-

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[216] We will explore these arguments concerning higher brain death at length in the following chapter.

[217] D. Alan Shewmon, “Recovery from ‘Brain Death’: A Neurologist’s Apologia,” *Linacre Quarterly* 64 (1997): 45.

[218] Tom Tomlinson, "The Conservative use of the Brain-Death Criterion-A Critique," *Journal of Medicine and Philosophy* 9(1984): 380.

[219]James L. Bernat, "How Much of the Brain Must Die in Brain Death?" *Journal of Clinical Ethics* 3.1 (1992): 22.

respiratory criterion simply informs us of the status of the brain since breathing is usually a direct measurement of brain function and heartbeat is contingent on the ability to breathe. Advocates of this line of reasoning would reject the suggestion that WBD was invented or that death has been redefined since they contend that all tests for death are and always have been merely instantiations of WBD.

The second is the biological claim that the brain is the primary integrator without which life cannot continue in the organism as a whole. This is generally regarded as the traditional or "orthodox" justification for why a dead brain is equivalent with a dead person. The functioning of the "organism as a whole" must be distinguished from the functioning of the "whole organism," as the definition of death requires the permanent cessation of the former but not the latter. WBD proponents do not require the death of every brain cell to declare brain death but only those that contribute to the integration of the organism as a whole.[220] Therefore, WBD proponents claim that death occurs when all "critical" parts of the brain that are responsible for integrated functioning cease, since the brain, according to this argument, integrates the entire organism.

Bernat describes the organism as a whole as being greater than the sum of its parts and as referring to a set of vital functions that supports the life and health of the person.[221] For example, someone who has lost a limb is no longer a whole organism proper, but nonetheless remains an organism as a whole since the body continues to exist as an integrated unit. It is not inconsistent that life in

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[220] James L. Bernat, "The Biophilosophical Basis of Whole-Brain Death," *Social Philosophy and Public Policy* 19.2 (2002): 337.

[221] James L. Bernat, "A Defense of the Whole-Brain Concept of Death" 17.

isolated cells or tissues can continue after death whereas organized and directed systems that work in unison cannot. Axiomatically, a definition of death cannot require the permanent cessation of the whole organism since the only reliable criterion then would be to await putrefaction.

Both proponents and critics of WBD agree on the distinction between organism as a whole and the whole organism; the point of contention focuses on whether a dead brain proves that the organism as a whole has permanently ceased functioning. In 1981 The President's Commission convened in order to answer this question and they began their deliberation with an anatomic presentation of the brain and its functions, which I will briefly sketch here. Occasionally a bit of imagery is more instructive than any amount of technical verbiage; thus the following description of the brain is offered. "Yes, the good Lord bricked that sucker in pretty good, and for a reason. We're not supposed to play with it. The brain is sort of like a '66 Cadillac. You had to drop the engine in that thing just to change all eight spark plugs. It was built for performance, not for easy servicing."[222]

Put more academically, the human brain floats in a bone encasement known as the cranium and in general is well protected from infection and from the usual bumps and bruises we encounter as itinerant creatures. It is divided into three regions: the cerebral cortex, the cerebellum, and the brainstem, which includes the midbrain, pons, and the medulla oblongata. Each area performs certain functions, which will be discussed below, but it would be a mistake to try

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[222] Frank Vertosick, *When the Air Hits Your Brain: Tales of Neurosurgery* (New York: The Ballantine Publishing Group, 1996) 8.

to quarter the brain into sections that perfectly correspond to a particular purpose or manifested action. For example, it was traditionally thought that awareness or consciousness was sponsored solely by the cerebral cortex but the brainstem also serves as an interface in the process.[223] This might not sound exceptionally exciting but it demonstrates that complex interactions occur within the brain diffusely rather than in isolated parts, which will be somewhat problematic for proponents of higher brain-death as we shall see in the next chapter.

The cerebral cortex is the largest part of the brain; it is divided into two hemispheres and is regarded as the center of our higher faculties, which includes our ability to summon consciousness, memory, learning, reasoning, emotions, judgment, and intelligence.[224] The cerebellum, literally, "little brain" facilitates fine motor skills and coordination and is involved with the brain stem in performing various voluntary movements such as posture and balance, walking, eating, and adjusting the speed and tempo of such activities.[225] The brainstem connects the cerebral hemispheres with the spinal cord and is responsible for the vegetative processes including regulating blood pressure, breathing, and various reflexes such as coughing, sneezing, and vomiting.[226] The breathing center is located within the medulla, which stimulates the diaphragm, which in turn causes the lungs to expand leading to the cellular process known as respiration.

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[223] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death,* 15.

[224] *Taber's Cyclopedic Medical Dictionary*, 1997 ed. 380.

[225] *Taber's Cyclopedic Medical Dictionary,* 378.

[226] *Taber's Cyclopedic Medical Dictionary*, 379.

Ventilation is not the same as respiration but a thoroughgoing explanation will be given later in this chapter. It is sufficient for the moment to note that if the medulla is destroyed or injured then the natural result would be for the lungs to fail followed by the heart and eventually all the cells would become anoxic culminating in the death of the organism as a whole. This process shows the relationship between the brain, circulation, and respiration and how they maintain the organism as a whole. The President's Commission focused specifically on the brain as having primacy in this triangle. "When an individual's breathing and circulation lack neurologic integration, he or she is dead."[227] According to this argument, since only the brain can direct the entire organism, the loss of brain function is equivalent with death. Accordingly, the brain is the primary integrator that organizes the body into an organism as a whole without which the body is simply a chaotic group of subsystems whose functioning serves no purpose.[228]

Having explored the main argument for WBD, we must press the issue of the legitimacy of declaring death in the presence of cardio-respiratory functioning. The Commission established that artificially maintained respiration and circulation in a WBD patient are irrelevant because they are controlled by mechanical intervention rather than by the brain. They conceded that though it may look as if patient is alive, in fact the body is not functioning in any integrated manner since it is being manipulated externally. Accordingly, they argue, "the

[227] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death*, 33.

[228] D. Alan Shewmon, "The Brain and Somatic Integration: Insights into the Standard Biological Rationale for Equating "Brain Death" with Death," *Journal of Medicine and Philosophy* 26.5 (2001): 457.

function and results are similar, but the source, cause, and purpose are different between those individuals with and those without functioning brains."[229] Moreover, the Commission suggests that there are "startling" differences between WBD patients and those with intact brain stems, such as yawning for instance, yet they fail to acknowledge the equally disturbing differences between a corpse in a morgue and a WBD patient.[230] We must now carefully examine whether it matters if vital functions are maintained artificially.

We immediately encounter problems if we determine life from death based on technology if we consider that a person is not any less alive if he requires an artificial intervention. By its very definition, life-sustaining treatment serves to sustain life. Hans Jonas asks us to consider if we would hesitate to make a dead brain function if it required an artificial intervention to do so.[231] More likely than not, he assumes most people would not care how the brain continued to function as long as it did.

The Commission seemed to conflate a function as identical with the mechanism that performs it.[232] However, there is a difference between the thing that sponsors the function (brain) and the function itself (respiration, circulation,

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[229] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death,* 37.

[230] Daniel Wikler, "Brain Death: A Durable Consensus?" *Bioethics* 7.2-3(1993): 244.

[231] Hans Jonas, "Against the Stream: Comments on the Definition and Redefinition of Death" in *Philosophical Essays from Ancient Creed to Technological Man* (Chicago: University of Chicago Press, 1974) 135.

[232] Tomlinson, "The Conservative use of the Brain-Death Criterion-A Critique" *377*.

etc.), and if the function itself is what is significant and if it continues, then it ought not to matter what causes it so long as it occurs.[233] Both circulation and respiration are diffuse throughout the body and brain failure does not stop them. It is true that artificial technology is required to support them, but as we have already established, reliance upon technology in determining life from death creates intractable problems.[234] These critical functions are of the same kind we require must cease in the WBD patient based on the argument that they

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[233] Tomlinson, "The Conservative use of the Brain-Death Criterion-A Critique" 380.

[234] The abortion debate is, in general, beyond the scope of our present purposes. However, the U.S. Supreme Court's position on fetal viability as articulated in *Roe* v. *Wade* is instructive in demonstrating the inherent problems in basing a definition of life or death on technology. In this landmark case the Supreme Court declared that a viable fetus, one that could survive outside the womb, would represent a compelling State's interest in potential life and its termination would be prohibited except when the life or health of the mother were at stake. However, the Court later conceded that viability was an elastic term and in *Planned Parenthood of Central Missouri* v. *Danforth* (1976), the Court declared, "The time when viability is achieved may vary with each pregnancy, and the determination of whether a particular fetus is viable is, and must be, a matter for the judgment of the responsible attending physician." The Court refused to rule on gestational limits saying that "it is not the proper function of the legislature or the courts to place viability, which is essentially a medical concept, at a specific point in the gestation period." In *Colautti* v. *Franklin* (1979), the Court continued: "Because this point [viability] may differ with each pregnancy, neither the legislature nor the courts may proclaim one of the elements entering into the ascertainment of viability—be it weeks of gestation or fetal weight or any other single factor—as the determinant of when the State has a compelling interest in the life or health of the fetus." Accordingly, fetal viability is directly dependent on the current state of the art. But the Court's position on fetal viability does not distinguish life from death as much as it attempts to define when a life is afforded the state's protection. What is the status of a fetus that moves from the womb to life support and is never independently viable? Fetal viability may be an arguable point on a continuum to prohibit elective abortion but the fetus before and after, regardless of technology, is still a *living* thing, though *what* it is remains up for debate. See also *Roe* v. *Wade*, 410 U.S. 113 (1973); *Planned Parenthood of Central Missouri* v. *Danforth*, 428 U.S. 52 (1976); *Colautti* v. *Franklin*, 439 U.S. 379 (1979).

represent integration in the organism as a whole. Thus, the biological argument for WBD espoused by the President's Commission fails as a criterion of death.

Tom Tomlinson argues that a paradox is possible wherein the criterion for death (non functional brain) may be fulfilled but not the definition (cessation of the integrated functioning of the organism as a whole) if something other than the brain supports integrated functioning.[235] He as well as others conclude that a functioning brain may not be necessary for the integrated functioning of the organism as a whole.

The Commission put forth the argument that the presence of integration indicates life and its absence death but considered integration in a WBD patient merely artifact because the brain does not direct it. Daniel Wikler concludes that such a position requires the Commission to dismiss any activity in a WBD patient as "unintegrated" unless it is directed by the brainstem.[236] Intensive Care Units (ICUs) can substitute many functions of the brainstem, reinforcing the fact that the source of integration is irrelevant provided it can continue. Wikler argues that the Commission commits the fundamental mistake of confusing necessary and sufficient conditions. He points out that an intact brainstem in general means that a patient can breathe spontaneously, but, as we shall see in the following section, WBD patients are capable of respiration with assistance, thereby showing that brainstem capacity is not necessary. Wikler further argues that the

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[235] Tomlinson, "The Conservative use of the Brain-Death Criterion-A Critique" 380.

[236] Wikler, "Brain Death: A Durable Consensus?" 243.

Commission's view implicitly holds spontaneous ventilation as the sine qua non for life but does not hold the standard consistently.[237] He writes,

> The problem is that any number of patients, be they sufferers of polio, ALS, or other maladies, are incapable of spontaneous respiration and yet are indisputably alive. Of course, most of them are also conscious. Occasionally, however, these respirator-dependent patients lapse into seemingly permanent unconsciousness (PVS). At that moment they become patients who lack both the capacity for consciousness and the capacity for spontaneous respiration, which in turn is a stand-in for integrated functioning. According to the concepts underlying the current consensus, therefore they should be counted as dead.[238]

We have thus far argued that determining life from death based on technology is untenable and that it ought not matter what causes the heart and lungs to function as long as integrated functioning can continue. We must now consider whether the functions that do continue in the WBD patient actually reflect integration in the organism as a whole or if they are merely disorganized subsystems.

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[237] Wikler, "Brain Death: A Durable Consensus?" 243.

[238] Wikler, "Brain Death: A Durable Consensus?" 243.

III. THE BRAIN AS THE PRIMARY INTEGRATOR OF THE ORGANISM AS A WHOLE

Here we need to examine carefully the claim that the brain is the sole integrator of the organism as a whole and evaluate the sorts of functions that continue in the WBD patient, that is, whether they are integrated or random collections of subsystems.

This requires that we define what is meant by integration and criticality. Unfortunately, these terms mean different things to different people.

Integration can be viewed on a sliding scale such that one could argue integration requires awareness of the external environment (meaning patients in PVS lack it) whereas another may interpret it is at the organic level though biochemical reactions. The President's Commission has taken the middle ground approach and defines integration as brain function that manifests as physiologic homeostasis.[239] Following this definition then, WBD patients should not be able to exhibit homeostatic control. It is clear, however, that some WBD patients will continue to regulate free water homeostasis through arginine vasopressin, which does not preclude a determination of WBD. Robert Truog argues that this is more physiologically integrative than brain stem reflexes such as pupillary constriction, which must be absent in WBD patients.[240] Thus, using the definition endorsed by the President's Commission, some WBD patients will continue to integrate and do not meet the requirements for the classic definition of death.

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[239] Robert D Truog, and James C. Fackler, "Rethinking Brain Death," *Critical Care Medicine* 20(1992): 1706.

[240] Truog, Fackler, "Rethinking Brain Death" 1706.

Bernat sidesteps the integration debate in favor of defining the critical functions of the organism as a whole that are required for its continued life, health, and unity.[241] Specifically, he defines three areas of biological functioning that must be permanently lost for the organism to fulfill the definition of death: 1) spontaneous breathing and circulation, 2) homeostatic control, and 3) consciousness.[242] Bernat concedes that any one of the three is sufficient to declare life and all three must be absent to declare death. He endorses the irreversible loss of the clinical functions of the entire brain to best satisfy the above conditions as both necessary and sufficient.

But his three areas of critical functioning are not always absent in all WBD patients, which means such patients cannot be dead according to these criteria. Concerning his first condition, demanding cessation of “spontaneous” breathing and circulation is problematic since the issue of technology is controversial in the definition of death as we have seen. Irreversible cessation of the *spontaneous* functions of the organism as a whole is irrelevant since spontaneous function is not necessary for life, as evidenced by the many patients who require technological interventions and who are very much alive.[243] The term spontaneous appears nowhere in the definition of death for this very reason. Assisted breathing and circulation can equally foster the life, health, and unity of

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[241] Bernat, "A Defense of the Whole-Brain Concept of Death" 17.

[242] Bernat, "A Defense of the Whole-Brain Concept of Death" 17.

[243] Robert D. Truog, "Brain Death: At Once "Well Settled" and "Persistently Unresolved" *AMA Policy Forum* 6(2004): http://www.ama-assn.org/ama/pub/category/12715.html

the organism as a whole. Second, as we have just shown above, some WBD patients can continue to regulate homeostatic control, and third, it is arguable that consciousness is, strictly speaking, a critical function of the organism as a whole. According to Bernat's argument, functioning of any one of the three critical groups indicates life; therefore WBD patients that can breathe and circulate blood (whether this is spontaneous is irrelevant) and regulate homeostasis ought to be considered alive.

D. Alan Shewmon, a prolific critic of the concept of WBD, argues that many of the integrative functions of the organism as a whole are not in fact mediated by the brain; thus "linking the loss of somatic integration exclusively to brain-based criteria is not a physiologically tenable rationale for equating brain death with the death of the organism as a whole."[244]

Shewmon lists seven requirements to fulfill the definition of integrative unity: 1) it should be generic, meaning that it applies to all living species and not specifically to humans; 2) it should be actively anti-entropic, meaning the organism maintains organization without which it would cease to exist; 3) all corpses should lack integrative unity when resuscitation is no longer possible but prior to rigor mortis; 4) it should distinguish a composite unity from a mere collectivity (Shewmon clarifies that a unity is de facto unified because it involves anti-entropic mutual interaction among all the parts as opposed to a collectivity that is artificially maintained that will tend toward increasing entropy); 5) integrative unity should be clear and not ambiguous; 6) it must not confuse

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[244] Andrew B. Lustig, "Theoretical and Clinical Concerns About Brain Death: The Debate Continues," *Journal of Medicine and Philosophy* 26.5 (2001): 448.

disability or reliance upon technology as being disintegrated; 7) consciousness is not a necessary condition for integrative unity.[245]

In light of the above requirements, Shewmon argues that a definition of integrated unity should meet the following criteria: 1) Integration requires that the organism possess at least one emergent, holistic-level property. Shewmon defines an emergent property as one that derives from the cooperation of parts and a holistic property as one that is not dependent on isolated parts but of the entire composite unity. 2) A body that requires less assistance to maintain life than another similar living body that possesses integrative unity should be regarded as a living whole.[246] According to this account, many WBD patients fulfill both criteria.

Briefly, some of the integrative functions of the organism as a whole that are not controlled by the brain include homeostasis, energy balance, wound healing, infection fighting, and gestation of a fetus.[247] These are not characteristics of the dead; they are not reflexes but evidence of a body that is integrated at the level of the organism as a whole. What is more disturbing is that these functions can occur in patients who have passed WBD protocol because they are not tested when making a determination of death, which we

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[245] Shewmon, "The Brain and Somatic Integration" 460. I will, however dispute this claim that the definition of death must apply equally to all things organic since the death of a human being is fundamentally different than the death of another animal.

[246] Shewmon, "The Brain and Somatic Integration" 460.

[247] Amir Halevy, "Beyond Brain Death?" *Journal of Medicine and Philosophy* 26.5 (2001): 495.

shall examine in the next section.[248] WBD criteria only test the irreversible cessation of a portion of intracranial functions. For instance the pituitary gland, cardiovascular tone, and thermoregulation are not generally tested.[249]

Shewmon's main argument is that the brain does not confer integration but that it contributes to a somatic unity that is already presupposed.[250] Earlier we discussed that the breathing center is located within the medulla, but it is important to note that while breathing is the same as ventilation neither is the same as respiration, which continues in WBD patients.

The brain regulates breathing, but this simply refers to the movement of air in and out of the lungs and such movement, Shewmon argues, is not a somatically integrative function, for ventilation is not a sine qua non for life as demonstrated by patients on cardio pulmonary bypass or a fetus in utero.[251] Respiration however is a complex cellular and biochemical process that refers to the exchange of oxygen and carbon dioxide, which is not controlled by the brain but is present diffusely within the body and is required for the life of the organism as a whole. In addition, Shewmon acknowledges that the brain controls eating, drinking, and swallowing, but argues that such functions are not somatically integrating. The brain does not play a pivotal role in nourishment or digestion,

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[248] Halevy, "Beyond Brain Death?" 495.

[249] Nereo Zamperetti, Rinaldo Bellomo, Carlo Alberto Defanti, and Nicola Latronico, "Irreversible Apnoeic Coma 35 Years Later," *Intensive Care Medicine* 30(2004): 1716.

[250] Shewmon, "The Brain and Somatic Integration" 464.

[251] Shewmon, "The Brain and Somatic Integration" 464.

which is properly regarded as the biochemical process of energy conversion, which is, unlike the mere act of swallowing, an integrative function of the organism as a whole.[252]

Severe cases of Guillain-Barre Syndrome (GBS) can mimic WBD and further undermine the argument that a body cannot live unless the brain is directing the organism. Such patients can lose all brain stem function including brain stem reflexes.[253] Only testing through EEG, which is not required to declare WBD, can differentiate these patients from WBD patients. A GBS patient would require life-sustaining treatment for continued integrated functioning but would still retain consciousness; thus we would be ill advised to declare this patient dead.

This shows that the underlying concept of WBD is theoretically inconsistent when a patient with a severe case of GBS can be in the identical clinical state as WBD whereby all critical integrative functions of the brain have been lost but the GBS patient will clearly be regarded as a living human being. Both patients continue to integrate and both require artificial assistance to do so; the only fundamental difference between the two is that the patient with GBS will eventually recover brain function whereas the WBD patient will not. The GBS patient proves that a functioning brain is not necessary for life.

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[252] Shewmon, "The Brain and Somatic Integration" 465.

[253] Yael Friedman, Liesly Lee, John R. Wherrett, Peter Ashby, and Stirling Carpenter, "Simulation of Brain Death from Fulminant De-efferntation," *The Canadian Journal of Neurological Sciences* 30(2003): 398.

Shewmon further proves that the body does not possess an integra*tor* but integra*tion* by demonstrating the clinical similarities between a brain dead patient and a patient whose brain is functionally disconnected in the case of high Spinal Cord Injury (SCI).

> If the brain is uniquely responsible for the organism's biological unity, so that in the absence of the brain's coordinating activity the organism becomes a mere disunited collection of organs and tissues, such somatic 'dis-integration' should be just the same regardless [sic] whether the absence of brain coordination is due to absence of a brain or merely to functional disconnection from the brain… The "central integrator of the body" rationale of WBD can therefore be tested by examining the vital status of brain-disconnected bodies, so long as the somatic physiology of the two conditions is indeed equivalent… The purpose of this comparison is *not* to advance a claim that WBD is clinically indistinguishable from high spinal cord injury (SCI), which would be absurd. Nor is the issue to which the comparison is relevant the *clinical criteria* for diagnosing a dead brain but rather one particular *conceptual rationale* for equating a dead brain with a

> dead individual: namely the one that claims that a dead brain equates with a dead *body*… Subjective consciousness is simply not a sine qua non of the 'orthodox' organism-rationale, so it is beside the point in this debate.[254]

Bernat counters that the spinal cord does not play a critical role for the organism as a whole since patients can live with minimal support following a devastating spinal cord injury. From this he concludes that the integrating functions of the spinal cord are not necessary for life and clearly their absence is not necessary nor is it sufficient for death.[255] This brings us full circle back to Bernat's justification that consciousness is a critical function of the organism as a whole. He argues that consciousness is an emergent function and that it is necessary for the continued health of the organism. However, if the absolute threshold of what makes a function critical is whether one can live without it, which is how he dismisses the spinal cord's role as not critical, then it is inconsistent to claim consciousness breaks it, as it is not necessary for life either. If consciousness is a critical function it must be on grounds other than a purely biological argument since a patient can live without it.

This is tangential to Shewmon's point, however, as he claims it is precisely *because* the spinal cord is *not* necessary for biological life that there exists a

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[254] D. Alan Shewmon, "The Critical Organ for the Organism as a Whole: Lessons from the Lowly Spinal Cord" *Brain Death and Disorders of Consciousness*, eds. Calixto Machado and D. Alan Shewmon (Kluwer Academic /Plenum Publishers, 2004) 24-26.

[255] Shewmon, "The Critical Organ for the Organism as a Whole: Lessons from the Lowly Spinal Cord" 25.

conceptual problem. He compares the similar somatic traits shared between a WBD patient and a SCI patient and concludes that brain function is not necessary for biological life (equally at the level of organism as a whole).

> According to the mainstream, “orthodox” rationale, the purported loss of somatic integrative unity in Brain Death is attributable to the destruction of the many brain-stem and hypothalamic integrative centers. But, is it *their destruction per se* or rather *the body’s nonreception to their influence* that most immediately affects somatic integration? Surely the latter, because it is more proximate to the phenomenon of interest, it is the means through which the former exerts its effect, and it can also be brought about by other possible causes such as mere disconnection from cephalic structures. That the impact on somatic physiology of nonreception of rostral influence should be indifferent to the *reason* for the nonreception implies that body A with a destroyed brain and body B with a disconnected brain (due to high SCI) should have the same vital status. Logical consistency demands that if we assert A is dead as a biological organism, we must be prepared to say the same of B; but if we insist that B is clearly alive as a biological

> organism (and not merely because it is conscious) then we must be willing to admit the same of A… From the *body's perspective* Brain Death and atropinized high cord transection are virtually indistinguishable because the caudal margin of total brain infarction *is* in fact a cervico-medullary junction infarction. Thus, *regardless how one might choose to define operationally terms such as "integrative unity" or "organism as a whole," if they are defined carefully enough to apply properly to any ventilator dependent quadriplegic with Diabetes Insipidus, then* ipso facto *they will apply as well to any Brain Dead patient*.[256]

Again, similar to the case of GBS discussed earlier, we have a patient who is in the same clinical state of WBD but is clearly still alive. The brain is functionally disconnected from the body, which means the patient relies on external support for integrated somatic activity. It should be clear then that the brain is not the primary integrator of the organism as a whole and the WBD criterion is theoretically and, as we shall see, clinically inconsistent.

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[256]Shewmon, "The Critical Organ for the Organism as a Whole: Lessons from the Lowly Spinal Cord" 34,35.

IV. Diagnosis of WBD

Shewmon further exposes a tension between the conceptual argument for WBD and the diagnostic tests used to confirm it. If the argument is that the brain is the primary integrator of the organism as a whole, Shewmon questions why the diagnostic criteria do not require the cessation of a single somatically integrative brain function. Truog concurs by arguing that "many of the components of the brain death exam measure functions that contribute nothing to physiologic integrity (such as determining whether the pupils react to light), yet functions that are critical to maintaining physiologic integrity (such as the regulated secretion of anti-diuretic hormone) are ignored.[257] Instead, WBD protocols only require loss of consciousness, cessation of cranial nerve function, and absence of spontaneous breathing.[258] Ironically, the regulation of blood pressure, maintenance of body temperature, or the presence of neurohormonal functions, all of which are brain mediated, are not tested in WBD protocols.[259]

Many patients who are declared WBD do not suffer from marked hypotension and, if supported on life sustaining treatment, many regain hemodynamic stability without requiring other cardiovascular aide.[260] Shewmon

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[257] Robert D. Truog, "Brain Death: At Once "Well Settled" and "Persistently Unresolved"," *AMA Policy Forum* 6(2004): http://www.ama-assn.org/ama/pub/category/12715.html

[258] Shewmon, "The Brain and Somatic Integration" 465.

[259] Shewmon, "The Brain and Somatic Integration" 465.

[260] Shewmon, "The Brain and Somatic Integration" 466.

recoils at the American Academy of Neurology's position that "normal blood pressure without pharmacologic support is compatible with a diagnosis of brain death."[261] Other WBD critics argue that loss of blood pressure control is the sine qua non of somatic "dis-integration" without which the body could not be declared dead.[262] It has been documented that 95% of patients show an increase in arterial blood pressure upon incision for organ recovery while others have exhibited increased heart rate and/or sweating.[263] One may ask how such patients who are said to be dead react to incision that may require the use of general anesthesia or paralytic agents before organ recovery.[264] The traditional response is that these are simply "reflexes" that do not have any bearing on the declaration of death. Further, WBD patients retain the ability to regulate their temperature to some degree spontaneously such that with the assistance of blankets they can tend toward normothermia.[265] Shewmon points out the obvious that a corpse cannot raise its temperature regardless of how many blankets are applied, thus forcing us to compare the bodies of those we know are dead with bodies that do not exhibit the same properties.

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[261] Shewmon, "The Brain and Somatic Integration" 466.

[262] Shewmon, "The Brain and Somatic Integration" 466.

[263] H.J. Gramm, M. Schafer, J. Link, and J. Zimmerman, *Intensive Care Medicine* 20(1994): 165

[264] David Albert Jones, "Metaphysical Misgivings About Brain Death" *Beyond Brain Death,* eds. M. Potts, Paul A. Byrne and Richard G. Nilges (The Netherlands: Kluwer Academic Publishing, 2000) 96.

[265] Shewmon, "The Brain and Somatic Integration" 471.

Halevy and Brody identify two areas of persistent functioning in some WBD patients that are critically integrating: neurohormonal regulation, and brain stem functioning. Further they argue that cortical function is present in some WBD patients, and though this is not a critical function as we have seen, there is a general agreement that declaring someone dead with higher brain functions intact is unacceptable.

Continued hypothalamic function in particular is troubling for many critics of WBD. When the brain is able to secrete anti-diruretic hormones it can prevent the development of central Diabetes Inspidus (DI), which confirms that the hypothalamus and posterior pituitary are intact. This is important since “a functioning neurohormonal pathway is essential to the viability of the organism as a whole and it is a major example of the integrative role of the brain.”[266] However, many patients who pass WBD protocols do not exhibit D.I., and retain residual neurohormonal regulation, which is readily assessable at the bedside and even according to Bernat’s most stringent definition of critical does not indicate mere activity but organized functioning.[267] Halevy and Brody observe, “neurohormonal regulation is a component of the integrative role of the brain in regulating the rest of the body—the very role that is emphasized in the whole-brain definition of death.

Bernat initially contended that persistent hypothalamic function in the WBD patient, which prevented D.I., was acceptable because hypothalamic

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[266] Halevy, "Beyond Brain Death?" 496.

[267] Amir Halevy and Baruch Brody, "Brain Death: Reconciling Definitions, Criteria, and Tests," *Annals of Internal Medicine* 119.6 (1993): 521.

function is not a critical function of the organism as a whole. However, Bernat recently amended his position regarding persistent hypothalamic function and admits to being skeptical of WBD patients that do not progress to D.I. or who have normal arginine vasopressin. He suspects such patients may not have sustained a complete absence of intracranial blood flow and concludes that cerebral blood flow studies should be mandatory in WBD protocols.[268]

Bernat does maintain, however, that the continued somatic activity that is maintained by artifice has no significance and is comparable to that of a kidney that lives outside of the body or of cells in a Petri dish.[269] Yet Wikler takes him to task by employing Bernat’s own argument of organism as a whole against him. For the WBD patient is an intact body where the parts clearly interact with one another, “the heart pumps blood, which carries oxygen to cells where metabolic processes continue and wastes are carried off and excreted”; therefore it is not a collection of disjointed parts in vivo.[270]

Bernat also takes liberty by modifying the definition of death to mean the cessation of the *critical* functions of the organism as a whole, with regard to how much of the brain must die in WBD.[271] While we stated in the beginning of this chapter that death is definitional, it would seem that modifying the definition, though possible, would require societal consensus rather than a decree through

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[268] James L. Bernat, personal communication, February 2005.

[269] Bernat, "The Biophilosophical Basis of Whole-Brain Death" *336*.

[270] Wikler, "Brain Death: A Durable Consensus?" *241*.

[271] Bernat, "A Defense of the Whole-Brain Concept of Death" 17.

a private citizen.[272] Further, Bernat claims that the UDDA's definition of death as the irreversible cessation of all functions of the entire brain was actually intended to have the qualifier "clinical" functions of the entire brain. The difference is that clinical functions are observable by bedside physical exam whereas "physiologic activities" require confirmation through laboratory tests.[273] Some scholars suggest that Bernat's conception of criticality is somewhat arbitrary but many are willing to grant him these indulgences since the functions that continue in a WBD patient usually meet his definition of criticality and are observable on clinical exam.

Bernat justifies his claim that only clinical functions are significant by referencing the President's Commission, which made a distinction between "systemic integrated functioning" and mere "physiologic activity."[274] Complex tests are not necessary to demonstrate the irreversible absence of the clinical and critical functions of the brain as they can be proven by bedside exam and include the following: apnea, profound coma, unresponsiveness, and absent brain stem reflexes. Clinical exams are performed at the bedside and focus specifically on brain stem function rather than on all brain function, but Bernat argues this is adequate since reversible drug and metabolic disturbance are

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[272] Robert M. Veatch, "The Impending Collapse of the Whole-Brain Definition of Death," *Hastings Center Report* 23(1993): 19.

[273] Bernat, "The Biophilosophical Basis of Whole-Brain Death" 337.

[274] Bernat, "A Defense of the Whole-Brain Concept of Death" 18.

already ruled out and a structural or organic etiology must be demonstrated before a diagnosis of WBD can be made.[275]

Differential diagnosis is mandatory to prove that some other less severe state is not mimicking WBD, since GBS and viral encephalitis are but two illness that can effectively feign WBD.[276] Yet if a patient with hypothermia, barbiturate overdose, or a severe case of GBS can meet the clinical WBD criteria we must ask why they are not declared dead when they pass the protocol. The obvious answer is because these are reversible conditions. But as R. Hayden argues, irreversibility is not an appropriate criterion for death since it is based on the current state of the art.[277] Thus, what will happen if/when brain failure can be reversed? The problem with irreversibility is not one we can address here but will become a focal point in the discussion on DCD. Suffice that such patients are being maintained without brain function, thus again calling into question whether a brain is required for biological integration.

Most diseases or neurologic events that are sufficient to cause the permanent cessation of cranial nerve and brain function usually result from massive head trauma, intracranial hemorrhage, hypoxic ischemic damage from prolonged cardiac arrest or some other defined condition.[278] In the absence of a catastrophic brain insult, a diagnosis of WBD should be held in abeyance, as the

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[275] Bernat, "A Defense of the Whole-Brain Concept of Death" 21.

[276] Richard Hughs and Glenn McGuire, "Neurologic Disease and the Determination of Brain Death: The Importance of a Diagnosis," *Critical Care Medicine* 25.11 (1997): 1923.

[277] Hayden, "A philosophical Critique of the Brain Death Movement" 243.

[278] Bernat, "A Defense of the Whole-Brain Concept of Death" 21.

brain obviously must be injured in some way before it can be declared dead.[279] Once such a devastating neurologic insult occurs, the ensuing process generally follows the same pattern: brain swelling and simultaneous intracranial pressure where the brain ultimately strangulates within the cranium. Subsequently, the brainstem herniates, becomes infarcted and blood supply to the brain is rendered impossible.

The brain, unlike some other organs, is delicate and cannot survive an interruption in blood flow for more than a few minutes without suffering varying degrees of irreversible damage; if blood supply is completely obstructed the brain has no chance to survive and will begin to self-digest or autolyze within days.[280] Bernat concludes that herniation and infarction are easily tested on bedside exam and provide conclusive evidence that there is extensive damage throughout the brain resulting in the irreversible cessation of the clinical functions of the brain.[281]

Despite the above, Bernat concludes that WBD is an “approximation.” In this regard, he argues it is not inconsistent that “nests” of neurons may survive and even show quantifiable output.[282] Any continued functioning that remains, he argues, does not contribute significantly to the organism as a whole and

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[279] Michael Williams and Jose Suarez, "Brain Death Determination in Adults: More Than Meets the Eye," *Critical Care Medicine* 25.11 (1997): 1787.

[280] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death*, 17.

[281] Bernat, "A Defense of the Whole-Brain Concept of Death" 21.

[282] Bernat, "How Much of the Brain Must Die in Brain Death?" 25.

therefore cannot be considered critical, in which case the criterion of neurologic death can be satisfied.[283]

Michael Potts argues that some WBD patients continue to show Electroencephalogram (EEG) activity, but as we saw earlier, Bernat and other WBD proponents do not find this at odds with the definition of WBD, since the residual function is not regarded as critical nor is it clinically apparent.[284] Halevy and Brody reference data where 56 patients passed WBD protocol in which 11 patients had non-isoelectric EEGs and 2 patients had EEG activity that resembled sleep patterns.[285] The post mortem exams revealed brain-stem destruction with little higher brain damage.[286] Such EEG activity meets the threshold for what the President's Commission considers functioning since the cellular activity is "organized and directed" thus showing another inconsistency in concept and clinical tests.[287] This is not simply an error in diagnosis since an EEG is not required for a declaration of WBD. This raises the specter of how many patients who are not given an EEG can actually support organized and directed activity.

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[283] Bernat, "How Much of the Brain Must Die in Brain Death?" 25.

[284] Michael Potts, "A Requiem for Whole Brain Death" 482.

[285] Halevy, Brody, "Brain Death: Reconciling Definitions, Criteria, and Tests," 521; M.M. Grigg, et al. "Electroencephalographic Activity After Brain Death." *Arch Neurol.* 44.9 (1987): 948-54.

[286] Halevy, Brody, "Brain Death: Reconciling Definitions, Criteria, and Tests" 521.

[287] Halevy, Brody, "Brain Death: Reconciling Definitions, Criteria, and Tests" 521

Siegler and Wikler note, “If the Whole-Brain Dead patient is a corpse, it has some unusual properties”; in which they refer to a body that breathes, circulates blood, digests food, filters wastes, and maintains temperature, which becomes difficult to reconcile as dead.[288] WBD critics refer to an exhaustive account of integrative functions that are not controlled by the brain but are present in some WBD patients, therefore delivering a critical blow to the assertion that the brain controls the entire organism and death of the brain is the death of the organism as a whole. We are obligated to consider why these non-brain mediated functions, which are clearly integrative, are discounted in the diagnostic and conceptual underpinnings of WBD. They include the following:

> Homeostasis of a variety of chemicals through the liver, kidneys, and cardiovascular and endocrine systems. Elimination, detoxification, and recycling cellular wastes. Energy balance through the interaction among liver, endocrine systems, muscle, and fat. Maintenance of body temperature (at lower than normal with the help of blankets). Wound healing, fighting infections, febrile response to infection, cardiovascular and hormonal stress responses to unanesthetized incision for organ retrieval, and gestation of a fetus.[289]

[288]Michael Potts, "A Requiem for Whole Brain Death” 485.

Working from what has been discussed above, Shewmon and others assert that somatic integrative unity is not derivative in that it clearly does not rely on one specific locus, such as the brain. Rather, the body itself has a unity that is already presupposed which the brain contributes to and enhances but does not control. In sum, the brain modulates a preexisting integrative unity but the brain is not a prerequisite for biological life; Shewmon reminds us that integration does not necessarily require an integrator per se as shown by plants and embryos.[290]

Perhaps the most convincing evidence that a WBD patient is not dead arises when such a patient successfully gestates a fetus to term. A 2003 article published in Critical Care Medicine reviewed 10 such cases of women who passed WBD protocols who were supported in ICUs in order to bring their fetuses to term.[291] The longest amount of time a WBD patient spent on life sustaining treatment was a woman who was fifteen weeks pregnant at the time of admission and required support for 107 days. Surprisingly, the authors note, “The clinical problems found in those women were similar to other long-term patients in ICU.”[292] Clearly this comparison to other ICU patients implies that these women were not corpses according to the traditional biological definition of death or the WBD criterion that ostensibly fulfills it.

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[289] Shewmon, "The Brain and Somatic Integration" 467.

[290] Shewmon, "The Brain and Somatic Integration" 473.

[291] David Powner and Ira Bernstein, "Extended Somatic Support for Pregnant Women After Brain Death," *Critical Care Medicine* 31.4 (2003) <http://gateway.ut.ovid.com.authenticate.library.duq.edu/gw1/ovidweb.cgi

[292] Powner and Bernstein, "Extended Somatic Support for Pregnant Women After Brain Death" <http://gateway.ut.ovid.com.authenticate.library.duq.edu/gw1/ovidweb.cgi

When the Harvard Committee first introduced irreversible coma as a criterion for death, which incidentally begs the question of how one who is in a coma could be considered dead since coma refers specifically to a condition of the living, they based it on a claim that rapid asystole inevitably occurred in such patients.[293] It is clear from what we have discussed thus far that WBD patients can continue on life sustaining treatment for much longer than originally postulated, but the fact remains that such a claim was merely prognostic in nature and not a legitimate way to determine that death had already occurred.[294] Shewmon and others admit that total brain destruction is predictive of death but refer to ample empirical evidence to prove that the organism as a whole, though disabled, is not yet dead.[295]

The biological argument that a dead brain indicates a dead organism is not necessarily true. A patient who respires and circulates blood, who can regain hemodynamic stability, metabolize and excrete waste, exhibit some brain function including measurable EEG output and an intact neurohormonal pathway, raise her temperature with the help of blankets, gestate a fetus, and react to surgical incision does not fulfill the definition of death on biological grounds.

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[293] Potts, "A Requiem for Whole Brain Death" 481; Richard G. Nilges, "Organ Transplantation, Brain Death and the Slippery Slope: A Neurosurgeon's Perspective," *Beyond Brain Death* eds. M. Potts, Paul A. Byrne and Richard G. Nilges (The Netherlands: Kluwer Academic Publishing, 2000) 253.

[294] Byrne et al "Brain Death-The Patient, the Physician, and Society" 28.

[295] Byrne et al "Brain Death-The Patient, the Physician, and Society" 33.

Further, as we have seen, the tests used to diagnose WBD are insufficient to prove all brain functions have ceased.

V. Debate and Reevaluation of the definition of death

Aristotle cautioned us to not require greater precision than the subject matter affords, and while we could devote an entire thesis to the epistemological problems inherent in WBD, necessity dictates a compromise must be reached between the unknowable and the practical in matters of life and death. However, the fundamental problem is that WBD has been imposed upon society by appealing to an unsound biological argument. As we have seen throughout this chapter WBD attempts to fulfill the definition of death as the permanent cessation of the integrated functioning of the organism as a whole despite overwhelming evidence to the contrary. At the conclusion of this chapter it should be clear that WBD patients are not yet dead on the biological merits of this definition.

Shewmon argues persuasively and presents enough clinical evidence that other scholars have no choice but to admit that the traditional biological basis of the brain as the primary integrator of the organism as a whole is insufficient. This should not be minimized since the reason we hold WBD as death is precisely because we have been told the brain integrates the organism as a whole, without which the body cannot survive. Bernat admits, “Alan Shewmon has written convincingly that the integration argument alone is inadequate. After numerous conversations with him over the years I have come to conclude that he is probably correct. I have struggled to discern what else is important in addition to the integrator theory."[296]

We might ask why the WBD concept continues to be endorsed given that the criterion fails the definition of death and the diagnostic tests do not guarantee a dead brain. It appears the reason is utilitarian, a view many hold and is well summarized by Truog:

> Given all of these problems with the concept of brain death, what are possible solutions? The current approach is simply to ignore all of these problems and inconsistencies. Surprisingly, perhaps, this approach has much to recommend to it. Our primary strategy for organ procurement and transplantation relies heavily upon the diagnosis of death by neurologic criteria. Any serious disruption in the transplantation enterprise could jeopardize opportunities to save the lives of those in need of vital organs. As epitomized in the name of the old game show "Truth or Consequences," sometimes it is better to sacrifice devotion to the truth in order to optimize important consequences.[297]

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[296] James L. Bernat, personal communication, February 2005.

[297] Truog, "Brain Death: At Once "Well Settled" and "Persistently Unresolved" *AMA Policy Forum* 6(2004): http://www.ama-assn.org/ama/pub/category/12715.html

Notwithstanding Troug's perspective, given the theoretical and practical problems associated with WBD, it is ethically irresponsible to maintain the status quo and grossly negligent to do so in order that transplantation may continue. As Wikler notes,

> Even though these beneficial effects arguably include the savings of thousands of lives, however, they do not in themselves constitute an argument in support of the thesis that a patient is dead whose brain as a whole has suffered irreversible cessation of functioning. They merely show that good things happen if we choose to operate with that definition of death. Unless one is an extreme pragmatist, the utility of such a belief does not demonstrate, let alone constitute, its validity or truth.[298]

WBD patients are not dead under the current definition of death and ought not to be used as organ sources unless the public agrees to abandon the dead donor rule or revise the definition of death. This final suggestion may prove to be the best response to this problem.

I will suggest the definition of death be amended from a purely biological model to an ontological definition that focuses on that which is essential to the human person, the loss of which constitutes death. In this regard, the justification for death will not be argued on purely organic terms, since as we

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[298] Wikler, "Brain Death" 240.

have seen, the body can continue to integrate despite a dead brain, and also because a strictly biologically oriented approach fails to capture that which distinguishes humans from other animals. An ontological definition will rest on the agreement that the human brain possesses unique functions and capacities, which are significant to the nature of the human person to the extent that when the individual has irreversibly lost such capacities he or she is dead.

In the following chapter I will argue that there is a difference between biological life and human life. The cessation of the latter occurs when one has irreversibly lost the capacity for consciousness or personhood despite the persistence of the former. I do not claim to be able to determine precisely the necessary conditions for personhood and/or consciousness; rather my intention is to demonstrate that the concept undergirding higher brain death (HBD) is a philosophically coherent alternative to WBD.

While I will endorse an ontological definition I will not advocate a HBD criterion due to the inability to clinically quantify the loss of such human properties, capacities, and functions. Therefore, revising the definition of death will not require discarding the WBD criterion, which as a purely practical matter, continues to work for society despite its shortcomings, though it may be supplanted by other criteria as medicine improves. As Youngner and Bartlett note, the various criteria used to fulfill the definition of death are determined by the current medical and technical armamentarium but the definition itself, at the philosophical level, will remain constant.[299]

It is true that organ transplantation can continue without a redefinition of death by either maintaining the status quo, by embracing an overt utilitarian perspective that such patients are “dead enough,” or by abandoning the dead donor rule in which some people will be considered candidates for donation if they are “beyond harm.” These are not ideal choices, however. The status quo requires that we accept that a dead brain ensures that the organism as a whole is dead, yet as we have presented throughout this chapter, there are compelling philosophical arguments and clinical data that suggest otherwise. Recently, at a closed meeting on DCD, the participants, composed of physicians, nurses, lawyers, and transplant coordinators, were strongly opposed to abandoning the dead donor rule.[300] The consensus was that it would actually be to the detriment of transplantation as it may fuel public distrust hinging on questions social justice such that individuals may fear they may not receive adequate medical care if another life is at stake.

It is perhaps painfully naive or impossibly arrogant to assume that we can implement a new definition of death and solve all of these issues. It should be clear at this point that this is a complicated issue and the best we can hope for is an answer with fewer problems than the current alternative. This chapter has reviewed the major conceptual issues surrounding WBD, both medical and philosophical, in which I have argued that a dead brain does not necessarily

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[299] Stuart J. Youngner and Edward T. Bartlett, "Human Death and High Technology: The Failure of the Whole-Brain Formulations," *Annals of Internal Medicine* 99 (1983): 252-58.

[300] James L. Bernat et al, "Report of a National Conference on Donation After Cardiac Death," *American Journal of Transplantation* 6 (2006): 281-91.

equal a dead human being on the merits of the traditional biological argument. The obvious tension we have exposed is that the biological model itself is insufficient for a definition of human death since a person cannot be dead until the brain is dead, but this requires more than a purely physiologic argument, one we shall discuss in the following chapter.

Donation After Cardiac Death relies on a different criterion of death than the WBD criterion but both criteria are said to rest on the same biological definition of death. I will argue that the neurologic criterion and the cardiac criterion do not inform the same definition of death, either biological or ontological, and thus DCD removes organs from the dying rather than dead regardless of which definition one espouses.

Chapter 4
Evaluating Higher Brain Death

I do not want to be confused with my gagging…I even take it as kind of an insult that I could be confused with any of these trivial bodily capacities.[301]

Having examined the traditional definition of death and the conceptual and clinical problems inherent with the whole brain death (WBD) criterion, we have an additional issue to resolve before we can argue against the legitimacy of Donation After Cardiac Death. This chapter will offer an alternative definition of death and evaluate a higher brain death (HBD) criterion. I will proceed by examining the various approaches used to evaluate any definition of death. I will ultimately choose an ontological one, which does not focus solely on the loss of organismic functioning, but considers that which is essential to the nature of the human person, the loss of which signifies human death. After identifying this specific approach to frame our discussion, I will then explore the conceptual basis for the neurologically oriented concept of death as opposed to the traditional cardio-respiratory concept. Following this, I will specify the formal concept of death, explore the philosophical underpinnings of HBD, and evaluate whether it can be used as a criterion to fit our new definition.

After exploring its conceptual roots, I will review the current criticisms of the HBD criterion and argue that it cannot yet be accurately quantified clinically

[301] Robert M. Veatch, "Whole Brain, Neocortical, and Higher Brain Related Concepts," *Death: Beyond Whole Brain Criteria*, ed. Richard M. Zaner (Boston: Kluwer Academic Publishers, 1988): 181

and therefore is relevant in metaphorical rather than public-policy-making terms for the determination of death. I will conclude this chapter by arguing that, although irreversible loss of consciousness is a more philosophically sound approach to determining death than the biological argument focusing on integrated functioning, diagnostic weaknesses preclude moving to a HBD criterion.

Consequently, I will recommend that the WBD criterion be maintained in order to fulfill our new definition of death until tests for HBD gain greater specificity, since all those who meet WBD will necessarily meet HBD. In so doing we recognize the need not only for a defensible concept of death, since the current use of WBD rests on the faulty premises that a functioning brain is required for integrative life and that any functions that are not regulated by the brain are necessarily unintegrated, but also the need for clinical confidence. I concluded the last chapter by claiming that WBD patients are not dead according to the traditional definition of death. I will conclude this chapter with the assertion that WBD patients are dead if we adopt a new definition of death.

In the modern era death is often no longer a singular event where all vital functions fail at once. Rather, technology has caused death to be fragmented, the result of which can be the preservation of biological functioning absent a human subject to experience it. While it is accurate to say that death is a process, we attempt to quantify it as a specific event purely for pragmatic purposes: mourning, burial practices, transfer of legal rights and responsibilities, organ and tissue procurement, etc.[302] However, in our attempts to cleave to an outdated binary model for what is now a nonlinear phenomenon we have encountered insurmountable problems. Our definition and criteria of death are no longer consistent; thus the reevaluation of when death is and how we determine it has occurred is mandated.

I do not claim to be able to solve unequivocally the question of when death has occurred or how it ought to be declared, but there is a pressing need for a more formidable alternative to the current definition and criteria that are in place given the conceptual and operational ambiguities. In embarking on this task to define death I am reminded that, “It is only the ideologue or the fool who acknowledges noon and midnight, but denies all the states of light and darkness that smoothly shade together in the real world, to create day and night.”[303]

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[302] Karen Grandstrand Gervais, *Redefining Death* (New Haven: Yale University Press, 1986) 4.; David Hendin, *Death as a Fact of Life* (New York: W.W. Norton & Company Inc, 1973) 28.

[303] Leslie Whetstine et al. "Pro/Con Ethics Debate: When is Dead Really Dead?" *Crit Care* 9.6 (2005): 541.

I. Revisiting the problem

As we have seen, the traditional definition of death is *the irreversible cessation of the integrated functioning of the organism as a whole*. This definition focuses solely on organic or biological functioning. The criteria used to fulfill this definition, discussed in the two previous chapters, are the cardio respiratory (CR) criterion and the WBD criterion as endorsed by the Uniform Determination of Death Act (UDDA). Heretofore we are concerned with the neurologic criterion, as the CR criterion will be carefully examined in the following chapter on Donation After Cardiac Death (DCD).

We encountered two primary problems with WBD as a criterion to fulfill the traditional concept of death in the previous chapter. First, we saw that a body that passes a WBD protocol often may continue to integrate at the level of the organism as a whole, such that though the criterion of death has been fulfilled (a dead brain), the definition of death has not (cessation of integrated functioning).[304] Second, we saw that patients who are diagnosed as WBD may not have lost *all* functions of the entire brain.[305] This forced the rather counter intuitive question of how much of the brain must be dead in “whole” brain death.

By way of a brief recapitulation, recall the integrated functions that occur in the organism as a whole that do not cease in the presence of a non functional brain including homeostasis, energy balance, wound healing, infection fighting,

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[304] Tom Tomlinson, "The Conservative Use of the Brain-Death Criterion-A Critique," *Journal of Medicine and Philosophy* 9(1984): 380.

[305] Robert D Truog, James C. Fackler, "Rethinking Brain Death," *Critical Care Medicine* 20.12 (1992): 1706.

gestation of a fetus, and circulation and respiration.[306] Consider also the following brain functions that may persist after a declaration of WBD including the presence of hypothalamic function sufficient to prevent the development of diabetes insipidus; the regulation of free-water homeostasis through arginine vasopressin, and continued EEG activity.[307]

It is clear that sometimes the *whole* brain is not dead after a declaration of WBD. WBD advocates concede this by arguing that some brain functions, those that contribute to the integration of the organism of the whole, are more important than others.[308] The functions they include and exclude are arguable, however, as pupillary responses, which must be absent for WBD, do not reflect integration whereas an intact neurohormonal pathway does reflect integration but may persist despite a declaration of WBD. Thus, purely from a linguistics perspective *whole* brain death is not necessarily an accurate term. We will have to arrive at some agreement on what parts and how much of the brain should be dead in order to be certain that a brain-based criterion has been met, but we must

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[306] Amir Halevy, "Beyond Brain Death?" *Journal of Medicine and Philosophy* 26.5 (2001): 495.

[307] Amir Halevy, Baruch Brody, "Brain Death: Reconciling Definitions, Criteria, and Tests," *Annals of Internal Medicine* 119.6 (1993): 521. An additional questionable aspect of WBD that was not scrutinized in detail was the ad hoc division of the spinal cord from the rest of the central nervous system. The exclusion of the spinal cord will be a particular point of contention for HBD supporters as we shall see, but for our present purposes it is noteworthy simply because continued spinal reflexes are not consonant with the cessation of *all* functions of the entire brain.

[308] See James L. Bernat, "How Much of the Brain Must Die in Brain Death?" *Journal of Clinical Ethics* 3.1 (1992): 21-26.

prescind from this issue for the moment as our first task is to decide on an appropriate foundation upon which to base our new definition of death.

II. Approaches to define death

In devising a coherent definition of death we must distinguish between three conceptual approaches: (1) biological arguments, (2) moral arguments, and (3) ontological/metaphysical arguments. The biological arguments are well represented by the traditional concept of death, which focuses on integrated biological functioning. Such a position makes no distinction between the death of Fido the canine or the death of Mother Theresa; death occurs for both when organismic functioning fails. The moral arguments focus on value and quality of life (QOL), such that death is determined when a person lacks the requisite features that make life more valuable than death. Ontological arguments establish what is significant to the nature of the human person; they are concerned with those characteristics that are necessary conditions for the existence of a human being.

We must evaluate these approaches in turn in order to determine which will best serve us in discovering what is the quantum change that differentiates life from death. We will see how the President's Commission identifies the human being solely on the basis of its being a biological organism without reference to its unique capacities. The biological argument focuses on several functions it considers necessary for life: the ability to breathe spontaneously, demonstration of cephalic reflexes, regulation of body temperature, metabolism, and blood pressure control.[309] Notwithstanding that many of these functions persist after a declaration of WBD, these represent the autonomic functions of the central nervous system and do not speak to any “human functions” such as consciousness, personhood, or self-reflection.[310]

By ignoring capacities specific to the human being, the President’s Commission commits itself to a purely biological perspective of life and death. This leads some to conclude that this approach is specious since it actually characterizes the death of the wrong type of organism, one that is not a human being.[311] To see clearly how the Commission focuses on biological functioning we need to consider their position on decapitation.

The Commission argues that if exsanguination were prevented in a decapitated body and a ventilator were attached to maintain respiration and circulation, such a body would not be alive despite such continued functions.[312] Roland Puccetti argues that the Commission must then regard a body that has been only partially decapitated, one with an intact brain stem that supports spontaneous custodial functions, as alive. He exposes the difficulty with the Commission’s position when he points out that if we excise the brain stem and

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[309] Roland Puccetti, "Does Anyone Survive Neocortical Death?" Death: *Beyond Whole Brain Criteria*, ed. Richard M. Zaner (Boston: Kluwer Academic Publishers, 1988): 84.

[310] Puccetti, "Does Anyone Survive Neocortical Death?" 84.

[311] Edward T. Bartlett, Stuart J. Youngner, "Human Death and the Destruction of the Neocortex" Death: Beyond Whole Brain Criteria, ed. Richard M. Zaner (Boston: Kluwer Academic Publishers, 1988): 207.

[312] President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death: A Report on the Medical, Legal, and Ethical Issues in the Determination of Death* (Government Printing Office, 1981)36.

substitute a ventilator the body is immediately considered dead though there is no discernable difference aside from assisted versus spontaneous function.[313]

We have discussed at length in the previous chapter the problems associated with determining life from death based solely on whether or not integrated functions continue spontaneously or with assistance. If integrated functioning can continue via mechanical assistance then the source ought not to matter. Moreover, as we have seen in the previous chapter, brain stem function is not a sine qua non for life as patients with high spinal cord injury rely on mechanical assistance to maintain biological integration yet are certainly not considered dead.[314]

Puccetti's example shows how the biological argument, which relies on integration to differentiate life from death, is inconsistent, since integration can continue in each of the decapitated bodies. It makes little sense to claim a body is alive on the basis of spontaneous brainstem function when a patient who lacks spontaneous brainstem function, such as someone with GBS, is not regarded as dead. What is truly at stake is consciousness, though if the traditional biological argument is to remain true to its position (that death is the loss of integrating function) then consciousness is irrelevant since it is not an integrating function of

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[313] Puccetti, "Does Anyone Survive Neocortical Death?" 84.

[314]Recall also severe cases of Gullain-Barre Syndrome (GBS) in which mechanical assistance maintains somatic integration until the patient can recover. Such patients can meet the clinical criteria for WBD, yet since they retain the capacity for consciousness they are not declared dead. Consciousness, as we have seen in the previous chapter however, does not play a role in biological integration, and as such GBS patients ought to be regarded as dead if the biological perspective is applied consistently.

the organism as a whole. Puccetti's argument shows that either integration or consciousness is of primary importance in determining life from death, but since they rely on entirely different justifications it cannot be both, as one rests on a biological argument and the other on an ontological one. Puccetti shows that a choice is mandated when he concludes, "Either human life is rooted in brain stem function or in the capacity for human experience."[315] We will argue for the latter in this chapter.

H. Tristram Engelhardt, Jr., offers an example to illustrate how the biological argument falls short of a meaningful conception of human life. He offers the following thought experiment: imagine a neurologist informs you that you are suffering from an untreatable, terminally degenerative brain disease. The doctor reassures you that the prognosis is not as grim as you might think, however, since modern technology will be able to keep your body functioning for a near normal life expectancy despite the fact that the entire brain will ultimately be destroyed. This condition is known as whole brain death. Not wanting to "live" in such a state, you seek a second opinion only to be told that the entire brain will not be destroyed. Instead, the brain stem will be functional and you will not only have a full life expectancy, but you will be able to ventilate independently. This condition is known as higher brain death. Engelhardt concludes that brainstem integration is not a sufficient condition for existence, but rather there is a difference between human and biological life. The former refers

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[315] Puccetti, "Does Anyone Survive Neocortical Death?" 84.

to at least some level of self-awareness or sentience while the latter refers to organic functions.[316]

Robert Veatch faults the biological perspective for primarily focusing on non-essential functions, which fail to recognize that human death has normative import.

> To view man as essentially a respiratory creature is to ignore most of the faculties which philosophers and anthropologists have considered essential to the species…It ignores man's rational capacity, his ability to experience emotion…It ignores his capacity for consciousness and memory which in turn gives rise to purposes, actions, and the eventual building of language and culture.[317]

It seems apparent that the biological approach has serious deficiencies and will not serve as a valid approach to determine death. Thus we must now evaluate a moral perspective. Jonathan Glover favors the moral approach to evaluating a proper definition of death by claiming that we must decide what type of existence has value.[318] Josie Fisher focuses the moral argument not solely on

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[316] H. Tristram Engelhardt, Jr., "Reexamining the Definition of Death and Becoming Clearer about what it is to be Alive" *Death: Beyond Whole-Brain Criteria*, ed. Richard M. Zaner (Boston: Kluwer Academic Publishing, 1988): 94.

[317] Robert M. Veatch, "The Whole-Brain-Oriented Concept of Death: An Outmoded Philosophical Formulation," *Journal of Thanatology* 3(1975): 25.

QOL but on the moral value of technology. She compares and contrasts two high-profile patients, Karen Ann Quinlan, who was in a persistent vegetative state (PVS) but ultimately was found to ventilate spontaneously, and Trisha Marshall who was WBD but maintained on life sustaining treatment (LST) for one hundred five days to deliver her child by Cesarean section.[319] The only difference between the two women was that Marshall continued to integrate as an organism as a whole with LST while Quinlan did so spontaneously. Fisher concludes that unless there is a morally relevant difference between spontaneous and assisted integrated functioning, the moral status of the two women was univocal.[320]

John C. Hoffman uses the moral approach to answer "what minimal quality of life in a human body preserves sufficient intrinsic value to obligate us to regard it as a living person?"[321] He concludes that the value of life is contingent on QOL such that we may not be obligated to regard all human life as inherently valuable if it falls below a specified threshold. In contradistinction, Hans Jonas, who also uses the moral approach, argues that human life simply by virtue of it being human life has intrinsic value that is unaffected by any change in QOL.[322] Jonas agrees with Fisher that technology has no bearing on distinguishing life

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[318] Michael B. Green, Daniel Wikler, "Brain Death and Personal Identity," *Philosophy and Public Affairs* 9.2(1980): 116.

[319] Josie Fisher, "Reexamining Death: Against a Higher Brain Criterion," *Journal of Medical Ethics* 25(1999): 474.

[320] Fisher, "Reexamining Death" 474.

[321] John C. Hoffman, "Clarifying the Debate on Death," *Soundings* 62(1979): 445.

[322] Hans Jonas, "Against the Stream: Comments on the Definition and Redefinition of Death," *Philosophical Essays from Ancient Creed to Technological Man* (Chicago: University of Chicago Press, 1974) 135.

from death, but disagrees with her that the WBD patient is dead. Jonas focuses on QOL as it pertains to the individual, such that when life is of no value for that individual it need not be prolonged, but a QOL argument does not justify a declaration of death.

Jonas shows that the moral approach is, though for different reasons, equally problematic as the biological argument, since QOL alone cannot distinguish life from death. As Green and Wikler note, some conditions, senility for example, may cause QOL to plummet long before a diagnosis of death. While one may prefer to be declared dead rather than to exist in a state that may be valueless for one, this does not make a person dead.[323]

Green and Wikler pose the question for moralists thusly, “The question to be answered is whether the moral proposition that maintenance of the brain dead preserves nothing of value and may be ceased when convenient, shows the brain dead are dead.”[324] They conclude that the QOL of the brain dead patient merely shows that the patient need not be supported, not that he is dead. The perils of determining death based solely on QOL assessments may well lead us to revisit reprehensible acts justified in Nazi Germany and in works such as *Permission to Destroy Life Unworthy of Living*.[325]

Taken on their own, the biological and moral approaches are insufficient to analyze a concept of human death. However, death does have biological and

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[323] Green, Wikler, "Brain Death and Personal Identity" 116.

[324] Gervais, *Redefining Death* 78.

[325] D. Alan Shewmon, "Recovery from "Brain Death:" A Neurologist's Apologia," *Linacre Quarterly* 64(1997): 45.

moral components; thus it may serve our purposes to utilize a tripartite approach that considers biological and moral elements while embarking on what is primarily an ontological pursuit. Thus I will attempt to define the death of the human being rather than a generic, biological definition of death that applies to all species, since humans are ontologically different from other animals. The death of a dog is categorically different than the death of a human. Fido cannot participate in morality; he cannot, most people would agree, ponder his inner Fidoness.[326] We cannot take up an excursus on the moral status of animals here; it must be enough to note that many philosophers would argue that when a human has lost the fundamental attributes that confer humanness, she becomes only a Fido-like entity; an organic, living thing but no longer a human being.[327]

Aristotle distinguished between accidental and essential properties. An accidental property is something a thing can lose without ceasing to exist as that particular kind of thing, hair color for instance. By contrast, an essential property is something that a thing cannot lose without ceasing to exist as that kind of a thing. Answering what this essential thing is that makes a human being a human being is an ontological question, which lies at the heart of any definition of death.

At this juncture we have established that the biological and moral arguments taken independently cannot provide a conceptual basis for human

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[326] Englehardt, "Reexamining the Definition of Death and Becoming Clearer about what it is to be Alive" 93.

[327] James LeRoy Smith, "What it Means to be Dead," *Hastings Center Report* 12.6(1982): 45; John P Lizza, "The Conceptual Basis for Brain Death Revisited: Loss of Organic Integration or Loss of Consciousness?" *Brain Death and Disorders of Consciousness* 550(2004): 52.

death. Our task now is to explore the basis of any neurologic concept of death, that is, to examine whether WBD and HBD rest on the same foundation or if HBD rests on a different concept entirely. If death declared by any neurologic criterion is conceptually distinct from death declared on the traditional CR criterion, then WBD and HBD differ in degree rather than kind, since both depart from the traditional definition of death.

III. Competing concepts of death

Despite the fact that the Harvard Ad Hoc Committee for the Redefinition of Death did not defend a conceptual justification for declaring the irreversibly comatose dead, it is instructive to review the language used and their motivation for endorsing a neurologic criterion of death. The Committee discussed the "burden" of those who fulfill the neurologic criterion and described them as "patients who suffer permanent loss of intellect." The Committee recognized that modern technology could "…restore 'life' as judged by the ancient standards of persistent respiration and continued heart beat" but such patients should nevertheless be declared dead because "…there is not the remotest possibility of an individual recovering consciousness following massive brain damage."[328]

In an unpublished paper delivered at the American Association for the Advancement of Science Meeting in 1970, Henry Beecher, chairman of the Harvard Ad Hoc Committee, defended his position that spinal reflexes could be excluded from the brain-based criterion because he did not consider its functions essential. He described essential functions as "the individual's personality, his

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[328] Bartlett, Youngner, "Human Death and the Destruction of the Neocortex" 201.

conscious life, his uniqueness, his capacity for remembering, judging, reasoning, acting, enjoying, worrying, and so on."[329] Clearly the language the President's Commission subsequently adopted for WBD, such as "the functioning of the organism as a whole" or "the body's ability to organize and regulate itself," is a clear departure from the original arguments for WBD, which not only acknowledged but seemed to favor higher brain functions.[330]

The President's Commission resisted moving to a new concept of death, favoring instead a conservative approach that did not disturb societal consensus.[331] However, we need to examine this claim more closely since first, as Veatch notes, simply because a concept is new is no basis for rejecting it; second, WBD actually is a conceptual change from the traditional cardio respiratory approach; and third, the Harvard Committee itself acknowledged that such a conceptual change was involved in the shift from a cardiac to a neurologic determination of death.[332]

The traditional use of the cardio-respiratory criterion focused on the importance of the heart and lungs to the extent that their failure served as

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[329] Bartlett, Youngner, "Human Death and the Destruction of the Neocortex" 201.

[330] Bartlett, Youngner, "Human Death and the Destruction of the Neocortex" 204.

[331] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death* 41.

[332] Robert M. Veatch, "Whole Brain, Neocortical, and Higher Brain Related Concepts" *Death: Beyond Whole Brain Criteria*, ed. Richard M. Zaner (Boston: Kluwer Academic Publishers, 1988): 178. Per the Harvard Committee, "If this position is adopted by the medical community, it can form the basis for change in the current legal *concept* of death (emphasis added). Report of the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death, "A Definition of Irreversible Coma," *JAMA* 205.6 (1968): 339; Gervais, *Redefining Death* 24.

indicators of death. WBD strategists piggybacked their concept onto the CR concept and declared that these were synonymous approaches since absence of CR activity would inexorably lead to brain failure; therefore such functions were used as indirect tests of brain status. The argument that heart and lung function were historically used only as signs of brain activity is suspect, however.

Julius Korein claims that the WBD criterion and the CR criterion operate under the same concept since WBD follows from CR failure, although he admits that we cannot conclude the traditional criteria are brain centered.[333] The shift to a neurologic criterion allowed death to be declared in the presence of heart and lung function. Never before in the history of humanity had death been declared while the corpse was warm, had spontaneous heart beat, and continued to breathe and circulate blood.[334] Heartbeat and circulation were traditionally used as indicators of death rather than as indicia of neurological status.

Gervais claims that the WBD criterion is not heart centered nor is the traditional CR criterion brain centered but that they are in fact disjunctive.[335] Veatch concurs by arguing that a neurological concept is clearly concerned with the functions of the brain, which was a distinct move away from the traditional criteria that regarded non-neurological functions as the sine qua non for life.[336] The President's Commission asserted that continued respiration and circulation

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[333] Gervais, *Redefining Death* 36.

[334] Green, Wikler, "Brain Death and Personal Identity" 105.

[335] Gervais, *Redefining Death* 37.

[336] Gervais, *Redefining Death* 40.

is not to be taken as a sign of life in the presence of a dead brain whereas the traditional CR criteria focused precisely on respiration and circulation to distinguish life from death.

The issue of spontaneous versus assisted life comes to the fore yet again. Green and Wikler note that if we define ‘spontaneous’ to mean independent of a mechanistic source, then the capacity for respiration and heart beat is a property of the body as a whole, in which case WBD is not equivalent to the loss of capacity of spontaneous respiration and heart beat.[337] Nevertheless, they continue, loss of such *spontaneous* function cannot be the litmus test for death as evidenced by those with pacemakers or high spinal cord injury.[338] It does not matter then that WBD may reflect the loss of spontaneous functions since cessation of spontaneous function is not a necessary condition for death. The use of the WBD criterion means that in some cases it does not matter that cardio respiratory functions continue, which is a clear departure from our traditional notion of death.[339]

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[337]Green, Wikler, "Brain Death and Personal Identity" 109. Alan Shewmon elaborates on this distinction between ventilation and respiration, which was covered in the previous chapter. It is noteworthy to reiterate, however, that ventilation refers to diaphragmatic stimulation mediated by the brain stem, which leads to expansion of the lungs. It is not a necessary condition for life as evidenced by fetuses in utero and patients on cardio-pulmonary bypass. Respiration, however, refers to complex biochemical reactions that occur on the cellular level and is not mediated by the brain. Respiration is a sine qua non for life. Refer to Alan D. Shewmon, "The Brain and Somatic Integration: Insights into the Standard Biological Rationale for Equating "Brain Death" with Death," *Journal of Medicine and Philosophy* 26.5 (2001).

[338]Green, Wikler, "Brain Death and Personal Identity" 109.

[339] Karen Grandstrand Gervais, "Advancing the Definition of Death a Philosophical Essay," *Medical Humanities Review* (1989): 9.

Some would dispute, however, the claim that cardiac activity in the WBD patient is spontaneous. Robert Schwager claims that since the heart will stop functioning once mechanical ventilation is removed, heartbeat is non-spontaneous; therefore there is no change in the concept of death, which requires permanent cessation of spontaneous cardiac function.[340] His argument is curious, however, since cessation of 'spontaneous' functions is not required for any statutory or conceptual definition of death. More to the point, however, he relies on a fallacious dependency clause between the heart and the lungs, arguing that if mechanical ventilation causes the lungs to function then heartbeat is by default non-spontaneous.[341]

Schwager's primary mistake is found in his dependency relation because, as Gervais reminds us, functions are only categorized as non-spontaneous when they directly receive mechanical assistance.[342] Schwager's argument is also clinically flawed since the heart can continue to beat for a prolonged period of time even after mechanical ventilation is removed.[343] Hence, there is a significant conceptual change that comes with using a neurological criterion when the spontaneous heartbeat is viewed as irrelevant.[344]

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[340]Gervais, *Redefining Death* 26.

[341] Gervais, *Redefining Death* 30.

[342] Gervais, *Redefining Death* 31.

[343] Gervais, *Redefining Death* 30.

[344] Gervais, *Redefining Death* 30.

This leads us to consider a crucial question posed by Gervais: why is it legitimate to declare death in a permanently comatose individual when technological intervention could successfully maintain somatic integration, but illegitimate to declare death for a patient who requires such artifice because his brain stem is dysfunctional (i.e. in high spinal cord injury)? The reason is because the first patient is permanently comatose whereas the second retains consciousness. As Gervais asserts, that somatic function is assisted in the second case is irrelevant because consciousness, not integrated functioning, is of fundamental import.[345] Thus, it seems disingenuous that the President's Commission would argue against HBD on the basis that it endorses a new concept of death when WBD itself is a new concept from the traditional CR criterion and rests on the same foundation as HBD.

The President's Commission attempts to assimilate WBD with the traditional CR criterion but, as others have noted, to do so embroils them in a severe case of conceptual schizophrenia. The Commission focuses on integrated functioning as evidence of life but is silent regarding how consciousness, which is not necessary for integrated life, is related. Further, functioning is dismissed as 'unintegrated' when it is artificially maintained in certain circumstances—when the brain stem is dead—but only if consciousness (which does not contribute to somatic integration) is also permanently absent. It fails to explain how consciousness fits into this biological argument.

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[345]Gervais, *Redefining Death* 33.

The core of WBD lies in the permanent loss of consciousness as essentially significant since it is only when consciousness is permanently lost that integrated functions are ever discounted.[346] But, if the Commission were to admit this, then they would have also to concede that integrated functioning (spontaneous or assisted) is not really the sine qua non for life; consciousness is, and as such, the entire brain need not be dead in order to fulfill brain death protocol.[347] This would require a shift from a biological to an ontological approach, one we will engage in presently.

We must now specify the formal concept of death, in that we must determine that which is essential to the human being, the loss of which signifies death. We will need to identify the conditions of existence for persons since I argued earlier that human death is the death of the person rather than the death of the human organism. We must bear in mind that if there were agreement on this issue it would no longer be a fertile philosophical debate; thus our purpose is not to make a sweeping conclusion on the matter but to present a variety of arguments and align with the most compelling.

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[346] Gervais, *Redefining Death* 42.

[347] Though, as a point of fact, a whole dead brain is a misnomer. According to the National Institute of Neurological Diseases and Stroke Study, two micro-volt electron potentials are permitted on electroencephalogram for the determination of WBD. As Veatch states, "If cells in the brain are generating electron potentials, they are not literally dead." Robert M. Veatch, "Brain Death and Slippery Slopes," *the Journal of Clinical Ethics* 3.3(1992): 183.

IV. A new definition of death

The President's Commission acknowledged that the concept of death is "fundamentally a philosophical matter" though they were not committed to pursuing what they classified as abstract definitions (necessary conditions of personhood for example) for the purposes of public policy.[348] The Commission wrote,

> Personhood consists of the complex of activities (or of capacities to engage in them) such as thinking, reasoning, feeling, human intercourse which make the human different from, or superior to, animals or things. One higher brain formulation would define death as the loss of what is essential to a person. Those advocating the personhood definition often relate these characteristics to brain functioning. Without brain activity, people are incapable of these essential activities. A breathing body, the argument goes, is not in itself a person; and, without functioning brains, patients are merely breathing bodies. Hence personhood ends when the brain suffers irreversible loss of function.[349]

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[348] John P Lizza, "Persons and Death: What's Metaphysically Wrong with our Current Statutory Definition of Death?" *The Journal of Medicine and Philosophy* 18(1993): 353.

The Commission claimed it could not endorse such an argument due to the lack of consensus regarding which characteristics are essential for personhood.[350] It appears they avoided a genuine philosophical analysis that would determine the conditions of existence of persons and instead endorsed a biological definition of death simply because it was less controversial, rather than because a person-centered definition was indefensible.[351]

John Lizza argues that the lack of consensus is overstated; for while there has been longstanding philosophical debate over which particular attributes or capacities are essential to personhood, there is agreement that *some* cognitive function is essential for being regarded as a person.[352] Lizza refers to the various philosophers who have articulated the necessary conditions for personhood: Aristotle defined it as rationality, Descartes as thinking, Locke as awareness of self over time, Hume as psychological characteristics, and Sartre as self- consciousness or intentionality.[353]

Lizza endorses a substantive account of personhood, meaning that it is not simply a manifestation of certain functions but personhood refers instead to

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[349] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death 38-39.*

[350] Alexander Morgan Capron, "The Report of the President's Commission on the Uniform Determination of Death Act" *Death: Beyond Whole Brain Criteria*, ed. Richard M. Zaner (Boston: Kluwer Academic Publishers, 1988): 159.

[351]Richard M. Zaner, "Brains and Person: A Critique of Veatch's View" *Death: Beyond Whole Brain Criteria*, ed. Richard M. Zaner (Boston: Kluwer Academic Publishers, 1988): 192.

[352]Lizza, "Persons and Death: What's Metaphysically Wrong" 355.
[353] Lizza, "Persons and Death: What's Metaphysically Wrong" 355.

the unique self; it is what makes you specifically you and no other.[354] The President's Commission adopts the contrary view; it does not define personhood as an entity but in terms of certain abilities. Lizza draws from twentieth century philosophers Peter Strawson and David Wiggins, who hold that persons are not merely states of consciousness but have corporeal characteristics as well. In this way they reject the dualistic stance of the President's Commission and endorse personhood as that which is embodied; the loss of either physical or mental attributes equally portends death.[355]

Lizza admits that specifying particular traits to determine personhood may be impossible, but at a minimum some cognitive function is required, though he defines the person as having both psychological and material qualities that equally apply; the loss of either is equivalent with death.[356] Lizza defines death as the irreversible loss of the person. The criterion he uses to fulfill this definition is the irreversible cessation of higher brain function, which renders any cognitive function impossible.[357] We will thoroughly discuss the HBD criterion in the following section; presently, however, we are concerned with evaluating a person-centered definition of death as opposed to the traditional definition of death as the irreversible cessation of the integrated functioning of the organism as a whole.

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[354] John P Lizza, "Defining Death for Persons and Organisms," *Theoretical Medicine and Bioethics* 20(1999): 442.

[355] Lizza, "Defining Death for Persons and Organisms" 446.

[356] Lizza, "Defining Death for Persons and Organisms" 446.

[357] Lizza, "Persons and Death: What's Metaphysically Wrong" 363.

Lizza, as well as those who advocate a person-centered rather than a biological approach, recognize that by making a distinction between conscious and biological life the death of the former is possible despite the continuance of the latter, which will leave an entity that may appear human but is actually a “humanoid” or “biological artifact.”[358] James Bernat, a supporter of the biological definition, argues that such a view is unacceptable since “most of the functions of their organism as a whole are in intact” in patients who are neocortically dead.[359] Robert Veatch responds that Bernat’s position focuses solely on enumerating a majority of functions to determine life from death rather than assessing whether the essential ones are present or absent.[360]

While it may initially appear counterintuitive to pronounce human death in the presence of biological life, we should bear in mind that continued biological functioning occurs in WBD patients and in this case it is regarded as artifact.[361] Thus, by using the WBD criterion to fulfill the biological definition of death, we

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[358] Lizza, "The Conceptual Basis for Brain Death Revisited” 52.

[359] Veatch, "Brain Death and Slippery Slopes" 185.

[360] Veatch, "Brain Death and Slippery Slopes" 185.

[361] In addition, cells at the biological level continue to live well after death is determined using the traditional approach. Unless we are to await putrefaction, there will always be some amount of life within a recently declared corpse. The issue we are faced with is what kind of life can be discounted in the determination of death. We can see clearly how the determination of death is a social construct, although we need not succumb to a nominalist perspective that death is merely whatever we decide to call it. On the contrary, the loss of what makes a human a human is something we must discover, and it is the aim of this chapter to prove it is something particular that arises out of the human brain; whether it is called consciousness, personhood, or rationality, its loss indicates the death of the person and therefore of the human being.

already do distinguish human life from organic life if only inconsistently.[362] Further, as Richard Zaner illustrates, the Commission itself implies that the death of a human being is the death of the person when they speak of “bodies lacking all brain function and patients with intact brainstems.”[363]

As Bartlett and Youngner note, the WBD criterion does not correspond with the biological definition of death, which would only require destruction of the brainstem. A WBD patient and a Locked-In patient have both lost the ability to integrate as an organism as a whole and would be classified as dead according to the biological definition of death, yet only the WBD patient is classified as dead according to the WBD criterion. [364] Bartlett and Youngner suggest that the definition of death ought to be consonant with the criterion, which requires that we identify which attributes are more important than others, precisely the issue the President’s Commission failed to address.

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[362]It is inconsistent because, as we discussed in the previous chapter, the biological argument claims that the brain regulates the organism as a whole; therefore, when the brain is dead the organism is dead. This position dismisses any functioning that persists in WBD as artifact or as ‘unintegrated’ if it is not controlled by the brain, although more accurately if it is not controlled by the brainstem since consciousness is not involved in any regulatory capacity. Though the biological argument draws the correct conclusion, that continued organic functioning be regarded as artifact in the WBD patient, it relies on the faulty notion that this is because such functioning occurs non-spontaneously. A quick reminder of a high spinal cord injured patient, who relies on mechanical assistance for continued integrated functioning and is regarded as alive, exposes the inconsistency in the biological argument. Regarding such a patient as alive is tacitly acknowledging that organic functioning itself is not of fundamental import; otherwise the source of such functioning ought not to matter as long as it continues. The fact that such functioning is discounted in the WBD patient demonstrates that more is at stake than biological functioning, and that is consciousness.

[363]Zaner, "Brains and Persons: A Critique of Veatch's View" 191.

[364] Bartlett, Youngner, "Human Death and the Destruction of the Neocortex" 207.

Gervais captures the problem succinctly: “In a theoretically blind maneuver we adopted a criterion for determining death, along with attendant tests to ensure it was fulfilled without clarifying the underlying concept of death.”[365] She frames the issue by focusing on the reasonableness of WBD, that is, she suggests WBD was accepted so readily because it assured us that a patient had irreversibly lost consciousness and *that loss* was the determinant factor in judging such a patient as dead.[366] As we have seen, patients who retain consciousness despite having lost the capacity to spontaneously regulate integrative functions are regarded as alive. Consciousness then is regarded as indicative of personal existence and its loss is regarded as death.

Robert Veatch, perhaps best known as the pioneer for HBD and a prolific critic of the biological definition of death, argues that we must identify those characteristics or attributes that are essential to *humanness* if we are to adequately define the death of the human being. In contradistinction to Strawson and Wiggins, and by association Lizza as well, Veatch aligns with a functionalist argument, that is, the notion that the physical substrate that supports the function is not the essence of a thing, rather the function itself is what is essential, and provided it continues it does not matter what causes it.[367] In other words, a clock is a clock by virtue of its telling time, not by virtue of what it is made of, since it

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[365] Gervais, "Advancing the Definition of Death” 9.

[366] Gervais, "Advancing the Definition of Death” 12.

[367] Adam Zeman, "Consciousness" *Brain* 124 (2001): 1283.

could be digital or composed of springs and dials.[368] Veatch argues that a patient with an artificial brain would be considered alive since it is not the neurological tissue per se that is important but rather the continuance of consciousness, experience, reason, etc.[369]

However, Veatch is often purposely ambiguous and fails to carry his arguments to a solid conclusion. For example, he claims that a person is dead when he loses higher brain functions but does not argue convincingly why this is the case. He states, “The question of what characteristics are essential for treating someone as alive can be dealt with without reference to the personhood debate or deciding what characteristics are essential to personhood.”[370] Though he effectively dismantles the President’s Commission’s biological argument, his own argument appears to sidestep the issue. He settles on what he deems critical to the human being: the embodied capacity for consciousness or social interaction although his use of the word ‘embodied’ is curious.[371]

If functions are important to the degree that an artificial brain, which could produce such functions would be regarded as alive, it is somewhat strange to then require it be embodied within a human form. That is to say, if the material brain is not important why is the material body of paramount concern? The

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[368] John Searle, *The Mystery of Consciousness* (New York: The New York Review of Books, 1997) 139.

[369] Robert M. Veatch, *Death, Dying, and the Biological Revolution* (New Haven: Yale University Press, 1977) 36.

[370] Veatch, "Whole Brain, Neocortical, and Higher Brain Related Concepts" 175.

[371] Veatch, "Whole Brain, Neocortical, and Higher Brain Related Concepts" 182.

analogy often used to flesh out the problems with functionalism is that if the brain is viewed as hardware and its functions as software, it may be theoretically possible to download such information onto a disc or a computer tape and upload it into another body whose brain has been stripped or even onto a computer. Though it incites discomfort, it would be difficult to argue such a computer was not alive if consciousness could in fact be transferred in such a way.[372] We cannot focus attention on the mind-body problem, which is beyond the scope of this dissertation. An unsettling notion to consider, however, is that since consciousness is a subjective phenomenon it would be difficult to be able ever to prove one is in fact a conscious entity.[373] We will revisit some of the problems inherent with the concept of consciousness when we explore the criticisms of the HBD criterion.

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[372] Zeman, "Consciousness" 1283. According to Alan Turing, a computer can think if it can fool a human in the 'imitation game.' As described by Daniel Dennett: "The two contestants are hidden from a human judge but able to communicate with the judge by typing messages back and forth via computer terminals. The human contestant simply tries to convince the judge that he or she is human, while the computer contestant likewise-tries to convince the judge that *it* is human. If the judge cannot regularly spot the computer, the computer is deemed a thinker." See Daniel C. Dennett, *Consciousness Explained* (New York: Little, Brown, and Company, 1991) 310.

[373]The mind-body problem is one that focuses on the relationship between the material brain and immaterial consciousness. The Philosopher's Zombie is a thought experiment, which claims there logically could exist entities that are physically and behaviorally identical to us but lack qualia, that is, subjective or qualitative states. If such a zombie existed, the argument follows that consciousness cannot be explained by materialism—the belief that mind *is* brain—but in fact some type of dualism is required.

A bizarre neurological affliction known as Cagras Delusion causes the patient to believe other individuals are robots or automata impersonating real people. To the patient such a robot looks and acts like a conscious human being; it may respond appropriately and have the composition of a human being but the delusion causes the patient to believe it is simply an illusion intended to fool him. There is nothing one could do to prove to the Capgras sufferer that one is an authentic, conscious being.

Similar to Veatch, Green and Wikler also focus on the conditions of existence of persons but rely on a theory of personal identity. Though I believe their position is inconsistent and ultimately indefensible, it is noteworthy both because of its prominence in the literature and because it exposes the weaknesses in the biological definition. Similar to Gervais, they note, “If the loss of capacity for mental activity which occurs at brain death constitutes death, it is not for moral or biological reasons but ontological ones.”[374] Accordingly, a person ceases to exist at brain death not for the biological justification, which as we have seen is vexed, but because the body has lost its psychological traits.

Green and Wikler advance their theory based on the view that personal identity cannot continue in the presence of brain death. They argue, “The continued possession of certain psychological properties by means of a certain causal process is an essential requirement for any given entity to be identical with the individual who is ‘Jones’.”[375] Brain death effectively rules out the ability of ‘Jones’ to retain psychological capacities and therefore his identity ceases to exist.

It appears that for Green and Wikler there must be more than the preservation of brain tissue; rather, certain brain processes that occur within the tissue are also required for personal identity. They claim, “A given person ceases to exist with the destruction of whatever processes there are which normally underlie that person’s psychological continuity and connectedness…These

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[374] Green, Wikler, "Brain Death and Personal Identity" 118.

[375]Green, Wikler, “Brain Death and Personal Identity” 121.

processes are essentially neurological so that the irreversible cessation of upper brain functioning constitutes the death of the person."[376] In what appears to be the undoing of their argument they go on to claim that their position does not assume death occurs upon loss of consciousness so long as brain matter is preserved. They refer to a comatose patient who might be alive if enough of the brain were structurally and functionally preserved. The question that arises is, how much is 'enough' and how could one evaluate, under such circumstances, whether functions were intact? That is to say, they do not articulate how a comatose patient could demonstrate 'enough' functions have remained intact. Moreover, we must question how psychological continuity continues in the absence of consciousness; it may be the case, although they fail to defend their contention.

Green and Wikler appear then to undermine their argument by claiming that simply because a human does not have the requisite matter to support consciousness does not necessarily mean she is dead.[377] They make reference to the anencephalic who, it appears, has no capacity for personal history or psychological functions or personal identity since it lacks a forebrain, yet they place it in a separate category of "never-to-be-conscious," which means the conditions are not the same as for those for persons. It would seem less ponderous to simply apply the absence of personal identity to such infants rather than construct a different category.

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[376] Green, Wikler, "Brain Death and Personal Identity" 127.

[377] Green, Wikler, "Brain Death and Personal Identity" 128.

Somewhat more difficult to accept, however, is the following position that "the issue is not whether the patient is a person after brain death. It is whether the person is *that* person, 'Jones'."[378] This commits Green and Wikler to declare a person who suffers an injury, amnesia for example, as dead if he does not retain the same psychological history. Clearly this is a conclusion we must reject. Gervais argues the loss of personal identity alone is not a sufficient condition for declaring death, but rather that personal identity is present as long as there remains some capacity for mental life.[379]

Karen Gervais offers perhaps the most cogent argument for the death of the person as the loss of consciousness. She, as well as the various philosophers discussed in this section, attempts to identify the conditions of existence for persons rather than for organisms. Accordingly the death of the human being is equivalent with the irreversible loss of the person as opposed to the cessation of integrated biological functioning, which we have demonstrated describes the death of something that is not necessarily a human being.[380] Gervais asserts that consciousness is the sine qua non for personal existence; she claims, "The individual's essence consists in the possession of a conscious, yet not necessarily continuous, mental life; if all mental life ceases, the person ceases to exist; when the person ceases to exist, the person has died…Upper

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[378] George J. Agich, "Personal Identity and Brain Death: A Critical Response," *Philosophy and Public Affairs* 15.3 (1986): 269.

[379] Gervais, *Redefining Death* 118.

[380] Gervais, *Redefining Death* 116.

brain death destroys all capacity for a conscious, mental life and it is therefore the death of the person."[381]

Gervais argues that neither WBD nor HBD rest on the same foundation as the biological argument, which focuses on integrated functioning. The WBD and HBD criteria move from an organismic concept to a consciousness-based concept and, as we have thoroughly examined, organismic functioning continues in both WBD and HBD. That such integrated functioning is assisted in the former but not in the latter is irrelevant. The shift to WBD was an epic change that made the transition from focusing on the human being as merely an organism to a person. However, as we have seen, despite the motivation of the Harvard Committee, later WBD advocates refused to concede that such a change occurred and continue to manipulate the legitimacy of WBD on organismic grounds, a legitimacy that WBD simply cannot consistently claim. The only option for conceptual clarity is to admit that WBD is fundamentally concerned with the death of the person though it includes parts of the brain that are extraneous in determining life from death. As Veatch notes, we need not include all portions of the brain; we need only to focus on those parts that produce the functions that are significant to man's nature.[382]

Gervais argues that any definition of death requires choosing a decision of significance, that is, agreement that the loss of a particular attribute or attributes constitutes the death of the human person. She views the continuance of

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[381] Gervais, *Redefining Death* 157

[382] Robert M. Veatch, *Death, Dying, and the Biological Revolution,* 38.

consciousness, regardless of its quality, as that which signifies life and its absence personal death.[383] She crafts her argument in a manner fit for public policy, which is not something that can be said of much of the academic arguments which attempt to grapple with such ontological issues. Her proposed statute is as follows:

> Human death is the death of the individual person.
>
> An individual person is dead when an irreversible cessation of brain functions necessary for consciousness has occurred. The cessation of these brain functions can be determined by the prolonged absence of spontaneous cardiac and respiratory functions. When artificial support systems are in use, the cessation of these brain functions may be determined by any means recognized by the ordinary standards of ordinary medical practice. When cardiac and respiratory functions continue spontaneously, the cessation of these brain functions may be determined by any means recognized by the ordinary standards of current medical practice.[384]

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[383]Gervais, *Redefining Death* 169.

[384]Gervais, *Redefining Death* 213. She also includes a conscience clause for those who believe death occurs only at WBD though for the purposes of legal situations (determining if one should be charged with murder, for example) death occurs when the brain has been damaged to the extent that consciousness has been irreversibly lost.

We have thus far examined how the biological argument is seriously flawed and how the WBD criterion is not consonant with it. We have also examined the conceptual foundation of WBD and HBD and concluded they both rest on a different justification than the traditional cardio-respiratory criterion, one that considers consciousness rather than organismic functioning as the sine qua non for human personal life.[385]

In light of this, we have also argued for determining the death of the human person, rather than the human organism because the death of the human is metaphysically distinct from the death of other animals. This required that we identify the conditions of existence for what it means to be a human being rather than a human organism. This section reviewed the various approaches used to identify what is essential to the human being, the loss of which equals death. Though there remains philosophical disagreement regarding the sufficient conditions for personhood, there is agreement that irreversible loss of higher brain function is the death of the individual and is a necessary and sufficient criterion for death since personhood cannot persist after neocortical death.[386] We need now to evaluate the criterion of HBD.

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[385] It is not the goal of this chapter to attempt to delineate the range of unique human functions that are necessary for consciousness or personhood. It is sufficient for our purposes to show how WBD is imperiled as a definition of death and how a higher brain approach is, at least, ontologically sound.

[386]Gervais, *Redefining Death* 191.

V. Conceptual and clinical difficulties with the higher brain death criterion

The Higher Brain Death criterion is used to fulfill the definition of death of the human person rather than the death of the human organism. Generally, as we have seen, this concept rests on the ontological claim that the death of the human being is the death of the person, whether it is described in terms of the irreversible loss of personhood, consciousness, rationality, or personal identity. The primary difficulty that arises, which must be addressed prior to the clinical concerns with HBD, is that consciousness and/or personhood are popular terms that philosophers frequently use; yet they are highly ambiguous.[387] The first task then is to define what we mean by consciousness.

Consciousness is typically defined in one of three ways: as a waking state/arousal, as experience, and as the possession of any mental state.[388] Self-consciousness can refer to an exhaustive account but is generally regarded as knowledge of awareness of self.[389] Certainly we are not the only creatures who have the capacity for experience, arousal, or mental states. Thomas Nagel attributes consciousness to an entity if there is something it is like to *be* that entity.[390] Whether or not other creatures have self-consciousness is arguable,

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[387] Max Velmans, *Understanding Consciousness* (London: Routledge, 2001) 5.

[388] Zeman, "Consciousness" 1264.

[389] Zeman, "Consciousness" 1264.

[390] Thomas Nagel, *Mortal Questions* (Great Britain: Cambridge University Press, 1996) 166; Searle, *The Mystery of Consciousness* 8.

although, as John Searle notes, capacity for consciousness does not necessarily imply self-consciousness.[391]

It would seem that most HBD advocates use consciousness as the possession of a mental life to the extent that this refers to an experiencing subject, one that is self-reflexive. Consciousness relies on several physiological conditions within the Central Nervous System (CNS) before it can manifest itself, though the neuroanatomy of consciousness is ill defined. Consciousness is often regarded as the product of higher brain function but as The President's Commission contends, "It is not known which portions of the brain are responsible for cognition and consciousness; what little is known points to substantial interconnection among the brain stem, subcortical structures, and the neocortex."[392]

The brain stem does play an important role in regulating arousal; specifically, the Ascending Reticular Activating System (ARAS) is a network that regulates conscious states, which diffusely affects the CNS but does not pinpoint a specific locus where consciousness occurs.[393] Consciousness is contingent on arousal, which is a vegetative function, but the two are not synonomous since it is possible to have arousal without cognitive content.[394]

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[392] Capron, "The Report of the President's Commission on the Uniform Determination of Death Act" 159.

[393]Zeman, "Consciousness" 1267.

[394] American Medical Association Council on Scientific Affairs, "Persistent Vegetative State and the Decision to Withdraw Support," *JAMA* 263(1990): 427.

The two primary conceptual objections to HBD are: slippery slope concerns that death will be declared based on the quality of conscious experience, and declaring death in the presence of spontaneous respiration. In regard to the first objection Lizza clarifies that there is no danger of a slippery slope since a HBD standard would never include the severely senile or mentally disabled because they continue to perceive and to experience the world. He draws a bright line between dementia, the deterioration of cognitive functions and amentia, the complete loss of cognitive functions.[395]

Veatch further responds to the criticism that HBD would entail declaring death when consciousness was diminished or when it resembled a type of existence that was deemed worthless by a specified intellectual metric.[396] The issue is not the quality of consciousness but whether or not it continues, regardless of its perceived value since, as we have argued earlier, quality of life may inform treatment decisions but it does not distinguish life from death. Gervais concurs, arguing that any capacity for consciousness regardless of its quality signals life, though she does suggest that one's moral standing may be impacted with regard to rights and responsibilities, though this is a separate issue from the determination of whether or not one is dead or alive.[397]

Gervais further responds specifically to the question of why profoundly compromised consciousness, which may even be intermittent, is considered

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[395]Lizza, "Persons and Death: What's Metaphysically Wrong" 363.

[396]Robert M. Veatch, "Brain Death and Slippery Slopes," *the Journal of Clinical Ethics* 3.3(1992): 182.

[397] Gervais, *Redefining Death* 159.

significant.[398] That is, what is the difference between a minimally conscious patient and one where such capacity is absent? She concludes that assessing the QOL of a patient for the purposes of directing treatment decisions is appropriate whereas the judgment that a patient ceases to exist as a person must not be a QOL determination. She claims that because there is no QOL experienced by the HBD patient it cannot be a QOL judgment. Thus, when there is no longer an experiencing subject, it can no longer be said to exist; QOL is no longer a consideration.[399]

In response to the second problem of how to handle a PVS patient who would be regarded as dead but continues to breathe spontaneously, Gervais endorses administering a drug to stop respiration or proceed to organ procurement if the patient is a donor.[400] Clearly this would not be killing, since the person is already dead according to the argument that human death is the death of a person, and the person is dead when consciousness is irreversibly lost. It is important to note as well that spontaneously beating hearts are excised from breathing patients at WBD. The fact that WBD patients ventilate with assistance is beside the point, both in terms of spontaneous versus assisted,

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[398]Gervais, *Redefining Death* 208.

[399]Gervais, *Redefining Death* 208.

[400] Gervais, *Redefining Death* 176. Gervais argues that administering a drug to remedy the paradox of a breathing corpse is favorable to the alternative, which would require waiting an indeterminate amount of time for organic cessation after removal of artificial nutrition and hydration. She argues that waiting for organic functioning to cease over a protracted period of time would unnecessarily utilize healthcare resources and could prove emotionally taxing for families. Since the issue is merely one of aesthetics the quickest solution is preferred.

which as we have noted is an empty distinction, and in view of the fact that while the WBD patient requires assistance to *ventilate* he continues to *respire* spontaneously.

According to HBD advocates, spontaneous respiration that supports organismic functioning in the absence of a person is irrelevant and comparable to respiration that continues in a WBD body. While it is true that patients have never been declared dead while spontaneously breathing, we have demonstrated that whether a function is spontaneous or assisted is not the issue; the point is whether functioning, which indicates human life, continues.[401] Spontaneous breathing is not a sine qua non for life; thus it is not conceptually inconsistent to have a 'breathing corpse.' However, despite its theoretical justification, there may be some degree of cognitive dissonance involved in declaring a spontaneously breathing body as dead, which we will explore in the concluding section.

A large part of the intractable problem with HBD is that consciousness cannot be reduced entirely to brain states since it has purely subjective qualities; it is a different kind of stuff from brain stuff yet there seems to be agreement that if the requisite brain material is absent or permanently and irreversibly damaged the phenomenon cannot persist. We are begging the questions however: does irreversible cessation of the functions of the higher brain assure consciousness is permanently lost and how much higher brain destruction is necessary for loss of consciousness to be permanent and irreversible? The answer to both questions is variable depending upon whom one asks.

In addressing these questions it behooves us to differentiate between three clinical conditions that affect consciousness: coma, Minimally Conscious State (MCS), and Persistent Vegetative State (PVS). Coma is referred to as eyes-closed unconsciousness without sleep-wake cycles; it is typically characterized as a transient state leading to recovery or to a terminus at PVS.[402] The MCS is characterized by intermittent, though undeniable, awareness of self or environment, although it does not prove a functional cognitive system is present.[403] PVS is characterized as eyes-open unconsciousness with sleep-wake cycles as demonstrated by EEG.[404] Such patients often ventilate independently because mid brain functions have been largely spared; this disjunction often allows subcortical reflexes, such as response to simple stimuli caused by sound for example, despite loss of cortical functions.[405]

Neither coma nor MCS patients would be considered dead under a HBD formulation, whereas patients in PVS would be considered dead on the basis that

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[402] Zeman, "Consciousness" 1271.

[403] N.D. Schiff, D. Rodriguez-Moreno, A. Kamal, H.S. Kim, J.T. Giacino, F. Plum, J. Hirsch, "FMRI Reveals Large-Scale Network Activation in Minimally Conscious Patients," *Neurology* 64(2005): 514; T. Bekinschtein, J. Niklison, L. Sigman, F. Maes, R. Leiguarda, J. Armony, A. Owen, S. Carpintiero, and L. Olmos, "Emotion Processing in the Minimally Conscious State," *Journal of Neurology Neurosurgery and Psychiatry* 75(2004): 788

[404] Joy Hirsch, "Raising Consciousness," *Journal of Clinical Investigation* 115(2005): 1102.

[405] Boris Kotchoubey, Simone Lang, Vladimir Bostanov, Niels Birbaumer, "Is There a Mind? Electrophysiology of Unconscious Patients," *News in Physiological Sciences* 17(2002): 40.

such brain injury obliterates any capacity for consciousness. The diagnosis of PVS is, however, complicated, and may be difficult to distinguish from other catastrophic brain conditions such as the Locked-In Syndrome in which the patient cannot demonstrate response to stimuli due to near complete paralysis despite an intact brain.[406] Event Related Brain Potentials (ERPs) constitute a technique used to evaluate whether unconscious patients can perceive their environment. It should be noted, however, that ERPs are not always demonstrated in healthy individuals; thus the presence of a response to ERPs will always imply the presence of a function whereas the absence of a response does not necessarily prove a lack of function.[407]

If PVS patients are accurately diagnosed, it would seem incompatible that such a patient could experience anything at all, though “evidence from ERP research suggests that many patients diagnosed as in coma or vegetative state are able to perceive and process various aspects of their environment including in some cases semantic elements of human speech.”[408] It could be claimed that such patients were not actually in PVS, however, as the incidence of misdiagnosis of PVS is substantial.

One retrospective study published in the *British Medical Journal* evaluated forty patients admitted to a rehabilitation unit between 1992-1995 with a

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[406]Kotchoubey, "Is There a Mind?” 40.

[407]Kotchoubey, "Is There a Mind?” 39.

[408]Kotchoubey, "Is There a Mind?” 41.

diagnosis of PVS. Of those forty patients 43% were concluded as having been misdiagnosed in PVS.[409] Review of patient records showed that the diagnosis of PVS had been made by a neurologist, neurosurgeon, or rehabilitation specialist; hence the expertise of such clinicians demonstrates the difficulty in clinically assessing “internal awareness.”[410] Perhaps the most terrifying discovery this study made was that some patients had been thought to be in PVS for several years but were, in fact, aware.[411]

Robert Truog claims that Positron Emission Tomography (PET) scans of PVS patients show extremely low metabolic brain activity comparable only to the rates shown in deep anesthesia. He hypothesizes that it is unlikely that such PVS patients with this type of marked reduction can conjure any experience.[412] However, in an article published in *Brain* the author claims it is not a closed debate as to whether PVS patients are wholly unaware.[413] Alan Shewmon, a prolific critic of the WBD criterion, rails against the loss of consciousness as the death of the person because it embraces actualism, the belief that a person is

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[409] Keith Andrews, Lesley Murphy, Rod Munday and Clare Littlewood, "Misdiagnosis of the Vegetative State: Retrospective Study in a Rehabilitation Unit," *BMJ* 313(1996): 13.

[410]Andrews, "Misdiagnosis of the Vegetative State" *1*5.

[411] Andrews, "Misdiagnosis of the Vegetative State" *1*5. For additional studies regarding the diagnostic accuracy of PVS see also Nancy L. Childs, Walt N. Mercer, and Helen W. Childs, "Accuracy of Diagnosis of Persistent Vegetative State," *Neurology* 43(1993): 1465-1467; Donald D. Tresch, Farrol H. Sims, Edmund H. Duthie, Michael D. Goldstein, Paul S. Lane, "Clinical Characteristics of Patients in the Persistent Vegetative State," *Archives of Internal Medicine* 151(1991): 930-932.

[412] Truog,"Rethinking Brain Death" 1710.

[413] Zeman, "Consciousness" 1271.

nothing more than his or her acts.[414] He claims there is a dearth of data to support the notion that without a functioning cortex consciousness is impossible.

Clinical diagnosis of PVS is exclusionary, meaning that it is made on the basis that patients do not reliably express awareness. Shewmon argues this is unacceptable since, “Diffuse cortical destruction results in spastic quadriplegia, pseudobulbar palsy, apraxia of motor control, global aphasia, dementia, cortical blindness, etc…How could anyone then externally manifest inner consciousness even if it were present?”[415] He considers the possibility that PVS may actually be a “Super Locked-In State” where the patient may be aware but cannot exhibit it due to cortical destruction.[416]

Another clinical difficulty with HBD arises with the timing of death. Even if we grant diagnostic accuracy and agree that consciousness has been irreversibly lost at PVS, such a determination of death would have to wait the requisite period of six months before such a determination could be made. Obviously such a time lapse would be unadvisable for any statutory definition of death for practical reasons.

Veatch asserts that the HBD criterion is in no worse a position than the WBD criterion as the latter must discount spinal cord reflexes, EEG activity, and explain why parts of the brain may not be dead in *whole* brain death.[417]

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[414] Shewmon, "Recovery from "Brain Death" 56.

[415] Shewmon, "Recovery from "Brain Death" 59.

[416] Shewmon, "Recovery from "Brain Death" 60.

Accordingly, he states "if there is a slippery slope, anyone who leaves the comfortable confines of the pericardium and begins ascending the spinal cord toward the cerebral cortex is already on it."[418] Veatch questions the significance assigned to brain stem reflex arcs, such as pupillary constriction, when spinal cord reflexes are discounted. Since the spinal cord is, properly speaking, part of the CNS he determines there is no principled reason to exclude one reflex arc but include another that is one-quarter inch higher.[419] Veatch suggests that such a distinction relies on the notion that integrative functions endogenous in the brain are more valuable or important than those that are exogenous, that is in the spinal cord. However, neither can be said to play a role in the integration of the organism as a whole or in the role of consciousness; thus it seems arbitrary to make an ad hoc division within the CNS.[420]

VI. A hybrid approach

We have carefully reviewed the conceptual and clinical arguments regarding HBD, but there is also an emotional component that ought not be ignored. It is not simply aesthetics not to wish to bury a breathing body nor is it clear that the slippery slope is impervious to putting the most vulnerable or

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[417] Robert M. Veatch, "What it Means to be Dead," *Hastings Center Report* 12.6(1982): 45.

[418] Veatch, "What it Means to be Dead" 45.

[419] Veatch, "Brain Death and Slippery Slopes" 184.

[420] Veatch, "Brain Death and Slippery Slopes" *18*4.

disenfranchised in danger. Perhaps it is the nature of man to be able to make a distinction intellectually that a breathing body may no longer be a person though there is a visceral objection to reconciling such a person as dead. We examined this epistemological issue in the previous chapter on WBD. Further, if a patient is stripped of his personhood rendering him no more than a fido-like entity, what is the status of a patient with severely diminished consciousness, one where Fido has much more self-awareness than the patient? According to David DeGrazia, capacity for consciousness cannot be a sufficient condition for personhood without classifying animals that also have consciousness as persons.[421] We have not solved what appears to be an intractable tautological argument: human beings are essentially persons because they are human beings.

Further, the clinical problems in determining HBD are substantial. The publicized case of Terri Schiavo showed how experts disagreed regarding her diagnosis and the emotional issues involved. Schiavo was diagnosed in PVS, which was confirmed on autopsy though she simply did not ‘look’ dead, which is what the HBD standard would require. She appeared to smile, to grimace and to visually track a balloon. Burying such a patient could scandalize society even if it is correct conceptually. We do not have the certainty we need to ensure that the diagnosis of HBD is accurate and that consciousness in such a state has irreversibly been lost.

However, the definition of death as the cessation of the person is more philosophically sound than the biological argument, which simply does not work

[421] David DeGrazia, "Persons, Organisms, and Death: A Philosophical Critique of the Higher Brain Approach," *The Southern Journal of Philosophy* 37(1999): 424.

as it stands with the WBD criterion. It seems we must make a compromise. As we have argued in this and the previous chapter, the WBD patient is not dead on the basis of the traditional biological argument of the loss of integrated functioning. In addition, human death is more than a biological event that describes the loss of organismic functioning as human death has normative import. The definition of the death of a human being should be reclassified as the death of the person rather than the organism. This can be determined by the irreversible cessation of the brain because the brain is that complex structure that supports, however mysteriously, the phenomenon of consciousness, a necessary condition for personal existence. However, it is a near impossibility to decide precisely which parts of the brain are absolutely necessary and which areas correspond to those functions we determine essential to the existence of human beings.

Perhaps the best solution is to adopt the *concept* of the higher brain death argument but apply the whole brain death *criterion and tests* until such issues can be resolved. In this way we have conceptual clarity with clinical confidence because WBD can be diagnosed with accuracy and any patient who passes a WBD protocol necessarily suffers higher brain death as well. It is not a perfect solution however; WBD is, even according to WBD supporters, an approximation and as such there are clinical issues that should be addressed. Some functions may potentially be excluded, such as cessation of certain brain stem reflexes for example, whereas other functions may need greater focus such as reevaluating the acceptability of continued EEG activity in WBD patients and perhaps requiring cerebral blood flow studies in all WBD protocols. These are clinical issues that should be resolved by those who are expert in medicine. What is important for our purposes here is to note that, regardless of how these remaining testing difficulties are resolved, anyone who is dead by WBD *criteria* is most assuredly dead according to the HBD *concept*. This preserves conceptual clarity on the one hand and protects against mistakes and abuse on the other.

We should take stock of what we have examined and concluded thus far in this dissertation. We began by exploring how death has been declared historically beginning in the 17th century, focusing on the inability to accurately determine death, which led to premature burial and the many macabre solutions posed to avoid untimely interment. We then followed a chronology of medicine, which enjoyed a shift from quackery and charlatanism to a respected field due to the scientific revolution. As technology progressed, the ability to determine death with sensitive equipment all but obliterated fears of misdiagnosis of death. Ironically, however, the concomitant boom in technology yielded devices and procedures that could now reverse conditions that were previously thought to be irreversible making the determination of death hazy once again.

Complicating matters further were the advances made in organ transplantation, which moved from science fiction to reality with the first kidney graft in 1954. Public policies would be crafted to regulate organ donation; perhaps the most important for our purposes was the Dead Donor Rule (DDR) stipulating that vital organs could not be removed prior to death nor could removal hasten death. Organ transplantation was largely contingent on the availability of organs, which remain in short supply today. The late 1960s experienced the downside of technology when physicians realized they could sustain vital signs but not cure irreversibly brain-damaged patients. The term coma depassé was coined and the Harvard Ad Hoc Committee subsequently introduced the notion of whole brain death. Despite the fact that a philosophical justification to equate such patients as dead would not come for another decade, WBD patients were declared dead and served as heart beating cadavers for the purposes of organ transplantation.

In the previous chapter we examined the WBD criterion and the biological argument, which was applied posthumously to justify it. We concluded that WBD patients are not dead under the concept of death as the *irreversible cessation of the integrated functioning of the organism as a whole* on the grounds that the whole brain is often not dead at a declaration of brain death and because integrated functions can continue in the absence of a functional brain.

We focused in this chapter on the concept of higher brain death, concluding that it is more conceptually sound to regard the death of the human being as the death of the person rather than the death of the organism, though we endorsed WBD as the appropriate criterion to fulfill the definition until we attain greater clinical accuracy for HBD. In this regard then, WBD patients are dead, not for the reasons endorsed by the traditional notion of death but because such patients have irreversibly lost the capacity for consciousness.

Having reviewed and criticized the traditional definition of death and argued for why an ontological definition is more coherent, we will use both definitions as a foundation for our argument in the concluding chapter that some Donation After Cardiac Death Donors are not yet dead at organ procurement.

Chapter 5
On the Legitimacy of Donation After Cardiac Death

Nobody would seriously argue that the condition of a patient, two minutes post arrest, who is unable on his own to return to normal rhythm, is ipso facto dead.[422]

Each chapter of this dissertation has laid the groundwork for this final one, in which I will evaluate the practice of Donation After Cardiac Death (DCD), specifically whether these donors are dead at the moment of organ recovery. We could not attempt to answer this question without first addressing the many foundational issues concerning death prior to this point.

We began this dissertation with a discussion of how death had been determined historically and reviewed how death was, prior to medical technology, perceived as a discrete event where the organism quickly and predictably failed when the heart and lungs ceased. In this time period the definition, criteria, and tests for death were not well articulated because death was largely understood as a binary event. Unfortunately, inadequate tools to test for the cardio-respiratory criterion occasionally led to misdiagnosis, resulting in premature interment where it became clear that a physician's declaration that a person was dead did not necessarily *make* him dead. In response to this, elaborate and often destructive tests were performed on the alleged corpse to ensure it would not revive and life signaling and life saving coffins were constructed as an additional safeguard. Putrefaction and the "death watch" became the standard

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[422] E.T. Bartlett, "Differences Between Death and Dying," *Journal of Medical Ethics* 21(1995): 274.

benchmark for the determination of death until embalming practices largely obviated the fear of premature burial and medicine began its ascent toward the modern era.

The development of highly sophisticated clinical tools allowed physicians to diagnose death accurately though advances in transplantation quickly demonstrated that the brain, not the heart and lungs, was of primary significance in the determination of death. The declaration of death had a direct and complex relationship with organ transplantation since it became clear that organs must be alive at procurement whereas the organ donor must be dead.[423] Thus, with the exception of a few vocal minority groups, we saw society readily accept a redefinition of death. This shift from a cardiac-centered criterion to a neurologic criterion facilitated organ transplantation since organs would not suffer warm ischemic damage after death but could be well maintained by artifice within a dead human being.

The brain was exalted as that primary organ responsible for integration within the organism as a whole. Cardio-pulmonary function could be used as an indirect indicium of brain function, but it was neurologic function alone that determined life from death as death could be declared in the presence of circulation, heartbeat, and respiration. It was not the task at hand to explore whether whole brain death was constructed to expand the donor pool but rather to evaluate whether the definition and criteria were conceptually sound.

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[423] As we have seen, the Dead Donor Rule (DDR) arose as a normative guideline in transplantation, which stipulated that persons would not killed for, or by, the removal of their organs. The DDR was silent on the definition or criteria necessary to fulfill it.

We then examined the whole brain death criterion and the traditional definition of death and found that the definition and criterion are not reflexive. That is, a dead brain does not necessarily indicate a dead organism as evidenced by the many integrated functions a brain-dead body performs. Therefore we argued that the traditional definition of death as the *irreversible cessation of the integrated functioning of the organism as a whole* is not necessarily fulfilled by a neurologic standard. Since it became clear in that discussion that the brain is the only substrate that sustains our unique human functions and capacities it would be necessary to define death, not in terms of cessation of biological functioning, but as the loss of that which is essential to the human person.

As such, we offered an alternative ontological definition of death as the *irreversible cessation of consciousness* as a more conceptually sound approach. Since irreversible loss of higher brain function coincides with the irreversible loss of human capacities (consciousness and personhood) a higher brain death definition could supplant the traditional biological definition. The criterion used to test this definition would be the whole brain death standard until the higher brain death standard could be reliably implemented since all those who pass whole brain death are necessarily higher brain dead as well. In changing the definition of death we addressed the clinical and conceptual incoherency with whole brain death and yet retained the societal standard.

Having come full circle I will now argue that some DCD donors fail to pass the traditional legal definition of death or its criteria as described by the Uniform

Determination of Death Act (UDDA). In addition, I will also argue that at least some DCD donors are still alive using the ontological definition of death as well.[424] Thus, regardless of whether one subscribes to the traditional notion of death as the *irreversible cessation of the integrated functioning of the organism as a whole* or to an ontological position that defines death as the *irreversible loss of consciousness*, I will argue that DCD remains incompatible with regard to either definition.

My central claim is that DCD donors have not fulfilled the irreversibility criterion of death and that a cardiac criterion of death prognosticates death but does not accurately diagnose it since, as we have argued in the previous two chapters and we will reiterate here, a person cannot be dead unless his brain is dead. In arguing that DCD donors are not irreversibly dead we will examine the medical literature on auto-resuscitation (return of spontaneous circulation) where it will be shown that the point at which auto-resuscitation may occur has not been sufficiently studied to conclude that 2-5 minutes of asystole forecloses the phenomenon. We will also review the literature on manual resuscitation where it will be shown that cardiopulmonary (heart-lung) and cerebral (brain) resuscitation

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[424] I cannot support the claim that *all* DCD donors are dying and not yet dead since the population of DCD donors is diverse and it is possible that after 2-5 minutes of asystolic arrest some donors would fulfill either the traditional definition or an ontological definition of death depending on the extent of the patient's injury. To make this diversity clear, one potential DCD candidate may suffer extreme neurologic injury but may possess some rudimentary brainstem function (i.e. pupillary reaction) that would preclude a diagnosis of WBD while another candidate may be neurologically intact at the time of withdrawal of LST. After a 2 or 5 minute interval of asystole the former patient will likely be unresuscitable and brain dead whereas the latter patient will not. In addition to different patient populations who undergo DCD the variability in DCD protocols further complicates matters since different institutions have different time intervals such that a donor could be dead according to the University of Pittsburgh Protocol but alive according to the Geisinger Medical Center Protocol.

techniques continue to improve such that some DCD donors could be successfully resuscitated after a declaration of death and time interval of 2-5 minutes, thus proving that such patients are not dead but in a dying process.[425]

In addition to discussing the problem of irreversibility, we will also focus on the logical inconsistency that a DCD donor may be heart-dead but not necessarily brain-dead, thus raising the question that perhaps the UDDA ought not to be used to justify the practice since its drafters could not predict this peculiar bifurcation that DCD poses. Finally, we will raise additional questions regarding the procedural variability within DCD protocols. The attached appendices include a copy of the University of Pittsburgh Medical Center (UPMC) DCD protocol (appendix A), the Pittsburgh Mercy Health System (PMHS) DCD protocol (appendix B), and the Geisinger Medical Center DCD protocol (appendix C). These represent three protocols approved for use in the Commonwealth of Pennsylvania in order to demonstrate the vast procedural variability between them.

Ultimately I will conclude this dissertation by arguing that that DCD is clinically problematic and conceptually inconsistent for three principal reasons. First, auto-resuscitation has not been sufficiently studied to confidently declare

[425] It should be noted that "successful resuscitation" is an ambiguous term. For example, Nancy Cruzan was "successfully" resuscitated to a persistent vegetative state (PVS). My definition of successful resuscitation will be more stringent, that is, based on the ability to resuscitate to a conscious state since I hold that a person is dead if she has irreversibly lost the capacity for consciousness. However, since the current definition of death does not view the severely neurologically injured as dead unless they fulfill a WBD protocol or unless cardio-respiratory function has irreversibly ceased, successful resuscitation can easily refer to the ability to simply restore coronary and cerebral blood flow with some measurable brain function.

that it will not occur after 65 seconds of asystole.[426] This notwithstanding, however, even if it could be established, the ordinary understanding of irreversible loss of function is not satisfied when auto-resuscitation does not occur or when an individual proscribes an intervention. Second, DCD focuses on a criterion of death that claims cessation of the organism as a whole can be determined by the loss of cardio-respiratory function only, independently of brain status. Finally, DCD conflates a prognosis of death with a diagnosis of death such that imminently dying patients are treated as if they were dead, thus violating the dead donor rule. I will conclude that in light of the analysis of death taken up throughout this dissertation, DCD equivocates the line between a dying patient and a corpse and as such violates the current rules that direct organ transplantation.

I. BACKGROUND: Defining Donation After Cardiac Death

Before we develop our arguments against DCD we must first define the practice itself and review its genesis. As discussed in chapter two, prior to the acceptance of whole brain death (WBD), cadaveric organs for transplantation,

[426] As we shall see, there have been no large-scale studies to chronicle the incidence of auto-resuscitation. However, Michael DeVita relies on a small number of 108 case observations in which no patient auto-resuscitated after a period of 65 seconds to conclude that 65 seconds represents the maximum point at which auto-resuscitation will no longer occur. Accordingly, the 2 minute interval has been adopted based on this empiric data and on the argument that a customary declaration of death using the cardio-respiratory criterion does not require a specific time interval to elapse before death is declared. Thus, according to this argument, if 65 seconds is sufficient to preclude auto-resuscitation and there is no set time requirement for declaring death using the cardio-respiratory criterion, 2 minutes is certainly long enough to ensure the patient is dead.

primarily kidneys, were initially recovered from uncontrolled DCD donors.[427] This meant that death occurred in a manner that was unplanned, such as when a patient arrived at a hospital dead on arrival, or had failed resuscitation.[428] An uncontrolled DCD donor was subsequently declared dead on the basis of irreversible cessation of cardio-respiratory functions following which consent was obtained from the family to proceed with donation.

Conceptually speaking this practice was not ethically problematic since it was thought at that time that cardiac death *was* death, as opposed to being a *mechanism* for death.[429] The clinical procedure was not ideal, however, since organs often suffered warm ischemic injury during the time that elapsed between declaring death, securing consent, and mobilizing a transplant team.[430] Because of these technical problems, though in larger part because WBD was introduced, which provided heart-beating cadavers, uncontrolled DCD was abandoned.[431] In the early 1990s, however, there was renewed interest in DCD since the need for

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[427] Dirk E.M. Van Raemdonck, Filip R. Rega, Arne P. Neyrinck, Nicole Jannis, Geert M. Verleden, Toni E. Lerut, "Non-Heart-Beating Donors," *Seminars in Thoracic and Cardiovascular Surgery* 16.4 (2004): 310.

[428] Edward M. Manno, "Management of the Organ Donor," Society of Critical Care Medicine, Phoenix, AZ, January 2005.

[429] E.T. Bartlett, "Differences Between Death and Dying" 271.

[430] Vassilios Papalois, Konstantinos Vlachos, Alexander Barlas, Zaki Anas Zarka, Adil El-Tayer, Nadey S. Hakim, "Ethical Issues in Non-Heart-Beating Donation," *Bulletin of Medical Ethics* (2004): 14.

[431] Michael A. DeVita, James V. Snyder, Ake Grenvik, "History of Organ Donation by Patients with Cardiac Death," *Kennedy Institute of Ethics Journal* 3.3 (1993): 126.

organs continued to increase while the number of organ donors reached a plateau and death on neurologic criteria was not commonplace.[432]

UPMC revisited DCD under controlled terms in 1993 in response to competent patients' requests to become organ donors following the withdrawal of life sustaining treatment (LST).[433] Controlled DCD could facilitate organ recovery from a patient who would not be declared dead using neurologic criteria but would undergo a planned withdrawal of LST and be declared dead using the cardio-respiratory criterion. In this way, as opposed to uncontrolled DCD, a patient's death could occur under carefully orchestrated circumstances, that is, the withdrawal could occur in the operating room with a transplant team in the adjacent room equipped to remove organs as soon as death was declared.

Our focus here is on controlled DCD, which is the more commonly practiced DCD category in the United States.[434] A request for organ donation using

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[432] Christopher James Doig, Graeme Rocker, "Retrieving Organs from Non-Heart-Beating Organ Donors: A Review of Medical and Ethical Issues," *Canadian Journal of Anesthesia* 50.10 (2003): 1070.

[433] Michael DeVita, Thomas May, "Decisions by Conscious Persons about Controlled NHBD after Death: Eyes Wide Open," *The Journal of Clinical Ethics* 11.1 (2000): 87.

[434] Currently, uncontrolled DCD is infrequently practiced due in part to the logistical drawbacks discussed above but also because it raises additional moral questions such as when, in the resuscitation process, does the goal switch from treating the patient to preparing him as a potential donor. Controlled DCD bases its legitimacy not only on the fact that cardio-respiratory function is said to be irreversible when the patient will not auto-resuscitate, but also because the patient or family has refused further intervention. This cannot be said of the uncontrolled donor.

Robert Arnold and Stuart Youngner suggest the possibility that uncontrolled DCD may cause patients to worry they will not be resuscitated to the fullest extent if they are known organ donors. In addition, they note that there are many individuals without health insurance who have not had the opportunity to forge a doctor-patient relationship that fosters trust and respect. Accordingly, it is possible that the only interaction such controlled DCD is made after a decision to forgo LST when it is clear the patient will not be declared dead using neurologic criteria. It is difficult to describe precisely how DCD protocols proceed since there is little consistency across the country, despite the repeated calls for protocol uniformity.[435] A common thread to all protocols is that discussion regarding DCD occurs only after a decision to forgo LST had been made and the physician declaring death cannot be associated with the transplant team.

Michael DeVita, MD, current chair of the UPMC ethics committee, rejects the assertion that reviving DCD was purely a utilitarian endeavor in order to expand the donor pool.[436] He maintains instead that DCD was reintroduced to actualize patient autonomy.[437] He argues that if the decision to forgo LST is made

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individuals have may be limited to a physician in an emergency department. Therefore it seems of little value to endanger an already fragile climate for short-term goals. See G. Koostra, R. M. Arnold, M.A. Bos, J. Southard, Stuart J. Youngner, "Roundtable Discussion on Non-Heart-Beating Donors," *Transplantation Proceedings* 27.5(1995): 2935-2939; also Stuart Youngner, Robert M. Arnold, Michael A. DeVita, "When is "Dead?" *Hastings Center Report* (1999):19.

Moreover, uncontrolled DCD raises additional clinical concerns given the possibility of the Lazarus Phenomenon in which the patient experiences return of spontaneous circulation (ROSC) after a declaration of death using the cardio-respiratory criterion. We will thoroughly address this phenomenon in our discussion on auto-resuscitation. Despite these concerns, however, uncontrolled DCD may become at least theoretically feasible since Florida, the District of Columbia, and Virginia allow post mortem in situ preservation until the family can be reached to consent or refuse donation. See B. Quick, B. Bastiani, "Prolonged Asystolic Hyperkalemic Cardiac Arrest With No Neurologic Sequelae," *Annals of Emergency Medicine* 24(1994): 305-311; W.H. Maleck, S.N. Piper, J. Triem, et al, "Unexpected Return of Spontaneous Circulation after Cessation of Resuscitation," *Resuscitation* 39(1998): 125-128.

[435] Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement* (Washington, DC: National Academy Press, 1997) 4.

[436] Jeffrey Spike, "Controlled NHBD Protocol for a Fully Conscious Person: When Death is Intended as an End in Itself and It has Its Own End," *The Journal of Clinical Ethics* 11.1 (2000): 74.

[437]DeVita, May, "Decisions by Conscious Persons about Controlled NHBD after Death" 88.

independently of donation there is no basis to prohibit this method for organ recovery and in fact, "patient autonomy demands it."[438] There are, however, limitations to autonomy that DeVita fails to recognize. Patients have the right to make their own choices to the extent that they do not harm others, but autonomy is constrained when it impacts greater societal goods; goods at stake in this case are the preservation of the dead donor rule and the prevention of homicide.[439]

Thus, simply because a patient desires something does not mean it must be provided *carte blanche*.[440] Patient autonomy does not justify commodifying the body, as evidenced by the prohibition against buying and selling organs. Thus, autonomy is better understood as an individual's right to privacy and the ability to make decisions in accordance with his values. It is not unconditional, but is a principle that must be balanced against other goods, rather than used as a means to justify all requests. Further, consent only applies so far in that one can consent to donate organs after death but one cannot consent to a procedure that arguably removes them prior to death.[441] In this regard it is irresponsible to base the legitimacy of a practice on whether or not patients desire it or consent to it.

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[438] DeVita, May, "Decisions by Conscious Persons about Controlled NHBD after Death" 88.

[439] Jerry Menikoff, "The Importance of Being Dead: Non-Heart Beating Organ Donation," *Issues in Law & Medicine* 18(2002): http://authenticate.library.duq.edu/login?url=http://proquest.umi.com.authenticate.library.duq.du/pqdweb?did=148498601&sid=1&Fmt=3&clientId=3262&RQT=309&VName=PQD>

[440] Elizabeth D. Motta, "The Ethics of Heparin Administration to the Potential Non-Heart-Beating Organ Donor," *Journal of Professional Nursing* 21.2 (2005):101.

[441] Menikoff, "The Importance of Being Dead."

Moreover, it does matter, contrary to DeVita's position, how a patient will be declared dead if that particular criterion cannot ensure the patient is truly dead.

It is important to note that interest in DCD in the 1990s was not isolated to UPMC, however, as the international community assembled to discuss the clinical, ethical and legal surrounding the practice.[442] The 1st International Workshop on DCD was held in Maastricht, Netherlands, March 30th and 31st 1995, in which the four categories of DCD donors were classified, now known as the Maastricht Categories. Maastricht Categories I and II are uncontrolled and refer to those patients pronounced dead on arrival (I) or to patients who have failed successful resuscitation (II). Maastricht Categories III and IV refer to controlled DCD, which refer to patients awaiting cardiac arrest after a planned withdrawal of LST (III) or patients who suffer cardiac arrest while awaiting WBD protocol or after a WBD diagnosis but prior to transfer to the operating theatre (IV).[443]

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[442] UPMC implemented their protocol two years prior to the international convocation, which raises concern that they were less interested in consensus and critical evaluation than in forging their agenda. This foreshadowed what would become typical of UPMC, that is, to operate independently of the recommendations set forth by the international community as well as by the recommendations established by the Institute of Medicine (IOM).

Further, when the United Network for Organ Sharing (UNOS) declared "This method of organ procurement is ethically problematic however, because it uses non standard cardiac criteria in order to pronounce death quickly" UPMC did not suspend, augment, or abandon their protocol. Frank Koughan, Walt Bogdanich, "60 Minutes Sets the Record Straight [Response to "From Pittsburgh to Cleveland: NHBD Controversies and Bioethics"]," *Cambridge Quarterly of Healthcare Ethics* 8(1999): 516. It should be noted, however, that UNOS has since radically changed their opinion on DCD and regards it as an ethically acceptable method for procurement.

[443] G. Kootstra, J.H.C. Daemen, A.P.A. Oomen, "Categories of Non-Heart-Beating Donors," *Transplantation Proceedings* 27.5(1995): 2893-2894.

II. DCD and The Institute of Medicine

In 1997, when it became clear that DCD had arrived with few guidelines in place, the Department of Health and Human Services (DHHS) commissioned the Institute of Medicine (IOM), a non-profit advisory board, which serves as the research arm of the National Academy of Sciences, to evaluate DCD and recommend how it may be utilized without violating prevailing ethical norms.[444] The IOM recommended seven primary guidelines for DCD protocols.

1) Written, locally approved non-heart-beating donor (NHBD) protocols
2) Public openness of NHBD protocols
3) Case by case decisions about the premortem administration of medications
4) Family consent for premortem cannulation
5) Conflict of interest safeguards
6) Determination of death (in controlled NHBD) by cessation of cardio-pulmonary function for at least 5 minutes by electrocardiographic and arterial pressure monitoring

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[444] Gail A. Van Norman, "Another Matter of Life and Death: What Every Anesthesiologist Should Know About the Ethical, Legal, and Policy Implications of the Non-Heart Beating Cadaver Organ Donor," *Anesthesiology* 98(2003): 769.

7) Family options (e.g., attendance at life support withdrawal and financial protection.)[445]

The IOM Report assigned a Principal Investigator, John T. Potts, to synthesize expert opinion from the transplantation community, the federal government, and donor families pertaining to DCD. Potts also had access to a panel of senior special experts who were considered “at arm’s length” from transplantation to inform the Report.[446] On the first page of the Report this general conclusion is offered:

> The recovery of organs from NHBDs is an important, medically effective, and ethically acceptable approach to reducing the gap that exists now and will exist in the future between the demand for and the available supply of organs for transplantation…The problems raised require attention, but they are, in fact, not significantly different from those that arise in cadaveric transplantation generally.[447]

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[445] Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement* (Washington, DC: National Academy Press, 1997) 4.

[446] Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement*, V.

[447] Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement*, 1.

The Report admitted that it accepted this basic premise at the outset.[448] Since the Report begins with a preordained conclusion that DCD is ethically acceptable and that it does not differ from other means of cadaveric procurement, the Report does not genuinely wrestle with the substantive issues. Regarding the most contentious issue, the concept of irreversibility, which we shall address at length, the Report adopts the weakest construal in which the patient's wish to forgo treatment is viewed as a sufficient criterion to meet the standard of irreversibility coupled with the fact that the patient will not auto-resuscitate. However, the Report admits that there are no scientific studies offering any definitive conclusion as to how long the interval must be to preclude auto-resuscitation. It further criticizes the 2 minute interval as "not supported by any experimental data on the probability of auto-resuscitation and is too short to support a determination of whole brain death due to circulatory arrest."[449]

The Report continues then to undermine the importance of establishing brain death by stating, "Although this is not relevant to a determination of death, the interval of absent circulation recommended here will, in a donor with normal body temperature, produce irreversible brain damage."[450]

If brain death is not necessary to declare death then this implies there are *two* kinds of death rather than two criteria that instantiate the same phenomenon of

[448]Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement* , 45.

[449] Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement*, 58.

[450] Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement*, 59.

whole brain death. Moreover, irreversible brain *damage* is not the same as whole brain *death* such that even if asystole resulted in devastating brain damage, such damage would not, according to the traditional definition of death, constitute death. It is beyond our purposes here, however, to focus on the many shortcomings of the IOM. Suffice for our interest that it recommends a 5-minute interval after cessation of circulatory function as confirmed by electrocardiographic and arterial pressure monitoring. The report concludes,

> Uniform adoption of this recommendation which is on the conservative end of the current range, could ensure death has occurred, diminish the appearance of haste and reassure the public, and eliminate the uncomfortable situation whereby a donor could be defined as dead in one OPO region and still, however briefly, be defined as alive in another. Since, in the final analysis, this recommendation is only an expert judgment, data should be collected to validate an interval.[451]

In 1999 the DHHS requested the IOM reconvene in order to follow up on their recommendations outlined in the 1997 report. The 1999/2000 IOM report indicates that few of their recommendations have been adopted. DCD protocols continue to differ across the country; some protocols administer medications post

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[451] Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement*, 59.

mortem whereas others stipulate ante mortem administration. Blanket orders for Heparin and/or Phentolamine are also written into some protocols without regard for the potential of low blood volume or intracranial bleeding. Perhaps the most serious problem, however, is that death can be determined and organs procured anywhere after 2-10 minutes of asystole, ventricular fibrillation (VF), or electromechanical dissociation (EMD), depending on the particular protocol.[452]

Both IOM reports are well known but not necessarily well regarded by those involved in the definition-of-death debate. On April 7th and 8th, 2005, a National Conference on Donation After Cardiac Death was convened in Philadelphia in which experts in neuroscience, critical care, transplantation, and bioethics were asked to address the controversy surrounding DCD and ultimately find ways to expand its practice.[453] Work Group I was charged with determining death by a cardiopulmonary criterion and exploring the conceptual problems it poses. This work group considered the IOM reports in their discussions but ultimately found them ethically hollow and took issue with specific points.[454] A major point of contention was the IOM recommendation that "accepted medical detection standards include electrocardiographic changes consistent with absent heart function by electronic monitoring and zero pulse pressure as determined by

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[452] Institute of Medicine, *Non-Heart-Beating Organ Transplantation* (Washington, DC: National Academy Press, 2000) 40-41.

[453] James L. Bernat et al. "Report of a National Conference on Donation After Cardiac Death." *American Journal of Transplantation* 6 (2006): 281-91.

[454] Work group discussion, April 7th, 2005.

monitoring through an arterial catheter."[455] The work group argued that electrocardiographic (ECG) silence is not necessary since the criterion for determining death via the cardio-respiratory criterion is based on the absence of *circulation* not on electrical heart activity, which may or may not be sufficient to generate a pulse.[456] This distinction may appear negligible, but in fact it becomes a point of contention with regard to auto-resuscitation and manual resuscitation, which we shall turn to now.

III. Auto-resuscitation and Manual Resuscitation

In this section on auto-resuscitation, cardiopulmonary, and cerebral resuscitation, I will assert and defend my central claim that some DCD donors are not irreversibly dead at organ procurement. I will argue that using the traditional definition of death, irreversibility has not been established if auto-resuscitation is possible or if manual resuscitation can return some amount of brain function that precludes a declaration of whole brain death. Further, I will also argue that using an ontological definition of death irreversibility is not met if revival to a conscious state is possible.

Auto-resuscitation is a phenomenon in which a patient's heart spontaneously regains pump function and effectively generates circulation after a

[455] Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement,* 59.

[456] Bernat, et al. "Report of a National Conference on Donation After Cardiac Death," 282.

period of circulatory arrest.[457] The issue of auto-resuscitation is pertinent to DCD since procuring organs during the time frame in which a patient could auto-resuscitate would mean that neither a strong nor a weak irreversibility criterion had been fulfilled; thus procurement would be tantamount to murder. Auto-resuscitation could theoretically occur in both controlled and uncontrolled DCD donors though it is more likely to occur in the latter. Thus we will examine the implications auto-resuscitation has in the uncontrolled DCD donor first.

When auto-resuscitation occurs after cardiopulmonary resuscitation (CPR) has been discontinued and after a declaration of death and has been made, it is often referred to as the Lazarus Phenomenon.[458] Since the Lazarus Phenomenon was identified in 1982 there have been upwards of 25 clinical case reports in the literature though it has been suggested that clinicians may be hesitant to disclose the phenomenon accurately due to the sensitive medico-legal concerns it presents.[459]

Named the Lazarus Phenomenon after the eponymous historical figure Jesus is said to have raised from the dead, the mechanisms for what causes the phenomenon are not yet fully understood. It is believed to occur either after

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[457] F.M. Eelco Wijdicks, and Michael N. Diringer. "Electrocardiographic Activity After Terminal Cardiac Arrest in Neurocatastrophes," *Neurology* 62 (2004): 673.

[458] The Lazarus Phenomenon is not the same as the Lazarus Sign, which refers to the movements that can be elicited in brain dead patients when certain pathways are stimulated. The Lazarus Sign is attributed to spinal cord reflexes and typically presents with the patient crossing his arms over his chest and/or rising from the bed at the waist.

[459] H. Maeda et al. "Death Following Spontaneous Recovery From Cardiopulmonary Arrest in a Hospital Mortuary: 'Lazarus Phenomenon' in a Case of Alleged Medical Negligence," *Forensic Sci Int*. 127.1-2 (2002): 82-87; W.H. Maleck et al. "Unexpected Return of Spontaneous Circulation After Cessation of Resuscitation (Lazarus Phenomenon)," *Resuscitation* 39.1-2 (1998): 125-28.

> 1) Delayed delivery of previously administered medications to the heart; 2) cardiac reperfusion due to a spontaneous dislodging of embolized cardiovascular plaque from the coronary artery; 3) recovery of venous return after cessation of artificial ventilation causing dynamic pulmonary hyperinflation, especially in a patient with obstructive airway disease (auto-positive and end-expiratory pressure); 4) electromechanical dissociation.[460]

The Lazarus Phenomenon would not likely occur in controlled DCD because CPR, which plays a major factor in the Lazarus Phenomenon, has been proscribed in such patients. However, it has direct relevance to category II uncontrolled DCD donors since such patients will have, by definition, failed resuscitation and are at risk for the constellation of circumstances that make the phenomenon possible. While 30 minutes of pulselessness at normothermia is typically considered incompatible with functional recovery, there is no exact time interval for how long CPR must be continued. Therefore establishing exactly when, in the resuscitation process, the individual should transition from being a patient to a donor remains ill defined.[461]

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[460] Maeda, et al. "Death Following Spontaneous Recovery From Cardiopulmonary Arrest in a Hospital Mortuary" 86.

[461] Peter Groth and George Garnett, "Clinical Guidelines for Delayed/Prolonged Transport: 1. Cardiorespiratory Arrest," *Prehospital and Disaster Medicine* 6.3 (1991): 336.

For example, if paramedics respond to a cardiac arrest they will likely initiate basic life support (BLS) measures in the field and transfer the patient to the nearest emergency room for advanced cardiac life support (ACLS). If the patient remains unresponsive after a number of ACLS algorithms, the physician may declare death. Generally speaking, there is no harm in such a declaration, but because the Lazarus Phenomenon has been documented up to 10 minutes after the cessation of CPR, longer time intervals between the declaration of death and organ recovery for uncontrolled DCD would be mandated to prevent the possibility of inadvertent vivisection.[462]

More relevant to our discussion here is the prospect of auto-resuscitation in the controlled DCD donor. Despite repeated calls for data, no large-scale studies have been designed to address this issue.[463] Only one 2004 study by Wijdicks and Diringer has undertaken the incidence of auto-resuscitation prospectively, though the authors admit that their small sample could not be the final arbiter on the issue.[464]

Wijdicks and Diringer report twelve patients undergoing withdrawal of mechanical ventilation who had cardiac function monitored via ECG. The patients had moderate to severe neurologic injuries, with a Glasgow Coma Scale

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[462] Maleck. et al. "Unexpected Return of Spontaneous Circulation After Cessation of Resuscitation” 127.

[463] Wijdicks and Diringer, "Electrocardiographic Activity After Terminal Cardiac Arrest in Neurocatastrophes"673.

[464] Wijdicks and Diringer, "Electrocardiographic Activity After Terminal Cardiac Arrest in Neurocatastrophes" 673.

(GCS) score between 3 and 4.[465] The patients were monitored with an ECG for at least 10 minutes post cardiac arrest and 3 patients had arterial catheters in place. Two recordings showed a burst of 5-20 heartbeats 6 minutes after asystole but the arterial catheters in place in those patients did not register circulation, indicating that the cardiac activity was not strong enough to generate circulation. Four other patients demonstrated broad, undefined complexes after 5, 7, 9, and 10 minutes after asystole but did not show a recognizable rhythm. The authors note that though this cardiac activity was disorganized, their observations are in conflict with the IOM recommendations that call for "at least 5 minutes of asystole by electrocardiographic and arterial pressure monitoring."

Despite the fact that pump function sufficient to sustain circulation did not return in these patients, bursts of cardiac activity after 6 minutes of standstill as well as unrecognized rhythms up to 10 minutes after the initial cardiac arrest challenges the traditional understanding of *irreversible* cessation of cardio-respiratory function as required by the UDDA. Furthermore, it is unquestionably contrary to the IOM recommendation. This study mirrors older studies cited by UPMC, which will be discussed hereafter, in that it confirms that cardiac activity has often not irreversibly stopped after a declaration of clinical death. However, the study was far too small to serve as convincing evidence to prove that circulation will not resume after a specific time interval.

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[465] Wijdicks and Diringer, "Electrocardiographic Activity After Terminal Cardiac Arrest in Neurocatastrophes" 673.

The Glasgow Coma Scale is a bedside assessment tool that is used to measure the depth of coma as well as brain stem function. By testing motor and sensory function it is used to predict neurologic outcome. A low GCS indicates a poor prognosis with pronounced neurologic deficits.

UPMC established its 2-minute protocol years prior to the 2004 study and has been criticized for using data that are sparse and quite old, dating back from the early to mid twentieth century.[466] These studies report a total of 109 cases in which cardiac rhythms were charted via ECG before and after the diagnosis of clinical death. The studies were not specifically undertaken to chronicle the incidence of auto-resuscitation but to document the changes that occur in the dying heart, specifically to prove which part of the heart was the last to die, or the *ultimum moriens*.[467]

Similar to the Wijdicks and Diringer study, the case reports do not establish reliable data on auto-resuscitation, but they do reveal that death on cardiac criteria, ironically, does not ensure a dead heart. One study noted, “A very interesting observation was the fact that evidence of cardiac activity was registered by the electrocardiograph from six to thirty-five minutes after all the usual clinical signs of death had occurred.”[468] Another noted, “Unless otherwise

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[466] MA DeVita, et al. "Observations of Withdrawal of Life-Sustaining Treatment From Patients Who Became Non-Heart-Beating Organ Donors." *Crit Care Med*. 28.6 (2000): 1711; G. A. Van Norman, “Another Matter of Life and Death: What Every Anesthesiologist Should Know About the Ethical, Legal, and Policy Implications of the Non-Heart Beating Cadaver Organ Donor,” *Anesthesiology*, *98* (2003): 767.

[467] G. Canby Robinson, "A Study With the Electrocardiograph of the Mode of Death of the Human Heart," *Exp Med*. 16 (1912): 291-302; M.W. Stroud and H.S. Feil, "The Terminal Electrocardiogram: Twenty-Three Case Reports and a Review of the Literature," *American Heart Journal*. 35 (1948): 910-23; Fredrick Willius, "Changes in the Mechanism of the Human Heart Preceding and During Death," *Medical Journal and Record*. 119.Suppl (1924): 50-54.

[468] Willius, "Changes in the Mechanism of the Human Heart Preceding and During Death" 50.

stated, clinical death occurred sometime before the electrocardiographic tracing became flat.[469] The same study concluded,

> In human subjects, ventricular fibrillation is not necessarily a permanent event, as there are a number of case reports in which spontaneous return to regular rhythm has been noted. In the literature we reviewed, although no recoveries occurred, a small number of the patients returned to orderly ventricular excitation after the burst of ventricular fibrillation.[470]

The case studies do not explicitly state that circulation had been restored after a declaration of death; that is, they do not report auto-resuscitation, though they do show that at the time of clinical death, cardiac standstill had often not occurred as predicted. Ventricular fibrillation (VF) and electromechanical dissociation (EMD) are not the same as cardiac standstill, or asystole. VF occurs when the heart is writhing like a bag of worms but not pumping blood whereas EMD refers to disorganized electrical activity in a still, motionless heart.[471] Since

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[469] Stroud and Feil, "The Terminal Electrocardiogram: Twenty-Three Case Reports and a Review of the Literature" 910.

[470] Stroud and Feil, "The Terminal Electrocardiogram: Twenty-Three Case Reports and a Review of the Literature" 921.

[471] Personal communication David W. Crippen, M.D., April 2006.

circulation is contingent on effective cardiac pump function, it is possible, according to this argument, that the cardio-respiratory criterion can be met while the heart continues to retain some ineffective movement or electrical activity. In other words, the cardio-respiratory criterion can be met while the heart is in a dying process but not yet dead.

However, as we have seen, some have argued that the UDDA does not require asystole but that the irreversible cessation of cardio-respiratory function refers only to the cessation of circulation.[472] Thus, when circulation will not spontaneously resume and when interventions to restart it will not be implemented, death has occurred.

According to this interpretation, the cardio-respiratory criterion could still be met while the heart was in VF or EMD provided such conditions did not generate circulation.[473] This means that a declaration of clinical death and cardiac death are not necessarily coextensive nor is asystole required to declare cardiac death. It is not our task to resolve this issue though the term Donation After Cardiac Death implies that organs are removed *after* the heart is dead. The limited studies on auto-resuscitation do not indicate what period of time is necessary to foreclose the phenomenon; however, the data do indicate that the heart is, in many cases, not dead though in a dying process after 2-5 minutes of a clinical declaration of death using the cardio-respiratory criterion.

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[472] Bernat et al. "Report of a National Conference on Donation After Cardiac Death" *282*.

[473] Of note, the UPMC protocol does not require asystole but zero pulse pressure according to an arterial catheter. This means that the heart could be in either asystole, EMD or VF at the time death is certified.

To briefly recapitulate, the current data on auto-resuscitation do not establish how long an interval is required to exclude the phenomenon. Thus, it is impossible to make a determination as to whether a 2 minute or a 5 minute no-touch period is adequate at this time. However, auto-resuscitation is not the crux of the issue because the inability to auto-resuscitate does not make an individual dead. Rather, the inability to auto-resuscitate prognosticates death but it is not death itself, for even if it is proven that auto-resuscitation will not occur after 65 seconds of asystole, as DeVita argues, that has only satisfied the weakest construal of irreversibility.

Using a weak construal of irreversibility that declares death on the inability to auto-resuscitate is problematic since many people may suffer an injury from which they cannot auto-resuscitate, though they could be successfully resuscitated with an intervention. Adopting such an approach to irreversibility would mean that the many patients who suffer a cardiac arrest each year who are successfully resuscitated were dead but subsequently resurrected. This seems counter-intuitive at best, as such patients were not dead but clearly in a reversible dying process.

The inability to auto-resuscitate is not equivalent with death; it merely reflects a condition that may or may not be terminal. For example, if I am speaking at a medical meeting and I suffer a cardiac arrest from which I cannot auto-resuscitate, it is likely that one of the physicians will start chest compressions and perhaps even find a defibrillator. If I am successfully returned to normal sinus rhythm, clearly I was not dead and brought back to life but I was in a dying process that would have culminated in death without an intervention. If I am on a deserted island and I suffer a cardiac arrest from which I cannot auto-resuscitate the outcome is assured; I will definitely die. But the argument cannot be made that because I cannot auto-resuscitate and do not have access to an intervention (either because I refused it or because it is unavailable) that I am already *de facto* dead.

Moreover, there is a difference between dead and dying that ought not to be minimized. Edward Bartlett clarifies the distinction between irreversibly dead and irreversibly dying. He argues,

> Even though in the past there was nothing to be done to save the patient's life after having suffered, for example, a cardiac arrest or kidney failure, the patient was, at the time of the failure, dying and not dead. What could have been reversed was not, strictly speaking, death but rather the dying process. Death does not occur, however, until that process has been fully completed. Only then do we properly say that the patient is dead.[474]

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[474] Bartlett, "Differences Between Death and Dying" 273.

We must now turn to the prospect of manual resuscitation to support the claim that some DCD donors are not yet dead at organ procurement if they could be successfully resuscitated with an intervention. Successful resuscitation must be regarded as a moving target; that is, the ability to resuscitate an individual varies greatly depending on the circumstances and the co-morbidities in place. Since the majority of DCD donors will undergo withdrawal of mechanical ventilation (MV), a typical scenario would be to initiate palliative measures and to extubate the patient in the operating room. Depending on the patient's ventilatory drive, respiratory insufficiency will deteriorate to respiratory failure and ultimately culminate in cardio-respiratory arrest. Though the lungs may quickly fail, the heart will often continue to beat for a variable amount of time as it draws on its metabolic reserves; the heart will not immediately arrest simply because the lungs have ceased.[475] When the heart finally depletes its energy stores it is unable to sustain pump action. When this occurs, blood flow stops and the brain will lose consciousness between 10-15 seconds.

If circulation is restored (reperfusion) within a variable few minutes, brain function may be recovered, but how much functional recovery can be regained without neurologic sequellae is contingent on a number of different "fate" factors including: arrest time, resuscitation time, time interval between collapse to CPR, core temperature, age, sex, and baseline neurologic status.[476] Effective

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[475] Personal communication David W. Crippen, M.D., April 2006.

[476] Antonio E. Muniz, "Postresuscitation Cerebral Dysfunction: Prevention and Treatment in Contemporary Cardiology: Cardiopulmonary Resuscitation," eds. JP Ornato, and MA Peberdy (Totowa: Humana Press Inc, 2005) 523; R. O. Cummins, M. S.

management of the reperfusion process is essential, as neuronal damage predominantly occurs during this phase rather than during the cardio-pulmonary arrest itself.

During a cardiac arrest, circulation effectively ceases. CPR often generates a low-flow circulation, meaning there is some diminished amount of blood circulating though often not enough to sustain full brain metabolism, which requires, at the very least, 20% of normal cerebral blood flow.[477] CPR on its own then is not optimal for successful resuscitation.

In addition to restoration of blood flow through numerous techniques, temperature regulation has proven critical in cardio-pulmonary and cerebral resuscitation. Exactly how many minutes the brain can sustain complete global ischemia and still be resuscitable remains debatable.[478] The literature indicates a potential range anywhere between 5, 7, and 11 minutes for acceptable

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Eisenberg, A. P. Hallstrom, & P. E. Litwin, "Survival of out-of-hospital cardiac arrest with early initiation of cardiopulmonary resuscitation," *Am J Emerg Med*, *3*.2 (1985): 114.

[477] Muniz, "Postresuscitation Cerebral Dysfunction: Prevention and Treatment in Contemporary Cardiology" 525; K. A. Hossmann, "Resuscitation potentials after prolonged global cerebral ischemia in cats," *Crit Care Med*, *16*.10, (1988): 964-71; Cummins, et al "Survival of out-of-hospital cardiac arrest with early initiation of cardiopulmonary resuscitation," *Am J Emerg Med*, *3*.2 (1985): 114-19; P. Safar, S. A. Tisherman, W. Behringer, A. Capone, S. Prueckner, A. Radovsky, et al. "Suspended animation for delayed resuscitation from prolonged cardiac arrest that is unresuscitable by standard cardiopulmonary-cerebral resuscitation," *Crit Care Med*, *28.* 11 Suppl. (2000): N214-8; Groth and Garnett, "Clinical Guidelines for Delayed/Prolonged Transport: 1. Cardiorespiratory Arrest" 335-40.

[478] Hossmann, "Resuscitation potentials after prolonged global cerebral ischemia in cats" 964.

neurologic outcome depending on the types of resuscitative mechanisms utilized.[479]

> The currently accepted maximal period of time of normothermic no-flow that is consistently reversible to complete recovery of neuronal function is less than 5 minutes…The 5 minute limit is being challenged by observation that occasional animals or humans recover after 10 minutes of arrest time.[480]

This 5-10 minute time frame may be much longer, however, considering some animal studies, which have shown promising results with induced hypothermia. Recent studies have shown complete neurologic recovery in dogs and cats after 16-60 minutes of complete cerebral ischemia.[481]

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[479] Muniz, "*Postresuscitation Cerebral Dysfunction: Prevention and Treatment in Contemporary Cardiology: Cardiopulmonary Resuscitation" 529*.

[480] Muniz, "*Postresuscitation Cerebral Dysfunction: Prevention and Treatment in Contemporary Cardiology: Cardiopulmonary Resuscitation" 529*.

[481] A. Nozari, P. Safar, S.W Stezoski, X, Wu, J. Henchir, A. Radovsky, et al. "Mild hypothermia during prolonged cardiopulmonary cerebral resuscitation increases conscious survival in dogs*," Crit Care Med*, *32*.10 (2004):, 2110-16; F. Sterz, P. Safar, S. Tisherman, A. Radovsky, K. Kuboyama and K. Oku, "Mild hypothermic cardiopulmonary resuscitation improves outcome after prolonged cardiac arrest in dogs*," Crit Care Med*, *19*.3 (1991): 379-89; J. Lemler, S.B. Harris, C. Platt, and T.M. Huffman, "The arrest of biological time as a bridge to engineered negligible senescence*," Ann N Y Acad Sci*, *1019 (2004):*559-63; Hossmann, "Resuscitation potentials after prolonged global cerebral ischemia in cats*"* 964-71; R.C. Merkle, R. C. "The technical feasibility of cryonics*," Med Hypotheses*, *39*.1 (1992): 6-16; K.A. Hossmann, R. Schmidt-Kastner, and B. Ophoff Grosse, "Recovery of integrative central nervous function after one hour global cerebro-circulatory arrest in normothermic cat*," J Neurol Sci*, *77*.2-3 (1987): 305-20.

Since neurons require an uninterrupted supply of oxygen and glucose to maintain brain metabolism, mild to moderate hypothermia can improve cerebral outcome by facilitating a “metabolic ice box” for the brain.[482] That is, hypothermia offers a neuro-protective effect by cooling the core body temperature to induce a clinical state similar to suspended animation or torpor, whereby neuronal metabolic consumption is suppressed. By lowering oxygen consumption needs, the brain struggles less to obtain its normal requirements and therefore less damage ensues. Induced hypothermia is also thought to be beneficial in reducing other co-morbidities associated with ischemia and reperfusion including cardiovascular and hemodynamic disturbances, hyperthermia, and coagulopathy.[483] Accordingly, the recent literature indicates “The 5 minute limit for neuronal survival from normothermic arrest has been extended to 11 minutes with the use of a combination treatment regime.”[484]

The scientific data are clear that between 2 to 5 minutes following circulatory arrest, successful cardio-pulmonary and cerebral resuscitation is technically possible. Given the diverse population of patients undergoing DCD we cannot make a sweeping generalization that *all* DCD patients could be successfully resuscitated. It is clear, however, that modern resuscitation

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[482] P. Groth and G Garnett, “Clinical Guidelines for Delayed/Prolonged Transport: 1. Cardiorespiratory Arrest*,” Prehospital and Disaster Medicine*, *6*.3 (1991): 337.

[483] Muniz, “*Postresuscitation Cerebral Dysfunction: Prevention and Treatment in Contemporary Cardiology”* 580.

[484] Muniz, “*Postresuscitation Cerebral Dysfunction: Prevention and Treatment in Contemporary Cardiology”* 525.

techniques are capable of successfully resuscitating patients following much longer downtimes than previously experienced. Thus, far longer than 2-5 minutes must elapse before successful resuscitation can be foreclosed.

We have thus reviewed the scientific data showing that the phenomenon of auto-resuscitation has not been sufficiently investigated. There are no convincing data showing that it cannot or will not occur after 2-5 minutes of asystole, VF, or EMD. Also, we have presented data indicating that successful manual resuscitation certainly remains a possibility in this 2-5 minute interim as well. The term “successful” resuscitation must again be qualified. If a DCD donor could be resuscitated to exhibit *any* brain function that would preclude a diagnosis of whole brain death (pupillary constriction, or any other rudimentary brain stem activity), then it cannot be claimed that the donor has met the criterion for death as outlined in the UDDA.

According to the statute, circulation and respiration can only be discounted in the presence of *whole brain death*. Therefore, if a DCD donor were resuscitated in whom circulation and respiration could be restored, the patient could only be declared dead on neurologic criteria. It is quite possible however, considering the data presented, that brain function could be restored in the 2-5 minute interim following cessation of circulation. Brain physiology has consistently demonstrated that the brain does not die instantly upon circulatory arrest and some parts, particularly the brain stem, are quite hardy and can withstand prolonged periods of anoxia.

Using the statutory definition of death, it does not matter whether brain function is restored to a marginal state or to a fully functional state; in other words, the quality of neurologic recovery is not important. If a whole brain death protocol is not fulfilled then death cannot be declared in the presence of circulation and respiration, even if such functions are supported by artifice.[485] Following this argument then, many DCD donors would be able to be resuscitated to some degree of brain function after 2-5 minutes of asystole, EMD, or VF after a declaration of death using the cardio-respiratory criterion and therefore are in a reversible dying process and not yet irreversibly dead.

In chapter four we argued against this traditional biological definition of death in favor of an ontological approach that determines death when the individual has irreversibly lost the capacity for consciousness. The argument still holds, however, that after 2-5 minutes of asystole, EMD, or VF, the DCD donor could be resuscitated to a conscious state and therefore proves that the individual was not irreversibly dead. In sum, regardless of whether one subscribes to the traditional or to an ontological definition of death, some DCD donors are not irreversibly dead at the moment of organ recovery based on the fact that “successful” resuscitation, as specifically defined by each approach, remains a viable possibility. These arguments only hold, however, depending on how one interprets the concept of irreversibility itself. We must now move from a scientific perspective to a conceptual discussion to address the issue of irreversibility.

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[485] We can clearly see this distinction is made with the PVS patient. A person in PVS who requires mechanical ventilation is not considered dead despite massive neurologic injury and the need for artifice to maintain integration.

IV. Defining Irreversibility

We must again revisit the classic definition of death: the *irreversible cessation of the integrated functioning of the organism as a whole*. Irreversibility is a component of any definition of death since death is a state from which one cannot return; it represents finality, a terminus.[486] The UDDA is clear that an individual who has suffered either *irreversible* cessation of cardio-respiratory functions or *irreversible* cessation of all functions of the entire brain is dead. Unfortunately, the UDDA never defines irreversibility. Before we examine the relationship between the two criteria as outlined in the UDDA, we must address the fundamental question, when is death irreversible?

This question is generally polarized between two ideological camps. The first camp argues that death is irreversible when the individual cannot auto-resuscitate and when further interventions will not be initiated. This is a weak construal of irreversibility. The second camp argues that irreversibility is an empirical statement regarding what is or is not technically possible to reverse. This is a strong construal of irreversibility that is not contingent on a choice but on the ability to affect a particular outcome.

Both positions are fraught with conceptual difficulties. A weak construal of irreversibility does not draw a clear distinction between the actively dying and the newly dead. It implies that individuals who cannot auto-resuscitate are instantly dead and that a moral decision to refuse treatment necessarily ensures that the

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[486] Bartlett, "Differences Between Death and Dying" 270

clinical state of death has occurred. In contradistinction, a strong conception of irreversibility could mean that a condition may not be determined to be irreversible until every known intervention is applied; essentially a retrospective analysis of irreversibility that can only truly be proven upon putrefaction.

John Lizza, who argues for a weak construal of irreversibility, attempts to reconcile the difficulties by identifying three factors that determine the condition: 1) The physical state of the person, 2) Physical factors external to the person, 3) Individual and social decisions. He concludes that irreversibility is met when the first and second conditions can reasonably predict that functions will not resume.[487] Lizza's presentation, though ultimately flawed, is helpful in fleshing out these difficult issues.

Using Lizza's analysis, the physical state of the person determines irreversibility to the extent that if a condition causes irreparable injury to the heart or lungs (or brain for that matter), the person is said to be irreversibly dead. If, for example, a motorist is crushed by a semi tractor-trailer, causing massive internal injuries, the condition is irreversible regardless of available interventions. Physical factors external to the patient refer to the types of interventions available at the time of injury. Accordingly, a person alone in the wilderness, who suffers a cardiac arrest, is said to be irreversibly dead since there is no way to reverse the process given his isolation.[488] Individual and social decisions refer to the rights

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[487] Lizza, "Potentiality, Irreversibility, and Death" *58*.

[488] Lizza, "Potentiality, Irreversibility, and Death" *57*.

individuals have to refuse such interventions despite the fact that they may reverse a particular condition.[489]

Lizza's analysis is helpful in determining when a function may be irreversible but not in determining when the person is dead, as these may be different points on the spectrum. His first factor for determining irreversibility is the strongest; if the physical substrate is damaged to the extent that it cannot be reversed, the condition of irreversibility is fulfilled. His second and third conditions are less convincing, however. Alexander Capron asserts that the absence of an intervention in the wilderness, for example, means certain death can confidently be predicted, more so than if the patient were in the emergency room. However, the person in the wilderness is not instantly dead and the point at which time the condition becomes impossible to reverse remains the same.[490]

Edward Bartlett recognizes the problems in Lizza's position by clarifying, "As long as there are no serious doubts about the medical possibility of reviving these patients after two minutes of asystole the condition is clearly reversible and therefore cannot constitute death."[491] Accordingly, we do know there are different points upon a continuum indicating stages in which function is probably reversible, probably not reversible, and certainly not reversible.[492] How closely we wish to tread between these lines is at stake.

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[489] Lizza, "Potentiality, Irreversibility, and Death" *57*.

[490] Alexander Morgan Capron, "The Report of the President's Commission on the Uniform Determination of Death Act" Beyond Brain Death," (1988): 132.

[491] Bartlett, "Differences Between Death and Dying," *274*.

If we take the literal definition of irreversibility, it means "incapable of being reversed," which Jerry Menikoff argues, is not contingent on our *intent* to reverse something but rather on our *ability* or *inability* to affect the empirical world.[493] We have discussed how cardiac arrest was irreversible prior to effective CPR whereas now it may be a reversible condition. That we choose not to reverse a condition does not make it functionally irreversible—a moral argument does not determine the empirical state of irreversibility—though such inaction will lead to an irreversible condition and culminate in death.

The counter argument to this point and to our claims made above is that it does not matter that resuscitation is possible because the patient or family has already refused it and as such it would be unethical to initiate a procedure on someone who has proscribed it. While it is true that resuscitation would not be initiated against one's will, the fact remains that if it is possible, then the patient is clearly not yet dead but in a dying process, regardless of the moral prohibition.

The argument that irreversibility can be understood as a moral choice is unconvincing. This holds that if a patient would not authorize resuscitation, it is not "ethically significant" that resuscitation is possible.[494] As to whether a moral choice to forgo resuscitation means the individual is dead, Bartlett rightly responds, "The issue here is not whether there are persuasive reasons to

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[492] Van Norman, "Another Matter of Life and Death:" 767

[493] Jerry Menikoff, "Doubts About Death: The Silence of the Institute of Medicine," *Journal of Law, Medicine & Ethics* 26(1998): 158.

[494] Tomlinson, "The Irreversibility of Death" 162.

resuscitate them but whether or not they are dead."[495] Thus, simply because a patient refuses resuscitation it does not make him dead. Accordingly, Youngner and Arnold draw the analogy that UPMC's version of irreversibility would be akin to saying a car has suffered irreversible loss of engine function if the engine stops and does not restart itself within 2 minutes and one chooses not to take it to a mechanic.[496]

James Dubois argues that it does not matter that resuscitation is possible since death is a unified phenomenon where the brain begins to shut down as soon as cardio-respiratory function ceases and it will not resume function if treatment has been forgone.[497] In a sense, the brain is turned off and will not turn on because a moral decision has ensured it will remain off; thus the condition is irreversible. This interpretation carries with it interesting implications, however, when we consider the cardio-respiratory criterion and the neurologic criterion each being instantiations of the same phenomenon (death), as per the UDDA.

If the cardio-respiratory criterion can be said to be irreversible by moral choice then brain death must be also become a moral choice, as it is inconsistent to apply different standards of irreversibility to determine death. But the neurologic criterion for whole brain death only applies when it is impossible that the brain can regain any function, not when the decision is made to refuse

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[495] Bartlett, "Differences Between Death and Dying" 274.

[496] Youngner, Arnold, "Ethical Psychosocial, and Public Policy Implications" 2772.

[497] DuBois, "Is Non-Heart-Beating Organ Donation too Aggressive?"

treatment that can reverse a potentially reversible brain injury. That is, a WBD protocol can only begin once it is proven that the brain is irreversibly damaged to the extent that it cannot be fixed under any circumstances or with any available interventions. If death is a unified phenomenon, as Dubois claims, the cardio-respiratory criterion should not operate under a weaker sense of irreversibility. Clearly the assumption is that irreversible cessation of cardio-respiratory functions is not death itself but is a mechanism for death, in which all death is brain death. Following such an argument then, the patient cannot be dead until the brain is dead.

It is further noteworthy that DCD advocates rely on the argument that if the patient or family refuses resuscitation such refusal is sufficient to determine irreversibly because patient autonomy demands we respect the decision. Patient autonomy is given such weight that it overrides the clinical possibility that resuscitation could be successful; that is, even though cardio-respiratory function is not technically irreversibly lost, it would be inappropriate to override a DNR. However, a DNR can be overridden with family consent in order to initiate uncontrolled DCD if the situation arises. For example, if a patient suffers a traumatic brain injury with a poor prognosis the family may enact a DNR before WBD protocol is begun. In the event of a code, however, the family can suspend the DNR order and allow resuscitation in order to facilitate an uncontrolled DCD protocol.[498] Such a situation indicates that patient autonomy is not inviolate but is only important insofar as the needs of the transplant community determine it.

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[498] Helen M. Nelson, Jonathan P. Lewis, "Donation After Cardiac Death: Two Case Studies," *Progress in Transplantation* 13.4 (2003): 277.

Another perplexing issue that arises with the notion of irreversibility is the use of cardiac massage, extracorporeal membrane oxygenation (ECMO), and cardio pulmonary bypass, which have been used to restore perfusion during DCD procurement.[499] These procedures essentially reperfuse the organs in order to minimize the damage from ischemia that begins as soon as circulation stops. This ability to restart respiration (not ventilation) proves that the DCD patient has not suffered clinical *irreversible cessation of cardio-respiratory function* using either a strong or weak construal.[500] In order to avoid cardiac or brain perfusion it is standard when using these procedures to implement a balloon catheter to occlude the thoracic aorta. This allows blood flow within the abdominal cavity

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[499] Arnold, Youngner, "Time is of the Essence," 2913.

[500] Joseph Magliocca, John C. Magee, Stephen A. Rowe, Mark T. Gravel, Richard H. Chenault, Robert M. Merion, Jeffrey D. Punch, Robert H. Bartlett, Mark R. Hemmila, "Extracorporeal Support for Organ Donation after Cardiac Death Effectively Expands the Donor Pool," *Journal of Trauma* 58.6(2005): 1096; Arnold Robert M., Stuart J. Youngner, "Time is of the Essence: the Pressing Need for Comprehensive Non-Heart-Beating Cadaveric Donation Policies," *Transplantation Proceedings* 27.5(1995): 2913.

In 1993 the University of Maastricht declared death after five minutes of asystole after which mechanical ventilation and chest compressions were initiated while awaiting family consent to proceed with DCD. Clearly reperfusion after 5 minutes of asystole could lead to reanimation. Arnold and Youngner note, “These protocols raise the specter of a patient feeling pain or worse, regaining consciousness when cardio pulmonary function (and brain perfusion) are restored by mechanical means. Arnold, Youngner, "Time is of the Essence" 2914.

By 1995 the International Workshop on NHBD held in Maastricht recommended a ten-minute wait time before such procedures should be initiated. G. Kootstra, "Statement on Non-Heart-Beating Donor Programs," *Transplantation Proceedings* 27.5(1995): 2965. Much of Europe abides by the 10-minute rule under the argument that after 10 minutes of anoxia the brain is certainly dead. H.B.M. Wezel, A.J. Hoitsma, J.A. van der Vliet, R.A.P. Koene, "The Introduction of a Non-Heart-Beating Donation Program and the Medical Ethics Committee," *Transplantation Proceedings* 27.5(1995): 2927. This is a contentious issue, however, since cardio-pulmonary function has been restored after more than 10 minutes of circulatory arrest. See Van Norman “*Another Matter of Life and Death”* 767**.**

only, but if circulation continues, this disproves the claim that the loss of cardio-respiratory function has been irreversibly established.

The fact that the aorta must be occluded proves that the transplant team is aware that cardio-respiratory function is not irreversibly lost and they must ensure that brain perfusion, and therefore potential brain function, will not resume. Joanne Lynn and Ronald Cranford rightly note that if artificial circulation is implemented, one must rely on neurologic death since cardio-respiratory functions have clearly not been established as irreversible.[501] ECMO and/or cardio pulmonary bypass have been used throughout Europe, usually after a 10-minute wait after cessation of cardio-respiratory functions occurs. This may be less worrisome as the brain is probably dead after 10 minutes without perfusion, yet WBD should be assured before such a procedure is implemented.

The irreversibility debate remains unresolved. In an attempt to reframe the issue, James Bernat suggests replacing the term “irreversible” with the term “permanent.” He admits that DCD patients are not irreversibly dead when organ recovery commences since the DCD patient can be resuscitated; thus such patients are dying but not yet dead.[502] However, he argues that using the concept of permanence, in which a loss of function will not be returned, either spontaneously or with an intervention, is sufficient for the purposes of DCD. Bernat clarifies this by claiming that irreversibility is stronger than permanence

[501] Lynn, Cranford, "The Persisting Perplexities in the Determination of Death" 109.

[502] James L. Bernat, "Are Organ Donors After Cardiac Death Really Dead?" Unpublished manuscript (2005): 3.

since all functions that are irreversibly lost are necessarily permanently lost whereas all functions permanently lost may not yet be irreversibly lost. Since he claims that most deaths are certified when functions are permanently lost rather than irreversibly lost, however, the difference is inconsequential.[503]

The state of permanence then relies on an earlier judgment of irreversibility since once functions are permanently lost they will inexorably proceed to being irreversibly lost. He argues that this reliance on permanence is similar to how death is declared in the clinical setting; thus it reflects our ordinary determinations for declaring death. Bernat acknowledges the counter argument, however, which is that determinations of clinical death often occur after a significant amount of time has passed, between the time when the loss of functions is first discovered to the time it takes for a doctor to arrive and perform a clinical exam to the subsequent declaration of death. Thus, in the course of 'ordinary' clinical declarations of death, far longer than 2 or 5 minutes of asystole has elapsed.[504]

Bernat admits that using permanence probably violates the dead donor rule (DDR) but argues that an exception to the DDR may be justified in DCD for the following reasons: the DCD donor will be dead within a matter of minutes if he is not yet dead at 5 minutes of asystole; irreversible loss of cardio-respiratory function will follow permanent loss in the natural progression of events; the outcome of using a permanence standard over an irreversible standard is

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[503] Bernat, "Are Organ Donors After Cardiac Death Really Dead?" 6.

[504] Bernat, "Are Organ Donors After Cardiac Death Really Dead?" 8.

negligible; the patient or surrogate authorized removal of organs at such a point; organ donation is regarded as an altruistic goal; the IOM encourages DCD; and finally, the DDR was devised to prevent people from being killed for their organs but removing organs prior to death in the context of DCD is not the cause of the donor's death, rather removal of LST is the primary cause of death.[505]

Bernat argues that DCD does not cause or hasten death since death eventuates when the brain is dead (WBD), which occurs as a result of the cessation of cardio-respiratory function from the removal of LST. Accordingly, the brain's dying process is unaffected by the removal of organs; that is, it continues to die at a fixed rate regardless of organ removal. It appears that Bernat does not consider that removal of organs would hasten death in the context of successful resuscitation. If the underlying disease process is ALS, for example, and a ventilator is removed to allow respiratory failure to naturally ensue, removing vital organs before the brain dies does hasten death if it precludes successful resuscitation.

For example, if a patient with ALS was mistaken for a DCD donor, he could be successfully resuscitated (as Bernat admits) after 2 or 5 minutes of asystole

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[505] Bernat, "Are Organ Donors After Cardiac Death Really Dead?" 13.

Bernat seems to misunderstand the fundamental distinction between killing a patient versus allowing a patient to die. In his book, *Critical Care Ethics,* David F. Kelly explains that there is no moral imperative to preserve life at all costs. Rather, the individual may forgo treatments when they produce a quality of life that is no longer consonant with his or her goals despite the fact that such therapies could effectively sustain life. When the burdens of LST outweigh the benefits—as judged by the patient—LST is considered morally extraordinary, or optional treatment, and may be forgone. Forgoing LST is not an act of killing but allows the individual to die of the disease process rather than be supported indefinitely by artificial means. It is not the removal of LST that is the cause of death then, but the illness itself. See David F. Kelly, *Critical Care Ethics* (Kansas City: Sheed & Ward, 1991) 4-9.

(which makes the patient dying rather than dead) once the error was discovered. However, if organs were removed at 2 minutes of asystole and the error was discovered then, the prospect of successful resuscitation is no longer possible if vital organs have been removed. Thus organ procurement using DCD can cause the death of the patient. Bernat's argument heavily relies on the utilitarian justification that because death is imminent a patient may be regarded as dead. This is contrary to the current laws and normative rules that regulate organ donation.

We should, once again, take stock of what we have established. We have marshaled the scientific data indicating that the studies on auto-resuscitation have not been comprehensive or authoritative and have argued that the inability to auto-resuscitate is not a legitimate understanding of irreversibility. We have further argued that a legitimate definition of irreversibility cannot be determined on the basis of a decision to refuse treatment because it conflates a prognosis of death with a diagnosis of death. If cardio-respiratory function is not irretrievably lost, and the brain is not yet dead, the DCD donor cannot be dead but is in a dying process.

Moreover, we have established that manual resuscitation remains a possibility far longer than the 2-5 minute interval after a declaration of death using the cardio-respiratory criterion, which indicates that the patient is in a dying process but not yet dead. Further, the fact that DNR orders may be suspended if uncontrolled DCD is possible proves that irreversibility has not clinically occurred. We have also examined Bernat's suggestion to move from an irreversibility requirement to a permanent requirement though his position requires making exceptions to the DDR, which has consistently been rejected by the philosophical and transplant communities. We have certainly not solved the contentious problem of when irreversibility occurs, though we have demonstrated why the weak construal of irreversibility used for DCD is incompatible with our customary notion of death as a finality that cannot be reversed in theory or practice.

V. Heart-dead versus brain-dead

Having attended to the issue of irreversibility, we must now turn to the last conceptual issue pertaining to DCD, that is whether the cardio-respiratory criterion can be used as a legitimate criterion of death independently of the neurologic criterion. Advocates of DCD argue that the process is licit because it uses the cardio-respiratory criterion promulgated by the UDDA. They maintain that the UDDA allows either criterion to be fulfilled to declare death.[506] The UDDA does in fact state that death may be declared when *either* criterion is met. Thus, DCD is in accordance with the way the statute is written; death can be declared using the cardio-respiratory criterion without also ensuring that the WBD criterion is fulfilled.[507] However, if we accept a literal interpretation of the UDDA we are offered two disjunctive criteria to ascertain when death has occurred with

[506] James M. DuBois, "Is Non-Heart-Beating Organ Donation too Agressive?"

[507] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, "Defining Death: A Report on the Medical, Legal, and Ethical issues in the Determination of Death," (Government Printing Office 1981): 34.

no explanation of how they are related to one another. This raises several complex problems.

Robert Veatch identifies the crux of the issue when he notes that if a cardiac arrest can be called irreversible at 2 minutes then death does not require that brain functions must cease.[508] Recall the discussion in chapter three on necessary and sufficient conditions. It has been agreed that the criteria to fulfill the definition of death should be both necessary and sufficient, yet only the WBD criterion fulfills this.[509] Death can be declared in the presence of continued respiration and circulation provided the whole brain is dead whereas death may not be declared in the presence of continued brain function when circulation and respiration have irreversibly stopped. This reflects the notion that all death is brain death. If the heart and lungs are not prerequisites for life, and are not necessary to declare death, as the President's Commission claimed, a criterion that is not necessary for life or death cannot logically be used independently of the brain to declare death. Yet this is precisely what DCD requires.

As stated in the *New England Journal of Medicine*, **"**It is clear that a person is not dead unless his brain is dead. The time honored criteria of the stoppage of the heartbeat and circulation are indicative of death only when they persist long enough for the brain to die."[510] But dying takes time; as James

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[508] Robert M. Veatch, "Non-Heart-Beating Cadaver Organ Procurement," *Transplantation Proceedings* 29(1997): 3339.

[509]It is arguable of course, whether WBD is both necessary and sufficient for death using the traditional organismic account of death as we addressed in chapter three, but for our purposes in examining the UDDA we will assume that it is.

Bernat notes, "It takes considerably longer than a few minutes for brain and other organ systems to be destroyed from cessation of circulation and lack of oxygen."[511] Stated in 1993, the following still applies, "There are no empirical data proving that a patient who meets the Pittsburgh Protocol's criteria for cardio pulmonary death also meets neurological criteria for death."

The UDDA has been criticized as an inconsistent statute, yet Menikoff suggests the legitimacy of DCD cannot be applied retrospectively to the UDDA since "It is clear from this language that Capron and Kass were not contemplating declaring dead the NHBD on the operating table with warm skin, partially functioning brain, and perhaps even reactive pupils."[512] This implies that the UDDA drafters did not foresee such a situation in which a criterion may have been fulfilled but not the definition of death itself. This is probably because brain failure will result from prolonged absence of cardio-respiratory functions; thus it is a contingent criterion. All things being equal, when a patient irreversibly loses cardio-respiratory function he will *become* WBD, such that irreversible absence of either criterion instantiates the definition of death. The problem is that DCD prevents all things from becoming equal.[513]

Using the cardio-respiratory criterion it is possible (and in some cases likely) that the whole brain is not yet dead, which is morally and legally

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[510] W.H. Sweet, "Brain Death," *New England Journal of Medicine* 299(1978): 410.

[511] James L. Bernat, "A Defense of the Whole-Brain Concept of Death," *Hastings Center Report* 28.2 (1998): 20.

[512] Jerry Menikoff, "Doubts About Death" 160.

[513] Bartlett, "Differences Between Death and Dying" 275.

unacceptable. The motivation behind the dual criteria set forth in the UDDA was somewhat pragmatic in that because cardiac death had been used historically to determine death, it was easier to integrate WBD as another criterion rather than replace the traditional one. This was not only because the President's Commission did not wish to endorse a new concept of death, which we have seen and discussed at length in the previous chapter as its primary error, but also because most deaths can be determined using cardio-respiratory criteria.

Using cardio-respiratory criteria to declare death has not been problematic outside of DCD because WBD naturally occurs as a result of cardio-respiratory failure.[514] The brain does not die instantaneously, however; thus DCD intervenes during the process and removes organs often before the brain has had time to die completely. If the brain is not dead, or the critical parts thereof depending on whether one espouses a traditional or ontological view, the patient cannot be dead. The President's Commission has been clear that all death is brain death.

DeVita argues that the two criteria endorsed by the UDDA are complementary in that both need not be fulfilled to declare death. He argues, "Most brains cease to function before the heart stops, usually when the blood pressure gets very low, about 50 or so (normal is usually about 120 or so.)"[515] DeVita continues, "In addition, when circulation stops, brain function always

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[514] Veatch, "Non-Heart-Beating Cadaver Organ Procurement" 3340.

[515] Michael DeVita, Renee Fox, William Ritchie, "The Waiting Game: Organ Transplant Controversy," (1998) <http://www.pbs.org/newshour/forum/january98/organ2.html>.

stops within 12 seconds except in a very few specific situations which are impossible during non-heartbeating organ donation."[516]

It is difficult to accept the conclusion that the whole brain is dead simply because brain function stops at 12 seconds. Lynn argues that no one would suggest that two minutes of anoxia indicates that the brain has irreversibly ceased to function.[517] The brain may have stopped functioning (unless EMCO or bypass is initiated without aortic occlusion) yet a non-functional brain is not a dead brain. As Lynn further notes, not only is there inadequate evidence pointing to global loss of brain function on the basis of cessation of circulation, but the available evidence shows that it must be longer than a 2 minute duration.[518] This is especially relevant when one considers the neurologically intact DCD patient rather than a patient who retains some ventilatory drive but has extensive brain destruction.

Given the clinical data reviewed**,** it is arbitrary to select a number of minutes to precisely determine when death has occurred in all cases.[519] There is no clear consensus regarding how much time must elapse after cardio-respiratory functions have failed to declare death and begin organ

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[516] DeVita, et al, "The Waiting Game" <http://www.pbs.org/newshour/forum/january98/organ2.html>.

[517] Joanne Lynn, "Are the Patients who become Organ Donors under the Pittsburgh Protocol for "Non-Heart-Beating Donors" Really Dead?" *Kennedy Institute of Ethics Journal* 3.2 (1993): 175.

[518] Lynn, "Are the Patients who become Organ Donors under the Pittsburgh Protocol for "Non-Heart-Beating Donors" Really Dead?" 175.

[519] Youngner, Arnold, DeVita, "When is "Dead?" 15.

procurement.[520] Whether 2, 5, or 10 minutes have elapsed after cessation of circulation and respiration, irreversibility has likely not been established since resuscitation to a conscious state is theoretically possible. This does not become "ethically insignificant" simply because of a moral choice; a decision to forgo treatment does not ensure death at that moment; it simply ensures that death will inevitably occur.

In their position paper regarding DCD, The Society of Critical Care Medicine (SCCM) argues that the manner in which death is declared should not differ depending on whether one is an organ donor.[521] This would seem appropriate in order to guarantee that individuals are not being treated differently because of their donor status. The SCCM argues that if it is customary to declare most deaths on clinical exam, after observing two to three EKG screens without evaluating brain function, it is inconsistent to apply a longer observation time for DCD.[522] DeVita suggests that in a DNR patient it is sufficient to wait approximately 30 seconds after pulselessness documented by a central arterial catheter to declare death.[523]

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[520] Adrienne R. Boissey, J. Javier Provencio, Cheryl A. Smith, Michael N. Diringer, "Neurointensivists' Opinions about Death by Neurological Criteria and Organ Donation," *Neurocritical Care* 3(2005): 115.

[521] "Recommendations for Nonheartbeating Organ Donation: A Position Paper by the Ethics Committee, American College of Critical Care Medicine, Society of Critical Care Medicine," *Critical Care Medicine* 29.9 (2001): 1828.

[522] "Recommendations for Nonheartbeating Organ Donation: A Position Paper by the Ethics Committee, American College of Critical Care Medicine, Society of Critical Care Medicine" 1827.

[523] DeVita, Snyder, "Development of the University of Pittsburgh Medical Center Policy " 139.

But DCD donors are different and they are treated differently than other dying patients. For example, a DCD donor's death is manipulated to occur in a specific setting, cannulae are inserted, medications that do not benefit the patient and may hasten death are given, and bypass or EMCO with occlusion may be initiated as soon as death is declared. Thus it is disingenuous to suggest donor status is irrelevant when a similar patient dying on the ward would be managed quite differently. Further, a patient who dies on the ward is not at risk for bodily harm if the diagnosis of death is made a few minutes or seconds prematurely. Such a patient's entire brain will assuredly die from prolonged lack of circulation; but in controlled DCD enough time must elapse not only to ensure auto-resuscitation will not occur but also that the brain is dead, lest we risk procuring organs from the dying rather than the dead.[524]

The SCCM recommendations also argue that there is no physiological difference between declaring death at 2 or 10 minutes following circulatory arrest since resuscitation during such time could be successful, as we have discussed above.[525] They conclude that once return of spontaneous circulation has been ruled out, "no less than 2 minutes is acceptable, no more than 5 minutes is necessary."[526]

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[524] Veatch, "Non-Heart-Beating Cadaver Organ Procurement" 3340.

[525] "Recommendations for Nonheartbeating Organ Donation: A Position Paper by the Ethics Committee, American College of Critical Care Medicine, Society of Critical Care Medicine" 1827-28.

[526] "Recommendations for Nonheartbeating Organ Donation: A Position Paper by the Ethics Committee, American College of Critical Care Medicine, Society of Critical Care Medicine" 1828.

Further, the SCCM claims that if irreversibility is regarded as a state that is impossible to reverse even with an intervention, a much longer observation time will be needed since a heart can resume function after being excised from the body.[527] The Committee commits its most formidable error here, for the traditional definition of death is not based on the cessation of the heart or any one of the sum of the body's parts, but on the irreversible cessation of the integrated functioning of the organism as a whole; this is precisely why the heart can continue to beat in a WBD body, because it is in itself irrelevant. Thus, as Capron notes, by only relying on the cardio-respiratory criterion in DCD and not the brain, how can their position not be proven false when a heart from a DCD patient is successfully transplanted?[528] It cannot be both ways; either cardio-respiratory function is important in itself or it is important only as it pertains to brain status. The heart cannot be used as the sole criterion for death only to be transplanted into another body, thus negating any criterion of irreversibility and its relationship to the organism as a whole.

Ultimately, it does not matter if loss of cardio-respiratory function is irreversible; what matters in the definition of death is whether loss of *brain function* is irreversible, though how much and what parts are involved will depend on which definition one accepts. Until the brain is irreversibly dead the patient cannot be said to be dead. At the 2 or 5 minutes of asystole that DCD requires, it

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[527] "Recommendations for Nonheartbeating Organ Donation: A Position Paper by the Ethics Committee, American College of Critical Care Medicine, Society of Critical Care Medicine" 1827.

[528] Capron, "The Bifurcated Legal Standard for Determining Death: Does it Work?" 133.

is clear the brain is not yet dead according to the traditional WBD argument or the higher brain death (HBD) argument presented in the previous chapter.[529]

Relying on the UDDA to solve the problem is fruitless because it offers two disjunctive criteria to determine death and it was not written with the current procedures in mind. The cardio-respiratory criterion is manipulated to legitimize a practice that was not foreseen by its drafters and is used independently of the neurologic criterion, which violates the underlying argument that death is a unified phenomenon.

VI. Additional Procedural Concerns

We have exposed the many conceptual problems pertaining to DCD but there are, however, additional procedural issues that must be addressed. The literature is clear that DCD protocols not only differ nationally and internationally but also by institution within the same state, depending on which OPO and surgeons direct the transplant.[530] The lack of consensus on major procedural issues, such as how long one must wait to declare death, undermines the practice's credibility and the confidence necessary to sustain it. For example, a DCD donor could be considered alive under the Geisinger Medical Center protocol but dead and undergoing organ procurement at UPMC. If the Geisinger protocol declares death only in a severely brain injured patient undergoing DCD

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[530] Leda Heidenreich, Coordinator for Trauma Services and CORE Liaison for PMHS, confirmed that protocols are driven by the needs of the local transplant surgeons and regional OPO; hence the discrepancies between protocols within the same state. Personal communication Leda Heidenreich, RN, BSN January 2006.

after 5 minutes of asystole, whereas a neurologically intact DCD donor at UPMC can be declared dead after two minutes of asystole, and at PMHS after 4 minutes, DCD is little more than “death by protocol.”[531]

The Geisinger Medical Center DCD policy only accepts comatose, ventilator dependent patients with severe irreversible brain injury as candidates for DCD. This is evident from the title of their protocol “Rapid Organ Recovery in Terminally Ill Brain Injured Patients.”[532] Conscious, ventilator dependent patients are forbidden to undergo DCD and uncontrolled DCD is not permitted.[533] The policy states, “Whenever possible, attempts will be made to fulfill brain death criteria.”[534] Gregory Burke suggests the rationale for prohibiting conscious patients was based on the fact that the policy was designed for a limited population with serious brain injury that would approach, though not fulfill whole brain death criteria.[535]

Under the Geisinger protocol, withdrawal is ideally performed in the OR, where staff may prepare the body for organ donation prior to withdrawal of life support.[536] After consent is obtained a femoral arterial line is placed to detect blood and pulse pressure for the declaration of death. Only when death is

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[531] Renee C. Fox, "An Ignoble Form of Cannibalism:" Reflections on the Pittsburgh Protocol for Procuring Organs from Non-Heart-Beating Cadavers," *Kennedy Institute of Ethics Journal* 3.2 (1993): 237.

[532] Appendix C

[533] Appendix C.

[534] Appendix C

[535] Personal communication Greg Burke, MD, January 2006.

[536] Appendix C

regarded as imminent may five thousand units of Heparin be administered to the dying patient. Heparin is administered at such time because “At this point the issue is less the life of the patient, than the viability of the donor.”[537] This is a blanket order despite the fact that Heparin is an anticoagulant, which can hasten death in patients with cerebral hemorrhage, and is recommended only on a case-by-case basis according to the IOM recommendations.[538] Geisinger justifies its usage by arguing that such a small dose is unlikely to cause harm and larger doses have not indicated better outcome for organs.[539] It should be noted that five thousand units of Heparin is considered a therapeutic dosage and is less problematic than at other hospitals, UPMC and PMHS included, that give upwards of sixty thousand units.

The Geisinger protocol certifies death using the cardio-respiratory standard when there is zero pulse pressure via the femoral arterial catheter and any one of the following:

5 minutes ventricular fibrillation or

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[537] Appendix C.

[538] Institute of Medicine, “*Non-Heart-Beating Organ Transplantation”* 50.

[539] Appendix C. When asked why only five thousand units of Heparin were given, when other institutions give upwards of sixty thousand units, Burke maintained that high doses may in theory, and possibly in reality, hasten death. Accordingly, the Geisinger policy is written in such a way to prevent the specter of euthanasia. Further, Burke suggested that the scientific benefit of these agents in organ procurement was questionable such that lower doses of Heparin seem safe and could give some protection from organ ischemia/thrombosis. Personal communication, Greg Burke, MD, January 2006.

5 minutes of electrical asystole, (no complexes, agonal baseline drift only),

or

5 minutes of electromechanical dissociation.[540]

The DCD protocol does not continue if the dying process is protracted, generally considered longer than two hours, due to warm ischemic injury, which renders the organs unsuitable for transplant. Under such circumstances, the patient is transferred to the Intensive care Unit (ICU) or a private room where the dying process can conclude.[541]

The UPMC DCD protocol is radically different than the Geisinger protocol. It does not restrict candidacy to severely brain injured patients; any patient who is not contraindicated for donation in general (HIV positive, certain cancers, Hepatitis infection) may undergo DCD provided death is predicted to occur ideally within 1 hour.[542] This means that conscious patients on Left Ventricular Assist Devices (LVADs) or other neurologically intact patients such as those with Amyotrophic Lateral Sclerosis (ALS) for example, can be candidates for DCD.

UPMC allows ante mortem interventions that may cause pain that would require adequate analgesia and/or sedation provided the patient or family consents, such as insertion of a femoral arterial catheter. The Geisinger policy

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[540] Appendix C.

[541] Appendix C.

[542] Appendix A.

requires a femoral line as well, though candidates are unlikely to perceive pain given their neurologic status. Also, similar to the Geisinger policy, UPMC notes "Organ procurement may proceed only if the patient or surrogate agrees to organ procurement upon death of the patient and signs the appropriate consent form."[543] Though it is not explicitly stated, CORE will proceed with DCD despite family refusal if a donor card is located.[544] Heparin is also given as a blanket dose per "CORE routine," though unlike Geisinger, which gives five thousand units, UPMC administers a total of sixty-thousand units of heparin with fifty thousand units given *prior* to extubation and ten thousand units mixed into the first bag of perfusion flush.[545] In addition, the UPMC protocol calls for 100 mgs of thorazine, though their rationale for doing so is not provided.[546]

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[543] Appendix A.

[544] This is in accordance with the Uniform Anatomical Gift Act (UAGA) but whether this is ethically appropriate is disputed.

[545] Appendix A.

[546] It is curious that a neuroleptic drug used to treat psychosis and/or disordered thinking, which is not used during traditional withdrawals, is given as a blanket standing order in the UPMC DCD protocol. Michael DeVita suggested Thorazine might be used because it may have secondary vasodilator effects, which could theoretically improve graft function post transplant. When asked why UPMC did not simply use Phentolamine, a drug used specifically for vasodilation, DeVita maintained it is controversial because Phentolamine clearly decreases blood pressure and can certainly hasten death. DeVita noted, however, that those protocols that use Phentolamine (the University of Wisconsin for example) do so in very low doses, making it unlikely to hasten death, though equally unlikely to have any effect on organ function. Personal communication, Michael DeVita, MD, January 2006.

It would appear then that UPMC favors Thorazine, not for its antipsychotic effects, but for any vasodilation properties it may have in lieu of Phentolamine.

DeVita could not explain why ten times the therapeutic dose of Heparin is administered, but argues that Heparin, given within 20 minutes of death, will not cause or hasten death. This rationale is similar to the Geisinger policy that requires Heparin be given (at five thousand units) only when death is imminent. DeVita clarified that CORE does "suggest" dosages and the times drugs are to be administered, but he provides

Skin preparation and draping can also be undertaken ante mortem but not before the patient has become unconscious and unresponsive.[547] If death does not occur within two hours, DCD may be cancelled and the patient returned to the ICU. UPMC recognizes the need for greater specificity and sensitivity in diagnosing death when DCD is utilized. Thus, absence of a palpable pulse in a large artery is insufficient to declare death. The policy requires continuous EKG and pulse oximetry wherein

> 1) Absence of circulation must be documented by either absent pulse pressure via a femoral arterial catheter or echocardiogram showing absent cardiac contraction (the pulse pressure must be zero, or by definition the heart is beating); 2) the patient must be apneic and 3) the patient must be unresponsive to verbal and tactile stimuli. These three criteria must be simultaneously satisfied, and the patient must be

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Heparin when blood pressure falls below 80. It should be noted, however, that the protocol is not written in such a way, which raises the question of how variable DCD is depending on which attending physician oversees the process.

The protocol states “Medications which do not harm the patient and which are necessary for DCD/NHBOD to occur are acceptable. For example, Heparin, in the time frame being considered, is not harmful to the potential donor, makes organ donation possible, and may be given.” However, the protocol fails to note that anticoagulants are contraindicated in certain classes of brain-injured patients because they may hasten death by exacerbating brain hemorrhage. DeVita’s argument that high doses of Heparin are not proximally the cause of death in the imminently dying patient is corroborated in the literature (see Bernat et al, "Report of a National Conference on Donation After Cardiac Death," *American Journal of Transplantation* 6(2006): 283), but the UPMC protocol, as it is written, does not leave room for the attending physician to make a prudential judgment as to when it shall be administered.

[547] Appendix A.

> observed to satisfy those criteria continuously for a minimum of two minutes.[548]

The PMHS protocol is fashioned similarly to the UPMC protocol, though it requires a longer wait time before death is pronounced. The PMHS protocol requires a DCD candidate must be terminally ill or that death be considered imminent. It is similar to UPMC in that neurologically intact patients are appropriate candidates for DCD. The PMHS protocol requires ante mortem cannnulation since absent circulation is determined via a femoral arterial line but the protocol is silent on whether ante mortem medication is administered.[549]

The following criteria must be met for death to be declared using cardio-respiratory criteria secondary to DCD at PMHS:

1) Prompt and accurate diagnosis of cardiac arrest must be made

2) Cardiac arrest must be present for at least 4 minutes to establish firmly death and the loss of integrative unity of the donor

3) Cardiac arrest is strictly defined as all of the following four elements:

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[548] Appendix A

[549] This is because the protocol is considered an administrative policy; it does not indicate all medical or nursing practices regarding the DCD procedure. Leda Heidenreich confirmed that ten thousand units of Heparin are given to the DCD donor en route to the operating room and fifty thousand units given upon extubation. Personal communication, Leda Heidenreich, RN, BSN, January 2006.

It should be noted that again Heparin is written as a blanket order, contrary to the IOM recommendations that it should be considered on a case-by-case basis only.

a. Electrocardiographic criteria (either I or II)

   I. 4 minutes of electromechanical dissociation (EMD)

   II. 4 minutes of electrical asystole

b. Absence of pulse by arterial catheter with a pulse pressure of zero (0) mmHg or a lack of pulse by Doppler by two independent observers

c. Apnea

d. No response to noxious or physical stimuli

4) It is only after the passage of 4 minutes without any return of the above four (4) elements that a patient may be declared dead for the purpose of organ procurement.

We have presented three DCD policies in the commonwealth of Pennsylvania that describe how death is determined using the cardio-respiratory criterion and the variable no-touch waiting period necessary to rule out the possibility of auto-resuscitation, after which organ procurement commences. We have reviewed how policies differ according to institution, the regional OPO and transplant service, as well as according to the attending physician overseeing the process. The use of Heparin continues to be debated as well with no real consensus on when it should be given or at what dosage. Ante mortem drugs have been justified under the Principle of Double Effect (PDE), though it is arguable whether the PDE should be invoked when it is clear that the patient will not benefit but may be subject to harm for the sole purpose of a third party.[550]

Using David F. Kelly's description, however, the PDE can be applied to any moral dilemma in which both good and bad effects will result, some which are good and rightly intended and some that are bad but not intended.[551] Four conditions must be passed if an action is said to be morally legitimate. The first condition states that the act in itself must not be intrinsically evil. The second condition states that the evil effect is not the cause of the good effect (in other words the end may not justify the means). The third condition states that the evil effect is not intended but only tolerated. The fourth condition states that a proportionate reason must exist for performing the action in which ontic evil may result.[552]

Using this construct we will evaluate whether ante mortem drugs that may hasten death can be justified provided the intent is not to cause or accelerate death but to ensure organ viability post transplant.[553]

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[550] M.D.D Bell, "Non-HeartBeating Organ Donation: Clinical Process and Fundamental Issues," *Journal of Anaesthesia* 94.4(2005): 478.
The counter argument can be made, however, that persons can consent to partake in medical experimentation despite the fact that they will not directly benefit but will be subject to some amount of risk. Some degree of risk, however, is not the same as potentially accelerating the dying process for secondary gain, but this is not something we can address here; for further reading on consent and experimentation see *Hastings Center Report* September/October 2005.

[551] David F. Kelly, *The Emergence of Roman Catholic Medical Ethics in North America* (New York: The Edwin Mellen Press, 1979) 247.

[552] Kelly, *The Emergence of Roman Catholic Medical Ethics in North America* 247-252.

[553] The issue of intent is ambiguous, however, as some authors have suggested that patients or their surrogates may authorize medication that may hasten death for that

It is clear that administering Phentolamine passes the first condition since there is nothing morally evil about giving such a medication. The second condition requires the bad effect (loss of blood pressure thereby hastening death) not cause the good effect (post transplant organ viability). It would seem this second condition is fulfilled since a lethal decrease in blood pressure is not the proximate cause of organ viability status post transplant. The third condition is fulfilled if a lethal drop in blood pressure is not intended in order to remove organs, but accepted as an unintended side effect. The fourth condition stipulates a proportionate reason must exist to perform the act.

This last condition is perhaps harder to justify than the first three since providing medications that are not for the patient's benefit and may hasten death, even if not for the primary purpose of removing organs, may cause disproportionate harm to the doctor-patient relationship, transplantation programs, and sully the professional image of physicians as willing to scavenge the living if utility is served.[554] Furthermore, there is little evidence-based medicine to show that Phentolamine necessarily improves organ outcome; thus the likely harms may far outweigh the possible benefits.[555]

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very purpose: "If the patient does not die within one hour the patient is returned to the floor and is not a candidate for organ donation due to the prolonged warm ischemic time. This is one reason why some donors or their families may opt for the use of Heparin or Phentolamine so that death would occur within the one hour time frame and the opportunity to donate organs would not be lost" Peter A. Clark, Uday Deshmukh, "Non-Heart Beating Organ Donation and Catholic Ethics," *National Catholic Bioethics Quarterly* 4(2004): 544.

[554] Van Norman, "Another Matter of Life and Death" 766.

[555] Personal communication Greg Burke, MD, January 2006; Personal communication Michael DeVita, MD, January 2006.

VII. Conclusion

In our attempt to determine what constitutes death and when it occurs, we began with an historical examination of how death was determined from the 18th century to the modern era. Chapter one focused on the misdiagnosis of death, instances of premature burial, macabre devices that were created in order to indicate or prevent live interment, and medicine's reputation for quackery and incompetence.

Chapter two chronicled the scientific advancements that restored medicine to a respected endeavor. In the modern era, technologically sophisticated tools including the stethoscope, thermometer, ophthalmoscope, and fluoroscopy were developed which could more accurately determine when death occurred. Such measures obviated the barbaric tests of the past, including applying a hot iron to the soles of the feet, incising the chest to manually feel the heart, or piercing the medulla to ensure death.

Ironically, however, as science progressed, specifically with the advent of organ transplantation and resuscitation, the tests for death became ambiguous once again. It became clear that heart and lung function was not the deciding factor in determining death, as such functions could be substituted by medical intervention. Further, effective CPR could reanimate those who had suffered conditions previously thought to be irreversible, thus prompting the issue of when is 'dead' ever really dead? As technology improved, and mechanical ventilation became widely available, individual organs and hemodynamic systems could be maintained indefinitely despite an illness or injury that could not be cured or reversed. While such patients were languishing in a state of life-in-death on machines, a new definition of death was endorsed.

Chapter three explored the conceptual basis of whole brain death (WBD), introduced in 1968. This chapter focused on how WBD was promulgated without any justification for why a dead brain ought to be equated with a dead human being, examined the many neurologic functions that may persist despite a declaration of WBD, and argued that the brain is not the sole integrator of the organism as a whole. Chapter three concluded that *whole* brain death may actually be a misnomer, and that WBD patients are not dead according to the traditional integrated functioning argument. This prompted us to question precisely what parts or functions were considered important in equating a dead brain with a dead human being and the possibility that some parts or functions were more important than others.

Chapter four argued for an ontological rather than an organismic account of death in which the death of a human being is not determined solely by the loss of its organic properties but on the loss of that which is essential to the nature of the human person, which I determined to be consciousness or personhood. Admittedly consciousness is difficult to quantify, but the aim of the chapter was to endorse a more conceptually sound framework for death since WBD is internally inconsistent and clinically dubious. Higher brain death (HBD) was suggested as a more coherent approach, although we noted the diagnostic weaknesses of tests to quantify higher-brain functions, which preclude moving to such a position at this time. A compromise was reached in which a HBD definition could be used with WBD as the criterion to fulfill it since all those who meet WBD are necessarily HBD. Accordingly, I concluded that WBD patients are dead but not for the traditional reasons espoused.

This final chapter evaluated Donation After Cardiac Death in order to determine whether it is a legitimate practice or if organs may be removed from the dying rather than the newly dead.

As reiterated at the National Conference on Donation After Cardiac Death, the fundamental axiom of organ donation is the preservation of the DDR.[556] We have presented clinical and philosophical evidence that DCD protocols violate the DDR by conflating a prognosis of death with a diagnosis of death, by relying on an unreasonable account of irreversibility, and by solely relying on the cardio-respiratory criterion, which is neither necessary nor sufficient for death.

Furthermore, we demonstrated that whether one subscribes to a WBD or a HBD concept is irrelevant to the legitimacy of DCD since it is clear that reanimation often remains possible at the moment of organ procurement. The fact remains that we do not know the exact moment when a human being transitions from life to death, but we accept that there is a distinction between the state of death and the process of dying, the former being an irreversible state while the latter may or may not be irreversible.

Advocates for DCD interpret the UDDA to support the claim that DCD is licit practice. Upon examination, we have shown that this literal understanding of

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[556] James L. Bernat et al. "Report of a National Conference on Donation After Cardiac Death" 281.

the UDDA also supports the counter intuitive claim that a human being can be dead regardless of neurologic status. A technical reading of the statutory definition of death ought not legitimize a practice that is both medically and philosophically contrary to our traditional understanding of what it means to be irreversibly dead. Finally, we reviewed the procedural differences in DCD protocols within one geographic region and discussed the problems associated with such variability, including the ethical implications of administering medications that may hasten death.

In this dissertation I challenged the traditional definition of death, *the irreversible cessation of the integrated functioning of the organism as a whole,* as biologically reductionistic and further claimed that the whole brain death criterion does not satisfy it. I suggested we move from an organic to an ontological understanding of death. In so doing I endorsed an ontological definition of death as the irreversible loss of the capacity for consciousness with the understanding that biological integration may continue in the absence of a human life. I exposed the clinical problems in testing for the irreversible loss of consciousness and argued that a WBD criterion should be maintained until such clinical confidence can be established.

This work has now come full circle with the examination of DCD in which I have formulated and defended the position that such patients may not be dead according to a traditional or to an ontological understanding of human death. Organ transplantation is a vital field that can often save or dramatically improve the quality of human life. It can only continue if the public supports it and if the public is confident that the normative rules and guidelines that have been implemented are upheld. At this juncture, DCD is likely an unknown procedure to the general population and it may continue without public debate. There is also the possibility, however, that these conceptual issues will eventually be addressed in a public forum. If society concludes, as I have argued, that some Donation After Cardiac Death patients are not yet dead at the moment of organ recovery, the field of transplantation may suffer reprisals that could cripple or endanger its viability. In order to safeguard against this possibility, DCD ought to be suspended until these issues are publicly resolved.

The purpose of this dissertation was to analyze the bio-philosophical literature on the definitions and criteria of death in order to evaluate whether DCD is a legitimate method for organ procurement. We conclude this work having argued that the traditional biological definition of death is fraught with scientific and conceptual difficulty; an ontological definition is more theoretically sound; and some donors who undergo Donation after Cardiac Death may not be dead according to either account.

Appendix A

UPMC PRESBYTERIAN SHADYSIDE
POLICY AND PROCEDURE MANUAL

POLICY: MS-03
INDEX TITLE: Medical Staff

SUBJECT: Donation after Cardiac Death (DCD) / (Non-Heartbeating Organ Donation) (NHBOD)
DATE: March 2, 2005

I. POLICY

It is the policy of UPMC Presbyterian Shadyside (UPMCPS) to strive to provide a policy that respects the rights of patients to have life support removed and to donate organs if they wish to do so. The UPMCPS presently has a policy regarding guidelines on life-sustaining treatment (UPMC Policy No. HS-PS0506). Patients or their surrogates can decide to forgo life-sustaining treatment, and the guidelines authorize comfort measures for patients wishing to forgo such treatment. Furthermore, all patients have the right to elect organ donation in the event of their death. For the last 30 years, the great majority of organ donors have been persons declared dead by brain death criteria. However, donation by persons who die from cardiac or respiratory failure is legal and was a commonly accepted practice before brain death criteria were established. The UPMCPS believes that it is ethically appropriate to consider organ procurement from non-heartbeating donors.

II. MANAGEMENT OF TERMINALLY ILL PATIENTS WHO MAY BECOME ORGAN DONORS AFTER DEATH

A. Principles

1. Decisions concerning the treatment and management of patients (including but not limited to the decision to withdraw mechanical support and/or medications) must be made separately from and prior to discussions of organ donation. This means that appropriate candidates for withdrawal of life support shall be identified independently of donor status. Decision about and consent for organ donation should be made independent of any decision about removal of life sustaining treatment in accordance with UPMC Policy No. HS-PS0506, "Guidelines on Life-Sustaining Treatment". Organ donation may be an important option for the patient and/or patient surrogate.

However, patient and family harm can result if the timing of a discussion about organ donation is inappropriate.

Consequently, health care professionals familiar with the concerns of the patient's family must use their judgment to determine when to recommend a discussion of organ donation whether raised by the patient, family or not. The health care team should consult with a representative of the Center for Organ Recovery and Education (CORE) to determine suitability for organ, tissue and eye donation prior to speaking with the family about organ donation, consistent with the Organ, Tissue and Eye Donation policy.

2. It is the health care professional's primary responsibility to optimize the dying patient's care. The process of removing life support shall be done primarily to promote patient comfort and respect patient autonomy. It is an important objective of this policy that the interest in procuring organs does not interfere with optimal patient management.

3. Appropriate candidates for organ donation shall be limited to those patients on life-sustaining treatment in whom withdrawal of that therapy is likely to result in death within an hour (e.g., patients who are respirator or intra-aortic balloon dependent).

4. Interventions intended to preserve organ function but which cause discomfort to the patient should be performed only after patient or surrogate consent, and should be limited to the procedures acknowledged in this policy.

5. This policy explicitly prohibits any intervention whose primary intention is to shorten the patient's life in accordance with UPMC Policy HS-PS0506, Guidelines on Life-Sustaining Treatment.

6. Utmost attention and caution shall be taken to protect the dignity and rights of donors.

7. Health care professionals shall not be required to participate in the procedures described below if such participation is against their personal, ethical, or religious beliefs.

8. In this policy, the term "surrogate" decision maker is defined as specified in the Patient Consent policy and UPMC policy Guidelines on Life-Sustaining Treatment (UPMC Policy HS-PS0506).

B. Procedures

1. The detailed discussion of organ donation shall be deferred until after the decision to withdraw life support has been reached. An agreement between the patient or patient surrogate and the attending physician that the patient is assigned the status of "comfort measures only" (as described in the Guidelines on Life-Sustaining Treatment (UPMC Policy HS-PS0506) is required for the patient to be considered an organ donor according to this policy. The discussions with the patient or patient surrogate, leading to the decision to withdraw all life-sustaining therapy, must be appropriately documented in the medical record.

2. After it has been decided to withdraw life support, and if a discussion of the option of organ donation has not been initiated by the patient or patient surrogate, the health care professionals should consult with a representative of CORE to determine suitability for organ, tissue and eye donation, consistent with the Organ, Tissue and Eye Donation policy. Drawing blood for testing to determine medical eligibility may occur after either the decision to withdraw support, or a consent to donate organs. If a patient is not eligible for organ donation CORE should be called for possible cornea and tissue donation in agreement with the required referral law and the Organ, Tissue and Eye Donation policy.

3. Organ procurement may proceed only if the patient or patient surrogate agrees to organ procurement upon death of the patient and signs the appropriate consent form. Consent for donation can be withdrawn at any time. No pressure or coercion shall be used to maintain consent.

4. Organ procurement may proceed only if, prior to signing the appropriate consent form, a member of the Ethics Consultation Service has been contacted and has reviewed and approved the case.

5. If any member of the health care team perceives an ethical problem, he or she is encouraged to notify the ethics consultant.

6. The administrator-on-duty (AOD)/off shift supervisor shall be notified that organ procurement from a non-heartbeating donor is being contemplated.

7. Appropriate support will be provided for the patient, surrogate, or family by the health care professionals. Discussion should take place with the family regarding whether they wish to be present at the moment of the patient's death. If organ donation is agreed to, health care providers should also discuss with the family their wishes regarding seeing the patient after organs have been procured. Pastoral care of the patient, surrogate, or family shall be provided by clergy, if requested.

8. The patient's attending physician(s) must agree with the proposed procedure and this should be noted in the chart.

9. The responsible anesthesiologist or his or her designee (e.g., anesthesiologist in charge or on call) will be informed of planned withdrawal of life sustaining treatment in the O.R. and the possibility of organ procurement.

10. The responsibilities of the ICU physician withdrawing support include the following:

    a. Review of the informed consent procedure to ensure that it has included discussion with the patient or patient surrogate of the following:

        - the UPMCPS's current policies regarding patients for whom the goal of care is comfort measures only;

- the process of removal of life-sustaining therapy;
- the process of organ procurement from non-heartbeating donors;
- that withdrawal of life-sustaining therapy may be completed in the operating room or the O.R. holding area;
- that a femoral arterial catheter or echocardiogram is required;
- that while death is expected during or shortly after discontinuation of life support, removal of support may not always lead to death of the patient in a very short time;
- that organs will not be procured until after the patient is declared dead;
- based on the medical judgment of the transplant surgeon, that organs designated for donation may not be procured if certain problems occur (e.g., due to ischemic injury);
- that death will be certified in accordance with existing Pennsylvania law; and
- that consent can be withdrawn at any time without cost or prejudice.

The physician withdrawing life support is also responsible for answering any questions the patient, family, or surrogate may have.

b. Deciding when to initiate transfer of the patient to the O.R.

c. Managing the patient's care with the assistance of an ICU nurse in the O.R. or holding area.

d. Informing the surgeon when it is acceptable to start surgical preparation of the patient's skin (see Section B, #17 of this policy).

e. Certifying death. The physician certifying death must not be involved either in procuring organs or the care of any of the transplant recipients. Completion of the death certificate and death summary in the medical record are the responsibility of the primary clinical service/attending physician.

f. Filling out and signing the Non-Heartbeating Organ Donor (DCD/NHBOD) record (Form 2013 A & B) jointly with the ICU nurse.

g. Notifying the coroner's office according to hospital procedures for deceased patients.

11. The following criteria shall be used for selecting the supervising ICU staff physicians:

a. The physician must attend in an ICU.
b. The physician must have familiarity with the UPMC Policy HS-PS0506, <u>Guidelines on Life-Sustaining Treatment</u> and this policy.
c. The physician must have personal experience with termination of life support, and specifically with removal of life support from patients who have been designated "comfort measures only."
d. The physician shall have no current clinical responsibilities on a transplantation service, or be caring for potential recipients of organs from the patient who may become a DCD/NHBOD.
e. Physicians allowed to manage patients for DCD/NHBOD shall be designated by the Chief of the service and/or a UPMCPS appointed credentialing committee.
f. ICU physicians who have any other basis for conflicts of interest in individual cases shall decline or not be asked to participate in withdrawal of life support and certification of death.

12. The surgical staff responsible for organ procurement shall in no way participate in the weaning process or in the donor's care, with the exception of vascular catheter insertion, if specific consent is provided by the patient or the surrogate decision maker. (This catheter may be placed by other physicians who are privileged to perform this procedure). It is preferable that the operating team not be present in the O.R. until certification of death except for skin preparation and draping as in Section II, B, #17 of this policy.

13. Anesthesiologists who later might be involved in the management of recipients of the donated organs shall not participate in the weaning process or other forms of the donor's medical management. During transport to the O.R. and during terminal management, all equipment (e.g., for assisted ventilation and monitoring) and drugs (e.g., sedatives and narcotics) shall be brought from the ICU. Technical support, including oxygen, compressed air, and suction equipment may be provided by any anesthesiology staff.

14. If narcotics and sedatives are administered, these drugs must be titrated to the patient's need for provision of comfort. The administration of clinically appropriate medications in appropriate doses to prevent discomfort is acceptable, with titration of medication predicated on signs compatible with distress.

15. Interventions intended to preserve organ function but which cause discomfort to the patient or hasten death are prohibited with the following exceptions.

    a. Medications which do not harm the patient and which are necessary for DCD/NHBOD to occur are acceptable. For example, Heparin, in the time frame being considered, is not harmful to the potential donor, makes organ donation possible, and may be given.

b. Interventions permitted include placement of arterial and venous cannulae. Such cannulae may be used for monitoring of circulation before death. Alternatively they may be used to infuse organ preservation solution AFTER the patient's death has been certified. If required, and after consent by the patient or surrogate, the cannulae may be placed by a member of the transplant procurement team.

16. If organ ischemia is prolonged (e.g., beyond two hours), it may not be possible to utilize organs designated for donation, and procurement may not be performed. The decision to cancel organ procurement because of prolonged ischemia rests with the responsible transplantation surgeon. Under these circumstances, the designated ICU physician may also decide to return the patient to the ICU.

17. No organs may be procured until death has been certified. To keep warm ischemia time to a minimum, all other appropriate preparations for the procurement operation may take place prior to death but never before the patient has become totally unconscious and unresponsive to noxious or painful stimuli. Skin preparation and draping may be performed, if approved, by the Critical Care physician.

18. <u>Certification Of Death.</u> The prompt and accurate diagnosis of death is extremely important. Procurement of organs cannot begin until the patient meets the cardiopulmonary criteria for death, that is, the irreversible cessation of cardiopulmonary function. The irreversible cessation of cardiac function is "recognized by persistent cessation of functions during an appropriate period of observation."[1]

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[1]Report of the medical consultants on the diagnosis of death to the President's commission for the study of ethical problems in medicine and biomedical and behavioral research. Guidelines for the determination of death in the President's commission for the study of ethical problems in medicine and biomedical and behavioral research. Defining Death: medical, legal and ethical issues in the determination of death. 1981:162.

Because of obvious concerns regarding conflict of interest, the criteria to be used in this policy are therefore more stringent than the standard clinical practice for declaring death in other patients who are designated "comfort measures only" but who are not candidates for organ donation. Clinical definitions of cardiac arrest, such as the absence of a palpable pulse in a large artery (i.e., the carotid, femoral, or brachial artery), do not suffice in the setting of DCD/NHBOD. The absence of a clinically palpable pulse does not necessarily mean cessation of circulation or mechanical activity of the heart. Thus more sensitive and objective monitoring must occur as described in the following paragraph. In addition, continuous EKG and pulse oximetry are required. The physician should regularly document the rhythm and saturation of the patient.

<u>To diagnose death by cardiopulmonary criteria</u>: 1) absence of circulation must be documented either by absent pulse pressure via a femoral arterial catheter or by echocardiogram showing absent cardiac contraction (The pulse pressure must be zero, or by definition the heart is beating); 2) the patient must be apneic and 3) the patient must be unresponsive to verbal and tactile stimuli. These three criteria must be simultaneously satisfied, and the patient must be observed to satisfy those criteria continuously for a minimum of two minutes.

19. Immediately after certification of death, organ procurement is to proceed following CORE protocol.

20. The procedure for organ procurement, cleaning of the body, and transfer to the morgue is to be conducted with respect and sensitivity to the deceased and his or her surrogate. This is the responsibility of the CORE.

21. Procured organs from non-heartbeating donors shall be distributed in accordance with current UPMCPS policies and United Network for Organ Sharing (UNOS) requirements.

22. Donor patients will not be charged for the costs of organ procurement (e.g., the use of the O.R., special personnel, or medications used in the O.R.).
23. Cases will be reviewed by the chairperson of the Medical Ethics Committee or designee. The responsible ethics consultant, ICU physician withdrawing life support, ICU nurse, and transplant surgeon or designee will be expected to provide a verbal or written report in whatever detail appropriate at the request of the ethics committee. The physician withdrawing support and the ICU nurse will both sign the records indicating clinical observations and medications administered. The purpose of this review is to:

    a. assure that the above principles are adhered to;
    b. assure that the above procedures are complied with;
    c. identify problems and complications, potential or actual, and recommend changes toward their solution;
    d. protect the interests of the donor, recipients, the UPMCPS, and involved health care workers; and
    e. assess the effect of these procedures on the family's grief process and determine whether changes could be made to improve the process for them.

III. PATIENTS UNDERGOING "BRAIN DEATH PROTOCOL" WHO ARE PRONOUNCED DEAD USING CARDIAC CRITERIA

A. Individuals who are in the process of having death declared using neurologic criteria may become non-heartbeating organ donors if:

1. consent for organ donation has been obtained from the patient or patient surrogate; and/or

2. the patient has been pronounced dead by a physician not on the transplant team using accepted cardiac criteria.

SIGNED: Andrea Schmid
Vice President, Patient Care Services

Tami Merryman
Vice President, Patient Care Services

ORIGINAL: May 7, 2003
REVIEW MONTH: May
Policy Review Committee: March 2, 2005
Medical Executive Committee: March 17, 2005/April 6, 2005
PRECEDE: May 7, 2003
SPONSOR: Chair, Medical Ethics Committee

Attachments

(ATTACHMENT)

GUIDELINES FOR REMOVAL OF LIFE-SUSTAINING SUPPORT IN TERMINALLY ILL PATIENTS WHO MAY BECOME ORGAN DONORS AFTER DEATH

I. GOALS:

1.1 Humane removal of life support.
1.2 Provision of comfort for all dying patients, without direct intention to cause death.
1.3 Promote quality of care.
1.4 Achieve accountability.

II. SPECIFIC GUIDELINES AND CORRESPONDING RATIONALE:

GUIDELINES		RATIONALE	
2.1	Patients will receive comforting medication only for demonstrated need, e.g., this could either be PRN medications or a fixed dose of narcotics for documented signs compatible with pain or other discomfort.		Refer to UPMC Policy HS-PS0506, Guidelines for Life-Sustaining Treatment
2.2	Although a drug is given with the primary intent of assuring patient comfort, it is recognized that the drug may have a secondary (unintentional) effect of hastening death. The justification for each intervention must be noted in the patient's record.		Refer to UPMC Policy HS-PR0506, Guidelines for Life-Sustaining Treatment
2.3	No physician may purposefully deliver or order administration of any medication with the primary intent of hastening or causing death, since this is strictly prohibited by law.		Refer to UPMC Policy HS-PS0506, Guidelines for Life-Sustaining Treatment
2.4	All patients who manifest objective evidence of stress or discomfort will be given comforting medication, unless there is proof that the patient cannot interpret these sensations.	2.4	There will be conscious patients who clearly can sense discomfort (e.g., patients with amyotrophic lateral sclerosis), and those who clearly cannot (e.g., cortical death). Clearly all patients who express discomfort should be treated. However, there is a continuous spectrum between those patients who clearly cannot sense discomfort and those who clearly can. Therefore, in order that no patient will suffer discomfort, all patients in whom cortical death has not been confirmed must be treated for objective evidence of discomfort. Examples of objective evidence compatible with discomfort include (but are not limited to) tachycardia, tachypnea, gasping or use of accessory respiratory muscles.
2.5	The ICU staff physician will titrate dosing of medication.	2.5	Each patient is an individual and his or her response to therapy is not reliably predictable. Some patients will be sensitive, others tolerant.
2.6	The ICU staff physician will adjust the removal of all life support in a sequence and rate that best serves the patient.	2.6	By decreasing the ventilator (or other life support) setting only when the patient is comfortable, it is less likely that the patient will have distress at the next lower ventilator setting. The timing and size of the decrement can be varied, but the patient shall be evaluated for distress prior to proceeding to the next level of support.
2.7	Neuromuscular blockade must be documented to have worn off or been reversed prior to initiating removal of mechanical ventilation.	2.7	See Rationale 2.8.

2.8	Prior to initiating weaning, the ICU physician will verify that the patient is not receiving substantially more medication than needed to provide comfort. Continuous, stable infusions of narcotics or sedatives are not contraindicated if one of the following criteria are met:	2.8	When more drugs may have been given than is required to maintain comfort, the concern is that when life support is withdrawn, the high level of drugs rather than the underlying condition will be the cause of the patient's death. This concern may be relived by the criteria listed:
	1) Spontaneous ventilation		1) Patients who have spontaneous ventilation are by definition not prevented from breathing; weaning may begin if there is no discomfort.
	2) Signs of discomfort		2) Patients may be apneic from narcotics but still manifest discomfort or cognition. Patients who are uncomfortable shall be made comfortable even if a secondary effect is suppression of ventilation (from <u>Guidelines on Life-Sustaining Treatment, UPMC Policy No. HS-PS0506</u>).
	3) Recovery of cognition (awareness)		3) Recovery of cognition adequately indicates reversal of sedation.
	4) No evidence of sedating drugs by toxicology analysis.		4) Sedating drugs are not the cause of unresponsiveness.
			The requirement for at least one of the above criteria to be satisfied may result in a patient manifesting some minimal sign of discomfort before receiving additional comfort medication.
2.9	Patients who have received general anesthesia will not have ventilatory support removed until the anesthetic drugs have worn off or been reversed sufficiently to meet any of the following criteria: 1) Spontaneous breathing present, 2) Patient shows signs of discomfort, 3) No evidence of sedating drugs by toxicology analysis, and/or 4) Recovery of cognition (awareness) observed.		Refer to UPMC Policy HS-PS0506, <u>Guidelines for Life-Sustaining Treatment</u>
2.10	The weaning process shall be documented, using the Non-Heart Beating Organ Donor Record (Form 2013 A & B). This shall include clinical signs justifying medications and clinical notes including time of loss or consciousness, apnea, etc.	2.10	By making the entire schedule PRN, with objective criteria for each step and physician and nursing documentation, the process may be audited retrospectively to determine that only as much medication as necessary was given to the patient.
2.11	This weaning procedure will be used for any patient during withdrawal of mechanical life support, regardless of the patient's cognitive state at the initiation of the weaning process.	2.11	The desire of a conscious patient for sedation may influence drug administration in that awareness of condition may be a form of discomfort. Therefore, a loss of awareness, as judged by clinical responses, may be provided at the patient's request. Profound sedation or narcosis may be provided only if required for comfort, because of the concerns expressed above (see 2.8). Because life support is withdrawn and comforting medications given according to patient need, progression of the weaning is titrated.

III. SAMPLE ORDERS FOR VENTILATOR WEANING AND SPECIFIC RATIONALE:

This section is for illustrative purposes only, and does not impose specific orders upon the attending physician.

	WRITTEN ORDER	RATIONALE FOR ORDER
3.1	Give premedication: diazepam, 10 mg. IV; may continue stable infusions of hypnotics/narcotics.	Anxiolytic, amnestic but not an apnea-inducing dose. Maintain current comfort medication.
3.2	Discontinue infusions of vasoactive drugs and other pharmacologic or mechanical life support that do not contribute to patient comfort.	Withdrawal of life support has been decided by the attending physician and the patient. Comfort measures only has been decided by the attending physician and the patient (or surrogate). Comfort measures only are provided in accordance with the Guidelines on Life-Sustaining Treatment (UPMC Policy No.HS-PS0506).
3.3	For a spontaneous breathing rate below 24 per minute and no distress, change mode to SIMV and decrease ventilator rate 50%. FiO_2 = 21% and decrease PEEP to 0.	Ventilator weaning occurs only if no distress is present. No additional sedation is given because it is not needed.
3.4	For signs of discomfort (e.g., respiratory rate above 24 per minute, tachycardia, tachypnea, gasping or use of accessory respiratory muscles) give morphine 10 mg IV).	Weaning is on hold and sedation is given because of evidence of distress.
3.5	When f SIMV $\leq$ 4, remove ventilator and extubate.	Weaning completed.

IV. **SAMPLE ORDERS FOR LEFT OR RIGHT VENTRICULAR DEVICE WEANING AND SPECIFIC RATIONALE:**

This section is for illustrative purposes only, and does not impose specific orders upon the attending physician.

	WRITTEN ORDER	RATIONALE FOR ORDER
4.1	Give premedication: diazepam, 10 mg. IV; may continue stable infusions of hypnotics/narcotics.	For conscious, alert patients, it is recommended that amnestics and anxiolytics be given prior to patient transport unless the patient refuses. The dose of the anxiolytic should be an amnestic but not an apnea-inducing dose. The goal is to maintain comfort.
4.2	Discontinue infusions of vasoactive drugs and other pharmacologic or mechanical life support that do not contribute to patient comfort.	Withdrawal of life support has been decided by the attending physician and the patient. Comfort measures only has been decided by the attending physician and the patient (or surrogate). Comfort measures only are provided in accordance with the Guidelines on Life-Sustaining Treatment (UPMC Policy No.HS-PS0506).
4.3	Turn off left ventricular assist device.	See rationale 4.2.
4.4	Give heparin per CORE routine.	
4.5	Wean ventilator per section 3.1 - 3.5 above.	See rationale 3.1 - 3.5 above.
4.6	For signs of discomfort (e.g., respiratory rate above 24 per minute, tachycardia, tachypnea, gasping or use of accessory respiratory muscles) give narcotics or sedation (e.g., morphine IV).	Sedation is given because of evidence of distress.

Appendix B

Administrative Policies and Procedures

TITLE: **DONATION AFTER CARDIAC DEATH (DACD)**

POLICY: In accordance with the Ethical and Religious Directives ("Directives") for Catholic Hospitals, Pittsburgh Mercy Health System (PMHS) shall "encourage and provide the means whereby those who wish to do so may arrange for the donation of their organs and bodily tissue, for ethically legitimate purposes, so that they may be used for donation and research after death" (Directive #63). Furthermore, this policy is written to be in compliance with Pennsylvania UAGA as amended in December 1994 (PA Act 102) and HCFA 3005-F regulations of August 1998 where it is required that all Acute Care hospitals establish written protocols for the identification and referral of potential organ, tissue, and eye donors. PMHS has a policy for identifying potential donors and for giving those persons (or their surrogates) the opportunity to donate (Administrative Policies and Procedures, "Anatomical Gifts," # 322).

DEFINITIONS: None

PROCEDURES: The purpose of this policy is to provide persons with the opportunity to provide anatomical gifts following the decision to withdraw life support treatment. This policy is designed to enable persons (or their surrogates) to donate organs, tissues, and eyes—should they desire to do so—only after they have decided to discontinue extraordinary or burdensome medical care and death has been determined by the irreversible cessation of cardio-respiratory function rather than brain death criteria. The anatomical gift may then be used for ethically legitimate purposes (e.g., transplantation, education, and research).

POLICY SOURCE:
United States Conference of Catholic Bishops. Ethical and Religious Directives for Catholic Health Care Services. 4th Ed. 2001.

ORIGINATION DATE: 04/22/04

DATE REVIEWED/REVISED:
10/5/04, 01/05/05, 02/09/05

CROSS REFERENCE:
Administrative Policies and Procedures
- 300—Healthcare Decision-Making
- 301—Advance Directives
- 302—Rights and Responsibilities of Patients
- 320—Foregoing Treatment
- 322—Anatomical Gifts

Criteria for Donation After Cardiac Death:

According to the Uniform Determination of Death Act of 1983 to declare death there must be either irreversible cessation of circulatory and respiratory function or irreversible cessation of all function of the entire brain. DACD utilizes the criteria that the patient has suffered irreversible cessation of cardiac and respiratory function.

DACD becomes an option once the patient or surrogate has made the decision to withdraw life support (i.e., the patient is treated under Comfort Measures Only Code Status—see Administrative Policies and Procedures, "Foregoing Treatment," #320) and a desire is expressed to donate organs and/or tissues. Therefore applying resuscitative measures would violate the patient's wishes. Thus, the loss of cardio-respiratory function is both naturally (i.e., auto-resuscitation) and morally (i.e., respect of donor's wishes) irreversible in these cases. (Auto-resuscitation refers to the ability of the body to regain spontaneous circulation once invasive measures to resuscitate the patient have ceased.)

In addition, the following conditions must apply:

1) The patient's condition is terminal and/or death is imminent;
2) The decision has been made by the patient or surrogate to withdraw life support prior to and independent of the decision to donate organs or tissues;
3) There is a high degree of medical probability that death will occur shortly after the withdrawal of life support; and
4) The patient or surrogate consents to the protocol that will allow for organ and tissue procurement.

Under the DACD program, life support will be withdrawn in a manner that will provide for the patient's dignity and will not produce any pain or discomfort for the patient.

Once death has been established (see criteria below), the goal will be to proceed rapidly to organ procurement in order to limit warm ischemia time thus minimizing the potential damage to the organs and/or tissues.

Definition of Death for Use in DACD

To define death in the case of DACD we must be certain that death as a cognitive and physiological process has occurred. Death is a unified function phenomenon. Death is the loss of integrative unity of the being: once cardio-respiratory function is completely lost, the integrative unity of the being is lost and consciousness ceases.

To declare death for the purpose of DACD, stringent criteria must be used. We must be certain that death of the patient has truly occurred so that the organ procurement process can never cause any harm or pain to the donor by premature procurement of the organs. Furthermore, "the physician who determines death should not be a member of the transplant team" (Directive #64).

To fulfill the criteria of death for DACD, death must strictly be defined and the following criteria must be present:

1) Prompt and accurate diagnosis of cardiac arrest must be made
2) Cardiac arrest must be present for at least 4 minutes to establish firmly death and the loss of integrative unity of the donor
3) Cardiac arrest is strictly defined as all of the following four elements:
   a. Electrocardiographic criteria (either i or ii)
      i. 4 minutes of electromechanical dissociation (EMD)
      ii. 4 minutes of electrical asystole
   b. Absence of pulse by arterial catheter with a pulse pressure of zero (0) mmHg or a lack of pulse by Doppler by two independent observers
   c. Apnea
   d. No response to noxious or physical stimuli
4) It is only after a the passage of 4 minutes without any return of the above four (4) elements that the patient may be declared dead for the purpose of organ procurement.

Patient Candidates

Who may be considered a potential donor?

PMHS wishes to facilitate organ, tissue and eye donation in the interests of the individual recipient and society without infringing on others' deeply held values and rights. PMHS recognizes the importance of allowing those who wish to give the maximum opportunity for organ donation, in the hope that solace may be provided to the grieving family by improving the quality of life for others. The principles of voluntary giving are always to be upheld while considering the wishes of the families of potential donors. The DACD policy assures that all potential donor families are provided the option of donation on behalf of their deceased loved one in the event of death by irreversible cessation of circulatory and respiratory function.

PMHS, in consultation with the Center for Organ Recovery and Education (CORE), has established medical requirements for organ, tissue, and eye donation. It is the policy of PMHS to contact CORE with every death or imminent death to determine suitability for organ, tissue, and eye donation. (Administrative Policies and Procedures, "Anatomical Gifts," # 322).

Potential Donors

Potential donors can be defined as patients who themselves (or through their surrogates) decide to withdraw life support. Consideration of (DACD) organ donation shall occur only after a decision has been made by the patient, surrogate, or family and after the patient has been assigned the status of "Comfort Measures Only" as indicated in the PMHS policy guidelines on foregoing life-sustaining treatment (Administrative Policies and Procedures, "Foregoing Treatment," # 320). Appropriate candidates for withdrawal of life support shall be identified independently of donor status.

Surrogates

This person may be named in a document called a Durable a Power of Attorney for Health Care Decisions (see Administrative Policies and Procedures # 301). Otherwise, consent may be granted by the following persons in the order of priority stated, as long as the person is capable of making decisions in the patient's best interest:

Class 1: court-appointed guardian,
Class 2: the surviving spouse,
Class 3: an adult child,
Class 4: either parent,
Class 5: an adult sibling, or
Class 6: other close relative or friend. (Administrative Policies and Procedures, "Healthcare Decision-Making," # 300).

Specifically, the law requires that PMHS shall inform the health care surrogate, if one is named, or the highest priority family member(s) available of the opportunity to give consent for donation of anatomical gifts from medically suitable candidates. Patients who do not have decision making capacity and who are without surrogates shall not be considered candidates for donation.

Organ procurement may proceed only if, prior to signing the appropriate consent form, the patient or patient surrogate is given an opportunity to meet with a member of the Ethics Consultation Service. At that meeting, the ethics consultant should review the decisions to have life support withdrawn and to become an organ donor. The ethics consultant will write a summary of the discussion with the patient or patient's surrogate in the patient's medical record.

Financial Responsibility

The family should incur no expenses related to the donation process. All expenses will be billed to CORE. The operating room identifies the patient on the outside of the chart as an organ donor prior to forwarding the chart to the Medical Records Department. The PMHS Finance Department shall bill CORE for direct costs incurred in connection with maintenance after death and with the anatomical gift(s) retrieval procedure. Charges to CORE are billed from the time the donor has consented. CORE will pay the hospital upon receipt of the bill.

Required Documentation

1. Documentation in the progress notes from the attending physician of the multidisciplinary care team reflecting the patient is suffering from a condition which is terminal and/or from which death is imminent.

2. Documentation in progress notes that discussion has begun with patient/surrogate concerning change in resuscitation code status.

3. Documentation in progress notes that the possibility of becoming a donor under the DACD policy exists.

4. An opportunity to meet with a member of the Ethics Consultation Service is given to the patient, surrogate, and/or family to discuss the ethical issues of withdrawal of support and impending death. Documentation of this opportunity should be made in the patient's chart.

5. Name of attending doctor implementing terminal wean. Documentation should also reflect that doctor has no clinical responsibilities on a transplant service (cf. Directive #64)
6. Consent form signed by patient/surrogate to donate organs and/or tissues after death.
7. CORE notified and documentation completed.
8. Document that CORE representative was at bedside and required testing is completed.
9. Orders written by doctor to proceed with Comfort Measures Only Code Status.
10. If sedation is implemented to ensure peaceful death, this must be documented.
11. Time of asystole.
12. Time death pronounced.
13. Time sedation discontinued (should correspond with time of death).
14. Time procurement implemented.
15. Time organs removed.
16. Time procedure completed.
17. Time body is released to the morgue.
18. Name of funeral home.

Donor/Family Wishes

The decision concerning the treatment and management of patients (including, but not limited to, the decision to withdraw mechanical support and/or medication) must be made separately from and prior to discussion of organ donation.

I, ____, give my consent for the

(patient's name)

procurement of______________________________________ or all of my organs upon my death.

(specify organ)

____________________________(patient or surrogate) ____________________________(witness)

(PRINT) (PRINT)

____________________________(patient or surrogate) ____________________________(witness)

(SIGNATURE) (SIGNATURE)

Appendix C

Patient Care Manual

Geisinger Health System	Policy	Section	Subject	Domain
	112A	Patient Care	Rapid Organ Recovery in Non Heart Beating Donors	Administration

Rapid Organ Recovery in Non Heart Beating Donors

Geisinger Medical Center presently has Guidelines on Forgoing Life Sustaining Treatment. Patients or their surrogates can decide to forego life-sustaining treatment. Furthermore, all patients have the right to elect organ or tissue donation in the event of their death. The great majority of organ donors have in the past been declared dead by brain death criteria. Donation of organs or tissues by persons who die from cardiac or respiratory failure is legal and was a commonly accepted practice before brain death criteria were developed. Geisinger Medical Center believes it is ethically appropriate to consider organ procurement from non-heart beating donors, providing certain requirements are met. The purpose of this document is to provide an ethically justifiable and auditable policy that respects the rights of patients to have life support removed and to donate organs if they wish to do so, providing certain conditions are met. Those conditions must respect the integrity of the medical profession by restricting the pool of donors to a patient population that we feel is appropriate for such consideration, and which does not present a moral quandary on the part of the health care providers nor for the community at large. The policy is consistent with recommendations published by the Institute of Medicine in 1997 in response to a request from the Department of Health & Human Services.

Principles:

1.Decisions concerning the treatment and management of the patient (including but not limited to the decision to withdraw life support) must be made separately from and prior to discussions of organ donation. This means that appropriate candidates for withdrawal of life support shall be identified independently of donor status. Consideration of organ donation shall occur only after a decision has been made by the patient through an advanced directive, surrogate, or family member to withdraw life support. The withdrawal of life support and provision of comfort measures shall be in the minds of the attending physician staff an ethically and medically appropriate decision. Once the decision has been made to withdraw life support, Gift of Life personnel may initiate discussions relevant to organ donation.

2.It is an essential objective of this policy that the interest in procuring organs does not interfere with optimal patient management. It is the health care professional's primary responsibility to optimize the patient's care. The process of removing life support shall be done primarily to promote patient comfort and/or respect patient autonomy with regard to removal of life support.

3.Not all requests for organ donation will be honored merely because a patient or surrogate desires withdrawal of life support and wishes to be an organ donor. For example, conscious ventilator dependent patients and patients undergoing active CPR (uncontrolled donation) will not be considered as possible donor candidates.

4. .Appropriate candidates for organ donation shall be limited to those patients who meet all of the following conditions:

- Controlled donor protocol (ICU patient on ventilator support)
- Patient should generally be > 18 yrs of age. Next of kin consent and ethics consultation must be obtained for patients less than 18 yrs of age.
- Patient must not have
    - Active sepsis
    - HIV, HbsAg, HTLV positive tests
    - Cancer except primary brain tumor, lip/skin cancer, in situ cancer
    - Patient must not be in a CDC defined high risk classification such as those with a high risk

      of transmissable disease or infection, current IV drug abuser, or have hemophilia or coagulation disorder.

- Identity of the patient must be known

- The patient should be incapable of decision making by virtue of coma, and

in the case of a minor does not have the legal authority for decision making, and he/she has an appropriate surrogate decision maker capable of determining the appropriateness of organ donation. Patients who do not have, or never had, the capacity for decision making due to mental retardation, or who do not have a surrogate decision maker will not be considered candidates for organ or tissue donation.

- Neuromuscular blockade must be documented to have worn off or been reversed prior to

initiating removal of mechanical ventilation

- The cause of coma shall have been determined, and reversible conditions mimicking irreversible

brain damage shall have been excluded (seizure activity, hypothermia, hypotension, drug effects, sepsis, metabolic conditions, etc)

- The above conditions having been met, and in those clinical situations in which patient, family,

  or other patient surrogate, and the responsible care physician decide to withdraw care from a patient who is dependent upon life support for survival,

    - And, when brain death criteria are not fulfilled because of either detectable cortical activity, or persistent brain stem function by detectable intact brain stem reflexes or spontaneous respiratory effort, and when the decision to discontinue life support fulfills hospital established criteria for withdrawal of life supporting care,
    - And, a DNR (Do Not Resuscitate) order has been written,
    - And, the patient has otherwise suitable organ function
    - The patient will be considered for non heart beating organ donation.

5. Patients who are not capable of decision making on the basis of mental

retardation or who have no surrogate decision maker shall not be considered for organ donation. Guardianship proceedings may occur for other reasons, but shall not be initiated solely to permit organ donation.

6. Ethics consultation is not required if the patient meets criteria for NHBD. If patients are considered for NHBD outside of criteria herein defined, an ethics consultation is required for case by case consideration. However, if any member of the health care team perceives an ethical problem, he or she is encouraged to request an ethics consultation. Under those circumstances, life support will not be withdrawn until the ethics consultation is completed and recorded on the chart.

7. This policy explicitly prohibits any intervention whose primary intention is to shorten the patient's life. Any act which intentionally causes the death of a patient is forbidden.

8. The preparation for organ retrieval prior to death shall be minimally invasive, shall not be intended to contribute to the patient's death, shall be of such a nature as to not be considered harmful, but shall be consistent with the patient's/surrogate's desire for organ donation.

9. Assuring patient comfort, (i.e., relieving the appearance or perception of discomfort as, for example, by grimacing) is the only indication for using medications during withdrawal of life support. The dose of the medication should be carefully titrated to this purpose.

10.Following withdrawal of life support, during the period of observation prior to a determination of death, there may come a time when it becomes apparent that the patient's spontaneous breathing is inadequate to sustain life and that death is imminent. At this time it is permissible to administer 5000 u of heparin IV with the understanding that:

- At this point the issue is less the life of the patient, than the viability of the donor

organ consistent with the patient's expressed desire to be an organ donor.

- The heparin dose is small and unlikely to be harmful
- No information exists to suggest that larger doses have any greater efficacy;
- In the event that ischemia time is prolonged or death does not appear imminent,

heparin shall not be administered

No procedures of a more invasive nature are contemplated with the exception of placement of an arterial catheter needed for the diagnosis of brain death; any more invasive procedure such as large bore cannulation, larger doses of anticoagulants or infusion of cooling or preserving solutions requires specific informed and documented family consent.

.11.Organ retrieval cannot proceed until the pronouncement of death;

12.Utmost attention and caution shall be taken to protect the dignity and rights of donors.

13.Health care professionals shall not be required to participate in the procedures described below if such participation is against their personal, ethical, or religious beliefs. However, if such professional is the attending physician or critical care physician responsible for the patient's care, he or she has an obligation to turn over the patient's management to another physician who is able to carry out the patient's wishes.

14.The following criteria shall be used for selecting the supervising ICU staff physicians:

- The physician must be an attending ICU staff physician;
- The physician must have familiarity with the
    - Guidelines for Withdrawing Life Support,
    - Guidelines for Organ Maintenance (Gift of Life Donor Program),
    - Policy: Rapid Organ Recovery in Non Heart Beating Donors
- The physician must have personal experience with termination of life support;
- The physician shall have no clinical responsibilities on a transplantation service;
- Physicians shall be designated specific clinical privileges for this responsibility by the Chairman of the ICU Committee with the approval of Director, Critical

Care.

- ICU physicians who have any other basis for conflicts of interest in individual

cases shall decline or not be asked to participate in withdrawal of life support and certification of death.

Procedure:

1.Whenever possible, attempts will be made to fulfill brain death criteria. When it becomes obvious that the patient will not meet brain death criteria, the patient's family/surrogate will be so informed. It is proper to discuss prognosis and outcomes with the surrogate decision maker, and to inquire of the patient's values and preferences under the circumstances.

2.An agreement between the patient's surrogate and the attending physician that life support is to be withdrawn with the expectation of death is required for the patient to be considered an organ donor according to this policy. The discussion with the surrogate, leading to the decision to withdraw all life sustaining therapy, must be appropriately documented in the medical record.

3.The detailed discussion of organ donation shall be deferred until after the decision to withdraw life support has been reached. After the decision to withdraw life support has been reached, the patient's attending physician or designate in collaboration withGift of Life personnel may initiate discussions regarding potential organ and/or tissue donation with the patient's surrogate decision maker. The ineffectiveness of spontaneous ventilation to sustain life shall be assessed, insofar as possible, prior to determining that the patient is a candidate for organ donation. If spontaneous ventilation is adequate to support life, the patient does not meet criteria for organ donation, although life support may be removed. Organ procurement may proceed only if the patient's surrogate agrees to organ procurement upon the death of the patient and signs the appropriate consent form. Consent for donation can be withdrawn at any time. No pressure or coercion shall be used to maintain or to gain consent. Patients who are not capable of decision making on the basis of mental retardation or who have no surrogate decision maker shall not be considered fororgan donation. Guardianship proceedings may occur for other reasons, but shall not be initiated solely to permit organ donation. Ethics consultation is not required unless patients failing to meet criteria herein defined are considered for NHBD. However, if any member of the health care team perceives an ethical problem, he or she is encouraged to request an ethics consultation. Under those circumstances, life support will not be withdrawn until the ethics consultation is completed and recorded on the chart.

4.The coroner will be notified and permission obtained for organ retrieval prior to withdrawal of life support.

5.Gift of Life personnel will be notified after the patient has been identified as an organ donor candidate, prior to withdrawal of support, and prior to discussion with the family regarding organ donation opportunities in order to facilitate organ procurementand to provide family support.

6.The patient's attending physician and critical care physician/consultant must agree with the proposed procedure and note this in the chart.

7.Appropriate pastoral care and social service staff will be consulted to provide support to surrogate and family members.

8.The responsible OR anesthesiologist or designee will be informed of planned terminal management and the possibility of organ procurement. Gift of Life personnel will arrange for availability of a transplant team to procure organs and will inform the charge anesthesiologist of available time. The charge anesthesiologist will then assign OR time and room.

9.The attending critical care staff physician will be responsible for management of the donor patient after a request has been made for organ procurement from a non-heart beating donor. The responsibilities of the critical care staff physician withdrawing life support shall include the following:

A. Review of the informed consent procedure to ensure that it has included discussion with the surrogate of all of the following: - GMC policy for withdrawing life support; - The process of removing life sustaining therapy; - The process of organ procurement;- That withdrawal of life sustaining therapy will be completed in the operating room (preferable) or the ICU, and that family members may remain with the patient until the pronouncement of death (Note: If a holding room is not available in the PACU, the patient might need to have life support discontinued in the OR. The family must be prepared to depart as soon as possible after the patient is declared dead so as to avoid prolonged ischemia time.)

- That a femoral artery line will be required;
- Notification of coroner;
- The pronouncement of death;
- That organs will not be procured until the patient is pronounced dead;
- That based on the opinion of the transplant surgeon, organs designated for donation may not be procured if certain problems occur (ischemia injury);
- That death will be certified in accordance with Pennsylvania law;
- That consent can be withdrawn at any time without cost or prejudice;
- Cost of care and organ procurement will be borne by Gift of Life after the patient is determined to be an organ donor candidate;
- That in the event of prolonged ischemia time or failure of death to occur in a timely manner to permit organ harvesting, the patient might return to the ICU and life support will be withdrawn. Under such conditions, the patient might not be a candidate for organ donation.
- Administration of 5000 u heparin IV at such time that it becomes apparent that the patient's spontaneous ventilation is inadequate to sustain life, and that death is imminent (within minutes).

B. Clinical examination of the patient and assurance that apnea criteria or ineffective spontaneous ventilation is present; (Note: The presence or ineffectiveness of spontaneous ventilation shall be assessed prior to determining that the patient is a candidate for organ donation. If spontaneous ventilation is adequate to support life, the patient does not meet criteria for organ donation, although life support may be removed.)

C. Deciding when to initiate transfer of the patient to the OR;

D. Managing the patient's care with the assistance of an ICU nurse in the OR/ICU; Provision of comfort care by administration of sedatives or analgesics to relieve any discomfort;

E. Informing the surgeon when it is acceptable to start surgical preparation of the patient's skin;

F. The physician certifying death must not be involved either in procuring organs or the care of any of the transplant recipients.

G. Completion of the death certificate and death summary in the medical record are the responsibility of the critical care staff.

10 .IV access shall be maintained for drug administration as indicated. Correct EKG lead placement will be confirmed. An arterial line will be appropriately monitored for BP and pulse pressure. At the discretion of the attending ICU physician, ventilator support will be terminated per protocol.

11. Prior to transfer of the patient to the OR for withdrawal of life support, or deciding to withdraw life support in the ICU, it will have been determined in the ICU by the designated ICU physician that the patient has met all the criteria for NHBD. The OR shall be ready to accept the patient and the transplant team in place before life support is withdrawn in the ICU. If life support is to be removed in the OR, inquire of the charge anesthesiologist if the patient can be held in a holding area in the PACU with the family present during removal of life support, or if it will be necessary to take the patient directly to the OR. In all cases; an acceptable OR time must first be obtained from the charge anesthesiologist. The transplant team must be ready to proceed and be present in the OR. The patient will be transferred to the OR accompanied by the ICU staff physician (not a physician assistant or resident). Life support will be removed by the ICU staff physician. After declaration of death, the family if present will be asked to wait in an ajoining area or waiting room. The surgical staff responsible for organ procurement shall in no way participate in the weaning process or in the donor's care. It is preferable that the operating team not be present in the OR until certification of death except for skin preparation and draping. If narcotics and sedatives are administered, these drugs must be titrated to the patient's need for provision of comfort. If necessary, analgesics may be administered prior to the institution of weaning in order to prevent discomfort and titrated to prevent grimacing, tachycardia, or other signs of possible distress.

12.The OR personnel may scrub, prep, and drape the body in preparation for organ procurement prior to withdrawal of life support.

13.The decision to administer heparin is the responsibility of the attending ICU staff physician. 5000 u heparin IV may be administered when, after a period of observation following withdrawal of life support, it becomes apparent that the patient's spontaneous unassisted ventilation is insufficient to sustain life and that death is imminent (minutes).

15. If organ ischemia is prolonged (e.g. beyond two hours), it may not be possible to utilize organs designated for donation and procurement may not be performed. The decision to cancel organ procurement because of prolonged ischemia rests with the responsible transplant surgeon. Under these circumstances, the designated ICU physician may decide to return the patient to the ICU. Life support will not be reestablished. The patient may be transferred to a private room in order to permit family presence and privacy.

16. No organs may be procured until death is certified by the ICU attending staff. For certification of death, the prompt and accurate diagnosis of cardiac arrest is extremely important. Procurement of organs cannot begin until the patient meets the cardiopulmonary criteria for death, i.e., the irreversible cessation of cardiac function is recognized by persistent cessation of function during an appropriate period of observation. In view of the previously made decision to withdraw life support, no attempt will be made to resuscitate cardiopulmonary function after termination of ventilatory and pharmacologic support per protocol. The diagnosis of death requires that the pulse pressure be zero and the pulse be absent by monitored femoral artery catheter. In addition any one of the following EKG criteria shall be sufficient for the determination of death per this policy:

- 5 minutes of ventricular fibrillation, or
- 5 minutes of electrical asystole (no complexes, agonal baseline drift only),or
- 5 minutes of electromechanical dissociation

17. Immediately after certification of death, organ procurement shall proceed. If life support was withdrawn in the ICU, the patient will be transported to the OR for organ procurement. No attempt at resuscitative efforts including mechanical ventilation or oxygen administration shall be made after the declaration of death.

18. The procedure for organ procurement, cleaning of the body, and transfer to the morgue is to be conducted with respect and sensitivity. Procured organs shall be distributed in accordance with medical center policies and UNOS requirements. Donor patients will not be charged for the costs of organ procurement (OR time,personnel, medication, etc.).

Attachments:

Document Information

Devised	*Revised/Reviewed**	*Source*	*Approved*
4/98	3/01 5/03 5/04*		Bioethics Committee1/2/01 Medical Executive Committee 4/8/98
APPROVED BY: CNO			

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Nursing

Appendix D

ORGAN PROCUREMENT MANUAL
SECTION VII
DONATION AFTER CARDIAC DEATH

CONTROLLED DONOR PROCUREMENT PROCEDURE

In the event of all imminent deaths in which the patient is on mechanical support, and/or the family has made a conscious decision to terminate the ventilator, organ donation should be considered.

- At the time the patient's physician or designee determines death is imminent, the CORE representative (Center for Organ Recovery & Education) will be notified.
- The Donor Referral Coordinator will conduct an initial evaluation to include:
    - Hospital
    - Caller's name
    - Telephone number of unit
    - Patient's name
    - Patient's age
    - Primary diagnosis
    - Patient care unit
    - Neurological evaluation
    - Respiratory evaluation
    - Significant past medical history
- If the patient is recognized as a potential donation after cardiac death (DCD) donor, the Donor Referral Coordinator will:
    - Notify the administrator on call
    - Notify the organ procurement coordinator
- It may be indicated that the organ procurement coordinator contact the referring health care professional to further evaluate the patient as a DCD donor.
- The organ procurement coordinator will then review the case with the CORE administrator on call for direction on proceeding to the hospital.
- Prior to going to the hospital, the organ procurement coordinator will review the hospital idiosyncrasy list and begin the local donor checklist.
- Upon arrival at the hospital, the organ procurement coordinator will:
    - Notify the nursing supervisor
    - Notify the primary nurse
    - Notify the charge nurse
    - Notify the attending physician
    - Review the hospital's DCD policy and procedure
    - Conduct a medical record review
    - Conduct a complete physical assessment of the patient, to include:
        - Neurological assessment
        - Cardiopulmonary assessment
        - Clinical laboratory (i.e.) BUN, ABO if available, creatinine, CBC with differential, LFT's, and Amylase and Lipase, if applicable.
        - Genitourinary assessment
        - Hemodynamics (i.e.) pressor support
    - Validate with the primary nurse that the family wants the ventilator disconnected

prior to discussion about donation
- Notify the administrator on call with the above information.

- Once the patient is accepted by CORE as a DCD candidate, the organ procurement coordinator will:
  - Obtain and follow CORE's DCD organ donor record form D-14
  - Obtain and secure consent, using CORE Form C-1, from the legal next-of-kin following the UAGA.
  - Secure medical/social history from the family.
  - Obtain two (2) red tops and one (1) purple top of patient serum for immunoserological testing.
  - Obtain eight yellow tops of patient serum for tissue typing and assure tubes are **not** placed on ice.
  - Coordinate with Donor Referral Coordinator the transport of the blood to the CORE office.
    - The method to be used will be the most expeditious method.
  - Coordinate an operating room time for the organ retrieval
  - Coordinate with the attending physician a licensed physician who will pronounce the patient dead by cardiac death criteria.
  - Contact the medical examiner/coroner and determine:
    - Permission for organ/tissue/eye recovery
    - Limitations
    - Specimen requirements
    - Photography requirements
  - Contact operating room personnel to determine time for recovery following the completion of:
    - Immunoserological testing
    - Time constraints of pronouncing physician
  - Contact the Donor Referral Coordinator
    - Provide
      - Patient clinical information
      - ABO
      - Operating room time
    - Obtain UNOS identification number
  - Inform operating personnel that anesthesia staff will not be required, other than initially connecting patient to the ventilator.

- <u>Several hours</u> before the recovery:
  - Determine if family wishes to have clergy notified.
  - Provide family as much time with patient as needed.
  - Encourage family to leave prior to transporting patient to operating room, however, if family will be present for the terminal wean, notify the administrator on call.
    - (CORE's policy is to conduct the terminal weans in the operating room to reduce the amount of warm time to the organ.)
  - Conduct a pre-recovery conference with recovering surgeons and operating room

personnel.

- Determine where the recovery team will be located during the terminal wean. (Ideally the team, including the circulating and scrub nurse should be located in an adjacent operating room, not in the patient's room.)
- Provide the operating room personnel the opportunity to opt out of the procedure if donation is against their personal belief system.
- Obtain blood and urine cultures for microbiology testing.

- One hour prior to transport to the operating room, and with attending physician's permission,
  - Determine what equipment the pronouncing physician will require in the OR, i.e., arterial lines, EKG, ECHO.
- Immediately prior to transport to the operating room, the organ procurement coordinator will:
  - Obtain portable oxygen
  - Obtain respiratory support personnel
  - Obtain 100 mg thorazine to be used in the 1st bag of HTK perfusion flush (50 mg into the first 2 bags of UW, if used for preservation).
  - Obtain 60,000 units of heparin:
    1) 50,000 units of heparin will be administered to the patient prior to extubation
    2) 10,000 units of heparin will be mixed into the first bag of HTK perfusion flush (As a back-up or if the host OPO doesn't use HTK, substitute 2 bags of UW [5,000 units each bag]).
  - Determine if pronouncing physician will utilize narcotics during the terminal wean
    - Intravenous access minimum of 14 g IV line
      - Emergency resuscitation drugs, i.e., epinephrine
- Transport the patient to the OR:
  - The patient will be transported to the operating room at the agreed upon time.
    - The hospital respiratory therapist, or their designee, will ventilate the patient to the operating room using 100 % O^2 and be placed on a cardiac monitor.
    - The licensed physician who is not involved in the care of any patient who may receive an organ from the donor will also accompany the patient.
  - In the operating room the organ procurement coordinator will:
    - Secure permission from the physician to shave and drape the patient
    - Administer 50,000 units of heparin IV push four minutes prior to extubation.
      - Immediately after the heparin is given, have the nurse flush the line with 50 cc of normal saline solution.
    - Secure any requested specimens for the medical examiner/coroner
    - Secure photographs as requested by the medical examiner/coroner
    - Identify one clock in the operating room that will be used by all staff for recording time of events.

- If family is present during the terminal wean, the organ procurement coordinator will:
    - Limit the number of CORE staff in the room to 2 (organ procurement coordinator and administrator).
    - Soften the lights
    - Provide family the opportunity to have music.
    - Cover all windows to the outer corridors.
    - Control outside noise.
    - Inform recovering surgeons to wait in designated room.
    - Assure family has access to patient's hands and face.
    - Assure face is clean.
    - Maintain patient dignity by covering patient at all times.
    - Provide stools for family members.
    - Provide the family the opportunity to touch patient and talk to patient, if they desire.
    - Provide clergy, if requested by the family.
    - Cover back tables with sterile towels.
    - Cover all instruments with sterile towels.
    - Have family wait in quiet conference room until patient is prepped.
    - Limit the exposure of daily operating room activities the family must experience.
    - Validate family's understanding of leaving room following pronouncement.
- The pronouncing physician will:
    - Determine when and how ventilator will be weaned.
    - Extubate the patient unless they are a medical examiner/coroner case.
    - Manage the weaning process and request medication as indicated which will be administered by him or his designee.
    - Determine when death occurs and pronounce the patient.
        - Normal protocol is for the physician to wait two to five minutes from asystole or electro-mechanical dissociation prior to pronouncing patient.
    - Write a written pronouncement note to include date, time of pronouncement and signature.
    - Grant permission to begin recovery.
- Following written pronouncement, the organ procurement coordinator will:
    - Escort family out of the room, if present, and assure a designee stays with the family.
    - Escort the surgeons to the operating room.
    - Limit the number of surgeons at the field.
    - Maintain an environment that is sensitive and dignified.
    - Continually assess operating room personnel psychosocial needs.
    - Assure that the first bag of perfusion solution contains:

- 10,000 units of heparin
- 100 mg of thorazine

- Following pronouncement, a rapid recovery of organs (liver, kidneys and pancreas) usually will take place.
  - At this time the recovery process will proceed following the CORE organ and tissue procurement manual.

* *Any hospital staff member who has personal concerns about this procedure is encouraged to inform the CORE coordinator.*
  - *The Center for Organ Recovery & Education can provide all necessary staff to carry out this procedure with the exception of the pronouncing physician.*

UNCONTROLLED DONOR PROCUREMENT PROCEDURE

In the event a potential brain dead organ donor arrests during the evaluation for Brain Death, the following procedure should be instituted.

- Begin Advanced Cardiac Life Support (ACLS), using several modifications:
  - Asystole (Cardiac Standstill)
  - No pulse present begin CPR
  - Establish IV access if not already done
  - Administer Epinephrine, 1:10,000, 0.5 - 1.0 mg IV Push
  - Obtain 2 red top tubes of donor blood
  - Assure adequate ventilation (Ventilate patient with 100% O_2)
  - Repeat Epinephrine, 1:10,000, 0.5 - 1.0 mg IV Push
    - DO NOT ADMINISTER ATROPINE (Useless in brain death)
  - (Consider Bicarbonate)
  - (Consider Pacing)
  - (If cardiac rhythm is not restored)
  - Administer 30,000 u of heparin after 15 minutes of CPR
- * If a representative from CORE is not present, designate a staff member to call 800-366-6777 immediately.
- The CORE representative will carry out the following responsibilities:
  - Speak with the attending physician regarding the feasibility of continuing CPR until the arrival of the procurement team. The recommendations of the attending physician will be honored by CORE.
  - Obtain consent from the next-of-kin in agreement with the Uniform Anatomical Gift Act (UAGA), using the following priority:
    - Spouse.
    - An adult son or daughter.
    - Either parent.
    - An adult brother or sister.
    - A guardian of the deceased at the time of his/her death.
    - Any other person charged with final disposition of the body.
  - Obtain consent from the Coroner/Medical Examiner.

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- Notify the operating room/anesthesia personnel of impending procurement. If the cardiac rhythm cannot be restored, anesthesia personnel will not be required. The procurement will be a rapid technique continuing with CPR.

- CORE will dispatch an organ procurement team using the quickest mode possible to travel to the hospital.
- CORE will notify the patient unit of the estimated arrival time of the procurement team and the scheduled operating room time. CPR will continue until a cardiac rhythm is restored, or until the procurement team arrives.
- 15 minutes prior to the arrival of the recovery team, the donor will be transported to the operating room. CPR will continue during transport in order to assure adequate organ perfusion.
- A licensed physician who is not involved in the care of any patient who may receive any organ from the donor will need to accompany the patient to the operating room.
- CPR will continue until the procurement team is scrubbed and present in the operating room. At this time, CPR will stop and the physician will pronounce the patient dead (EMD may occur before cardiac standstill).
- Immediately following pronouncement of death, the procurement team will begin a rapid recovery of those organs deemed suitable for transplant.
- At this time, the procurement process will proceed following the CORE Organ and Tissue Procurement Manual.

* If a CORE representative is present, eliminate step 2 and the CORE representative will begin with step 3.

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