ANESTHESIOLOGY™2014
OCTOBER 11-15 | NEW ORLEANS, LA

Session: L071
Session: L134

Anesthesiologists and Terminal Live Organ Donation: You Want Me to Do What?

Richard L. Wolman, M.D.
University of Wisconsin School of Medicine and Public Health, Madison, WI

Disclosures: This presenter has no financial relationships with commercial interests

Stem Case and Key Questions Content

A 48 year-old male physician with amyotrophic lateral sclerosis (ALS) requests a meeting with your hospital's ethics committee. He has been living in a hospice environment for the past 3 months, is not yet ventilator dependent, and he refuses long-term intubation and ventilatory support. After a brief telephone conversation, the chair of your hospital's ethics committee, who has known the patient professionally and socially for years, agrees to meet the patient at the hospice center. During their meeting, the patient acknowledges that his death is inevitable and expresses an altruistic interest in organ donation. In order to insure that the organs are most viable at the time of donation and therefore attempt to insure the best possible outcomes of transplantation, the patient requests that he be placed under general anesthesia (he will allow short-term endotracheal intubation), allowed to donate any or all of his perfused organs, and allowed to die in peace under general anesthesia or, following extubation, with comfort/palliative care. The chair of your ethics committee agrees to present the case to a meeting of the entire ethics committee and return with an answer.

1. What additional information do you need?

2. Does the entire ethics committee need to meet with the patient?

3. What additional parties need to meet with the patient?

4. How do you determine decisional capacity in this situation?

5. Are the patient's requests legal and ethical?

The hospital's ethics committee, hospital legal services, the University's attorney, the patient's attorney and patient meet at the hospice center. The patient is adamant in his requests. The patient presents an evaluation from his friend, a well-respected psychiatrist at your institution, stating that the patient has decisional capacity and, although he has some component of situational depression, clearly meets all medical and legal criteria for decision-making.

6. Is complying with the patient's requests ethical and legal?

7. Do you need to permission from any judicial or regulatory agencies, or professional societies

(e.g., ABA, ASA, AMA, State Medical Board, State Medical Society, District Attorney, courts, etc.) before proceeding?

8. How does this differ from passive euthanasia, active euthanasia, and physician assisted suicide?

9. How does this differ from organ donation after brain death and donation after cardiac death?

10. Which organs would it be ethical to procure?

11. Does it matter if the procurement results in immediate, imminent, or eventual death?

12. Should anesthesiologists be involved, and if so, when should the involvement end?

13. Would you participate? If so, would you establish any conditions?

Model Discussion Content

The transplantation program in the United States, the largest in the world, is a voluntary, opt-in, altruistic system where organ donation represents a gift. The program is dependent upon public confidence for survival and any violation of this confidence could have dire consequences. Despite the generosity of donors and their families, there have been a rather static number of donors and transplants with an ever-increasing number of patients on waiting lists for transplantation resulting in an absolute shortage of organs. As of April 20th, 2014 there were 122,238 candidates on waiting lists for transplantation. In 2013, organs were procured from 14,255 donors (8,267 deceased, 5,988 live) resulting in 28,951 transplants (22,965 from deceased donors, 5,986 from live donors).[1] The consequence of this shortage is that up to 18 people die each day while waiting for an organ transplant.

To protect and maintain public trust in the transplantation program, in the 1960's the Dead Donor Rule (DDR) was established as an ethical axiom of organ donation. The DDR states that "it is unethical for organ procurement to cause death or injury" and "except in the case of living donation, it is unethical for organ procurement to precede death." [2] The DDR was felt to illustrate society's respect for the individual donor, donor's interests and life (nonmaleficence), and was thought to be necessary to protect the interests of vulnerable populations, avoid slippery slope situations, and insure public support for a voluntary system of organ donation. [2] Although clearly a moral framework for organ donation, the DDR is not, and has never been, a "rule" and has complicated the process and discussion of organ donation. The DDR requires a stringent definition of death to protect the potential donor, patient population, and all those involved in organ donation.

In the early days of transplantation, the definition of death was cardiopulmonary death and all donors were nonheartbeating donors. The advent of mechanical ventilation and aggressive life support resulted in an increasing population of unconscious patients kept "alive" in intensive care units. This population represented a potential source of needed organs (kidneys), however, due to the DDR, a new definition of death was required if they were to be considered dead. Based upon Mollaret and Goulon's concept of irreversible coma, Henry K. Beecher and the ad hoc committee of the Harvard Medical School defined the clinical criteria for irreversible coma or

brain death (death of the whole brain and brain stem). [3] These validated criteria led the way for the 1980 Uniform Determination of Death Act (UDDA) that defined death as either cardiopulmonary death (irreversible cessation of circulatory and respiratory function) or brain death (irreversible cessation of all functions of the entire brain and brain stem).

Despite this expansion of the definition of death and source of potential organs, the shortage of viable organs for transplantation continued. In 1992, the Pittsburgh Protocol defined the process for donation after cardiac death (DCD). [4] DCD, a terminal event, has raised many ethical and practical issues including but not limited to the administration of organ preservation agents and the DDR, the timing and irreversibility of death and the DDR, the difference between irreversibility of death (cannot resuscitate) and will not resuscitate, conflicts between deontologic and consequentialist theory, informed consent, and where and who withdraws life-sustaining therapies. [5] Despite a slow but steady increase in the number of DCDs, DCD only represented 13.6% of deceased donors in 2012. [1] Furthermore, with DCD there is a problem with organ viability. Of the 9,149 DCD donors from whom organs were recovered from January 1, 1993 to July 31, 2013, 23.3% of the recovered organs were nonviable and discarded prior to transplantation. [1] Controversy regarding anesthesiologists' participation in DCD resulted in action by the ASA's House of Delegates in 2005 and creation of the ASA's "Sample Policy for Organ Donation after Cardiac Death". [6] This policy reinforces the concept that in cases involving DCD, non-critical care anesthesiologists should not withdraw life-support to avoid any perception of conflict of interest, avoid misconceptions of why anesthesia is needed, respect for the patient and the established patient-doctor relationship, respect the moral and professional dilemmas the participation of anesthesiologists raises, and respect the primary principle of palliative care (continuity of care). [5,7]

Multiple other attempts to increase the donor pool by legislation and regulatory agencies have had little success. However, this case does not involve all the ethical controversies that previous discussions have raised. [5] Similar to donation after cardiac death (DCD), this case combines two ethically difficult concepts, end-of-life care and organ donation. However, with DCD, we presume that death has occurred and is followed by organ donation, although some will argue this fact. [5] In the case being presented, the patient is requesting that his organs be procured prior to his death and following donation he be euthanized, either actively or passively. The case presented involves discussions of individual autonomy, ethics of end-of-life care, the dead donor rule, definitions of death, how this case differs from donation after cardiac death (DCD), and the participation of anesthesiologists in these processes.

Moral issues in the case presented involve the patient's autonomous decision and interests and these are represented by his informed consent. Respect for this patient's interests are supported by respect for his autonomy, traditional notions of moral autonomy, positive and negative liberty rights, and the Harm Principle. Beneficence, nonmaleficence, justice, and intellectual and moral honesty must also be examined.

In a pluralistic liberal society, with no privileged perspective of the good, respect for individual autonomy is one of the basic guiding principles governing the ethical basis of health care. The strong judicial deference toward individual autonomy, in which an individual has a legal and moral right to be free of nonconsensual interference, and the basic moral principle that it is wrong to force a person to act against his will, resulted in the concept and practice of informed consent. [8] The questions raised in discussion of this case can be supported by the theory of

liberal neutrality and its three basic tenets [9] and can be found in common law. In cases where the patient exhibits capacity, the concept of patient autonomy was established in Schloendorff where Justice Cardozo wrote, “Every human being of adult years and sound mind has a right to determine what shall be done with his own body.” [10] This includes the right of a competent person to “refuse any medical treatment, even that which may save or prolong his life,” [11] and this right is guaranteed by a liberty interest in the Due Process Clause of the Fourteenth Amendment.

However, what is legal may not always be ethical or moral. In order to discuss the patient’s “autonomous” decision, it is necessary to differentiate between autonomy and moral freedom. Autonomy is the right to live your life your own way. Combining deontological and utilitarian concepts defined by Kant [12] and Mill, [13] Beauchamp and Childress defined autonomy as “personal rule of the self that is free from both controlling interference by others and from personal limitations that prevent meaningful choice.” [14] If autonomy is just self-mastery then, according to Rawls and Dworkin, “autonomy is ‘neutral’ with respect to any particular substantive conception of the human good” [15] and it is “the freedom to choose and the activity of choosing that matter, not what is chosen.” [16] Autonomy involves “negative liberty”, or according to Justice Louis Brandeis, the “right to be left alone” free of others [17] as well as a “positive liberty” or right of self-control. Moral autonomy is more than just independent thought and actions, it encompasses concepts of moral individualism, moral choice and consent, and Kant’s concept that “you should obey only those rules and play only those roles that have passed rational and moral muster by your autonomous, judging ego.” [18] Therefore, self-mastery, or “freedom from outside restraint and the freedom to live one’s life in one’s own way” [19] neither presupposes nor negates the supposition that a person’s autonomous decision is indeed moral. Morality must also consider the larger context of how the individual’s actions affect others directly as well as society as a whole.

The doctrine of informed consent provides a structure to respect the autonomous rights of patients to determine their own treatment options and guides health care decision-making by defining the boundaries of the physician-patient relationship. The four elements of informed consent are: the patient is decisional (has capacity) and can cognitively make the decision; the patient receives adequate information; the patient weighs the information vis-à-vis his goals, values, and desires; and the patient reaches a decision in light of the above and has the ability to express it. Therefore, autonomy provides the basis for this decision process and informed consent supports the concept of autonomy. The requirements of informed consent reflect the concept of autonomy and result in the patient’s permission to commence or not commence on a course of therapy.

In this case, the patient was an internist, knowledgeable of his disease process, end-of-life care, organ donation and transplantation. Clearly, if he had decisional capacity, he defined the ultimate patient with informed consent. Once he was found to be decisional, and coercive and psychiatric considerations were ruled out, he clearly complied with all the elements of informed consent.

Arguments that unlike brain dead donors and perhaps DCD donors, he would not be dead at the time of organ procurement, and therefore, his donation would be a violation of the DDR, must be addressed. To be intellectually honest, we have been harvesting the organs of patients who are not dead for over 50 years. Life and death are mutually exclusive; therefore, you cannot be

both alive and dead at the same point in time. Not all brain dead donors meet the criteria for brain death under the UDDA. For the purposes of this discussion, I am willing to stipulate that not all DCD donors meet the criteria for cardiopulmonary death under the UDDA too. Although most anesthesiologists are quite comfortable with participation in the procurement of organs from brain dead donors, in some cases acceptance of and participation in these procurements may be inappropriate.

Brain death is a clinical diagnosis defined by medical criteria and therefore, the concept is medically flawed. [20] The criteria for brain death was only understood by 35% of physicians and nurses involved in organ donation [21] and the diagnosis of brain death has been inappropriately applied. [22] Several studies have shown that brain dead donors do not have "irreversible cessation of all functions of the entire brain and brain stem". Many brain dead donors exhibit hypothalamic and/or posterior pituitary function sufficient to maintain normal salt and water homeostasis. [23,24,25] In addition, recovered stem cells from brains of brain dead donors have been propagated in vitro. [20] Therefore, the statutory definition of brain death may not be met, yet we accept these patients as brain dead donors in violation of the UDDA and DDR. Furthermore, the justification for considering brain dead patients dead (that regardless of therapy they incur imminent death from cardiac arrest, [26] they are permanently unconscious, and without the organizational influence of the brain the body undergoes disintegration and death [25]) is no longer valid. The reason for imminent death in these patients is withdrawal of life-support and cardiac death. [25] If supported in the acute phase of injury, death is not imminent and long-term "survival" is possible. [27] Finally, brain dead patients may exist as a level sufficient to prevent disintegration of the organism. [25] Therefore, "the signs and symptoms that constitute brain death are clearly diagnostic of severe and irreversible brain injury, but diagnostic of death only by stipulation." [28] So, why are we comfortable with this possible violation of the UDDA and DDR and yet uncomfortable with the requests of the patient in this case?

The patient presented in this case fits the Institute of Medicine's expanded 2000 criteria for a suitable DCD candidate. The moral considerations of the concept of DCD include the right of a person to have non-beneficial life sustaining therapies withdrawn and undergo organ donation. Consequentialism (utilitarianism) supports this ethical right in persons with decisional capacity or precedent autonomy based on the greatest happiness and harm principles. Failure to allow this is clearly maleficent. Deontologic ethics bases morality on intentions and not consequences and a pure Kantian would forbid this donation if such action caused harm to the donor or if the donor was treated as a means to someone else's end, rather than an end unto himself. However, less orthodox deontologists might consider the decision moral, with small harm, if the patient made an a priori autonomous decision not to burden himself, family, and society with continued life.

Although our patient may raise concerns regarding the public's perception of this proposed process, our patient differs from a standard DCD case. In DCD, the patient is declared dead by circulatory criteria (controversial [5,7]), and then donation occurs. In our case, similar to live donors, the patient is alive at the time of donation and thus the organs are perfused until removed. Therefore, unlike DCD, there is no need for the administration of organ protective agents prior to procurement and thus, no violation of the DDR or deontologic principles. In our case, the procurement is planned to occur before death and therefore the questions regarding the timing of death, irreversibility of death, and autoresuscitation, which complicate DCD, are

moot. Although questions regarding the misapplication of double-effect are not applicable in our case, questions regarding whether our donor is a means to another's end must be considered. Questions regarding euthanasia and physician assisted suicide must also be addressed. It is generally accepted that withdrawal of life-support and passive euthanasia are not the same as active euthanasia. Here the concept is that withdrawing what has been determined to be non-beneficial life-sustaining medical therapies allows the patient to die a natural death and avoids interventions that prevent a natural death. This does not mean withdrawal of comfort care and appropriate medications (opioids, anxyolytics) can be administered to prevent the pain and anxiety of ischemia. There is no ethical difference between withdrawing and withholding life-sustaining therapies. These concepts are supported by the AMA's Code of Medical Ethics, [29] the American Thoracic Society,[30] and the Society of Critical Care Medicine. [31] Active euthanasia, or making interventions that directly cause a patient's death and physician assisted suicide (PAS) are not condoned by the AMA's Code of Medical Ethics. [32,33]

The public seems more willing to accept changes in the DDR and the public's perceptions are changing regarding the DDR, DCD, euthanasia, and PAS. The public failed to react to a 1997 "60 Minutes" expose regarding the UW transplantation program and DCD, a 2004 Ohio study showed that 45% of those with consistent answers were willing to violate the DDR and donate organs of patients they considered to be alive, [34] and a study of terminally ill adult cystic fibrosis patients showed increased interest in terminal live kidney donation. [20] The failure to convict Jack Kevorkian of murder until his fourth trial, despite statutes specifically written and directly forbidding euthanasia and PAS, the fact that there is widespread euthanasia illustrating that the law does not reflect public opinion, [20] the holdings of the U.S. Supreme Court to "permit the [PAS] debate to continue" in Vacco v. Quill [35] and Washington v. Glucksberg, [36] and the holding of the Supreme Court in Gonzoles v. Oregon [37] illustrate these changes. However, the case being presented differs from DCD in other ways and several questions must be raised. Unlike DCD, in the case presented we cannot ignore physician complicity. Will the patient's death be secondary to the removal of vital organs, ALS, or anesthesia? At the end of the case will you allow the patient to die under anesthesia or will you allow him to waken and extubate? Do you only remove one kidney, a portion of his liver, a single lung wake the patient up, extubate him, and provide comfort care in a palliative care setting awaiting an eventual death? Do you remove both kidneys and liver and prepare the patient for an imminent death, either in the OR or in a palliative care setting? Do you remove vital organs (heart, lungs) and accept an immediate intraoperative death or should you employ extracorporeal oxygenation and circulation techniques and move the patient from the OR to a palliative care unit to die? Are we accepting a role in active euthanasia and PAS? [38] And, if we accept this role do we have to question whether premortem organ retrieval is lawful. [39]

According to the ASA's Sample Policy and House of Delegates resolution, non-critical care anesthesiologists have no role in DCD other than to be supportive of the process in general and not negatively interfere with the process in their own institutions. In the case being discussed anesthesiologists will be directly involved. Do we only administer the general anesthesia? If so, who extubates the patient? Who withdraws non-beneficial therapies and who provides comfort care? In the case of DCD, we decided that it should be those with the most expertise and this does not include non-critical care anesthesiologists. Finally, where will the withdrawal of non-beneficial life support occur: in the OR, ICU, PACU, or palliative care unit?

The DDR requires an answer to the question when does death occur? Perhaps it is time to

abandon the DDR? Do we need to seek permission or promise that no legal or regulatory action or sanction will be taken against those involved or should we just keep the donation quiet? Clearly legal counsel for both the hospital and physicians should be involved.

The underlying question remains what conditions make it morally acceptable to remove or procure vital organs from dying patients? Respect for patient autonomy is the only moral basis that can justify exceptions to the principle of nonmaleficence. Duty to avoid exploitation and harm, to protect vulnerable populations, and avoid "slippery slope" situations are essential to protect the moral basis and society's continued support of organ donation. This case challenges the traditional methods of organ donation. Strict adherence to ensuring respect for the patient's informed, moral, and autonomous decisions and interests should be promoted. Finally, no physicians or other medical personnel should be required to participate in this process against their will.

References

1. Accessed April 20th, 2014 from: optn.transplant.hrsa.gov
2. Robertson JA. The dead donor rule. Hastings Cent Rep 1999;29(6):6-14
3. A definition of irreversible coma: a report of the ad hoc committee of the Harvard Medical School to examine the definition of brain death. JAMA 1968;205:337-40
4. University of Pittsburgh Medical Center policy and procedure manual. Management of terminally ill patients who may become organ donors after death. Kennedy Inst Ethics J 1992;3:A1-15
5. Wolman RL. Ethical issues in organ donation after cardiac death. In: Van Norman GA, et al (eds), Clinical Ethics In Anesthesiology: A Case-Based Textbook. Cambridge, UK: Cambridge University Press, 2011:114-22
6. Available at http://www.asahq.org/clinical/OrganDonationsamplepolicy.pdf
7. Van Norman GA. 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 2003;98(3):763-73
8. Furrow BR. Health Law. St. Paul, MN: Thompson West, 2001:356
9. Gaylin W, Jennings B. The Perversion Of Autonomy: Coercion And Constraints In A Liberal Society. Washington, D.C.: Georgetown University Press, 2003:229-30
10. Schloendorff v. Society of New York Hospital, 211 N.Y. 125, 105 N.E. 92 (N.Y.1914)
11. Bouvia v. Superior Court, 179 Cal.App.3d 1127 225 (Cal.App 2 Dist. 1986)
12. Kant I. Fundamental Principles of the Metaphysic of Morals. Amherst, NY: Prometheus Books, 1988
13. Mill JS. On Liberty. Amherst, NY: Prometheus Books, 1986
14. Beauchamp T, Childress J. Principles of Biomedical Ethics, 4th edition. NY: Oxford University Press, 1994:121
15. Rawls J. A Theory of Justice. Cambridge, MA: Harvard University Press, 1971 and Dworkin R. "Liberalism" In Hampshire S (ed.), Public and Private Morality. NY: Cambridge University Press, 1978:113-43
16. The Perversion Of Autonomy: Coercion And Constraints In A Liberal Society: 36
17. Olmsted v. United States, 277 U.S. 438 (1928)

18. The Perversion Of Autonomy: Coercion And Constraints In A Liberal Society: 38
19. The Perversion Of Autonomy: Coercion And Constraints In A Liberal Society: 72
20. Fost N. Reconsidering the dead donor rule: is it important that organ donors be dead? Kennedy Inst Ethics J 2004;14(3):249-60
21. Youngner SJ, et al. 'Brain Death' and Organ Retrieval: A Cross-sectional Survey of Knowledge and Concepts Among Health Professionals. JAMA 1989;261:2205-10
22. Van Norman GA. A matter of life and death: what every anesthesiologist should know about the medical, legal, and ethical aspects of declaring brain death. Anesthesiology 1999;91(10):275-87
23. Lynn J, et al. The persisting perplexities in the determination of death. In: Youngner SJ, et al (eds.), The Definition of Death: Contemporary Issues, Baltimore: Johns Hopkins University Press, 1999:101-13
24. Truog RD, et al. Rethinking brain death. Crit Care Med 1992;20(12):1705-13
25. Truog RD, et al. Role of brain death and the dead-donor rule in the ethics of organ transplantation. Crit Care Med 2003;31(9):2391-6
26. Palis C. Brit Med J 1983;286:123-4
27. Sherwon DA. Neurology 1998;51:1538-45
28. Dagi TF, et al. Clarifying the discussion on brain death. J Med Philos 2001;26:503- 25
29. Council on Ethical and Judicial Affairs, American Medical Association. Opinion 2.20: Withholding or withdrawing life-sustaining medical treatment. Code of Medical Ethics, Current Opinions with Annotations, 2010-1011 Edition, Chicago: American Medical Association:88-9
30. American Thoracic Society, Withholding and withdrawing life-sustaining therapy. Am Rev Respir Dis 1991;144(3 Pt 1):726-31
31. Task Force on Ethics of the Society of Critical Care Medicine. Consensus report on the ethics of forgoing life-sustaining treatments in the critically ill. Crit Care Med 1990;18(12):1435-9
32. Council on Ethical and Judicial Affairs, American Medical Association. Opinion 2.21: Euthanasia. Code of Medical Ethics, Current Opinions with Annotations, 2010-1011 Edition, Chicago: American Medical Association:109
33. Council on Ethical and Judicial Affairs, American Medical Association. Opinion 2.211: Physician-assisted suicide. Code of Medical Ethics, Current Opinions with Annotations, 2010-1011 Edition, Chicago: American Medical Association:112
34. Siminoff LA, et al. Death and organ procurement: public beliefs and attitudes. Kennedy Inst Ethics J 2004;14(3):217-34
35. Vacco v. Quill 521 U.S. 793 (1997)
36. Washington v. Glucksberg 521 U.S. 702 (1997)
37. Gonzales v. Oregon 546 U.S. 243 (2006)
38. Morrissey PE. The case for kidney donation before end-of-life care. Am J Bioeth 2012;12(6):1-8
39. Cantor NL. Could premortem organ retrieval be lawful? Am J Bioeth 2012;12(6):12-13