

Death and Organ Donation

Summary: This project encompasses conceptual research on ethical issues relating to vital organ donation, the determination of death, and death-causing medical interventions (withdrawing life-sustaining treatment and active euthanasia).

Principal Investigator: Franklin G. Miller, Ph.D.

Collaborators: **Bioethics:** Seema Shah, J.D.

Non-NIH: Robert Truog, M.D., Harvard University

 Dan Brock, Ph.D., Harvard University

Background: Development of the intensive care unit and organ transplantation in the mid 20th century posed unprecedented ethical challenges. Clinicians were faced with the questions of whether and when it could be ethical to withdraw life-sustaining treatment (LST) and how it could be ethical to procure viable vital organs for transplantation to patients in need of organs to survive or to enhance their quality of life. The ethical challenges derived from potential tensions between the practices of withdrawing LST and vital organ transplantation and commitment to the traditional norm of medical ethics that doctors must not kill (deliberately cause the death of) their patients. Medical ethics and the law responded to these challenges by conceptualizing withdrawing life-sustaining treatment and vital organ transplantation in ways that did not conflict with the prohibition on medical killing. Withdrawing life-sustaining treatment became understood as (merely) allowing patients to die from their underlying otherwise terminal medical conditions. In doing so, clinicians did not cause, or did not intentionally cause, the death of patients. Vital organ transplantation was held to be justifiable provided that organ donors were legitimately determined to be dead at the time of organ procurement. This is known as “the dead donor rule.” To make vital organ transplantation consistent with the dead donor rule, the standards for medical determination of death had to be transformed or updated from the traditional circulatory/respiratory criteria to include neurological criteria—the irreversible cessation of the functioning of the entire brain. The diagnosis of “brain death” became established in the decade following 1968, culminating in official endorsement by the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research in 1981 and the simultaneous promulgation of the Uniform Determination of Death Act. More recently, the growing shortage of organs for transplantation led to the development of protocols to procure vital organs from donors who do not meet the diagnostic criteria for brain death, in the context of planned withdrawal of life-sustaining treatment. Organs are procured a

very short interval after the cessation of circulation, raising questions about whether the donors are really dead at the time. The established position has been that in view of the prior decision to withdraw treatment and not to attempt resuscitation, cessation of circulatory functioning could be considered irreversible, consistent with the dead donor rule.

Empirical, conceptual, and normative considerations have called into question the consensus positions in medical ethics supporting withdrawing life-sustaining treatment and vital organ transplantation. Some philosophers and bioethicists have challenged the traditional stance that there is a bright line ethical distinction between withdrawing life-sustaining treatment and active euthanasia by means of injecting lethal medication. The latter has always been understood as the deliberate intervention to cause the death of the patient in response to a voluntary request by the patient and/or to relieve unbearable suffering. Is it true that withdrawing life support such as mechanical ventilation does not (intentionally) cause the death of patients? Moreover, the same ethical principles of respect for patient autonomy and relief of suffering appear to equally support both practices of withdrawing LST and active euthanasia. With respect to the ethics of vital organ transplantation, the established position that the correct diagnosis of “brain death” constitutes death—understood biologically as the irreversible cessation of the functioning of the organism as a whole—has been challenged by empirical investigation of patients diagnosed as “brain dead” but maintained on mechanical ventilation for substantial periods of time. Not only do most patients who meet the criteria for “brain death” continue to sustain some brain functioning, particularly the secretion of vasopressin which maintains the body’s balance of fluid and salt needed to sustain life; these patients also display a wide array of biological functioning with the aid of mechanical ventilation and nursing care, including circulation, respiration, temperature regulation, wound healing, fighting infections, etc. Most strikingly, pregnant women diagnosed as “brain dead” have been able, with continuing intensive care intervention, to gestate a healthy fetus for an extended length of time. It is difficult, if not impossible, to square these facts with the thesis that the “brain death” diagnosis coincides with the biological death of the organism as a whole. Additionally, determining death for the purpose of vital organ donation based on circulatory criteria a very short interval after the heart has stopped beating poses conceptual problems. It is argued that cessation of circulation cannot be known to be irreversible within 5 minutes of asystole in view of the possibility that resuscitative measures might be successful in restoring circulation. Reflecting the ethical ferment relating to the determination of death, and its implications for organ donation, the President’s Council on Bioethics, issued a “White Paper,” entitled, “Controversies in the Determination of Death,” in December 2008.

Departmental Research Initiative: Research on this topic area began with collaboration between Miller and Truog to develop a systematic account of the ethics of vital organ donation on the premise that under current practices patient-donors are not dead or not known to be dead when organs are being procured, in contravention of the dead donor rule. Central to the proposed justification of vital organ donation from still-living donors is the argument that withdrawing life-sustaining treatment causes the death of patients, and that this is legitimate in light of the principles of respect for autonomy, beneficence, and nonmaleficence. The argument relies on applying the common-sense understanding of causation to the situation of withdrawing LST. As such, it becomes patently mistaken, for example, to describe withdrawing mechanical

ventilation from patients unable to breathe spontaneously as an omission that merely allows them to die; rather, it is an intervention that causes death, which would not occur at the time that it does absent the treatment withdrawal. This understanding of causing death is relevant to the ethics of vital organ donation in the following way. Given that it is legitimate for clinicians to cause the death of patients by withdrawing life-sustaining treatment, an absolute norm that clinicians must not cause the death of their patients must be rejected. Hence, the legitimacy of life-terminating acts of vital organ donation from still-living patients becomes an open question. Furthermore, given that it is legitimate to cause death by withdrawing life support, patients are not harmed or wronged by procuring vital organs prior to stopping treatment, provided that valid consent has been given both to the treatment withdrawal and the organ donation. This argument was set out in detail in a paper published in *The Hastings Center Report*. An abbreviated version of the argument was published in a Perspective article in *The New England Journal of Medicine*. Several collaborative papers followed this initial effort, including 1) a critique of the white paper issued by the President's Council on Bioethics, 2) an account of "moral fictions" characterizing the established understanding of withdrawing life-sustaining treatment and the bright line between this practice and active euthanasia, 3) a critical examination of the dead donor rule, and 4) proposing a "legal fictions" approach to the determination of death as an interim pragmatic solution to the controversies relating to vital organ donation.

This collaborative research program led to plans for Miller and Truog to write a book incorporating and more systematically developing the positions staked out in the papers described above and listed in the publications below. Based on review of a book proposal, a contract was entered into between the authors and Oxford University Press. A first draft of the book, entitled, "Death in Medicine: Reconstructing Medical Ethics at the End of Life," has been prepared. It includes the following chapters: (1) Withdrawing life-sustaining treatment: allowing to die or causing death? (2) Active euthanasia; (3) Death and the Brain; (4) Donation after Circulatory Determination of Death; (5) Vital Organ Donation without the Dead Donor Rule; (6) Legal Fictions Approach to Vital Organ Donation; and (7) Reflections on Bioethics. It is anticipated that a revised draft of the manuscript will be sent to Oxford for external peer review by the end of 2010.

Impact of research: It is somewhat premature to assess the impact of this research program, as the first papers were published in August and December of 2008. These papers already have been cited numerous times in the literature (respectively, 25 and 24, as of 8/19/10). Truog is frequently invited to address medical audiences on issues of determination of death and organ donation. In response to published work, Miller has given a grand rounds presentation on death and organ donation at University of Texas Southwestern and was invited to present on this topic at the American Philosophical Association's Central Division Meeting, with commentaries by two philosophers. Publication of the book is likely to increase attention to this research in the bioethics and medical communities.

Publications:

Miller FG, Truog RD. An apology for Socratic bioethics, *American Journal of Bioethics* 2008;8(7):3-7.

Miller FG, Truog RD. Rethinking the ethics of vital organ donations, *Hastings Center Report* 2008;38(6):38-46.

Truog RD, Miller FG. The dead donor rule and organ donation. *New England Journal* 2008;359:674-5.

Miller FG, Truog RD, Brock DW. Moral fictions and medical ethics. *Bioethics*, in press (published online July 7, 2009).

Miller FG, Truog RD. The incoherence of determining death by neurological criteria: Commentary on *Controversies in the Determination of Death*, A White Paper by the President's Council on Bioethics. *Kennedy Institutes of Ethics Journal* 2009;19:185-93.

Miller FG. Death and organ donation: back to the future. *Journal of Medical Ethics* 2009;35:616-20.

Miller FG, Truog RD. The incoherence of determining death by neurological criteria: reply to John Lizza. *Kennedy Institute of Ethics Journal* 2009;19:397-99.

Miller FG, Truog RD, Brock DW. The dead donor rule: can it withstand critical scrutiny? *Journal of Medicine and Philosophy* 2010;35:299-312.

Truog RD, Miller FG. Brain perfusion scans to diagnose brain death: more than meets the eye. *Pediatric and Critical Care Medicine* 2010;11:527-8.

Truog RD, Miller FG. Counterpoint: are donors after circulatory death really dead, and does it matter? No and not really. *Chest* 2010;138:16-18.

Shah S, Miller FG. Can we handle the truth? Legal fictions in the determination of death, *American Journal of Law and Medicine*, in press.

Miller FG, Truog RD. Decapitation and the definition of death, *Journal of Medical Ethics*, in press.