

6.1.2 Organ Donation after Cardiac Death

Increasing the supply of organs available for transplant serves the interests of patients and the public and is in keeping with physicians' ethical obligation to contribute to the health of the public and to support access to medical care. Physicians should support innovative approaches to increasing the supply of organs for transplantation, but must balance this obligation with their duty to protect the interests of their individual patients.

Organ donation after cardiac death is one approach being undertaken to make greater numbers of transplantable organs available. In what is known as "controlled" donation after cardiac death, a patient who has decided to forgo life-sustaining treatment (or the patient's authorized surrogate when the patient lacks decision-making capacity) may be offered the opportunity to discontinue life support under conditions that would permit the patient to become an organ donor by allowing organs to be removed promptly after death is pronounced. Organ retrieval under this protocol thus differs from usual procedures for cadaveric donation when the patient has died as a result of catastrophic illness or injury.

Donation after cardiac death raises a number of special ethical concerns, including how and when death is declared, potential conflicts of interest for physicians in managing the withdrawal of life support for a patient whose organs are to be retrieved for transplantation, and the use of a surrogate decision maker.

In light of these concerns, physicians who participate in retrieving organs under a protocol of donation after cardiac death should observe the following safeguards:

- (a) Promote the development of and adhere to clinical criteria for identifying prospective donors whose organs are reasonably likely to be suitable for transplantation.
- (b) Promote the development of and adhere to clear and specific institutional policies governing donation after cardiac death.
- (c) Avoid actual or perceived conflicts of interest by:
 - (i) ensuring that the health care professionals who provide care at the end of life are distinct from those who will participate in retrieving organs for transplant;
 - (ii) ensuring that no member of the transplant team has any role in the decision to withdraw treatment or the pronouncement of death.
- (d) Ensure that the decision to withdraw life-sustaining treatment is made prior to and independent of any offer of opportunity to donate organs (unless organ donation is spontaneously broached by the patient or surrogate).
- (e) Obtain informed consent for organ donation from the patient (or surrogate), including consent specifically to the use of interventions intended not to benefit the patient but to preserve organs in order to improve the opportunity for successful transplantation.

- (f) Ensure that relevant standards for good clinical practice and palliative care are followed when implementing the decision to withdraw a life-sustaining intervention.

AMA Principles of Medical Ethics: I,III,V

Background report(s):

CEJA Report 3-A-16 Modernized *Code of Medical Ethics*

CEJA Report 10-A-05 Organ procurement following cardiac death, amendment

CEJA Report 3-I-94 Ethical issues in organ procurement following cardiac death: in situ preservation of cadaveric organs

CEJA Report 4-I-94 Ethical issues in organ procurement following cardiac death: the Pittsburgh protocol

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 10 - A-05

Subject: Organ Procurement Following Cardiac Death, *Amendment*

Presented by: Michael S. Goldrich, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(Art L. Klawitter, MD, Chair)

1 After reviewing Opinion E-2.157, “Organ Procurement Following Cardiac Death,” (AMA Policy
2 Database) the Council on Ethical and Judicial Affairs (CEJA) has determined that several sections
3 of the policy are outdated and need to be amended. The proposed changes below aim to bring the
4 policy up-to-date by (i) introducing more contemporary terminology; (ii) acknowledging the
5 different circumstances – controlled and uncontrolled – under which donation after cardiac death
6 might arise; (iii) removing the specific reference to how much time should elapse between cardiac
7 arrest and the pronouncement of death, and (iv) eliminating language that calls for further pilot
8 programs of organ removal following withdrawal of life-sustaining treatment.

9
10 Generally, edits of a current Opinion that simply provide clarification and do not change the
11 substance of guidelines are presented to the House of Delegates in the form of a CEJA Opinion,
12 which is then filed. Because the proposed amendments to current Opinion E-2.157 introduce
13 substantive changes, CEJA presents the edited Opinion to the House of Delegates in the form of a
14 Report, to foster discussion of these changes before it issues the amended Opinion.

15
16 RECOMMENDATIONS

17
18 The Council recommends that Opinion E-2.157, “Organ Procurement Following Cardiac Death,”
19 be amended as follows and the remainder of the Report be filed.

20
21 E-2.157 Organ Donation After Procurement Following Cardiac Death.

22
23 Given the increasing need for donor organs, protocols for procurement following donation
24 after cardiac death (DCD) have been developed. ~~In some instances, Controlled DCD~~
25 allows patients who have agreed to be taken off of life support or their surrogate decision
26 makers the opportunity to donate the patients’ organs once death has been declared request
27 ~~withdrawal of life support and choose to serve as organ donors.~~ In these cases, the organs
28 can be preserved best by discontinuation of life support is discontinued in or near the

* Reports of the Council on Ethical and Judicial Affairs are assigned to the reference committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

1 operating room so that organs can be removed ~~two minutes following cardiac~~
2 ~~death promptly after death is pronounced.~~ In other scenarios, patients DCD also may be
3 considered from patients who suffer unexpected cardiac death (uncontrolled DCD). It
4 requires that they may be cannulated and perfused with cold preserving-preservation fluid
5 (in situ preservation) within minutes after death to maintain the viability of organs. Both of
6 these methods may be ethically permissible, with attention to certain safeguards.

7
8 (1) Hospital policies should specify important details of the DCD process, such as the
9 required time delay before death can be pronounced after cardiac arrest.

10
11 (2) In controlled DCD, the decision to withdraw life support should be made by the
12 patient or the patient's surrogate decision maker before any mention of organ donation
13 (unless the patient or surrogate spontaneously broaches the subject). When securing
14 consent for life support withdrawal and organ retrieval, the health care team must be
15 certain that consent is voluntary. This is particularly true where surrogate decisions
16 about life-sustaining treatment may be This is meant to ensure that withdrawal of life
17 support is not influenced by the prospect of organ donation. If there is any reason to
18 suspect undue influence, a full ethics consultation should be required.

19
20 The informed consent for controlled DCD should include specific discussion of pre-
21 mortem interventions aimed at organ preservation, to improve the opportunity for
22 successful transplantation, rather than to benefit the patient. Interventions that are
23 likely to hasten death must not be used.

24
25 (23) In all instances, it is critical that there be no to avoid perceived or actual conflicts of
26 interest in the health care team with respect to caring for the patient versus facilitating
27 organ donation. These The health care professionals providing care at the end of life
28 must should be separated distinct from providers those participating in on the
29 transplant team. No member of the transplant team may have any role in the decision
30 to withdraw life support or in the process leading to pronouncement of death.

31
32 (3) Further pilot programs should assess the success and acceptability of organ removal
33 following withdrawal of life-sustaining treatment.

34
35 (4) Palliative care for DCD candidates should continue after removal of life support until
36 death is declared.

37
38 (45) In cases of uncontrolled DCD in situ preservation of cadaveric organs, the prior
39 consent of the decedent to organ donation or the consent of the decedent's surrogate
40 decision maker makes perfusion is ethically permissible required. Perfusion without
41 either consent to organ donation prior specific consent to perfusion or general consent
42 to organ donation violates requirements for of informed consent for medical
43 procedures and should is not be permitted permissible.

44
45 (5) The recipients of such procured organs should be informed of the source of the organs
46 as well as any potential defects in the quality of the organs, so that they may decide
47 with their physicians whether to accept the organs or wait for more suitable ones.

48
49 (6) Clear clinical criteria should be developed in place to ensure that only appropriate
50 candidates, whose organs are reasonably likely to be suitable for transplantation, are
51 considered eligible to donate organs under these protocols. (I, III, V) (Modify
52 HOD/CEJA Policy)

1
2 Issued June 1996 based on the reports “Ethical Issues in the Procurement of Organs
3 Following Cardiac Death: The Pittsburgh Protocol” and “Ethical Issues in Organ
4 Procurement Following Cardiac Death: In Situ Preservation of Cadaveric Organs,” adopted
5 December 1994; updated June 2005.

APPENDIX

The amended Opinion would read as follows:

E-2.157 Organ Donation After Cardiac Death.

Given the increasing need for donor organs, protocols for donation after cardiac death (DCD) have been developed. Controlled DCD allows patients who have agreed to be taken off of life support or their surrogate decision makers the opportunity to donate the patients' organs once death has been declared. In these cases, life support is discontinued in or near the operating room so that organs can be removed promptly after death is pronounced. DCD also may be considered from patients who suffer unexpected cardiac death (uncontrolled DCD). It requires that they be cannulated and perfused with cold preservation fluid (*in situ* preservation) within minutes after death to maintain the viability of organs. Both of these methods may be ethically permissible, with attention to certain safeguards.

- (1) Hospital policies should specify important details of the DCD process, such as the required time delay before death can be pronounced after cardiac arrest.
- (2) In controlled DCD, the decision to withdraw life support should be made by the patient or the patient's surrogate decision maker before any mention of organ donation (unless the patient or surrogate spontaneously broaches the subject). This is meant to ensure that withdrawal of life support is not influenced by the prospect of organ donation.

The informed consent for controlled DCD should include specific discussion of pre-mortem interventions aimed at organ preservation, to improve the opportunity for successful transplantation, rather than to benefit the patient. Interventions that are likely to hasten death must not be used.

- (3) In all instances, it is critical to avoid perceived or actual conflicts of interest in the health care team with respect to caring for the patient versus facilitating organ donation. The health care professionals providing care at the end of life should be distinct from those participating on the transplant team. No member of the transplant team may have any role in the decision to withdraw life support or in the process leading to pronouncement of death.
- (4) Palliative care for DCD candidates should continue after removal of life support until death is declared.
- (5) In cases of uncontrolled DCD, prior consent of the decedent to organ donation or consent of the decedent's surrogate decision maker is ethically required. Perfusion without consent to organ donation violates requirements of informed consent for medical procedures and is not permissible.
- (6) Clear clinical criteria should be in place to ensure that only appropriate candidates, whose organs are reasonably likely to be suitable for transplantation, are considered eligible to donate organs under these protocols. (I, III, V)

Issued June 1996 based on the reports “Ethical Issues in the Procurement of Organs Following Cardiac Death: The Pittsburgh Protocol” and “Ethical Issues in Organ Procurement Following Cardiac Death: In Situ Preservation of Cadaveric Organs,” adopted December 1994; updated June 2005.

CEJA Report 3 – I-94

Ethical Issues in Organ Procurement Following Cardiac Death: In Situ Preservation of Cadaveric Organs

INTRODUCTION

Resolution 6, introduced at the 1993 Annual Meeting by the Medical Schools Section and referred to the Board of Trustees, called upon the AMA to review various options to enhance the availability of transplantable organs. This report is one of a series presented by the Council in response.

It is widely recognized that the chronic shortage of organs available for transplantation results in a large number of potentially preventable deaths.^{1,3} A number of policy changes have been proposed to try to alleviate this shortage, including presumed consent, mandated choice, financial and non-financial incentives, and protocols for organ procurement following cardiac death. The Council has previously addressed presumed consent,⁴ mandated choice,⁴ and financial incentives.⁵ In addition, the Council has addressed the strategy piloted by the University of Pittsburgh Medical Center for organ procurement following cardiac death (the "Pittsburgh protocol").^{6,7} In this report, the Council considers a separate protocol for organ procurement following cardiac death. In this protocol, instituted by the Regional Organ Bank of Illinois (ROBI), cadaveric organs are preserved in situ through the perfusion of a cold preserving fluid (the "ROBI protocol").

DEFINITIONS

Brain death: A "brain dead II patient is declared dead according to neurological criteria (i.e., the irreversible cessation of all functions of the entire brain, including the brain stem). Though the patient has died, cardiopulmonary function may be maintained through artificial means.

Cardiac Death: Cardiac death occurs when death is declared according to traditional cardiopulmonary criteria (i.e., the irreversible cessation of circulatory and respiratory functions).

HISTORICAL BACKGROUND ON THE PROCUREMENT ORGANS FOLLOWING CARDIAC DEATH

Prior to adoption of neurological criteria for death in the early to mid-1970s, the medical community defined death solely as the cessation of cardiopulmonary function. Organs for transplantation had to be retrieved and cooled quickly after death to minimize warm ischemia until the period between circulatory arrest and commencement of cold storage. (During this period, organs suffer cell and tissue damage due to the lack of oxygenated blood. Cooling the organs decreases oxygen demand therefore limits ischemic injury.) Prior to the adoption of neurological criteria, nearly all cadaveric organs procured for transplantation came from persons declared dead according to cardiopulmonary criteria.⁸

Adoption of neurological criteria for death, codified in the uniform Determination of Death Act, greatly enhanced the ability of transplant personnel to retrieve viable organs.⁸ The Uniform Determination of Death Act expanded the definition of death to include patients who experienced "the irreversible cessation of all functions of the entire brain, including the brain stem."⁹ Patients whose brains no longer functioned, but whose cardiopulmonary function could still be artificially maintained, could for the first time serve as organ donors. The organs of these cadavers continued to receive an ample supply of oxygenated blood through artificial support up until the actual moment of retrieval. This minimized ischemic damage and generated better organ functioning in transplant recipients. In addition, the ability to sustain cardiopulmonary function through artificial means in persons who were declared dead according

neurological criteria provided ample time to obtain consent for donation, assemble the transplant team and other personnel necessary to retrieve the organs, and identify and locate a suitable organ recipient. Thus, more transplants could occur. Since adoption of the Uniform Definition of Death Act, the vast majority of organs in the United States has been procured following brain death.⁸

Recently, given the chronic shortage of organs for transplantation, there has been an effort in the U.S. to find new ways to procure organs following cardiac death. Since the vast majority of people die in such a way that cardiopulmonary function cannot be maintained artificially, procuring organs following cardiac death could potentially enable many more people to serve as organ donors. One estimate states that the supply of organs could increase 20-25%.¹⁰ In situ preservation of cadaveric organs has been proposed as one way to achieve this commendable goal. The ROBI protocol, discussed below, is one such approach that has received attention from the transplant community and the media. The technique of in situ organ preservation is not limited to ROBI's efforts; the Washington Hospital Center in Washington, DC, for example, recently initiated its Rapid Organ Procurement Program for the retrieval of organs from trauma victims following cardiac death. However, the Council has chosen to focus on the ROBI protocol in this report, for it provides the most extensive clinical information on the practical applications of policy of in situ organ preservation to date.

IN SITU ORGAN PRESERVATION (THE ROBI PROTOCOL)

In situ preservation refers to a process of cannulation of a cadaver and subsequent perfusion of the abdominal cavity with a cold preserving fluid. In its original design, the ROBI protocol required consent from the decedent's surrogate decision maker prior to perfusion. However when the original design was implemented, none of the initial 35 surrogates consented to perfusion¹¹ (this number does not distinguish between those who could not be reached in time and those who actively refused). To enable a trial of in situ preservation, the protocol was revised to allow the commencement of perfusion without consent of the decedent's surrogate decision-maker.

In cooperation with the Regional Organ Bank of Illinois, two hospitals affiliated with Loyola University and Southern Illinois University ran a limited trial to investigate in situ organ preservation after cardiac death.¹² In this protocol, which involved fourteen emergency room patients, the kidneys of the cadavers were cooled through perfusion of a cold preserving fluid into the abdomen. Perfusion was begun as soon as possible (on average, 56 minutes) after the declaration of death in order to minimize warm ischemia time. Examination after retrieval revealed that, while the kidneys generally had suffered some ischemic damage, they might still have been suitable for transplantation.¹¹ (Organs procured through similar approaches in the Netherlands, Japan, and other countries have been successfully transplanted.^{13,14}) While perfusion was taking place, patients' surrogate decision makers were contacted to inform them of the patient's death and ask permission to retrieve the organs. Perfusion of the cadaver thus protected the viability of the organs while giving physicians more time to request permission and make arrangements for organ retrieval. The surrogates of 11 of the 14 cadavers undergoing perfusion consented to organ harvesting. Surrogates were informed that the organs would be examined but not actually transplanted; one family that refused permission indicated that they would have consented to retrieval if transplantation of the organs had been an option.

Since the completion of the study, at least forty bodies have undergone perfusion after cardiac death.¹⁵ Unlike the initial trial, none of these organ retrievals have been pursued in an emergency setting without the consent of the surrogate decision maker. Rather the protocol has only been carried out in a controlled environment and with the consent of the surrogate to organ donation before cannulation and perfusion. To reflect this shift, ROBI recently changed the protocol so that general consent to organ donation is required before perfusion of the cadaver can begin. Specific consent to perfusion is not required unless the catheter is inserted before cardiac death occurs.

ETHICAL ASPECTS

There are two distinct concerns about adequate provisions for consent in the ROBI protocol. The first is whether or not general consent for organ donation is necessary for perfusion of the cadaver. The second is whether or not general consent to organ donation represents sufficient consent for perfusion. The Council concludes that prior consent to organ donation is both a necessary and sufficient condition for perfusion and subsequent organ retrieval.

Necessity of General Consent

It is imperative that the patient or surrogate give general consent to organ donation before perfusion is started. As ROBI recognized in reverting to its original protocol, perfusion without consent is ethically problematic. It is important to address this issue in detail to limit future attempts to extend this or similar techniques to the emergency room and other uncontrolled environments where there may again be demand for perfusion without consent.

Because only a minority of individuals who are willing to donate the organs actually document their willingness, the decedent's surrogate is often called upon to consent to donation on the decedent's behalf. It could be argued that in situ organ preservation without prior consent to donation provides more time to contact the surrogate decision-maker, secure consent for organ retrieval, and assemble the transplant team to perform the surgery. Requiring surrogate consent prior to perfusion would preclude donation in many cases because the organs could suffer significant damage before such communication could occur. In one Dutch transplant program, which employed a similar in situ preservation approach, more than 20% of potential donor kidneys were lost because surrogate consent to perfusion could not be obtained in time.¹⁶

Furthermore, the benefits of obtaining more organs for transplantation, it is argued, outweigh the harm done by perfusion to the cadaver.¹² The patient in this case is already dead and by definition cannot suffer harm. The perfusion itself is minimally intrusive and disfiguring. In some cases in the ROBI study, in fact, families arrived at the hospital while perfusion was still taking place. The perfusion catheter, which is inserted in the groin, was hidden from view under a sheet and was not considered disturbing by the families. None of the families, even those who ultimately refused organ retrieval, objected when they learned that perfusion had occurred without their consent.¹⁷

These arguments, however, ultimately cannot justify the violation of informed consent that occurs when perfusion takes place without prior consent to organ donation. One important problem with perfusion without consent is that death could be declared prematurely to salvage organs. In situ protocols could enable physicians to preserve the organs of emergency room patients who die in the ER or shortly before arrival. Physicians trying to save these patients must weigh the likelihood of success of further resuscitation efforts against their desire to retrieve the patient's organs. It is difficult to know precisely when resuscitation may no longer be of value, and delaying perfusion of the cadaver increases the chances of ischemic damage. Thus, it is possible that resuscitation efforts may be cut short in order to begin perfusion of the cadaver. Patients who might be saved by aggressive resuscitation efforts may not receive them.

Even if this problem could be overcome by clear practice guidelines on resuscitation, the violation of informed consent still makes the perfusion without consent problematic. While it is true that patients who are truly dead cannot suffer harm in any intelligible sense, ethicists have drawn a distinction between being harmed and being wronged.¹⁸ The principle of informed consent rests on respect for the patient as an autonomous decision maker. As such, the patient has the right to control the disposition of his or her

own body, even after death.^{19(p.207)} While this right is not absolute, it does give patients the ability to consent to or reject most postmortem procedures (such as organ retrieval) performed for the benefit of others. Honoring the individual's wishes after death demonstrates respect for the individual and provides reassurance to the individual prior to death that matters of great personal importance, including postmortem procedures, will be handled as he or she would have wanted.

Given that there will always be some patients who would object to postmortem invasive procedures, violating their interest in bodily integrity denigrates the respect properly owed to the patient and to the patient's wishes. The failure to respect the patient's rights in this regard wrongs the patient even if he or she is unaware of the violation. In addition, postmortem procedures without consent can cause distress for the patient's surrogate, who may object to the procedures on religious or personal grounds. Though such objections did not occur in the initial study of the protocol, their absence may stem in part from the difficulty in objecting to procedures that have already been initiated.

The patient's interest in protecting his or her body from unwanted postmortem invasive procedures is not absolute but must be weighed against the benefits to others that may be gained from organ retrieval. Though these benefits are undisputed, creating an exception to informed consent to promote the social goal of organ procurement would set a troubling precedent that society has resisted in other contexts. If informed consent were to be set aside to promote organ transplantation, it is difficult to give principled reasons why it should not be set aside for other important social goods as well. For instance, informed consent could be set aside to perform research or practice incubation and other techniques on dead patients.^{8,20-22} In an even more extreme example, cadavers could be used without consent as subjects in automobile crash tests.²³ Like the perfusion of cadavers without consent to organ donation, both of these practices would promote society's interest in saving lives and would cause no real harm to the cadavers themselves. However, professional and public resistance to these practices despite their social benefits indicates society's general unwillingness to tolerate violations of informed consent, even for important causes.

It could be argued that, by allowing some nonconsensual violations of bodily integrity, society has distinguished between acceptable and unacceptable reasons for setting aside informed consent. Social goals may override informed consent when the violation is minimal, does little or no harm, and is the only way to accomplish a crucial goal. Thus, patient may be vaccinated against their wishes in order to protect public health or the state may require an autopsy despite the decedent's wishes in order to promote law enforcement and public safety.

However, it is doubtful that perfusion without consent to donation meets these criteria. First, while the perfusion procedure may seem minimally invasive to physicians or other health care workers, the prospects, patient's perception may differ. Because the patient is the one who will undergo the procedure, the patient's perception of its degree of invasiveness is highly relevant. It is at least questionable whether the insertion of catheters into the abdomen and the ensuing perfusion of the cadaver would be viewed as a trivial procedure by prospective patients. Second, perfusion of a cadaver without consent is not the only promising strategy for increasing the availability of transplantable organs. It is unlikely that such a protocol for organ retrieval could be as crucial to organ transplantation as vaccinations are to public health or autopsies are to law enforcement. There are many ways to improve procurement efforts without turning to strategies that violate informed consent. Mandated choice or limited financial incentives could be employed to increase the number of people who voluntarily identify themselves as donors.^{4,5} To consider the perfusion of cadavers as a permissible violation of informed consent, despite the existence of alternative means of increasing the organ supply, could weaken the importance with which the concept is viewed and undermine the perception of patients as autonomous decision makers whose wishes deserve respect.

Sufficiency of General Consent

General consent covers those cases in which there is express consent to organ donation, although not necessarily consent to perfusion itself. This might include cases in which the patient has signed an organ donor card or the patient's surrogate has previously consented to organ donation without specifying a technique of retrieval.

There are compelling arguments for the sufficiency of general consent. The first is simply that requiring specific consent to perfusion following general consent to donation places an unreasonable demand on protocols involving the in situ preservation of organs. In some cases, such as when the patient has signed a donor card, there may not be consent to perfusion simply because perfusion was not even presented as an option to which to consent. Perfusion may simply have not crossed the donor's mind. More importantly, in consenting to organ donation, the patient or surrogate implicitly consents to the procedures necessary to retrieve the organs unless there are grounds to believe that a reasonable person would not consent to the procedures (if, for example, a procedure was needlessly invasive and did not respect the dignity of the cadaver). However, cannulation is a relatively minor violation which does little to no physical harm. Indeed, inserting a catheter is far less invasive than retrieving an organ. Given these circumstances, specific consent to perfusion, while by no means prohibited, is not necessary. In including provisions for obtaining general consent prior to perfusion, the ROBI protocol meets the existing ethical standards for informed consent to organ donation.

A second consideration is that perfusion of the cadaver following consent to organ donation enables more people to act on their previously expressed desire to donate organs.^{8,12} In a recent survey, 69% of respondents indicated that they are likely to want their own organs donated after death.²⁴ However, because relatively few patients become heart beating cadavers, relatively few are currently able to act on their desire to donate. In situ organ preservation would expand the potential donor pool to include persons who die a cardiac death, thereby increasing the number of patients who are able to exercise their preference for donation.

In sum, the in situ preservation of organs is permissible if and only if the harvesting of organs is authorized by the decedent while living or, in the absence of clear knowledge of the decedent's wishes, by the decedent's surrogate. Under these circumstances, perfusion may take place to preserve the organs until the necessary arrangements for organ retrieval can be made.

CONCLUSIONS

In light of its potential to increase the organ pool, the ROBI protocol is permissible in its current form, as are other protocols which make appropriate provisions for consent. However, as evinced by the history of the protocol, in the effort to procure more organs for transplantation, the boundaries of ethically acceptable behavior may be at risk of being over-stepped. It is crucial that the ethics of the profession be maintained in the important effort to retrieve more organs and benefit even more patients.

RECOMMENDATIONS

For the reasons described in this report, the Council on Ethical and Judicial Affairs recommends that the following guideline be adopted and the remainder of this report be filed:

The in situ preservation of cadaveric organs, in which the abdomen of the cadaver is perfused with a cold preserving fluid with the consent of the decedent while living or the decedent's surrogate, is an

acceptable way to increase the availability of transplantable organs and thus the overall health of the public. Perfusion without either prior specific consent to perfusion or prior general consent to organ donation violates the requirement of informed consent for medical procedures and should not be permitted.

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CEJA Report 4 – I-94

Ethical Issues in the Procurement of Organs Following Cardiac Death: The Pittsburgh Protocol

INTRODUCTION

It is widely recognized that the chronic shortage of organs available for transplantation causes a large number of potentially preventable deaths.¹⁻³ In this report, the Council examines the protocol developed by the University of Pittsburgh Medical Center for expanding the pool of transplantable organs by retrieving organs following cardiac death. In the "Pittsburgh protocol," patients who request withdrawal of life-sustaining treatment may consent to serve as organ donors. If a patient has lost decision making capacity, surrogate consent is accepted for withdrawal of treatment and for organ donation. Organs are retrieved upon the declaration of cardiac death, which occurs, in the Pittsburgh protocol, after two minutes of cardiac arrest.

DEFINITIONS

Brain death: Brain death occurs when a person is declared dead according to neurological criteria (i.e., the irreversible cessation of the functions of the entire brain, including the brain stem). Though the person has died, cardiopulmonary function may be maintained through artificial means. *Cardiac death:* Cardiac death occurs when a person is declared dead according to cardiopulmonary criteria (i.e., the irreversible cessation of circulatory and respiratory functions).

HISTORICAL BACKGROUND ON THE PROCUREMENT OF ORGANS AFTER CARDIAC DEATH

Prior to adoption of neurological criteria for death in the early to mid- 1970s, the medical community defined death solely as the cessation of cardiopulmonary function. Organs for transplantation had to be retrieved and cooled quickly after death to minimize warm ischemia time, the period between circulatory arrest and commencement of cold storage. (During this period, organs suffer cell and tissue damage due to the lack of oxygenated blood. Cooling the organs decreases oxygen demand and therefore limits ischemic injury.) Prior to the adoption of neurological criteria, nearly all cadaveric organs procured for transplantation came after cardiac death.⁴

Adoption of neurological criteria for death, codified in the Uniform Determination of Death Act, greatly enhanced the ability of transplant personnel to retrieve viable organs.⁴ The Uniform Determination of Death Act expanded the definition of death to include patients who experienced "the irreversible cessation of all functions of the entire brain, including the brain stem."⁵ Patients whose brains no longer functioned, but whose cardiopulmonary function could still be artificially maintained, could for the first time serve as organ donors. The organs of these cadavers continued to receive an ample supply of oxygenated blood through artificial support up until the actual moment of retrieval. This minimized ischemic damage and generated better organ functioning in transplant recipients. In addition, the ability to sustain cardiopulmonary function through artificial means after brain death provided ample time to obtain consent for donation, assemble the transplant team and other personnel necessary to retrieve the organs, and identify and locate a suitable organ recipient. Thus, more transplants could occur. Since adoption of the Uniform Definition of Death Act, the vast majority of organs in the United States has been procured following brain death.⁴

Recently, given the chronic shortage of organs for transplantation, there has been an effort in the U.S. to find new ways to procure organs after cardiac death. Since the vast majority of people die in such a way that cardiopulmonary function cannot be maintained artificially, procurement of organs after cardiac death could potentially enable many more people to serve as organ donors. One estimate states that the supply of organs could increase 20-25%.⁶ The Pittsburgh protocol is one recent approach that has received attention from the transplant community and the media.

THE PITTSBURGH PROTOCOL

In the protocol employed by the University of Pittsburgh Medical Center, patients who request withdrawal of life-sustaining treatment may choose to serve as organ donors; surrogate consent is accepted for patients who have lost decision making capacity. These patients are weaned from life support in the operating room, where a transplant team is standing by to remove the organs once death has been declared. Death is declared two minutes after the heart stops beating.⁷

ETHICAL ASPECTS

Analysis of the Pittsburgh protocol has raised a number of ethical issues, including the appropriateness of declaring death only two minutes after cardiac arrest,⁸⁻¹⁰ the potential conflict of interest for physicians in managing the withdrawal of life support for a patient whose organs are to be retrieved for transplantation,^{11,13} the appropriateness of having death occur on an operating table¹⁴ and the use of surrogate consent to the protocol. These concerns are discussed below.

DECLARATION OF DEATH

As noted, death is currently defined as the irreversible cessation of neurological or cardiopulmonary function.⁵ The Pittsburgh protocol relies on the cardiopulmonary component of this definition in declaring patients dead two minutes after cardiac arrest. Critics argue that because many patients could be resuscitated at the two-minute mark, these patients have not experienced irreversible loss of function and therefore are not truly dead.⁸ Thus, the protocol may violate the "dead donor rule," which states that essential, non-renewable organs should only be procured from dead patients.¹⁵ However, as others have pointed out, the patient's request to be free from life support and permitted to die indicates that resuscitation would be contrary to the patient's expressed wishes.⁹ The council shares the view that the patient's loss of cardiopulmonary function may legitimately be viewed as irreversible because resuscitation is ethically precluded.⁹

A separate problem with declaring death only two minutes after cardiac failure is the possibility of auto-resuscitation.¹⁰ Obviously, a patient whose heart resumes beating on its own has not suffered irreversible cessation of cardiopulmonary function and is not dead under the current legal definition. It is unclear whether auto-resuscitation is possible two minutes after cardiac failure.¹⁰ However, some argue that even a small possibility of auto-resuscitation raises important concerns that organ procurement, rather than underlying disease, could be the cause of death.

This concern should not be exaggerated. Any definition of death involves some degree of ambiguity. For example, under current neurological criteria for death, residual biological activity may continue in the brain for some time after the patient meets the clinical criteria for brain death. It is debatable whether all functions of the entire brain may be said to have ceased when some biological activity remains.¹⁶ The ambiguity in defining the precise moment of death is also revealed when physicians decide to cease resuscitation efforts for a patient who is not responding.

When physicians stop CPR and declare death, there is usually some vanishingly small chance that the patient could still be revived. Ambiguity does not mean that declaration of death in these instances is improper; rather, ambiguity is a necessary feature of any definition of death and is tolerable as long as the real interests of patients are not violated.

The ambiguity involved in declaring death under the Pittsburgh protocol, then, is a problem that arises in many clinical situations, regardless of the criteria in use. Thus, for patients whose hearts stop when life supports are withdrawn, the possibility of auto-resuscitation should not be a major consideration. If auto-resuscitation were to occur, it would not be capable of sustaining itself beyond a few seconds or minutes.

A more important issue is the possibility that patients will not undergo cardiac arrest when life supports are removed. As required by the Pittsburgh protocol,^{7(p.A-4)} this possibility must be disclosed to patients in obtaining informed consent. When cardiac arrest does not occur, the patient should be returned to the intensive care unit, a hospice setting or other patient care setting, whichever is preferred by the patient or the patient's surrogate. Patients' preferences should be solicited in advance to prepare for this contingency.

CONFLICTS OF INTEREST

There has been some concern that, with implementation of the Pittsburgh protocol, physicians may compromise the care of candidates for the protocol in order to protect the viability of their transplantable organs.¹¹⁻¹³ The protocol contains several safeguards to address this concern, including the following:

- (a) the decision to forgo life-sustaining treatment must be made prior to and independent of the decision to donate organs^{7(p.A-2)}
- (b) physicians supervising the withdrawal of life-sustaining treatment in the operating room must have no clinical responsibilities on a transplantation service^{7(p.A-5)}
- (c) no physician who receives direct funding from a grant involving the transplantation team shall be involved in the management of donors in the operating room.^{7(p.A-5)}

These safeguards separate the physicians and other providers responsible for caring for the patient at the end of life from those responsible for organ retrieval.⁷

It has been argued that even stringent safeguards cannot provide sufficient protection against the conflicts of interest of physicians managing the death of a potential organ donor. Subtle pressures may influence the treating physician, who undoubtedly knows of the possibility of organ procurement even if not personally involved in it, to alter treatment to protect the availability of the patient's organs, especially when the patient has no chance of recovery.¹¹ These pressures may be even stronger in institutions whose income and prestige depend heavily on its transplantation activities.¹²

While it is unrealistic to suggest that all potential conflicts of interest can be eliminated, conflicts that do exist can be monitored and sufficiently controlled to protect patients' interests. The care provided to living patients should be carefully monitored to guard against any compromises to inpatient care. Review could be conducted, as some have suggested, by an objective panel of qualified physicians outside the institution in which the protocol is implemented.¹³ In addition, to minimize conflicts of interest and the possibility of harm, it is crucial to maintain separation of

physicians and other providers caring for the patient at the end of life from those responsible for organ retrieval.

THE APPROPRIATENESS OF DEATH OCCURRING ON AN OPERATING TABLE

The Pittsburgh protocol has been viewed by some as a significant departure from traditional efforts by the medical profession to make the dying process as comfortable and humane as possible. The concept of a "good death" has been defined as one occurring in a comfortable, low-technology environment, surrounded by family and loved ones, such as might occur at home or in a hospice program.¹⁷ In contrast, patients participating in the Pittsburgh protocol die in a sterile, high-technology operating room, removed from family and friends.

While some may view the circumstances of death in the Pittsburgh protocol as intrinsically intolerable and unjustified,¹⁴ others see it differently. While most patients may prefer to die in a low-technology environment, not all patients share this preference. It may reassure some patients to know that trained health professionals will be present, with the necessary equipment, to provide quick responses to discomfort. This may not be possible in a home hospice or similar program. In addition, some people may prefer to die without the presence of family members, so that the last memory of family members will be one of life rather than death. For some patients, the knowledge that their death will benefit others through organ transplantation outweighs the perhaps uncomfortable thought of dying on the operating table, apart from loved ones. To deny these patients the right to exercise their choice to donate organs would be an unjustified infringement of patient autonomy.

The Pittsburgh protocol properly addresses concerns about the location of death through its process of informed consent. The physician who will oversee the withdrawal of life-sustaining treatment must discuss with the patient or surrogate the fact "that the withdrawal of life sustaining therapy will be completed in the operating room."^{7(p.A-4)} With such a discussion, if the patient would not want to die in a sterile high-technology environment, then the patient could decide not to participate in the protocol.

SURROGATE CONSENT

A potential cause for concern is the use of surrogate consent in the Pittsburgh protocol when the patient has lost decision-making capacity. Under the protocol, a surrogate decision-maker can request that life-sustaining treatment be withdrawn from the patient and that the patient's organs be used for transplantation. Permitting surrogates both to withdraw life support and donate the patient's organs after death risks the possibility that the surrogate's desire to donate organs, which many view as a way of bringing some good out of an otherwise tragic event, could inappropriately influence the surrogate's decision to withdraw further life support. Requiring permission directly from the patient would protect against this potential conflict of interest. It would also encourage discussions between the patient and physicians early on in the patient's care, when the patient is able to describe his or her treatment goals and preferences regarding life-support and organ donation. Physicians often find it awkward to initiate such discussions. Thus, there may be a natural tendency to broach these issues with the family, after the patient has become incompetent, rather than with the patient directly. Indeed, with do-not-resuscitate orders, physicians generally do not discuss CPR with patients while they are competent but delay discussion until after the patient is no longer competent and the discussions must be held with family members.¹⁸ Requiring consent from the patient would resist this tendency and emphasize patient self-determination over surrogate decision making.

While these are important arguments, they do not justify the elimination of surrogate consent from the Pittsburgh protocol. Surrogate consent is widely accepted, ethically and legally, both for the withdrawal of life sustaining treatment and for organ donation, and there are very good reasons for such acceptance. Without surrogate consent, the wishes of many patients would go unfulfilled. While the desire to forgo life-sustaining treatment at the end of life is common,¹⁹ most patients do not complete living wills or give other evidence of their treatment preferences. Consequently, if surrogates could not consent to the withdrawal of treatment, the societal presumption in favor of treatment would result in many patients receiving treatment that they would not have wanted. Similarly, although most people express a preference for organ donation, many fewer actually document their wishes with organ donor cards. Presumably, given the opportunity, many of these incompetent patients would have wanted to be organ donors under the Pittsburgh protocol. Accordingly, without surrogate consent, many people would have their desires to donate organs unfulfilled.

Surrogate consent also enhances the important social role of family decision making. In part, family decision making is valued because it helps facilitate patient autonomy. In cases in which it is not clear what the patient would have wanted or in which the patient never had formulated any preferences, it is likely that the patient would have wanted whatever outcome that was desired by family members. Indeed, according to recent data from the SUPPORT study of end-of-life decision making, most patients prefer that, in the event they lose decision making capacity, medical decisions be made by their families and physicians rather than in accordance with their advance directives.²⁰ Patients generally want to minimize the emotional and financial burden that falls on their families at the end of their lives, and that goal can best be served if families are authorized to make decisions about life-sustaining treatment. Family decision making about organ donation can also help serve the desires of patients to minimize their family's suffering. Often families can gain some comfort from the knowledge that their loved one's death led to some good in the form of another life saved through organ donation.

Family decision making has value for its own sake, independent of concerns about patient autonomy. When a person is dying, it is the family that has the closest personal attachments and therefore the most at stake emotionally. Moreover, it is the family that is most likely to take actions that respect the dignity and humanity of the dying person. Consequently, rather than physicians, legislators, judges or other potential surrogates, it is most appropriate if the family has authority to decide about life-sustaining treatment or organ donation.

It is true that, if families can decide both about withdrawing life sustaining treatment and organ donation for the same patient, there is a risk that the organ donation decision will unduly influence the life-sustaining treatment decision. Yet, such conflicts of interest have not been considered sufficient reason to disqualify surrogate decision making in other situations. Indeed, we allow families to discontinue life-sustaining treatment even if they are named as beneficiaries in the patient's will. While society recognizes the risks of surrogate decision making in the presence of conflicts of interest, it has appropriately concluded that families can be trusted as long as there are reasonable safeguards to protect against abuse.

The Pittsburgh protocol includes important safeguards. For example, there can be no consideration of organ donation until after a decision has been made to discontinue life-sustaining treatment.^{7(p.A-2)} In addition, members of the health care team are encouraged to request a full ethical consultation if they suspect any ethical problems.^{7(p.A-3)} Given the seriousness of the concern about surrogate conflicts of interest, the protocol should explicitly warn members of the health care team to be sensitive to the possibility that organ donation decisions may influence life-sustaining treatment decisions when surrogates are deciding on behalf of patients. Further, if

there is some reason to suspect undue influence, then the health care members should be required, not merely encouraged, to obtain a full ethics consultation.

The other concern with surrogate decision making is also insufficient reason to eliminate surrogate consent. As mentioned, the possibility of surrogate consent may lead physicians to refrain from discussing organ donation with patients, but that is true about surrogate consent in all settings. It is not a problem created by, or even exacerbated by, the Pittsburgh protocol; rather, it is an element of surrogate decision making generally. Accordingly, it should be dealt with as it is in other settings - by more vigorous educational efforts, not by prohibiting surrogate consent.

CLEAR CRITERIA FOR SUITABLE DONORS

Not all technology-dependent patients are appropriate candidates to serve as organ donors. Many will have illnesses that render their organs unsuitable for transplantation. Clear clinical criteria should be developed to identify patients whose organs may still be viable and who therefore may appropriately decide to participate in the Pittsburgh protocol. Identifying appropriate candidates in advance will help ensure that patients do not undergo this protocol in vain and that recipients of organs retrieved through this protocol are protected from unsuitable organs.

The protection of organ recipients is an important consideration. Due to the circumstances in which death occurs, the quality of the organs retrieved through the Pittsburgh protocol may be inferior to organs retrieved after brain death. When the quality of the organs is suspect, potential recipients should be informed so that they may decide to accept the organs or wait for more suitable ones.

CONCLUSIONS

In the important effort to procure more organs for transplantation, the boundaries of ethically acceptable behavior may be at risk of being overstepped. The Pittsburgh protocol generally falls within ethical bounds of behavior. If carefully implemented with strict criteria for protecting against the conflicts of interest faced by surrogate decision makers, the Pittsburgh protocol is ethically acceptable.

As with all changes in organ procurement policy, the Pittsburgh protocol should be fully debated prior to widespread implementation.^{21,22} Input from the public is crucial. Policy changes that, however unfairly, encourage public perception of organ procurement as ghoulish or disrespectful of decedents or their families should be avoided. Societal support for transplantation as a whole must be protected. The Pittsburgh protocol should continue to be pursued as a pilot project in order to generate more evidence regarding public support and its effectiveness in procuring more organs.

RECOMMENDATIONS

The Council on Ethical and Judicial Affairs recommends that the following guideline be adopted and the remainder of this report be filed:

The Pittsburgh protocol, in which organs are removed for transplantation from patients who have had life-sustaining treatment withdrawn, may be ethically acceptable and should be pursued as a pilot project. The pilot project should (1) determine the protocol's acceptability to the public, and (2) identify the number and usability of organs that may be procured through this approach. The protocol currently has provisions for limiting conflicts of interest and ensuring voluntary consent.

It is critical that the health care team's conflict of interest in caring for potential donors at the end of life be minimized, as the protocol currently provides, through maintaining the separation of providers caring for the patient at the end of life and providers responsible for organ transplantation. In addition to the provisions currently contained in the protocol, the following additional safeguards are recommended:

- (a) To protect against undue conflicts of interest, the protocol should explicitly warn members of the health care team to be sensitive to the possibility that organ donation decisions may influence life-sustaining treatment decisions when the decisions are made by surrogates. Further, if there is some reason to suspect undue influence, then the health care team members should be required, not merely encouraged, to obtain a full ethics consultation.
- (b) The recipients of organs procured under the Pittsburgh protocol should be informed of the source of the organs as well as any potential defects in the quality of the organs, so that they may decide with their physicians whether to accept the organs or wait for more suitable ones.
- (c) Clear clinical criteria should be developed to ensure that only appropriate candidates, whose organs are reasonably likely to be suitable for transplantation, are considered eligible to donate organs under the Pittsburgh protocol.

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