The CEP is Moving!
The rumors are true, the offices of the Consortium Ethics Program are relocating on the campus of the University of Pittsburgh. As of March 15, 1996, we will be on Fifth Avenue, directly opposite Children's Hospital of Pittsburgh. Please make note of our new mailing address, telephone numbers, and FAX. Of course, those of you who reach us electronically can still reach us at the same e-mail addresses, reprinted below.

U.S. Mail:
Consortium Ethics Program
Center for Medical Ethics
3701 Fifth Avenue, Suite 300
Pittsburgh, PA 15213

Jody Chidester: (412) 647-5832; <chid@med.pitt.edu>
Alan Joyce: (412) 647-5884; <aj3@pitt.edu>
Mark Kuczewski: (412) 647-5852; <mk@med.pitt.edu>
Rosa Lynn Pinkus: (412) 647-5822; <pinkus@med.pitt.edu>
FAX: (412) 647-5677

IN THIS EDITION:
More on Familiar Themes,
Hints of Things to Come

Community Ethics (CE) prides itself on sharing a variety of experiences regarding perennial problems and alerting you to new problems in medical ethics. This issue embodies elements of both.

The familiar: Alan Joyce reviews "Truly Useful Literature" on informed consent. This review is a fitting supplement to the recent CEP seminar (12/15/95) that Bob Arnold, M.D., conducted for our newest hospital representatives. Elaborating on a theme we developed at length in one of our special issues (Vol. 2, No. 2), Adrianna Selvaggio, M.D., the Chairperson of the Biomedical Ethics Committee of Shadyside Hospital, shares her experience in revitalizing the ethics committee of a large urban, tertiary care hospital. A friend of the CEP from the Midwest, Patrick McCruden, continues our thread regarding the JCAHO ethics interview by describing his hospital's experience. Finally, one of the CEP's adjunct faculty, Alan Steinberg, J.D., teams up with Mr. McCruden to summarize HCFA's Final Rule on Advance Directives.

A New Old Problem: We include in this issue an "Electronic Roundtable" on brain-death. Although brain-death is a relatively old issue in contemporary clinical ethics, this discussion will demonstrate that this concept is again behind certain clinical dilemmas. Because such dilemmas are occurring with increasing frequency, we will devote a future edition of CE (Vol. 3, No. 4) to a more complete exploration of brain-death.

While we're talking about special issues, I'm proud to announce that our next edition of CE will focus on ethical issues in rehabilitation care. This thematic issue is designed to follow up on issues addressed by Giles Scofield, J.D., Director of the Health Law Program at Pace University, during his recent visit to the CEP to discuss rehabilitation ethics.

We once again extend our invitation to you to contribute an article on any previously covered theme, a new problem or issue that we have not yet discussed, or experiences and thoughts pertinent to one of our thematic issues.

—Mark Kuczewski, Ph.D.
Editor
HCFA's "Final Rule" on Advance Directives

by Patrick J. McCruden, Director of Pastoral Care, Marian Health Center, Sioux City, IA and Alan Steinberg, Esq., Hory, Springer, & Mattern, P.C., Pittsburgh, PA

Editor's note: The following contributed article, a "duet" of sorts, was originally to include some comedy. We tried to make it something of a spoof on NPR's famous team of "Click and Clack," e.g., "Click & Duck," "Clear and Zap," etc. However, as you can tell from these pseudonyms, it was not funny. This once again highlights the current state of bioethics; it is a field in need of someone to do for it what the "Tappet brothers" have done for auto repair.

McCruden: With very little fanfare the Health Care Financing Administration passed the Final Rule regarding Advance Medical Directives on June 27, 1995. This final rule responded to the questions and comments which HCFA had received since the passage of the Interim Final Rule on March 6, 1992.

As expected, the substance of the rules on Advance Directives have not changed, but the final rule does clarify several questions raised by commentators. What follows are a few highlights; the complete text of the final rule can be found in the Federal Register, Vol. 60, No. 123, Tuesday, June 27, 1995, Rules and Regulations.

Many commentators had asked that the provision of advance directive information to the families of incompetent patients suffice for compliance with the law. The HCFA's response was to maintain the current regulation that the information may be provided to the family of incompetent patients (there is no requirement this be done), but reaffirmed that the above action does not relieve the institution of the requirement to provide the information to the patient/resident when and if they regain competency. Institutions then must have some sort of tracking mechanism to reassess the decisionmaking capacity of these patients/residents.

On a related matter, the final rule refused to grant an exemption to provide advance directives information to classes of patients whose conditions might be exacerbated by the information, e.g., agitated or suicidal patients.

Regarding the provision of advance directive information to non-English speaking individuals, the final rule affirmed that information must be provided in a manner that is understandable to the individual. The provider should have written translations of advance directive information in foreign languages common to the locality. For languages that are seldom encountered locally, the provider could rely on an interpreter or the patient's representatives to attest that the individual understands the information provided.

On another matter related to cultural differences, the final rule does not allow the non-provision of advance directive information based on a belief that it would be an imposition to some cultural beliefs or values, i.e., talking about the possibility of death.

Two points regarding the community education component of the regulation were clarified. First, providers must be able to document their community education efforts. The final rule continues to allow a great deal of latitude in terms of how this education is carried out, but interestingly states that the community education "should involve not only a discussion of an individual's right to execute an advance directive, but also of a patient's broader right to accept or refuse medical or surgical treatment." (Federal Register 60.123 p.33275) Second, the final rule omits the suggestion found in the interim rule that community education efforts have the dual purpose of providing information and obtaining advance directive information from prospective patients which would then be documented in the individual's medical record. Many commentators had noted that this kind of information gathering was incompatible with the nature of most community education efforts. HCFA concurred and so removed this suggestion from the final rule. A final note on community education was the HCFA's refusal to reimburse providers for any costs incurred providing the required community education.

Regarding documentation in the medical record, HCFA addressed the suggestion that providers request and keep on file copies of individuals advance directives. In this regard, the final rule does not mandate such record keeping. Instead the final rule points providers towards applicable state laws, i.e., if state law requires that providers maintain copies of individuals' advance directives then they should do so, otherwise there is no federal requirement.

The final rule makes explicit the amount of time that may elapse between changes in state law in advance directives and the change in the information disseminated to individuals under the terms of the regulations. When state law changes, the state has sixty days to notify providers of the changes in state law. The providers then have ninety days to revise the informational material they use.

The above are a few highlights of the changes and
clarifications found in the final rule. Essentially the regulations haven't changed, but the final rule does clarify some points that had been a bit unclear in the past. On a concluding note, this author observes that although the HCFA does not mandate that providers maintain copies of individual's advance directives, the JCAHO surveyors who visited this Marian Health Center this Fall did require this and indeed wanted them on the patient's chart and available for review.

Steinberg: I agree with all of Patrick's comments. In addition to his highlights, let me point out a few others.

In the comments section preceding the Final Rule, there were a variety of operational and process issues addressed. (These were all the operational odds and sods and quirks we were so worried about when the PSDA first came out. They don't seem like such big questions now, and it is nice to see how common sense and actual practice seem to have answered most of those issues.)

What are some of the more interesting of these issues? First, on the pre-admission front, it is acceptable for providers to include a form in the pre-admission materials sent to the patient (and to be completed by the patient) that sets forth whether or not the patient has executed an advance directive. So, yes, pre-admission PSDA tools and approaches used correctly are acceptable for satisfying PSDA responsibilities.

Second, do you remember how we used to debate about patients in labor? Many of us figured that the last thing the woman (or partner) wanted upon admission to the hospital while in labor was forms and questions concerning her advance directive rights! And also, what about patients who have multiple admissions? Do we have to “PSDA them” with every admission for what is part of a larger, ongoing treatment plan? Is the patient going to say, sooner or later, “what is going on here?”

According to the Final Rule, all of these people, in labor and in repeat admissions, must receive the PSDA information and go through the PSDA process whenever they are admitted to the hospital. (Note. For the patient in labor, pre-admission materials are something of an answer.) As HCFA states in its response, "we note that hospitals repeat many admission procedures as part of every separate admission, often in accordance with applicable state and federal laws."

And what about transfers to a nursing home? The hospital has already provided PSDA information to the patient (and/or family). We always knew that the nursing home has the same responsibility, but was there some way to coordinate the hospital's and nursing home's efforts so that the patient (and family) didn't have to be processed again in the same manner? Each institution has its own PSDA responsibilities, but to the patient (and/or family) it can come across as something of a bother—particularly if the two admissions (hospital and nursing home) are close in time to each other.

To address this, HCFA picked up on a theme it stated in its Interim Final Rule:

We suggested [in the Interim Final Rule] that if an individual is being transferred from a hospital to a nursing home, the hospital discharge planner may provide the information (including the nursing home's policies regarding the implementation of advance directives) on behalf of the nursing home in the course of coordinating the smooth transfer of the patient. However, we reemphasize that the nursing home is still responsible for inquiring about the existence of an advance directive and documenting in the individual's medical record whether or not the individual has executed an advance directive.

Another line of comments and responses dealt with the enforcement of the PSDA rules, particularly for nursing facilities, home health agencies and managed care organizations (MCOs). HCFA already set up in 1992 a reporting mechanism for hospitals and hospices to provide evidence of PSDA compliance. That was done so that there would be no need to conduct on-site inspections of the nearly 8,000 hospitals and hospices to determine compliance.

But for home health agencies and nursing homes, these providers will be assessed for compliance during routine on-site surveys conducted by HCFA. That is the regulatory response. As for the right of the individual to challenge what he or she sees as a PSDA wrong done, a person can file a complaint for PSDA noncompliance by following the usual procedure with state survey agencies. To give that right some teeth, the Final Rule now requires all providers—hospitals, nursing homes, managed care organizations, etc.—to include in their written materials a statement of the individual's legal right to file a complaint with the survey and certification agency concerning noncompliance with the advance directive requirements.

Finally, the comments and new rules covered a lot of ground concerning managed care organizations. These entities sometimes get overlooked when it comes to the PSDA, though there are definite and significant responsibilities under the Act for them as well. The following are
First, the managed care organization under the Act is required to provide PSDA information to the individual at the time of enrollment. That terminology has raised a certain amount of confusion. HCFA's response:

In view of the comments we received on this issue, we recognize that it would be helpful to clarify how managed care plans may meet this requirement. For enrollees that join managed care plans as individuals, the meaning of "at the time of enrollment" is relatively straightforward, that is, as soon as possible after the application is received, but before the effective date of coverage. However, for individuals that join managed care plans through an employer group, we are clarifying that "at the time of enrollment" means at the time that the employer group enrolls the beneficiary into the plan. In such situations, the managed care plan may not be informed of the enrollment immediately; therefore, to implement the requirements of the statute, we believe it would be permissible for the employer group to provide, on behalf of the organization, information concerning an adult individual's right to accept or refuse medical or surgical treatment and to formulate an advance directive. In keeping with other provisions of this rule, the HMO or CMP may incorporate such information into the marketing material that the managed care plan supplies to employer groups so that the information is disseminated when the employer distributes other plan marketing materials to potential enrollees.

Second, as the required PSDA information is to be provided at the time of initial enrollment, there is no need to provide that information to individuals when they renew their enrollment.

Third, managed care organizations usually have more than one institutional provider in the network. Often they have several. The MCO has PSDA responsibilities to have its own PSDA policies. Should the MCO adopt a policy that tries to encompass the policies of all the healthcare institutions in its network? Or should it simply alert its enrollees that there are numerous institutional policies involved in the network? What is an MCO to do?

HCFA provides the MCO with two options to address this issue:

The first option allows a managed care plan to develop a policy that embraces all of its providers' policies. The second option allows a managed care plan to simply note that differences among its providers' policies exist, and that more information is available from the organization upon request. These options do not necessarily require detailed information regarding each provider's policies. For example, if all contracting providers implement all advance directives that meet State requirements, the plan could simply note this information. On the other hand, if one or more of the contracting providers have a more limited policy (for example, a hospital exercising a reservation of conscience), the plan may either (1) provide a written policy that states the restrictions these providers placed on advance directives or (2) note that some providers may object to implementing an advance directive, but that more information is available upon request. At a minimum, plans should have information available upon request as to which contracting institutions place limits on implementing advance directives.

Lastly, MCOs, like hospitals and other providers, have to update their own PSDA materials within 30 days after a state has changed its law.

Talking about the PSDA materials reminds me to point out one final thought—the Final Rule states that if the provider's policies include a "conscience clause" that could have the effect of limiting a patient's rights, then that policy statement of limitation and its description in the PSDA materials must be very clear and specific. This should include a description of (i) any differences between institution-wide conscience objections and those that may be raised by individual physicians; (ii) the state's legal authority permitting such objection; and (iii) the range of medical conditions or procedures affected by the conscience objection.

Finally, this Final Rule replaces the previously published Interim Final Rule. Do you think HCFA would have been better off calling this the "Final Final Rule" or maybe "The Rule, Finally"? Just a thought....

Visit the Consortium Ethics Program on the World Wide Web!
http://www.pitt.edu/~caj3/CEP.html
The past four years have been a time of great growth and development for the Biomedical Ethics Committee of Shadyside Hospital. We have evolved into a productive, cohesive group of individuals with a common interest: biomedical ethics. Many changes have been necessary to achieve our current state. I can still remember that, in the beginning...

* The Biomedical Ethics Committee was a medical staff committee that embodied the form and substance typical of such a committee. To a large extent, the rules governing such committees did not fit a well-conceived ethics committee. Therefore, we appealed to our staff president for permission to deviate from certain rules. The first thing we had to do was give away our copy of Robert's "Rules of Order." Ethics is probably best seen as a consensus-building process and we wanted to hear from all of our members when discussing difficult topics that affect our patients and staff. Dropping the hierarchical traditions proved beneficial in many ways.

* The 90 minute monthly meeting was our only working tool. This was not viable. So, we developed five subcommittees: consultation, policy, education, membership, and patient rights. Because these subcommittees are "where the action is," I would like to tell you about them at length.

The subcommittees each have a group leader, most of whom are non-physician professionals. The small size of the groups allows for more input from each member. The distribution of responsibility over the five group leaders and the chairperson broadens the focus of the Biomedical Ethics Committee. The real work of the committee now occurs in the subcommittee setting. Therefore, subcommittee attendance is mandatory, whereas monthly committee meetings are not.

The consultation subcommittee began monthly reading groups. Each individual who conducts consultations attends regularly to improve and maintain his or her skills in consultative ethics. Case consultation is provided by teams. Each team has an experienced leader and two or three more members from varying disciplines. The teams rotate responsibility for coverage (The group leader and Chairperson of the Biomedical Ethics Committee fill in for emergencies). All consultations are answered within 24 hours, Monday through Friday. Consultations are discussed first among this subcommittee and then presented to the larger meeting. A consultative worksheet was developed to organize the thinking of the team. A summary of the consultation process and the consultants' recommendations are written or dictated and placed on the permanent medical record, and a confidential file is kept in the chairperson's office. The subcommittee and larger Biomedical Ethics Committee offer constructive criticisms following each consultation. The reputation of our consulting service has grown, and we pride ourselves on becoming effective mediators who meet the needs of our patients, their families, and the hospital staff in a timely and confidential manner.

Our policy subcommittee rewrote the staff policies for do not resuscitate orders, withholding/withdrawal of treatment, and advance medical directives. The parsimonious outcome was that these policies were combined and renamed "patient medical directives." Furthermore, during this process, we succeeded in obtaining agreement between anesthesia and surgery to allow for the continuation of a "do not resuscitate" status in the operating room. A special consent form was developed to allow the patient and medical team to agree to limitations on resuscitation during surgery.

The education subcommittee plans an educational meeting every third month for all members of the Biomedical Ethics Committee. This subcommittee is currently developing a handbook for new or returning members of the committee. The handbook will allow individual members to review basic ethical concepts and to study the background materials necessary for productive participation.

The membership subcommittee monitors the composition of the Biomedical Ethics Committee. It is our basic tenet that cross sectional representation is crucial to our success. This subcommittee recognizes three types of members: full members (requires subcommittee participation), visiting members (do not participate in subcommittees but may attend monthly meetings but lack voting privileges), and guest (by invitation to a particular meeting). It periodically reviews the committee's size, compo-
sition, and patterns of participation.

The patient rights subcommittee addresses all patient issues. This group reviews patient informational materials, the accessibility of the Biomedical Ethics Committee to patients and their families, and the nature and number of patient/family complaints. This group addresses patient complaints with staff in-services to allow all members of the healthcare team to benefit from past errors.

The evolution of the committee has been wonderful in recent years. It has led to cohesiveness among a diverse group of professionals that share a common concern for biomedical ethics. The egalitarian nature of our structures has created a broader base of ideas which has led us to clearer concepts and practices. We have written and attempted to meet the goals in our mission statement.

**Mission Statement of the Biomedical Ethics Committee of Shadyside Hospital**

Shadyside Hospital is committed to the delivery of skilled, compassionate care to all patients, family and staff. The focus of this care is to ensure health care with dignity, privacy and respect. We support the right of the patients to determine their health care by working with the health care team in decision making regarding treatment. These rights are fostered and promoted by Shadyside Hospital and the Biomedical Ethics Committee by providing consultative services to physicians, hospital personnel, patients and families at their request.

The Biomedical Ethics Committee is available to educate employees, families and physicians in Biomedical Ethics and decision making. This commitment is demonstrated through the provision of consultative process and education programs. We are an additional general resource to the hospital community. We hope to keep patients, employees and physicians well informed regarding current ethical responses to medical technology and the treatment of patients and their families with the highest ethical standards and respect.

---

**Ethics, AIDS, and the CEP**

Since 1994, the Consortium Ethics Program has been actively pursuing ways to address ethical issues related to the treatment of AIDS patients. We recently received a grant from the Jewish Healthcare Foundation which will fund a continuation of these efforts over the next two years.

The newly-funded program, entitled “AIDS & the Community: Developing an Ethics Provider Network,” begins in earnest this month. A dinner-workshop on March 13th brings together our previous “core” group of local health care workers and draws on the expertise of new representatives from hospice and long-term care. This meeting will be followed by a larger-scale educational retreat this summer, and further workshops and retreats in 1997.

These meetings are not only intended to facilitate development of an Ethics & AIDS provider network -- they will also serve as the testing grounds of a teaching manual and video on this subject. Videotaped interviews from past workshops will be linked to current, topical articles and cases. Eventually, all of this material will be compiled into a package designed for use by healthcare providers in providing in-house or community education on ethical issues related to AIDS.

When teaching materials are ready, we plan to make use of the Consortium’s established network of providers and educators to disseminate the information. CEP participants will be the first recipients of the completed manual/video package, and as always, Consortium faculty will be available to assist representatives in planning educational sessions at the institutions. We’ll keep you posted as our work progresses in this important and rapidly-expanding area of ethics.

---

**BACK ISSUES**

For more information about the earlier phase of our Ethics and AIDS projects, see Connie Rakela’s article, “CEP Addresses Ethical Issues in the AIDS Crisis” in Community Ethics 2(3), p. 2.

For another view of the JCAHO Ethics Interview (to complement Patrick McCruden’s article at right), see Colleen Allison’s article, “The New, Anxiety-Producing Ethics Interview: One Hospital’s Experience With the 1996 JCAHO Survey” in Community Ethics 2(4), p. 3.

Contact Alan Joyce if you wish to order back issues of the newsletter (phone: 412-647-5834; fax: 412-647-5877; e-mail: caj3@pitt.edu).
You might be asking yourself: "why is a hospital chaplain from the heartland writing an article on the JCAHO survey for Community Ethics?" That is a reasonable question. I am a hospital chaplain but out here in Sioux City, Iowa, I wear several hats. One of those involves coordinating the efforts of our hospital's medical ethics committee and reviewing and implementing our institution's policies on advance medical directives. Currently I'm in the process of trying to build a local ethics network to serve rural hospitals, long-term care facilities, home health and hospice organizations in the Northwest Iowa and Northeast Nebraska area. As a result, I've relied heavily on the resources of the Consortium Ethics Program. Although the CEP's mission may be to serve its members in Western Pennsylvania, its methods and insights are of great interest and help to me in the rural midwest.

What follows is a brief description of our institution's experience with the JCAHO ethics survey this past fall. My institution, Marian Health Center, is a 484 bed tertiary referral and trauma center in Northwest Iowa. We are a division of a larger health care corporation, Mercy Health Services, which operates hospitals, home health care agencies, Medicare approved hospice and long-term care facilities throughout Michigan, Indiana, and Iowa.

Our hospital Ethics Committee's experience with the surveyor of the JCAHO appears to have been somewhat different from that of other institutions. Our Medical Ethics Committee worked long and hard to prepare for the site visit of the JCAHO. We reviewed all of our policies, double checking to make sure that all had been updated and conformed to JCAHO standards. We worked hard at staff education to be sure that everyone would be able to articulate the existence of an ethics committee and could describe how the committee was accessed by patients, families and staff. We made sure all committee members were able to articulate the role and purpose of the ethics committee and the methods used for ethics consultation.

We believed that we had little to be concerned about. Our ethics committee has been in existence for almost ten years and it is an active committee that fulfills the three functions of education, policy development/review, and case consultation. We felt we were completely prepared for the interview with one of the surveyors. We were wrong.

The JCAHO surveyor asked us almost nothing about clinical ethical issues. Although he reviewed our documentation (Ethics Committee Guidelines, Case Consultation Procedure, minutes of meetings etc.) in the document review session, he seemed completely uninterested in this aspect of ethics. The surveyor's whole focus was organizational and business ethics. His primary concern was with our relationship to the home health care organization that is a "sister" organization to us, i.e., a subsidiary of the same not-for-profit health care corporation. Some of his questions: "Do you refer patients to this home health agency?" "Do you tell patients that you are related to this home health agency?" "What written documentation do you give to patients to explain your various interests in other health care organizations in the area (the hospital also has interests in a freestanding surgery center and cancer treatment center)?"

The committee members were somewhat nonplused by this line of questioning. Our ethics committee is a medical ethics committee that deals almost exclusively with clinical issues. The only "business" issues we ever addressed were those with clinical overtones, e.g., conscientious objection to certain medical procedures by employees. In our institution, another committee, called the Mission Effectiveness Committee, addresses business ethics issues such as amounts of charitable care, advertising policies, associations with other institutions/enterprises etc. Most of ethics committee members had no idea of the answers to these questions but the surveyor seemed to think we should have them. The interview ended after thirty minutes when it became clear that the surveyor was more interested in business ethics than clinical ethics and that we didn't have the answers to his business ethics questions.

The interview left a bad taste in the mouths of committee members. It seemed as if all our hard work was misplaced. The surveyor's questions are certainly valid ones, but I don't know that they are questions that properly belong in the ethics interview. These types of questions would seem more appropriate to an interview with leadership/administration or perhaps with the Mission Effectiveness Committee. My concern is that the JCAHO is now going to ask hospital ethics committees to become experts at business ethics and to somehow be knowledgeable of the complex relationships that are developing in the world of modern healthcare. To those facing JCAHO surveys, I must say that having your clinical ethics "ducks in a row" doesn't insure a smooth interview with the JCAHO surveyor.

The good news is that the institution received no citations or deficiencies in the area of ethics. Although the surveyor didn't appear very interested, we certainly met the standards as outlined in the JCAHO accreditation manual.
Electronic Roundtable: Brain-Death Dilemmas

Editor’s Note:

Healthcare professionals, policy makers, and medical ethicists have been successful at developing a consensus on a number of issues. One of these “settled” issues is brain-death. When a patient meets certain criteria that indicate cessation of function of the whole brain, the patient is dead. Because healthcare professionals do not treat dead people, there are no treatment decisions to be made regarding the patient’s well being; all treatment is to be withdrawn. Of course, because such cadavers are often suitable organ or tissue donors, mechanical ventilation and various other interventions may be continued until the family is approached regarding donation and if they consent, until harvesting of the organs. Nevertheless, consensus doesn’t always solve all clinical riddles.

A family who refuses to believe the patient is dead poses a problem for healthcare providers. Thus, we bring you the following excerpts from such a discussion on the MCW listserver (For more information on this listserver, see Alan Joyce. “Ethics Online,” Community Ethics, 2(4), 1995.).

The Question:

If a patient is clearly brain-dead, but the family will not accept the diagnosis, what should the caregivers do? For instance, suppose the family says that the patient is alive and demands that all supports be continued. The physicians initially continue support to facilitate organ donation in case the family should consent. This motivation recedes as it becomes more important to help the family to come to grips with the reality of death. Several more days pass and the nursing staff becomes really distressed. Should there be a limit on the length of a grace period given by clinicians for ethical and psychological reasons? For example, it might make sense to have a policy recognizing that it is within the scope of clinical judgment to use a grace period to help families come to grips with death and grieve but also place a limit upon it, e.g., 12 hours after the family has gathered. At this time, physicians could invoke this limit to move towards disconnections, withdrawals, etc.

John C. Fletcher, Ph.D, jcf4x@virginia.edu
Kornfeld Professor of Biomedical Ethics, University of Virginia

Response #1:

We have been occasionally cursed with the dilemma John Fletcher poses — the brain-dead patient whom the family refuses to acknowledge as dead. [New York has a statute that makes it complicated if you have religious reasons for objecting to a declaration of death by brain-death criteria, but I will ignore that multiply extraordinary situation.] Our hospital has no official policy for dealing with reluctant families except “mediation.”

In the cases with which I am familiar, we cut a deal with the family. We will formally PRONOUNCE “Chris” dead in 24 hours though you should understand Chris is dead already.

Problems? You bet, but not, I believe, very often ethical ones.

1) “We aren’t ready to accept Chris’ death, so Chris isn’t dead.”
2) “If you pronounce Chris, we’ll sue you for wrongful death.”
3) “We want Chris Sr. here when Chris is declared dead. We are trying now to get in touch with him in the upper Amazon.”
4) “Chris isn’t dead. He looks better now than he has for years.”

In spite of the difficulty “normal” people have appreciating this new way of deciding when people are dead, pronouncing someone dead isn’t a performative utterance that transforms a person from being alive to being dead. They already ARE dead. There may be unusual humane, practical or economic reasons for treating dead people as if they were alive, but I would be surprised if there were a workable policy or an algorithm for doing so. My worry is that any policy would be used to manipulate family or staff as it easily might have been in John’s scenario.

Until we — as health care providers and their camp followers — begin to speak of, and respond to, the brain-dead in the same we do to the “really” dead, we can expect the problems to continue.

Peter C. Williams, JD PhD
PWILLIAM@PREVHED.SOM.SUNYSB.EDU
Chief, Division of Medicine in Society
Health Sciences Center
Stony Brook, NY
Response #2:

It is presupposed that therapeutic treatment modalities are decisively contraindicated for all patients who are dead, including patients who are “brain-dead.” One might consider whether insurance companies are being defrauded by claims that are made for services administered after the client’s death. This is one area in which cost-cutting and ethics are on the same side.

I have found that it is generally unwise to use the expression “brain-dead” with families. The state referred to is not one of qualified death. The patient may properly be characterized as having died, adding that some of the bodily organs are being supported mechanically in case they may be used for transplants.

It is inappropriate and potentially problematic to ask relatives for permission to disconnect support equipment. After death has occurred, that which used to be the body of the patient may be kept on “organ support” — not “life support” — until organs usable for transplant purposes are harvested or until it is established that consent to harvest the organs is not available.

Grace periods can create horrifying problems when physicians find themselves unable to explain why it was O.K. to keep the body on mechanical support yesterday but not O.K. today. What change in condition now requires withdrawal of treatment? The families become cruely stressed as the progressively wasteful, unrealistically hopeful, near-grief-ridden, zombie-like charades progresses. Has anyone seen psychological benefits?

This is not medical care. Better to call a spade a spade. Much better.

Kenneth Kipnis, Ph.D. (kkipnis@hawaii.edu)
Department of Philosophy, University of Hawaii at Manoa
Honolulu, HI

Response #3:

My approach in the situation of brain-death is as follows:

(1) I make the determination of death according to accepted clinical procedures. There is no specification of these procedures in Wisconsin in the state laws. I may or may not use additional tests such as brain flow studies depending upon the circumstances.

(2) If the patient is dead according to brain-death criteria, I write this in the medical record and assign a time of death.

(3) I then tell the family about this set of facts. Whether they agree or disagree with the facts, I allow for a period of visiting before removal of machines. (I do not say “life-support” in this circumstance. Part of a family’s acceptance may be our lack of care in the words we use.)

(4) If the family disagrees with the fact that their loved one is dead, I still allow a period of visiting and so forth. I also tell them that I need to call the medical examiner “by law” to report the death (as is our hospital policy).

(5) Although it may be the luck of the draw, I have not had any longer than a 24 hour period of ambiguity before a family accepted the situation. I do not claim that this approach helps, although I believe we should not withhold our diagnosis based on the desire for a waiting period.

Robert M. (“Skip”) Nelson, M.D., Ph.D. (rmnelson@post.its.mcw.edu)
Medical College of Wisconsin
Children’s Hospital of Wisconsin
Milwaukee, WI

Response #4:

I would add to Skip Nelson’s description that the ongoing discussion with families throughout the process of the brain-death determination is all important. Because most guidelines call for some time interval (6 to 48 hours, depending on age) between examinations, families should be told of the impending diagnosis of brain-death at the first exam, or even before, if progression appears inevitable. This 6 to 48 hour period essentially functions as a “grace period” for both families and healthcare providers, the former to understand and accept and the latter to understand and confirm the diagnosis. Furthermore, having families present to observe the neurologic examination and apnea test is often quite convincing for those who understandably feel their loved one is just “asleep”.

Barry P. Markovitz, MD
Markovitz@kids.wustl.edu
Depts. Anesthesiology and Pediatrics
http://PedsCCM.wustl.edu
St. Louis Children’s Hospital
Washington University School of Medicine

Response #5:

It is our practice to pronounce a person, and record in the medical record, that they are dead when they die. The method for determining death may relate to accepted criteria, such as cardiovascular or neurologic criteria. That is, brain-death is death. In some cases the family needs some time to gather at the bedside and to cope with the issues before the person is moved from their hospital room; and compassionate support is certainly important.

Before this was clearly established practice, we had people die with death established by brain-death criteria, whose care continued because of strong family advocacy and confusion as to whether brain-death is really death; and, in one case, the person who was brain-dead (i.e., dead) was transferred to another hospital unit with a compromise agreed to by the family that the person would be “no code” — “DNR”.

One of the functions of bioethics committee members, and the committee chair in particular, is to assist in clarifying clinical situations such as this, so that consistent appropriate
practice is supported. Families often are very appreciative when this is clarified and they receive personal support regarding their grief, even though they had previously made various inappropriate demands. They usually accept a clear explanation from the Bioethics Committee when it is not adversarial. No option is given regarding the reality of death, but care and support is given to them.

Edward Anthony Oppenheimer, M.D.
Physician Co-Chair, Bioethics Committee
Dulmonary & Critical Care Medicine
Southern California Permanente Medical Group
Los Angeles, CA
Internet: eaopp@ucla.edu or edward.oppenheimer@kp.org

Response #6:

I am aware of the scientific and medical consensus on the definition of brain-death, and I personally subscribe to this position. On the other hand, I am reluctant to impose my own definition of death on people who feel otherwise and define death differently. I do not think that a medical consensus is necessarily normative.

In our pluralistic society, I think that we are ethically bound to acknowledge and validate positions which differ from our own. And so, if an Orthodox Jew or a fundamentalist Christian insists that death has not occurred so long as there is a heartbeat (albeit maintained by artificial means), I think that this position should be treated with respect.

On the other hand, I am not certain that we should cater to these alternative views of death to the extent that we allow a patient to occupy a scarce and expensive ICU bed. I think that it is incumbent on the involved family to find another facility for continued life support — either at home (with visiting nurse support) or in a hospital or long-term care facility which shares the family's understanding of death.

I think that a more thorny issue is whether a tertiary center should accept the transfer of a patient who meets the criteria for brain-death. It is conceivable that such a center would accept a patient like this in the hopes of harvesting transplantable organs. But, if we really believe that brain-death is truly death, it makes no sense to admit a corpse.

Ev Vogeley, M.D., J.D.
EvVogeley@aol.com
Children's Hospital of Pittsburgh
Pittsburgh, PA

Response #7:

Our Ethics Committee struggled with a case several months ago similar to John Fletcher's hypothetical one. It proved to be a "straw" one which got us to face up to the needlessly painful confusions surrounding 'brain-death'. We rewrote our policy. It omits the troublesome term 'brain-death' in favor of 'determination of death by neurological criteria'. It addresses ethical issues associated with notification and when interventions may be withdrawn. It avoids time limits in favor of the discretion of the attending physician. I would be pleased to share our background working paper. Contact me directly.

Response #8:

Several commenters have urged that we should accommodate a range of definitions of death. I don't agree. There are dangers in being too open-minded, too pluralist, in our thinking about death.

For all of the other things it is, dying marks a change in legal status. It is permissible to do certain things to a corpse that it is impermissible to do to a living human being. One wouldn't do an autopsy on a living human being, or bury her, even if the cultural group believed the person had died. There are good reasons for having professionals attest to death in a legal certificate. Key legal entitlements cease and begin with that declaration and significant legal processes commence.

Consider two patients — Smith and Jones — who, though still on ventilators, have been declared dead by neurological criteria. Suppose we were pluralist in our approach and, because one of the two bodies used to belong to Smith who believed in cardiac criteria only, Smith is legally alive while Jones is legally dead. One supposes that Smith's family will continue to receive Social Security payments while Jones' family will be cut off. This seems unjust and poor public policy. Suppose two assassins break into the ICU. Each shoots bullets into one of the two neomorts. The assailant shooting Smith's body has committed murder but the one who shooting Jones' body has only desecrated a corpse. This seems profoundly unjust. People should not receive increased protection solely because of their metaphysical views.

I expect such examples can be multiplied. They go to show, I think, that at the end of the day, medicine needs to make its best judgment about how death is to be clinically determined. While we may be able to do better tomorrow, the brain-death criterion for the death of the person, and the clinical indicia used to mark it, for all the caviling around its edges, is the best standard we have today.

There is a tribe in the far east that does not acknowledge death until many months after we would. As a colleague of mine once put it, you can be so open-minded your brains fall out.

Ken Kipnis
Department of Philosophy
University of Hawaii at Manoa
Honolulu, HI
kkipnis@hawaii.edu
Truly Useful Literature: Informed Consent

by Alan Joyce


Summary:
Lidz, Appelbaum, and Meisel suggest that many criticisms of informed consent stem not from flaws in the doctrine itself, but from the ways in which it is implemented in the healthcare setting. To illustrate the problems with and possibilities for informed consent in this environment, the authors introduce two models of implementation: the event model and the process model.

In the event model, informed consent is seen as an act of decisionmaking which occurs at one specific point in time. The physician or other healthcare workers sets forth a reasonably comprehensive list of details, risks, and benefits for a particular treatment; the patient signals acceptance of this treatment by signing a consent form. The authors identify several serious flaws with this model, including: (1) the emphasis is usually on complete disclosure of facts by the physician rather than complete understanding of these facts by the patient, which means that the patient's consent may not be truly "informed"; (2) because the patient's understanding of facts is not stressed, both patient and physician may come to view informed consent as a waste of time; and (3) this model makes the physician-patient relationship seem "more bureaucratic and less humane."

The process model, in contrast, emphasizes continuous and active patient participation in medical decisionmaking. Three conditions must be met before this can be achieved: (1) physician and patient role expectations must be shifted so that the patient is accepted as a valued member of the healthcare team -- one with knowledge of important contextual facts that are necessarily unavailable to the healthcare providers; (2) differences between physician and patient "illness models" -- their ideas and concerns about particular medical problems and their ramifications -- must be more closely examined; and (3) the physician's and patient's values and expectations must be thoroughly explored and discussed to ensure that a particular treatment will be appropriate for the patient. The authors recognize that this ongoing, time-consuming model may not be practical in all healthcare situations, but they offer it as, at least, "a direction in which to move."


Summary:
Veatch focuses not on how to implement consent, but on whether consent is even an appropriate concept in medical decisionmaking. He begins by summarizing various theories of good, arguing that it is virtually impossible and generally inappropriate for a healthcare provider to presume that they can decide upon a course of treatment that will provide the most benefit to a patient. Veatch's conclusion -- that consent "will have to be replaced with a much more radical, robust notion of active patient participation" -- is clearly compatible with Lidz, Appelbaum, and Meisel's process model of informed consent.

Veatch's new contribution to this dialogue is the idea of physician-patient pairings based on "deep values". If healthcare delivery systems organize around and announce particular value orientations (Catholic, feminist, holistic, etc.), then it should be easier for patients to choose healthcare providers whose "deep values" are more closely aligned with their own. Ideally, this would result in less conflict and fewer misunderstandings in the patient-physician relationship, thereby strengthening the patient's position as an active participant in the decision making process.

Other Informed Consent Resources
Of course, there is a vast body of literature on this topic. Some further recommended reading includes: Howard Brody's "Transparency: Informed Consent in Primary Care," (Hastings Center Report, September/October 1989, pgs. 5-9) which provides another view of consent as a conversation process; Nancy M.P. King's "Transparency in Neonatal Intensive Care," (Hastings Center Report, May-June 1992, pgs. 18-25) which applies Brody's consent model to the care of severely premature infants; and Ruth R. Faden and Tom L. Beauchamp's book, A History and Theory of Informed Consent (Oxford University Press, 1986). This work examines informed consent's foundations in moral and legal theory, its role in clinical medicine and research, and concepts of understanding and coercion as they relate to the process of consent.
As always, we extend special words of thanks to the Vira I. Heinz Endowment for its continued support of the Consortium Ethics Program. We are also deeply indebted to the Ethics Committee of the Hospital Council of Western Pennsylvania for the continued encouragement, guidance, and assistance that it lends to the CEP.

If you have suggestions or questions regarding the Consortium Ethics Program, wish to submit information for an upcoming edition of Community Ethics, or wish to receive this newsletter, contact Mark Kuczewski, Ph.D., Center for Medical Ethics, 3708 Fifth Avenue, Suite 300, Pittsburgh, PA 15213, phone (412) 647-5824, FAX: (412) 647-5877, or e-mail <mgk@med.pitt.edu>.

Consortium Ethics Program
Center for Medical Ethics
University of Pittsburgh
Medical Arts Building
3708 Fifth Avenue, Suite 300
Pittsburgh, PA 15213