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In the last several years, hospitals have experienced more and more encouragement from organ procurement organizations (OPOs) and others to adopt protocols to facilitate the procurement of organs from patients who are seriously and irreversibly brain-injured but not brain dead. This encouragement has been constant from the OPOs for at least a decade. The difference now is that policy-making organizations, such as the Health Resources and Services Administration (HRSA) and the Joint Commission, have inaugurated a cascade of support for the procurement of organs under conditions of controlled cardiac death. The main attitude underlying these directives and policies can be summed up this way: Increase the donor pool because transplants save lives.

Ordinarily, policy set at a national level reflects either prevailing political interests or a settled consensus of opinion. In the 1970s, the lowering of the speed limit to 55 mph probably did not reflect a general public feeling about the right speed to drive on a freeway. What it did reflect was a decision on the part of lawmakers to lower freeway mortality and save oil, both of which were national political interests. The 1991 Patient Self-Determination Act, on the other hand, probably did reflect a general public consensus that it was appropriate for persons to express in advance any desire they had to limit the lengths to which medicine might go to sustain their lives, particularly under dire circumstances.

In the case of donation after cardiac death (DCD), it would be comforting to believe that the push toward widespread adoption of DCD policies stems from agreement among most people that on the whole, there is a duty to save lives by donating one’s organs if one is irreversibly brain damaged and uninterested in prolonging one’s life under those circumstances. But we have no evidence of such a consensus, or even of public awareness of DCD, much less a public conviction about it. Nor is there evidence that some sinister or benign political interest is really behind the push. The absence of either motivation makes the widespread regulatory support of DCD puzzling, except for one thing. The technology of organ donation has been successful, and the more we widen the group of people on whom it is therapeutically tried, the more successful it is. This sets up a presumption in its favor.

But sometimes a presumption discourages the examination of assumptions. In this article, I suggest that the examination of three fundamental assumptions is precisely what is called for on the subject of DCD. If we are to wholeheartedly embrace such a change in the manner of securing organs for transplant, we should do it with a deep understanding of the ideas that undergird the change, and we should be as transparent in our public conversation about those ideas as possible.

Assumption 1: There is an organ shortage. When hospitals do not have DCD protocols, transplant candidates die needlessly.

The literature on organ donation typically begins with a statement of the number of candidates suitable for organ transplantation, followed by a dramatically smaller number...
of organs available for transplant. These candidates have conditions resulting in the life-threatening deterioration of a kidney, liver, lung, pancreas or heart. In the end stages of their disease, they will die without effective treatment. No treatment is as effective as organ transplant for these patients (although even a transplant is not 100 percent certain and not without side effects). The shorthand for this state of affairs is that these patients will “die waiting” with the implication that it is therefore our obligation to try to increase the pool of organs for transplantation so that more of these patients can be saved.

Another way to look at this situation, however, is to compare it to the early quandaries about the removal of life-sustaining treatment. The Quinlan Court, for example, went to some trouble to assert that it was not the removal of life support that caused the death of someone, but her underlying disease. In the same way, it is not the lack of a transplantable organ that causes the death of someone who “dies waiting,” but the underlying disease. This is not to say that we shouldn’t try to increase the donor pool. Indeed, some will find it a duty. It is simply to remind us that both medicine and human life have limits, and that increasing the pool, although a laudable goal, must be done in an ethically reflective way, characterized by the same features as other ethical decisions—respect for persons, beneficence, justice, an honest telling of the truth, informed consent.

The number of diseases and the severity of disease, for which transplantation is now the indicated treatment, has grown dramatically in recent years and may be expected to continue. When the candidate list grows, we must realize that not everyone who might benefit from a transplant will get one. It is a hard fact but a real one. This kind of understanding might lead to a more balanced view of all organ donations, including DCD, and could situate the good of organ transplantation more rationally within other health care goods.

Assumption 2: DCD is essentially the same as the already accepted procedure(s) for procuring organs for transplantation, and therefore it is uncontroversial.

In an effort to help people embrace the new DCD protocols, OPOs have stressed that DCD is simply a return to an earlier and accepted form for determination of death. In the old days, the thinking goes, we knew someone was dead and declared them such by noticing and confirming the absence of breath and pulse, evidence that the heart had stopped. Then came the determination of death by neurological criteria—in essence, using signals (or lack thereof) from the brain, rather than from the heart, to declare someone dead. The reason for this move toward neurological criteria was twofold. First, with the rise in use of the technology for mechanical ventilation, the cessation of heart and lung function was effectively camouflaged, so it was harder to declare some people dead the old-fashioned way. Second, the desire to improve outcomes in the relatively new procedure of organ transplantation meant that deterioration of organs under conditions of “uncontrolled” or spontaneous cardiac death should be minimized. These two combined to produce, in 1968, criteria for determining death using neurological measures. This greatly increased the number of organs suitable for transplantation, because the time gap between the cessation of blood flow and the procurement of the organ during which the organ’s quality diminished was eliminated.

However, the move from cardiac death to brain death to facilitate the transplant of organs came at the expense of the general public’s understanding. Brain death is not uncontroversial or well-understood. In fact, according to one study, less than half of the American public understands that neurological criteria are legitimately used to determine the death of a potential organ donor. Anyone who works in an emergency department or ICU has experienced a family’s disbelief when told that their loved one is “brain dead.” This is in part due to the fact that often these deaths are the result of sudden trauma in an otherwise healthy young person, where the coping mechanism of denial enters the picture. It is also due to the fact that a very seriously ill person looks about the same on a mechanical ventilator as a brain dead body. In fact, hospital personnel are sometimes a little confused as well, as evidenced by the number of times we tell families their loved one is brain dead and then ask if we can remove “life support.”

Embedded in the assumption that DCD is just a variation on an accepted theme are two other assumptions. One is that brain death is generally understood and accepted, which as we see above, it is not. The other is that old-fashioned cardiac death is not relevantly different from cardiac death under controlled circumstances. The counterargument—that DCD is different—is more difficult to make since it turns on the question of what makes something relevantly different. It is true that the means of determining death are the
same; it is the absence of pulse and breath that count as signs of death. But the circumstances under which the death occurs are vastly different. In the earlier case, death was an accomplished fact. Whether witnessed or not, there was nothing that could be done to reverse it. Death came to the patient uninvited, and it served no particular end.

In the case of DCD, cardiac death is not immediately inevitable. This is precisely what recommends it for transplantation purposes: we resist death by mechanical ventilation and then we decide to stop resisting, and the time elapsed between this decision and surgery to get the organ is short. Death is invited, by the justifiable decision to limit life-sustaining treatment in a severely brain-damaged patient, and it serves the end of organ transplantation. Neither its invitational status nor its service to the (good) end of organ transplantation necessarily makes DCD ethically suspect. But it does make it different. This is why suggesting that DCD is a “simple return” to earlier criteria seems disingenuous. It is also why the adoption of DCD protocols should only be done with serious regard to the opinion of the community the hospital serves and the experience of organ donation there in general. Such protocols should also be accompanied by transparent informed consent procedures that stress the real features, risks, and alternatives of the procedure.

**Assumption 3: The language of organ donation is neutral.**

How we describe or frame something shapes our further judgments about it. In an unfortunate appropriation of an agricultural term, the early word for taking an organ from a dead body was *harvest*. Granted, this term was coined in the same utilitarian mentality that gave us *salvageable* patients and *pulling the plug* on life support, but for a while at least, *harvest* was uncontested. When we realized how impersonal and callous *harvest* could sound, we changed the word to *organ procurement*. In this terminology, *procure* is a fancy way of saying “get.” This terminology lives in the acronym for regional transplant networks, also called organ procurement organizations, or OPOs.

Now transplant advocates have further improved the language, at right about the same time as DCD protocols have come into sharper view. In an effort to link the work of organ transplantation to the good works of saving, recycling and loss prevention, what used to be called organ *harvest* and then organ *procurement* has now become organ *recovery*, as though the burial of a potentially transplantable organ in the body of its original owner would be a loss.2 Getting the organ for transplantation has become, in the minds of some, the default, with any other disposition of the organ regrettable.

It may be unrealistic to hope that the general public can be any better informed about DCD than they are presently about brain death and organ donation, which is to say, not very informed. But given the inadequately analyzed assumptions underlying DCD, the subtle shift in language that marginalizes those who might wish to be buried with all their component parts, and the support DCD is enjoying from regulatory agencies like HRSA, at least a place should be preserved for patients and hospitals that might not be so enthusiastic about it in light of their other values. This is best accomplished by keeping DCD as optional as possible.3 The Joint Commission recognized this when they recently issued a clarification of their standard regarding DCD, which originally seemed to suggest that hospitals were required to adopt policies allowing DCD. Now the commission and all their surveyors recognize that what is more helpful is to expect that hospitals will justify their position on DCD and make that position clear.4 Furthermore, it would be wise to continue the present practice of allowing DCD to be considered only if family members raise it, rather than suggest or allow the OPOs, which have vested interests, to “educate” the families of potential candidates about it.

Finally, some of the public is already distrustful of the motivations of hospitals and practitioners in limiting life-saving treatment. Groups who have historically been denied equal treatment or equal access to treatment have just cause to be resentful of that fact. Presuming that DCD is in everyone’s best interest risks further alienating this public. We should not move in the direction of institutional or individual default to DCD without regard for them.

**Notes**

2. Unfortunately, this has resulted in sentences that are somewhat unintelligible, such as, from one DCD policy, “The patient is allowed to die in a way that facilitates recovery.”
3. “Keeping it optional” includes keeping DCD institutionally optional.
Both CMS and the Joint Commission have recently mandated that all hospitals develop a protocol in conjunction with their local organ procurement organization that outlines the procedures by which organs can be harvested after cardiac death. The mandate was issued in the expectation that more organs, particularly kidneys and livers, will be available for patients who will die without such transplants. Clearly, the goal of increasing the number of organs available for transplantation is important to providing care for patients with liver and kidney disease; indeed it is a significant social goal. However, this new mode of organ donation should occasion some significant ethical reflection within the health care community as we proceed to the implementation of these new protocols.

Until recently, most livers, kidneys and hearts have been transplanted from brain dead bodies. The deceased was declared brain dead, but the respirator and other medical interventions were kept in place so that the organs continued to be perfused until the moment of their removal from the body. The basic ethical principle that justified this type of transplantation was the dead donor rule. By medical, legal and ethical standards the entire procedure was performed on a dead body.

Abandoning dead donor rule
As Troug and Cochrane have pointed out, donation after cardiac death marks the abandonment of the dead donor rule. (Robert Troug and Thomas Cochrane, “The Truth about Donation after Cardiac Death,” *The Journal of Clinical Ethics* 17, No. 2: 133-38). They contend that it is medically uncertain whether the donor is permanently and irreversibly deceased at the time of transplantation. Donors, they assert, “are dying but not yet dead” (p. 138). Their point is not that donation after cardiac death is ethically reprehensible, but, rather, that the dead donor rule is an inappropriate standard. The criteria that justify organ transplantation should be the patient’s prognosis and the patient’s consent. Thus, given the appropriate consenting process, immanently dying patients become potential donors for transplantation after cardiac death.

In her excellent anthropological study of death in American hospitals, Sharon Kaufman has documented the way in which natural death has been supplanted by death by choice (*And a Time to Die: How American Hospitals Shape the End of Life*, Scribner 2005). The death of the imminently dying in hospitals is not simply the result of natural processes, but, rather, the result of decisions by physicians and family members to remove a respirator and/or step down treatment so that death occurs as the result of the absence of life-supporting technology. As choice marks the transition between life and death, the possibility of identifying potential donors for donation after cardiac death becomes easier. The rational for the abandonment of the dead donor rule becomes patent.

If transplantation medicine has come to the point that it is appropriate to abandon the dead donor rule, and if American society concurs in that judgment, then we must also acknowledge that potential donors are still living, that their human dignity remains intact and that they are owed, like all other vulnerable persons, ethical and medical respect. What becomes important is to craft canons of ethical respect appropriate to their particular vulnerability.

Questions of consent
Many Americans indicate at the time of their driver’s license renewal their willingness to be organ donors. They do so with absolutely no foreknowledge of the conditions under which their death may ultimately occur. Is such a level of consent when coupled to a prognosis of imminent death sufficient to classify them for donation after cardiac death? When measured against the consenting process of a patient for even a minimally invasive procedure, to say nothing of the consenting process for major surgery or a research protocol, the consent represented on a driver’s license seems to fall far short of the appropriate ethical standard.
Some individuals who consent to transplantation on their driver’s license also have living wills that indicate they do not want to be resuscitated or intubated if they are imminently dying, if they have such a poor prognosis. If such a person becomes an imminently dying patient, should the living will or the consent on the driver’s license prevail? Which document more clearly construes the person’s moral choice in the light of imminent death?

Ultimately, this is a legal issue, but a legal issue that needs to be resolved in the context of ethical considerations. One solution would be to provide sufficient information to persons at the time of license renewal so that they have an adequate understanding of what they may be consenting to. Since that solution is unlikely to occur, these individuals should not become candidates for donation after cardiac death without the consent of their durable power of attorney for health care or family.

Generally, organ procurement protocols require hospitals to inform their local organ procurement organization when they have identified a patient whose condition renders him or her a potential donor. The organ procurement organization usually wants its representatives to approach the family and seek their consent to organ donation. At Catholic Healthcare Partners we have written into our protocol for donation after cardiac death that pastoral care representatives will be involved in the consenting process. We have made this a requirement for two reasons.

**Role of pastoral care**

First, pastoral care staff have worked with the families of potential donors for some period of time before the issue of donation arises. They have developed a relationship with the family and frequently have been involved in assisting the family in grappling with the difficult decision to step down the level of aggressive care. In general, the families want pastoral care staff to support them when they are asked to make yet another difficult decision.

Second, pastoral care staff will continue to support family members as they move through the grieving process after the death of their loved one. Not infrequently, family members will question whether they made the right decision in authorizing the removal of life-supporting medical interventions. They may also question whether they made the right decision in authorizing organ donation after cardiac death.

Pastoral care staff can be effective in helping families make these very difficult decisions and resolving this sort of “second guessing” and lingering doubts. For precisely these reasons, some organ procurement organizations actually encourage the role of pastoral care in the consenting process.

**Perfusing drugs**

Some organ procurement organizations require the administration of drugs (heparin and/or phentolamine) into donors prior to their death in order to ensure that the organs remain perfused (Clark and Deshmunks, “Non-Heart Beating Organ Donation,” *National Catholic Bioethics Quarterly*, Autumn 2004). It is important to note that these drugs are not intended to provide a medical benefit to the donor, but, rather, to maximize the likelihood that the organs being transplanted will remain viable for that purpose. The consent form for donation after cardiac death needs to make explicit reference to the administration and purpose of these drugs. That a physician should be compelled by a protocol to administer drugs that are not intended to benefit the patient appears to be a unique medical practice. The protocol in place within Catholic Healthcare Partners leaves to the discretion of each attending physician whether or not such drugs will be administered.

After the donor has been fully prepped and moved to an area adjacent to an operating room, and after the family has had an opportunity to say their final goodbyes, all life-supporting equipment is disconnected from the donor. To remain a viable donor, the patient must expire within a 60 to 90 minute window. If he/she does so, the transplant team steps in and the process of organ procurement begins. However, if the patient does not expire within the appropriate time frame, he or she is no longer deemed an appropriate candidate for organ donation. In this eventuality, the patient is returned to a hospital room until death occurs. The Catholic Healthcare Partners’ protocol requires that an appropriate room is identified and prepared prior to the removal of life support, and that appropriate palliative care staff and pastoral care are prepared to step forward to provide care for the patient and family.

The ethical challenges presented by donation after cardiac death do not result from an inherently immoral process. The ethical challenges posed by this procedure are much more subtle. The key question is how to perform a procedure, to which the patient or his or her surrogate has consented, in a manner that continues to honor and respect the human dignity of a profoundly vulnerable member of our moral community.
THE DEAD DONOR RULE is very much alive and well. It has been articulated as a fundamental ethical commitment by every major policy body that has supported DCD—U.S. and Canadian consensus conferences, three separate IOM committees, and several major professional associations. It is true that some ethicists—mostly those who once embraced questionable “higher brain death” criteria and then rejected them in favor of a very conservative concept of death as “cold, stiff and gray”—question the death criteria used in DCD. But most such authors, including those cited by Jack Gallagher, also question brain death criteria; they do not reflect mainstream medical views.

Particularly given Catholic health care’s commitment to following the Ethical and Religious Directives for Catholic Health Care Services, which require a patient to be dead prior to the donation of vital organs, it is important to understand why it is that DCD donors are dead before organ procurement begins. Typically, in DCD a patient is not pronounced dead unless a) circulation has been lost and the patient has stopped breathing for 2-5 minutes, and b) a valid DNR order is in place. This has at least three morally significant consequences. First, the patient has lost all major organ functions before being pronounced dead: the patient is not breathing, the heart is not beating, and the brain has lost all function (consciousness, for example, is lost only 15 seconds after circulation is lost). Second, available data indicates that after 2 minutes of absence, none of these functions will spontaneously resume. Third, given that a valid DNR order is in place, it would be contrary to legal and ethical standards to attempt resuscitation. Hence, the loss of all major organ functions is permanent.

The fact that resuscitation is contraindicated is also relevant to the second point: Every reliably documented case of the so-called Lazarus effect (spontaneous resumption of functions after being pronounced dead) has involved attempted resuscitation, typically with positive pressure and excessive ventilation which can cause pulselessness even with a beating heart. Finally, it is important to recall that in DCD, the decision to withdraw treatment is supposed to be made independently of the decision to donate organs; that is, DCD has nothing to do with the withdrawal of life support and the expected death.

Gallagher also references the use of heparin (an anticoagulant) in DCD, asserts that it is not for the benefit of the donor, and recommends that protocols leave it to the discretion of individual physicians whether to administer heparin. He cites a 2004 article in making these claims. However, that article greatly underestimates the need to use an anticoagulant when procuring organs and overestimates risks to donors. (A more recent article challenges several of the medical and ethical allegations made against the use of heparin.) Moreover, it is not that unusual to undergo medical procedures for the sake of another; and it is ethically acceptable to perform such procedures when consent is given, as is the case in DCD. Living organ donation, blood donation, genetic testing for the sake of offspring, all these procedures are routinely done for the sake of others. Finally, if the donor feels strongly about the act of organ donation—believes that it is a duty of charity—then is it really true that the donor receives no benefits by receiving medications that enable organ donation?

While transparency is important and DCD protocols should be made publicly available, we should not exaggerate what is possible or even desirable regarding community consent. Educating the community about donation is extraordinarily difficult, perhaps because people do not really want to know what happens during organ donation any more than they want to know what a coroner or mortician does with their bodies post-mortem. Moreover, if DCD is consistent with widely embraced medical-ethical principles, then the gatekeepers to DCD should not be communities—which are poorly educated—but family members and potential organ donors through the informed consent process. It is also a mistake to assume that the public will find DCD to be controversial. Most people who sign their donor card believe that they will be able to donate organs.
when they die; they don’t know that less than 1 percent of people are actually eligible when one restricts donor eligibility to those declared “brain dead.” Moreover, your average person is more baffled that a patient can be dead while on a ventilator with a beating heart than by the fact that a patient is dead when their heart has stopped beating and will never again resume beating.

I agree with Gallagher that a signed donor card is not sufficient to justify proceeding with controlled DCD, even as “first-person consent” or “donor designation” grows more widely accepted. The reason for this has less to do with how well informed patients are—they just assume they will be dead when organs are procured—but rather the fact that while the patient is still alive and on a ventilator, they must be treated as organ donors. Because DCD requires a decision to withdraw life support and affects the timing and location of the withdrawal of treatment, families should have a much greater role in decision making. But to be perfectly clear, this position does not challenge the status quo: no OPO currently treats a signed donor card as sufficient to proceed with controlled DCD. (Uncontrolled DCD, described in the 2006 Institute of Medicine report, is another matter, as the patients are dead before they are treated as candidates for organ donation.)

I disagree with Carol Bayley’s suggestion that it is a best practice to make DCD an option only if the family requests it. Most families do not know enough to request DCD; and yet very many families find organ donation a meaningful way to heal their grief. If DCD is consistent with the principles of medical ethics, then there really is no good reason to withhold a request. Withholding a request makes the institution the decision-maker regarding organ donation rather than the patient (who may have signed a card) or the family (who might welcome donation).

Though convinced DCD can be done ethically and should be offered to families, we should not underestimate how difficult it is do DCD well. DCD requires a commitment of resources (e.g., frequently an intensivist is pulled off the unit for 60-90 minutes in order to observe and pronounce the potential donor dead; particularly in non-academic settings, where residents are unavailable, this can be taxing). DCD is also psychologically more complex for critical care and operating room staff. Critical care staff are asked to begin modifying the treatment of a living patient for the sake of donation (e.g., by changing the timing and location of withdrawal or by administering heparin pre-mortem). With consent, these sacrifices can be appropriate, they can be expressions of love of neighbor. But DCD still involves critical care staff in uncomfortable dual roles. Similarly, OR staff are unaccustomed to death in the OR. DCD sometimes presents the first occasion when OR staff witness the withdrawal of life support. The withdrawal of life support sometimes occurs outside of the OR for the sake of the family; doing so may also increase comfort among OR staff.

Given the above considerations, hospitals that plan to implement a DCD policy should engage in extensive discussion with staff, particularly pastoral care, critical care and surgical staff. Discussions need to engage not only the medical facts that are relevant to DCD—which are often misunderstood—but also the ethical and psychological issues that often trouble staff as they begin participating in DCD. Finally, to whatever extent possible, staff who are uncomfortable with DCD should not be asked to participate, both out of respect for their consciences and for families who must interact with caregivers.

We encourage you to share your reaction to these three articles on DCD with other readers of Health Care Ethics USA. Please send your comments to smcconnahab@chatusa.org for publication consideration in the next issue’s “Readers’ Forum” section.

NOTES
Artificial Nutrition and Hydration: Advancing the Conversation

By Birgitta N. Sujdak Mackiewicz, Ethics Fellow, OSF Saint Francis Medical Center, Peoria, IL

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ple, many bishops remain unclear on how to interpret the allocution, leading to a request by the U.S. Conference of Catholic Bishops for further clarification from the Vatican’s Congregation of the Doctrine of the Faith. No answer has been received thus far. Additionally, O’Rourke cautioned, statements such as the allocution are recognized as opinion rather than magisterial teaching, and have not been repeated, suggesting that they are thus non-binding. Finally, such statements must be evaluated in light of subsequent allocations like that of November 2004 regarding pastoral and palliative care. In this document, the pope emphasized “True compassion . . . encourages every reasonable effort for the patient’s recovery. At the same time, it helps draw the line when it is clear that no further treatment will serve this purpose.”

Feeding by hand
Agreeing with O’Rourke that it was possible to make judgments in the appropriate application of principles, Kavanaugh approached the issue from a different angle. He did not focus on the question of whether one has a moral obligation to provide ANH to patients in a PVS, rather, he argued that if we discern that ANH is inappropriate or not morally required, the burden lies in showing why we are not then required to attempt to feed those patients by hand. This hand feeding approach is called “assisted feeding” and involves massaging the throat to initiate the patient’s swallow reflex.

Reflecting on the example of the death of John Paul II and his refusal of a PEG tube and large doses of antibiotics, Kavanaugh proposed that this might inform our discussions on the question of ANH for patients in PVS or other diseases such as Alzheimer’s. He raised two particular concerns: 1) the absence of a phenomenology of feeding, and 2) what we understand to be our goals in life.

Acknowledging that ANH may not be morally obligatory for those in PVS, and taking a self-described metaphysical approach, Kavanaugh questioned why an alternative method of feeding, such as assisted feeding, is not offered. If the intention is to withhold or withdraw treatment or care that is overly burdensome, is there not an obligation to attempt to find a different, less burdensome means of providing nutrition and hydration? Sharing his experiences abroad, Kavanaugh noted that the vast majority of patients in PVS could be fed by hand as their swallowing reflex can be provoked, but currently we lack the human resources to provide this hand feeding. Concerns about the cost of providing assisted feeding may be addressed by reexamining our mission in Catholic health care. Why would we question the provision of resources for assisted feeding, but not hesitate to provide more expensive technological interventions of various kinds? By medicalizing feeding, Kavanaugh argued, we have lost the human meaning associated with feeding: touch, companionship, presence, and accompaniment in their illness.

Initially meant as a short-term means of providing nutritional support, Kavanaugh lamented that we now often choose the PEG tube because it is the easier mechanism of feeding, not the more effective or less risky means. The use of the PEG has led us to forget what it is that we are trying to accomplish with the placement of the PEG. He suggested there is a personal interaction integral to the act and experience of feeding. If the hand feeding fails, however, this does not mean that there is a moral obligation to place a PEG. The moral obligation was to attempt to provide not only physical sustenance via assisted feeding, but also human solidarity. To emphasize how we have depersonalized the purpose of the PEG and the phenomenology of feeding, Kavanaugh recalled a story of a patient with a PEG (though clearly not in PVS) who asked for a beer. He desired the experience (taste and sensation) of enjoying a beer. Rather than handing the beer to the patient, it was poured into his PEG!

Goals of life
Kavanaugh concluded by challenging O’Rourke’s notion of friendship with God as the ultimate goal. He argued that there is a more complex goal and capacity we have as human persons. We are challenged, he asserted, to “accept the kind of beings we are . . . beings who are limited and dependent.” To ask whether or not our intervention benefits the person is not the issue. Rather, we must ask ourselves if we exhibit care, love, and honor for the person even in his or her “brokenness.” Forgoing ANH may be morally justifiable, Kavanaugh argued, but not to attempt to feed by hand represents a “profound betrayal of friendship” of the one we must encounter and to whom we have an obligation both in “full flourishing” and in our “vulnerability.” We must recognize the centrality of the human relationship in which we recognize the PVS patient not simply as a human person but as “the living God, word made flesh in his weakest moments.”
The complex issues surrounding the question of the provision of nutrition and hydration for those in PVS and the inherent difficulty in making objective statements about the morality of the utilization or withholding of either ANH or assisted feeding was brought into sharp focus by O'Rourke's final comments during the discussion. Reemphasizing the subjectivity of an intervention such as assisted feeding, he remarked that from his perspective the “notion that I'm unconscious and someone is going to massage my throat so I swallow, is to me abhorrent. I don’t want treatment of that nature.” Perhaps the most human solidarity can provide is the guarantee that the subjectivity required to evaluate the burdens of either of these approaches assures that these questions will continue to be answered on a case by case basis, and always reflecting the dignity of the human person in PVS.

NOTES
1. For a detailed look at O’Rourke’s position on ANH, see his recent article, “Artificial Nutrition and Hydration and the Catholic Tradition,” Health Progress, May-June 2007: 50-54.
4. Ironically, the question was submitted by the USCCB which, at the time, was headed by Cardinal William Levada. He is now the head of the CDF and must, therefore, answer his own question.
5. O’Rourke references a conversation he had with a member of the Pontifical Council on Life which has issued statements on the issue of PVS. This conversation affirmed that these documents, though signed by John Paul II, were recognized by the council as opinion rather than magisterial teaching.
Sample Policy 1: Donation After Cardiac Death

POLICY/PURPOSE:
To outline policy and procedure for referral, consent, medical management, recovery of organs, and support of patients and their families and their right to donate organs in the event of irreversible cessation of cardiopulmonary function.

DEFINITION:
Organ Donation after Cardiac Death, or DCD, is defined as a procedure whereby organs and tissues are surgically recovered after pronouncement of death based on irreversible cessation of circulatory and respiratory functions.

STATEMENT OF POLICY:
It is the policy of [name of health care organization] and its Medical Staff to provide appropriate guidelines for donation of organs by Donation after Cardiac Death donors. Consistent with the Ethical and Religious Directives for Catholic Health Care Services (ERDs), we “encourage and provide the means whereby those who wish to do so may arrange for the donation of their organs and bodily tissue, for ethically legitimate purposes, so that they may be used for donation and research after death.” (Directive 63)

1. Introduction
   1.1 Donation and procurement of vital organs after death is reasonable and ethical provided informed consent is obtained from the patient’s Surrogate or Power of Attorney for Health Care.
   1.2 An ethical cornerstone of organ donation is informed consent, which is required before every donation.
   1.3 Organ procurement must not cause death and death must precede procurement of organs. This fundamental principle is intended to protect the rights and interests of the donor.
   1.4 Death must be certified using standardized, objective, and audible criteria and must follow applicable state law.

1.5 The critical care professional is first and foremost caring for the dying patient. The care of the dying patient is paramount and will not be compromised in an effort to improve transplant outcome.

2. Recommendations for donation after cardiac death donors:
   Patients who intend to become Donation after Cardiac Death donors have the right to humane care, including the presence of family members as they are dying. Organ donation from a person whose death was certified using cardiopulmonary criteria has several special concerns that must be considered.

   2.1 The patient must be certified dead by an attending physician or attending designee using objective, standardized, audible criteria that are not different from those utilized for patients not destined to be DCD.
   2.2 No patient may be certified dead by a physician who takes part in the procurement or transplantation of organs.
   2.3 The decision on the part of the patient or an appropriate surrogate to withdraw life-sustaining therapy that has been deemed non-beneficial and/or excessively burdensome must be made independently of the decision to donate organs and tissues.
   2.4 When therapy is withdrawn, patients have the same right to medications that prevent and alleviate pain and suffering as do patients who do not intend to be DCD.
   2.5 No medication may be given to the patient for the purpose of hastening death. Medications may, however, be given to provide comfort even if they have the unintended side-effect of hastening death.
   2.6 Therapies that are harmful to the dying patient should be avoided even if they might improve the...
chances of a successful organ transplant.

2.7 Pastoral Care will provide assistance as needed during possible DCD cases to assist the patient, family, staff and/or physician with the emotional, moral, and ethical concerns that they may have about organ donation decisions.

2.8 If there is significant disagreement between the attending physician and surrogate and/or the patient’s family about the decision to make organ donation through DCD, the following options are available both to the attending physician and to the surrogate and/or family for the resolution of disagreement in the following order:
   a. Continued discussion between attending physician and surrogate and/or family.
   b. A Multidisciplinary Care Conference involving caregivers, surrogate and/or family.
   c. Transfer of care to another physician by attending physician.
   d. Surrogate request for another physician.
   e. Time-limited trials.
   f. Consultation with the Ethics Committee.

2.9 Staff members who have a conscientious objection to DCD may opt out of taking part in the protocol. Patient care, however, ought to never be compromised in an attempt to honor the employee’s wishes.

3. Qualifying patients for DCD include those who meet all of the following criteria:

3.1 Patients who want to be (or whose surrogates want them to be) removed from artificial ventilation on which they are irreversibly dependent and who have either:
   a. Irreversible brain damage that permits no interaction with the environment.
   b. The patients (through their surrogate) wish to donate their organs after death. AND
   c. In the opinion of the health care team, cardiopulmonary death will likely occur within sixty to one hundred-twenty (60-120) minutes following withdrawal of life support, a Transplant Network (TN) coordinator will assist in this determination.

3.2 TN, in coordination with the attending physician and/or specialty physician involved in the patient’s care, will determine if the patient is a suitable candidate for DCD and will utilize the most current criteria in determining the patient’s suitability for organ transplantation. A second physician will examine the patient and concur that the patient is a candidate for DCD.

4. Procedure

4.1. Potential DCD donors will be identified based on the above criteria.

4.2. Imminent neurological deaths will be referred to Transplant Network within sixty (60) minutes of identification (1-800-xxx-xxxx).

Definition: Imminent Neurological Death is defined as: a patient who 1) is severely brain injured, ventilator dependent, with either clinical findings consistent with a Glasgow Coma Score of less than or equal to five; or 2) a plan to discontinue mechanical/pharmacologic support.

Clinical triggers for this referral include the following:
   a. Severe brain injury
   b. Patient on mechanical support
   c. Discussion of deceleration or withdrawal of mechanical and/or pharmacological support
   d. Absence of two (2) or more of the following brain stem reflexes (determination must be made with the absence of drug intoxication, hypothermia, severe hypotension, neuromuscular blockade, CNS depressants, and metabolic disturbances):
      1. Absence of cough
      2. Absence of gag
      3. Absence of pupillary response
      4. Absence of respiratory effort
      5. Absence of response to pain

4.3. An initial phone screening will be performed by the TN person-on-call.

4.4. If the patient meets initial criteria for potential organ donation, a representative from TN will come to the hospital unit for further evaluation and to collaborate with hospital staff regarding approaching the family.

4.5. Consent:
   a. Only after the family and medical staff have determined that life support will be discontinued, the Transplant Network representative, in collaboration with the chaplain or house administrator, will inform the patient’s legal next of kin of their opportunity for organ donation.
b. When the request for donation is made, an associate (need to define) of [name of health care organization] must be in the room as either the designated requestor or to offer support, information, and/or services.

c. The patient’s legal next of kin will be informed of donation options and recovery procedures by the TN coordinator.

d. The legal next of kin must be available in the hospital or by phone to grant consent. TN will be responsible in phone-recording consent as required by the Uniform Anatomical Gift Act (UAGAS).

1. The TN coordinator will provide the following information to the legal next of kin to ensure informed consent:
   a. the process of withdrawal of life-sustaining therapy in conjunction with medical/nursing staff
   b. the determination and declaration of death/time of death
   c. options for organ donation
   d. reason(s) a case could be aborted
   e. the process of organ procurement
   f. evaluation process including consults, laboratory work, and medications
   g. the role of the medical examiner, if applicable
   h. follow-up communication
   i. coercion shall not be used to obtain/maintain consent
   j. a contingency plan will be discussed regarding comfort care should the patient not expire within sixty to one-hundred twenty minutes (60 to 120) from withdrawal of life-sustaining therapy
   k. if any conflict among next of kin, the MTN coordinator will consult the MTN risk management or administrative supervisor to obtain legal guidance

2. Explicit, informed consent must be obtained from the appropriate surrogate for administration of medications that offer no benefit to the patient (i.e., heparin). This consent must be listed separately and signed by the surrogate.

4.6. Medical management and evaluation:

a. The medical staff, in collaboration with TN, will implement management guidelines in the care and evaluation of the patient while in the ICU. Physicians will be responsible for writing orders.

b. The patient must be maintained on a ventilator and hemodynamically supported for organ perfusion until the withdrawal of life support.

c. The TN staff member is responsible for arranging the donation, including notifying the OR staff, arranging the arrival of the procuring surgeons, and arranging for a bed for the patient to receive palliative care if the patient does not expire within the prescribed time limits or is otherwise found unsuitable for donation.

d. Withdrawal of life support may take place in the ICU or operating room, always accommodating loved ones’ wishes to remain with the patient. Loved ones should be informed of the need to move the patient quickly to surgery after death if withdrawal occurs in the ICU. If family will not be with the patient, the withdrawal of life support will take place in the OR.

e. Within the planned and designated location, withdrawal of life support then occurs.

f. A standard OR team is needed for the DCD process; to include a circulating RN and scrub technician/RN.

g. The patient shall be extubated and non-essential monitoring devices are disconnected under the direction of the attending physician or designee. EKG, SpO2 and arterial pressure monitoring will continue. At least one intravenous line will remain in place for medication administration if necessary and ordered by the pronouncing physician.

h. No sooner than five minutes after cardiac arrest (as demonstrated by asystole and lack of measurable arterial blood pressure), the attending physician or designee will pronounce death.

i. In accordance with the Uniform Anatomical Gift Act (UAGA), the physician pronouncing death cannot be involved with the retrieval or transplantation of organs.

j. The physician will write an appropriate progress note and complete the death certificate attesting to the death.
k. If cardiac arrest does not occur within the 60-120 minutes after life support has been withdrawn, the organ recovery effort will be aborted. The patient will be transferred to a palliative care bed for continued care. Support measures will not be re-initiated.

l. Once the patient is declared dead, organs and tissues are recovered by the procurement surgeons, and or technicians.

m. If the family wishes to view the patient’s body after procurement, every effort will be made to ensure the patient is suitable for viewing. A location for viewing will be determined by the house supervisor.

REFERENCES:


Sample Policy 2: Donation After Cardiac Death

PURPOSE:
The purpose of this policy is to assist families, health care representatives, physicians and health care professionals to appropriately implement the right of each patient to choose both to have artificial support withdrawn and to donate their organs by establishing principles and procedures to be followed in these cases. [Name of health care organization] believes it is ethically appropriate to consider Donation after Cardiac Death (DCD). The policy will apply to those patients deemed medically acceptable for donation of at least one organ but who do not meet brain death criteria. This policy is a reflection of our mission and values and places the highest emphasis on patient dignity and family support.

DONOR SUITABILITY
1. The patient has a devastating irreversible neurological illness or injury with a hopeless prognosis requiring ventilator support.

2. The patient, family or other authorized party has chosen to discontinue life support and a formal DNR order is placed in the patient’s chart. This decision is made entirely independently of and prior to any consideration of organ donation.

3. Medical suitability for donation after cardiac death will be determined by [name of local organ procurement organization].

4. The patient is expected to die within 120 minutes after termination of ventilator support.

I. CONSENT PROCESS
1. The option of organ donation will be offered only after the decision to terminate life support has been made. The donation option will be made through collaboration with [name of local organ procurement organization], the ICU team and a member of spiritual care. [Name of local organ procurement organization] should be notified when the family meeting or discussion will take place to allow an appropriate amount of time to evaluate the patient prior to offering the option of donation.

2. After consultation with the patient’s attending physician or his/her designee, the [name of local organ procurement organization] coordinator will discuss the possibility of organ donation with the patient’s family or other authorized party. This conversation should include a member of the health care team and/or spiritual care.

3. A general overview of the DCD process will be shared with the family, including the need to perform testing to determine medical suitability and the likelihood of the patient dying soon after the withdrawal of support, and the need to administer medication prior to withdrawal of support.

4. If after testing the patient appears to be an acceptable candidate for DCD, the family (or other authorized party) will be given a detailed account of the entire DCD process including the possibility that their loved one may not die as expected, in which case he or she will be returned to a predeter- mined area and supportive care will be provided. Family members will also be told that they may accompany their loved one to the operating room and be present during the withdrawal of support care, but they must leave the operating room as soon as cardiopulmonary arrest occurs.

5. Once all the family’s questions have been answered and they have had time to assimilate the information, they will be asked to give consent for organ donation after cardiac death.

6. If consent is given, the [name of local organ procurement organization] Consent Form for Organ Donation will be completed.

7. The family will be provided emotional support throughout the entire process by the health care team, spiritual care and [name of local organ procurement organization] staff.

II. PRERECOVERY DONOR MANAGEMENT
1. The patient must be maintained on a ventilator and
hemodynamically supported until withdrawal of support takes place.

2. With the cooperation of the patient's attending physician (or his/her designee), the Procurement Transplant Coordinator will request consultations and studies needed to determine the suitability of the organs for transplantation and the likelihood of the patient dying soon after withdrawal of life support. [Name of local organ procurement organization] staff, associated recovery teams, and recovery surgeons will not write orders in the patient's chart prior to the pronouncement of death.

3. If the case falls under the jurisdiction of the coroner/medical examiner, the Procurement Transplant Coordinator will contact the appropriate person(s) to arrange for organ/tissue recovery.

4. The well-being of the patient is the primary responsibility of the attending physician and healthcare team. Comfort measures for the patient should be made available as per usual hospital policy.

III. STAFF COMMUNICATION

1. The [name of local organ procurement organization] Coordinator will obtain and review copies of the hospital's Withdrawal of Support and Organ Donation after Cardiac Death policies.

2. The [name of local organ procurement organization] Coordinator will contact the appropriate hospital staff, which may include the attending physician, clinical nurse manager, spiritual care, OR, anesthesiologist (lung recovery), supportive care and any other responsible party deemed appropriate by hospital staff or [name of local organ procurement organization] personnel.

3. The [name of local organ procurement organization] Coordinator will review the case and the details of the DCD procedure with all medical, surgical, anesthesia and nursing staff that will be involved with the case.

4. No employee or medical staff member of [name of health care organization] shall be required to participate in a DCD recovery because of personal, moral or ethical objection. [Name of health care organization] will not discriminate against any employee or medical staff member who informs [name of health care organization] that he/she does not wish to participate in the DCD organ recovery.

5. The Ethics Committee is available for consult when requested.

IV. PRERECOVERY PROCEDURES

1. Operating room staff will be briefed on the procedure and prepared for the patient.

2. The [name of local organ procurement organization] Procurement Transplant Coordinator will assemble the organ recovery team.

V. WITHDRAWAL OF SUPPORT

1. Withdrawal of support will take place in the Operating Room. OR staff members will have the option to be present during the withdrawal of support.

2. The patient will be transferred to the operating room fully supported and accompanied by the ICU nurse, respiratory therapist, spiritual care (if not attending to family needs), and the [name of local organ procurement organization] Procurement Transplant Coordinator.

3. Prior to the withdrawal of life support, the organ recovery team will prep and drape the patient. Once prepping is completed, the organ recovery team will leave the operating room.

4. The organ recovery team may not be involved in the withdrawal of support, provision of comfort care, or the determination of and declaration of death.

5. Blood samples will be obtained as needed prior to the administration of medication and withdrawal of support.
6. Medication may be administered at this time at the discretion of the responsible attending physician or his/her designee.

7. The withdrawal of support will be performed by an attending physician, house physician/officer or resident in collaboration with the ICU team.

8. Family members may accompany their loved one to the operating room and be present during the withdrawal of support, but they must leave the operating room as soon as cardiopulmonary arrest occurs. Family presence in the OR will be coordinated with the [name of local organ procurement organization] Family Support Liaison and a member of the spiritual care team.

9. The organ recovery team will only reenter the operating room after the patient experiences cardiopulmonary arrest.

10. Comfort measures should be continued as per hospital protocol and at the discretion of the attending physician, house physician/officer or resident.

**Process for Lung Procurement**

1. If bronchoscopy is ordered, attending physician/designee will perform procedure in ICU or OR. Organ procurement team may observe bronchoscopy, but not take an active role in procedure. When procedure is complete, procurement team is excused from room.

2. The following procedure will be utilized:
   a. Prior to extubation, the attending physician, anesthesia or designee must verify that reintubation can be easily performed, in the event it is deemed that reintubation may be difficult, consider the use of an ET Tube exchanger.
   b. If reintubation is not feasible, then the patient must remain intubated with a room air T-piece or flow-by system in place.
   c. The RN/RT/MD or designee will withdraw ventilator support
   d. Cardiac monitoring and invasive blood pressure monitoring will be maintained.

**VI. PRONOUNCEMENT OF DEATH**

The donor recovery will not be initiated until either:

a. The donor is pronounced dead by the attending physician or his/her designee independent of the transplant team after a determination that there has been a five-minute interval of asystole determined accurately by continuous arterial pulse pressure monitoring and that the donor has sustained irreversible cessation of circulatory and respiratory function.

b. The donor is pronounced dead by the attending physician of his/her designee, independent of the transplant team, after a determination that the donor has sustained irreversible cessation of circulatory and respiratory function, followed by a five minute interval of continuing asystole determined accurately by continuous arterial pulse pressure monitoring from the time of pronouncement.

1. Death will be pronounced by the attending physician, resident or house physician/officer who may not be part of a transplant or procurement team.

2. If the patient dies within 120 minutes, organ recovery will begin.

3. If the patient does not die within 120 minutes, or there are extenuating circumstances that precipitate abandoning the case, organ recovery will not take place and the patient will be transferred to a previously designated area. Supportive care will be provided for the patient and the family.
Conscientious Objection for Health Professionals
The June 2007 issue of The American Journal of Bioethics (vol. 7, no. 6) has an article and several commentaries on conscientious objection for health professionals, especially as it relates to emergency contraception.

End of Life


HPV Vaccine


Spirituality in the Clinical Setting
The July 2007 issue of The American Journal of Bioethics (vol. 7, no. 7) has an article and several commentaries on “talking about spirituality in the clinical setting.”
Emergency Contraception: What’s Happening?

State legislatures continue to take up the issue of requiring all the hospitals in their state to provide emergency contraception (EC) to women who have been sexually assaulted. California, Massachusetts, New York, New Jersey, New Mexico, Minnesota and Washington have already passed such legislation. Most recently (May 30, 2007), the Connecticut and Oregon legislatures also passed such a bill. Florida, Pennsylvania and Wisconsin legislatures are considering similar legislation.

State Catholic conferences have differed in their approaches to this type of legislation. In some states, such as Connecticut and Pennsylvania, the bishops have strongly opposed the legislation, believing emergency contraception (Plan B) to be abortifacient and the requirement of its use to be a violation of religious freedom. Several state Catholic conferences have pursued conscience clause protection, but to no avail. In other states, the bishops have either not opposed the legislation or have taken a more conciliatory approach. The Wisconsin Catholic Conference, for example, has remained neutral on the matter, and the New York Catholic Conference worked with their legislature several years ago to develop legislation that they could live with.

As noted above, the two issues for Catholic conferences and for Catholic health care are 1) whether the medications are abortifacient and 2) the inclusion of conscience clauses so that Catholic hospitals are able to deliver health care in a manner that is consistent with their religious convictions. Conscience clause provisions would seem to be important whether or not these particular medications are abortifacient.

But are the medications abortifacient? After doing a review in 2004 of most of the literature on the mechanism of action of EC, CHA staff came to the conclusion that “at this time, scientific studies on the mechanism(s) of action of EC are not conclusive. While there is substantial evidence of the anovulant effect of EC, there is no definitive evidence of its other possible mechanisms of action, including possible abortifacient effects (i.e., making the endometrium inhospitable to implantation).”*

CHA recently concluded an update of its literature review with a particular focus on the mechanism of action of levonorgestrel (Plan B). Of the nine articles describing “original research,” only one strongly suggested a possible abortifacient effect, but the researchers who wrote that article employed a “simulation model” rather than physical examination of endometrial tissue. The other research studies were either inconclusive about post-ovulatory effects or found none or none sufficient to prevent implantation. One 2007 study concludes this way: “A larger study is needed to prove our hypothesis that LNG [levonorgestrel] ECP has a major contraceptive effect when taken prior to but not after ovulation and that it does not interfere with postfertilization events” (Novikova, N., et al., “Effectiveness of levonorgestrel emergency contraception given before or after ovulation—a pilot study,” Contraception 75 (2007): 117).

Two studies with animals (one with rats in 2003 and the other with Cebus monkeys in 2004) found no interference with implantation. Hence, while it seems to be the case that EC medications have several mechanisms of action, there is no definitive evidence, and, in many research studies, no evidence at all, of any effect on the endometrium such as to render the endometrium inhospitable to implantation of a fertilized egg.

Despite the continued scientific uncertainty about the mechanism of action of EC, there seems to be a move in the direction of not permitting the administration of EC in Catholic hospitals if the woman is at or around the time of ovulation, when conception could possibly occur, and of claiming, without any qualification, that EC is abortifacient.

Dying in America, Post Schiavo

Over the past 30 or so years, a “fragile consensus” has been forged in the United States regarding end-of-life decision making. This has been due to multiple factors, including court cases, the developing field of bioethics, the literature on the subject, conferences and lectures, people’s experiences, the growth of hospice and palliative care, and much more. The consensus consisted in agreements on three principle issues. The first is a belief that there are limits to the use of medical technology at the end of life and that the limits can be discerned through an assessment of the benefits and burdens of the treatment upon the patient. The second is general (though surely not universal) agreement that there is a difference between killing (euthanasia and assisted suicide) and allowing to die (forgoing or

* Excerpted from CHA’s preface to the summary of the literature. CHA members can view the summaries of the literature on the mechanism of action of Plan B by visiting www.chausa.org/planb.
withholding life-sustaining treatment). And the third is the conviction that patients (or their surrogates) have the moral and legal right to make treatment decisions in light of their own values, resources, lifestyle, etc.

This fragile consensus may well be eroding, especially post Schiavo. Why is this the case? On one hand, there are those who wish to see the legalization of physician assisted suicide (PAS) and/or euthanasia. While only Oregon permits PAS, several states have considered legislation that would permit it, California being the most recent. It is probably only a matter of time before more states follow Oregon’s lead. Legalization of PAS and/or euthanasia absolutizes autonomy and banishes the distinction between killing and allowing to die. It also makes an assessment of benefits and burdens unnecessary.

On the other hand, there is increasing evidence from a number of sources of a “tightening” around end-of-life decisions. Of course, there is the Schiavo case and all that was said and written about that. Then there is the papal allocution of March 2004 and the controversy that followed. Since these two significant events, there have been several bishops who have made public statements about end-of-life care, several state Catholic conferences that have either issued pastorals on the topic or revised advance directive forms, state legislatures that are revisiting advance directive legislation or, in the case of Texas, revisiting their “futile treatment” legislation, and several groups proposing legislation with regard to withdrawing nutrition and hydration from patients without expressed wishes.

There seem to be recurring themes in some, but certainly not all, of these developments, namely:

- Considering artificial nutrition and hydration to be basic care and generally morally required for all dying patients, not just patients in a permanent vegetative state.
- Restricting the withdrawal of life-sustaining treatment to the time when the patient is imminently and irreversibly dying.
- Narrowing the understanding of benefit to the treatment achieving its physiological or biological purpose.
- Not permitting the withdrawal of artificial nutrition and hydration from patients who cannot speak for themselves and who do not have expressed wishes regarding such withdrawal.
- Considering the refusal of artificial nutrition and hydration in an advance directive to be morally unacceptable.
- Reframing advance directives so that they are no longer an attempt to limit treatment, but are, rather, requests for life-sustaining treatment, except in a narrow range of circumstances.

If these directions take hold, it is quite likely that the fragile consensus will collapse, for they begin to erode the traditional understanding and practice of ordinary/extraordinary means and when it is morally permissible to forgo or withdraw treatment. They could even have the effect of diminishing patient autonomy. Some would say that in response to efforts to legalize PAS and euthanasia, these developments move in the direction of vitalism. In any case, they could well have a significant impact on the way that Catholic health care currently cares for the dying in its midst.
The use of Plan B has increased dramatically since the federal government approved the over-the-counter sale of the emergency contraceptive medication in August 2006. Sales, in fact, have doubled from about $40 million a year to an expected $80 million for 2007. Barr Pharmaceuticals, producer of the drug, has been advertising in women’s magazines and has provided an online training program for more than 54,000 pharmacists. Some pharmacists refuse to provide the drug on moral grounds. Several states have passed laws that either require pharmacists to provide Plan B, or protect those who refuse. Nineteen other states are considering legislation. (The Washington Post, July 13, 2007)

Doctors can be deeply affected by medical mistakes according to a survey conducted by researchers at Washington University in St. Louis. The vast majority of the 3,171 physicians surveyed in St. Louis, Seattle and Canada said they had been involved in a minor or serious medical error, or a near miss. Sixty-one percent said they felt increased anxiety about the potential for future mistakes, 44 percent said they became less confident in their job abilities, 42 percent experienced sleep problems, and 42 percent had a decrease in job satisfaction. Most doctors said they would have liked counseling or other help after making mistakes, but that hospitals and other health care organizations didn’t offer much assistance. Only 10 percent said hospitals offered them adequate resources for dealing with mistake-related stress. Survey results will appear in the August edition of The Joint Commission Journal on Quality and Patient Safety. (Associated Press, July 18, 2007)

A rule that dismisses a pharmacist’s right of conscience was unanimously adopted in May by The Washington State Pharmacy Board. The rule requires a pharmacy to fill a patient’s lawful prescription, even if the pharmacist has a moral objection. It does allow for another pharmacist on staff to fill the prescription. The major debate is primarily over emergency contraception. Currently, nine states have pharmacists’ conscience clauses, 17 states have proposed such legislation, and six states have proposals that would require the pharmacy to fill the prescription. (National Catholic Register, May 13-19, 2007)

Supreme Court upholds constitutionality of Partial Birth Abortion Act. On April 18, by a vote of 5-4, the U.S. Supreme Court upheld the Partial Birth Abortion Act, overturning the previous decisions of six federal courts which ruled that the act unconstitutionally restricted a woman’s right to an abortion. (Gonzales v. Carhart, 127 S. Ct. 1610 (2007)). In the 1990s, Congress twice passed a partial-birth abortion ban, but these efforts ended with vetoes by President Bill Clinton. In 2003, Congress again passed such a ban and President Bush signed the bill. However, due to numerous court challenges, the law never went into effect. In the most recent rulings, Justice Anthony Kennedy, writing the majority opinion in the Gonzales v. Carhart and Gonzales v. Planned Parenthood cases, said the law’s opponents “have not demonstrated that the act would be unconstitutional in a large fraction of relevant cases.” (Catholic News Service, April 18, 2007)

HHS allocates $430 million to improve hospital disaster preparedness. On June 29, HHS awarded $430 million to states, territories and four major metropolitan areas “to improve the readiness of hospitals and other health-care facilities in their jurisdictions.” These funds are to be used to better respond to bioterrorism attacks, infectious diseases, and natural disasters by allowing for the implementation of interoperable communications, systems to track available hospital beds, advance registration of volunteer health professionals and planning for both fatality management and hospital evacuations. (Modern Healthcare, June 30, 2007)

FDA task force report urges increased oversight of human-tissue industry. An internal task-force report released June 12 recommends that the Food and Drug Administration require more extensive tracking of non-organ tissue such as tendons, bones and heart valves from the cadavers where they are retrieved to the patients where they are implanted. Although the agency’s issues chief, Dr. Celia Witten, pronounced the industry safe, critics like U.S. Senator Chuck Schumer (D-NY) emphasize that the industry still does not require certification and specific training of tissue-recovery operators. These critics believes that the task force’s recommendations do not go far enough, as they do not bar funeral homes from recovering body parts and don’t require background checks or certification or immediate inspection of new companies (Associated Press, June 13, 2007)

OHRP to consider incidental findings policy. The Department of Health and Human Services Office for Human Research Protections agenda includes a number of controversial items, Director Bernard A. Schwetz said June 7. One of these issues includes how to deal with incidental findings in human research studies. Although discussed for decades, renewed interest in this area has been driven partly by new technologies that make incidental findings more likely and give rise to more possibilities for secondary research on archived data sets. Incidental findings pose ethical
dilemmas on several important questions, suggesting the need for institutions to devise guidance to help find the answers and prevent internal policy inconsistencies, Schwetz said. “HHS regulations do not address incidental findings directly, so investigators need to be sensitive to the issues they raise,” he said. “Very few institutions have policies to provide guidance on these issues. At this point, I think the institutions have to step forward to propose guidance.” (BNA Medical Research Law & Policy Report, June 20, 2007)

Skin cells may be used as stem cells, researchers say. Researchers have come much closer to a major goal of regenerative medicine, the conversion of a patient’s cells into specialized tissues that might replace those lost to disease. The advance is an easy-to-use technique for reprogramming a skin cell of a mouse back to the embryonic state. If the technique can be adapted to human cells, researchers could use a patient’s skin cells to generate new heart, liver or kidney cells that might be transplantable and would not be rejected by the patient’s immune system. But scientists say they cannot predict when they can overcome the considerable problems in adapting the method to human cells. Previously, the only way to convert adult cells to embryonic form has been by nuclear transfer, the insertion of an adult cell’s nucleus into an egg whose own nucleus has been removed. The egg somehow reprograms the nucleus back to an embryonic state. That procedure is known as therapeutic cloning when applied to people, but no one has yet succeeded in doing it. (New York Times, June 7, 2007)

Study shows that coverage for general medical care is better than coverage for substance abuse treatment. A recently released Health Affairs analysis of health benefits trends illustrates the incongruence between those benefits offered for general medical care and those offered for substance abuse treatment. While employer-sponsored coverage for substance abuse treatment continues to have annual limits and lifetime caps on treatment visits and inpatient days, and also requires higher cost sharing than coverage for general medical care, such limitations do not apply to general medical care, where nearly all covered workers had unlimited medical-surgical hospital days and office visits. Additionally, many workers are exempt from state mental health “parity” laws aimed at bringing private-sector mental health benefits more in line with coverage for other types of disorders. As a result, as of 2003, only one-fifth of U.S. workers with employer-sponsored health insurance were covered by “strong” parity laws that mandated mental health benefits, prohibit limits on outpatient visits and inpatient days, and limit the extent to which enrollees can face higher cost sharing for mental health services. (Health Affairs Press Release, June 7, 2007)

Students from the Center for Health Law Studies and Student Writers Association at Saint Louis University’s School of Law contributed to this installment of “Of Note.” Center Assistant Director Kelly Dineen supervised the contributions of health law students Kristen Ratcliff, Amy E. Scherer and Nathan Sturycz.
GOT SOMETHING TO SAY?
Future issues of HCEUSA will contain a section titled Readers’ Forum. If you have comments on things you’ve seen in HCEUSA, please share them with your fellow readers. Send all Readers’ Forum comments to smcconnaha@chausa.org.