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At the Bedside

Patients May Benefit from Postponing Assessment of Mental Capacity

Edmund G. Howe

In this issue of *The Journal of Clinical Ethics,* Daniel J. Brauner and Susan E. Merel present a highly nuanced approach to determining the mental capacity[1] of patients who have Alzheimer's disease (AD). In "How a Model Based on Linguistic Theory Can Improve the Assessment of Decision-Making Capacity for Persons with Dementia," they describe how careproviders can better assess these patients' decision-making capacities by using techniques such as listening for paraphrases and *anaphora* (words that refer to prior words), and conducting what they call "indirect repair and frame analysis." It is crucially important to find ways to better understand patients' capacity, particularly because patients may retain full emotional awareness even when they lose cognitive capacity. With better understanding, implementation of their preferences can be improved, allowing us to respond to them more as we do to patients who are clearly competent. In this way, we will be able to treat patients who have AD more justly.

But determining patients' capacity may have a downside: the patients may understand what careproviders are doing, and may infer, correctly, that the result may be that they can no longer make decisions for themselves. This may be something that a patient accepts or even wants; but many will not. Patients may experience the possible loss of being able to make decisions shattering. This may be so, in large part, because as the patients lose cognitive capacity, they find it more important to continue to have control. When patients fear control may be taken from them, it may abruptly end their capacity to feel trust, and they may no longer see their careprovider or other careproviders as allies, but as adversaries. This rupture in the relationships can extend to patients' loved ones, especially if the loved ones asked for the assessment, or just tacitly support it. This loss of feeling an alliance with loved ones may increase if loved ones later make decisions the patient opposes. As a result of an assessment, patients may lose not only their independence, but trust in others. Even when their choices are given great weight, these losses may completely change

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what they want.[2] Their new want may be for death, rather than for life-sustaining interventions. Several critically important clinical implications follow; I shall discuss these here.

INTERACTION WITH PATIENTS

Testing for the AD genotype

Persons may ask for genetic testing for AD before they receive a diagnosis of AD, and leading organizations have recommended that careproviders not refer them for genetic testing, if possible.[3] There are good reasons: the AD genotype, the APOE gene, is only a marker for susceptibility. Testing offers relatively little prognostic significance; yet, if patients test "positive," they may become highly alarmed. Recent findings indicate that this recommendation perhaps should be challenged. In one study, adult children of parents who had AD were offered the opportunity to be tested; one-quarter wanted to be tested, and, of those who tested positive, 95 percent said they would do it again.[4] It has been a common belief until recently that research participants shouldn't be given access to results that have too little "scientific meaning," or access to results that do not meet the standards of statistical significance commonly used for providing medical care. It was thought that such results may be unduly harmful if given before then.[5] Innovative, eminent thinkers recently asserted that this approach may be wrong; they suggest that our present disclosure policies be reconsidered, in light of new data that suggest the levels of distress that research participants actually experience in these situations may be low.[6]

It is important to note that patients and research participants may find such results highly, personally meaningful. Some claim that persons who aren't scientifically trained can't adequately understand data when they lack scientific significance, but careproviders and researchers could explain what that lack of significance means, or, more importantly, what it does not. These considerations are exceptionally important to patients who want testing for the APOE gene for two reasons. First, when they may fear that they will acquire AD, it may be not this fear, but their uncertainty that is unbearable. For these patients, any degree to which they can relieve uncertainty may be a godsend. Helping patients to understand data should improve the patient/careprovider relationship, which may enhance the likelihood that patients will return for early diagnostic screening if and when they have memory loss, and for treatment, if they test positive. Also, if the relationship is positive, if and when the patients have AD, they may be more willing to listen to and follow their careproviders' advice.

Initial Screening for AD

Currently, careproviders generally screen for AD when patients first complain of memory problems, and are at risk due to their age or to having family members who have AD.[7] Early testing is beneficial because medications now can slow the progress of AD. Careproviders can screen brief procedures, for example, a standard mental status exam that involves asking several questions, or asking patients to draw a clock showing a specific time.[8] Some patients may not want this testing.[9] Patients with AD are in some ways like the patients with incurable cancer that Paul R. Helft describes in his article in this issue of *JCE,* "An Intimate Collaboration: Prognostic Communication with Advanced Cancer Patients." The patients, he says, face an "extraordinary set of circumstances." They "possess a life-ending disease" and yet are still "functional and alive." He asks, "Is it ethically acceptable to support some patients' desires to avoid the cold, hard facts about their prognosis?"

Patients with AD also have a life-ending disease, but, in its earlier stages, at least, patients are functional and alive. They differ, in that, as they die, their capacity to function may markedly decrease. Careproviders usually conduct a brief screening for AD unless the patient takes the initiative to avoid it. In light of the "extraordinary circumstances" all pa-

tients may face, however, careproviders could ask all patients if they want screening. This may seem like asking patients if they want careproviders to take a medical history or do a physical exam, but making this offer furthers the interests of patients who don't want testing, but who will not take the initiative to avoid it. This approach furthers equity for less-assertive patients. These patients may come to feel greater trust for their careprovider as a result, and later may better accept what the careprovider recommends to them. The "price" of doing this is, obviously, when patients defer testing and treatment, their AD may more rapidly progress. Careproviders should always tell patients about this risk before they ask what they want to do.

Referring Patients for Further Testing

The brief tests mentioned above have high rates of false positives and false negatives.[10] More elaborate testing can reduce both. An exam by a neurologist can rule out other, sometimes reversible, causes of memory problems or other symptoms that are common to AD. If the results of the brief tests are positive, patients can be referred for further tests. If the initial tests are negative, careproviders generally reassure patients it is highly unlikely that they have AD, at least for the present. Some patients may remain highly fearful, and their careproviders may wish to depart from common practice and refer them for more testing. This is more respectful of patients' autonomy, and may enhance trust.

INTERACTING WITH PATIENTS AND THEIR LOVED ONES

While careproviders strive to maximize the autonomy of patients with AD, they should also paternalistically urge patients to bring their loved ones to meet with careproviders as soon as they can. As Lyness says, "The diagnosis of dementia provides an opportunity to (indeed, mandates that we) engage in ongoing end-of-life discussions with the patient and family, and to begin doing so early in the course of the disease."[11] This may be most difficult when patients' relationships with their loved ones are at their worst — but that is when it is more important than ever.

When a patient and loved ones meet with the careprovider, they can discuss all the possible outcomes, best and worst, that may be encountered in the future, if this is what the patient and loved ones want to do. These discussions may help loved ones decide what to do, and to help them feel less guilty about the decisions they make for the patient after the patient loses decision-making capacity. To the degree that the patients' loved ones feel less worry, it will benefit the patients. It may be more important for patients and loved ones to discuss, when they still can, what each can do at different stages of the patients' disease to provide the patient maximum benefit. The should share three goals. (1) Loved ones should learn to defer to the patient initially, as long as what the patient wants doesn't "court disaster," and to continue this as long as they can. (2) As patients get worse and "court disaster," they should defer to their loved ones as long as they can. (3) At first, patients and loved ones should work together to alter maladaptive interactive patterns of behavior; later, loved ones should work independently to do so.

Persuading Patients to Bring in Loved Ones

Careproviders should urge patients to bring in their loved ones from the outset. They can share with patients several rationales that will be discussed throughout this section. If a "logical approach" doesn't work, careproviders can try appealing to patients' emotions and — shamelessly — appeal directly to the patients' feelings for their loved ones. Careproviders can suggest that if they won't do this for themselves, they might be willing to do this for those they love, as it may, in one way or other, take care of them. The following is an example of an instance in which I succeeded in this way.

A patient in his late 40s had been briefly, involuntarily, psychiatrically hospitalized. He had been brought in by police the day after he told his wife he would take his life. If he was to be kept as an in-patient against his will for much longer, he needed to be formally evaluated. To keep him in the hospital, a court would have to declare that he was mentally ill, and a danger to himself. I was asked to assess this. The patient was initially suspicious and very withdrawn. I had learned from others, beforehand, that he had paranoid ideas. He adamantly denied that he was at all suicidal, and indicated to me that, above all else, he wanted to leave the hospital. Under these circumstances, I felt that it was most likely that a court would not be willing to continue to involuntarily commit him. Yet, I believed he really needed to stay there for a longer time to get the treatment he needed, so that he could get better quickly, or perhaps, get better at all. He said also in response to my specifically asking that, yes, he greatly loved his wife.

"She is scared beyond belief, I would guess," I told him. "She is scared that if you go home, you'll kill yourself. Do you agree?" I asked him. He did. I continued, "Even if you sign yourself out now, which I expect you soon could, and go home, what will it be like there? I expect she will be sitting there with you, but not feeling love, only terror. Is this what you want her to have to feel?" He agreed that he didn't. "The only way at all, I think, she could feel less afraid," I then said, "is if you leave this ward only when your doctors can tell you and her that they think this is safe. Even if, for yourself, you want to go now, the only way you can meet her needs is to stay here until that happens." Then the real guilt trip: "You would stay, if you are telling me the truth that you really care about her." He did.

Discussing the Future and Advance Directives

Discussing the future and advance directives with patients and their loved ones during the earliest stages of AD can greatly benefit both. There are no limits to what can be discussed at this time; there is evidence such discussions do not cause patients to become depressed.[12] It may even be helpful to discuss what patients would want if they had to be kept in restraints, and what they would want if they could no longer eat by mouth. Careproviders generally are reluctant to pursue these kinds of discussions.[13] Regardless, such discussions respect patients' autonomy, and can help loved ones make decisions for patients later on, based on actual, expressed preferences, which frees loved ones from guessing and feeling undue, unavoidable guilt. There may also be some less obvious positive effects. This may, for example, help patients and loved ones to grieve. It may also help patients and loved ones experience greater bonding.[14]

The discussions may enable loved ones to make different decisions later on than they might have made otherwise. A particularly difficult issue is, for example, what to do should the patient lose the capacity to recognize loved ones, but seem to be happy in this state. This issue may be especially difficult to discuss if, under those circumstances, a patient wouldn't want the careproviders to maintain the patient's life. Patients may feel so strongly about this that, if they believe their wishes might not be honored, they might want to end their life before this comes to pass. This issue may be difficult, because even if a patient indicates his or her wishes unequivocally beforehand, if the patient appears to be happy later on, careproviders, an ethics committee, or a court may not be willing to withhold or withdraw life-preserving care. Some believe that patients in the initial stages of AD shouldn't be able to dictate advance directives that apply after they lose capacity, because, they assert, later on the patients are altogether different persons.[15]

Post argues, vehemently, against artificially sustaining patients' lives under these conditions. He believes that the patients may not be genuinely happy, and, even if they are to some extent, this state most likely will be very short-lived.[16] A compromise between these views may be the best: careproviders could keep patients alive, but only so long as they continue, as best can be guessed, to enjoy their lives, regardless of their prior preference; but once the benefit/burden ratio changes, such that patients have more pain, careproviders can allow them to die by withholding or withdrawing life-preserving treatments — unless, perhaps the patients indicated beforehand that they would want to stay

alive in this condition. It is unlikely that loved ones would feel willing to implement this kind compromise unless they had discussed it previously with the patients. Discussing this situation may be exceptionally harrowing because, regardless of what patients and loved ones say in early discussions, it is possible that later, if the patients seem "happy" enough, the prior, joint decision could be reversed. Still, careproviders should discuss even this possibility with patients and their loved ones, if this is what they want.

Some patients still do "exhaustive" personal research on AD, even after they have suffered some initial losses.[17] There are many possible reasons; some may want to know all they can about AD while they still can, or even just because they still can. A less evident reason may be existential: knowing may be better than not knowing, when there is nothing else that a patient can do.

Helping Patients and Loved Ones to Help Each Other

In time, patients' loved ones may provide care for them 24 hours a day. Consequently, the earlier they can learn how best to do this, the better the outcome is likely to be for both loved ones and patients. The following example shows what occurs, unfortunately, all too often.

Mr. C had mowed the lawn for years. After he was diagnosed with probable AD in the mild to moderate stage, his wife thought that it would be dangerous for him to continue. Thus, she locked the lawn mower in a shed. Later, Mr. C broke the lock, Mrs. C and their oldest son then removed the lawn mower. Mr. C thereupon found it missing and thought that it had been stolen. Mrs. C and this same son then explained what they had done. This same son and two other, younger sons afterwards came to join their parents, Mr. and Mrs. C, for their traditional Sunday dinner. When the oldest son arrived, "Mr. C uncharacteristically ignored him completely. When asked if he was angry with John, Mr. C replied that he was. When asked why, he replied, "I don't know." Mr. C had not, previously, behaved in such a way with his eldest son. [18]

Mr. C felt angry but didn't know why. Sabat, the author who related this anecdote, believes that Mr. C's anger resulted from what he calls Mr. C's "implicit memory" of what his son had done. Most importantly for the purpose of this discussion, this anecdote illustrates how patients and loved ones often don't know the best way to help each other, which can result in harm to patients. Sabat states, "Absent an understanding of implicit memory, it is increasingly likely that caregivers will engage in 'malignant positioning' [and] interpret that patient's behaviour as being dysfunctional when it likely may not be and [in doing this] exacerbate the problems that stem from the brain damage itself."[19]

During early discussions, patients and loved ones can learn to become allies, working together so that, in all instances, they can do the best that they can. During the first stages of AD, patients still have the capacity to learn how to do this. With their loved ones, they can anticipate what may occur, and, when it is helpful, alter what they might otherwise normally do. As the example involving the lawn mower illustrates, as patients' disease worsens, it is increasingly likely that their interests and those of their loved ones will conflict. One of the skills patients and loved ones can learn that may be most helpful when the earliest conflicts occur, is for loved ones to defer to patients' choices as long as they can. This possibility is illustrated by Maeckelberghe, when she states, referring to an 87-year-old man with AD, he "has certainly lost various abilities, [but] dependency should not be conceived as implying a loss of autonomy, provided that caregivers help him. . . . He is portrayed as a person who seems totally incompetent, wandering around. . . . It is possible to imagine a situation where the old man can actively live a life of wandering (after all, he has been physically active for all of his life)."[20]

Maeckelberghe's conclusion is quite relevant to the current discussion: "assessment of competence will not only be directed at this

particular person whose competence is in doubt, it will focus on what means are being used in order to enhance someone's competence."[21] She presumes that it is often possible that loved ones' efforts can improve patients' capacity, and can change lives. Her reasoning is challenging: she states, "The female doctor who is asked about restraints for an 87-year-old man reacts differently whether this man is her patient or her father. As a daughter, the balance is different."[22]

As patients' capacity worsens, they may increasingly make poor decisions or act in ways that endanger themselves or others. When patients and loved ones discuss such possible situations while patients can still participate, patients may be more willing to defer decisions to loved ones when it becomes necessary — even when, at that later time, they disagree. At this time, patient may not be able to change their behavior or learn new skills, so this will fall to loved ones alone. Loved ones may, for example, unlearn dysfunctional beliefs. As Hepburn and colleagues note, for instance, loved ones may think, " 'Laying down the law' to my elder is something I must do," or, " 'I have the responsibility of confronting my elder with his/her mistakes.' "[23] Both of these beliefs are dysfunctional, as, in most case, they will serve only to "pour fuel" on patients' "fire." Hepburn and colleagues note that such beliefs may reflect the ways that loved ones believe they should respond, "based on social norms."[24] Rather, the authors suggest, loved ones can and should learn to base beliefs on "an appreciation of what the disease has done to the care receiver's capacity for performing in a socially acceptable manner."[25]

An example of a new behavior that loved ones might learn is to talk to patients while they are "feeding, dressing, bathing, or moving them." This may "personalize" the interactions for patients.[26] Loved ones may respond in negative ways that have become patterns, and so may be less easy to change. They may, for example, be passive-aggressive, expressing their anger with patients in ways such as "giving them the silent treatment."[27] Such habitual dysfunctional responses, over time, will greatly harm patients. Early discussion with loved ones can prevent this. As Lyness notes, "Depending on the family's needs, interventions may range from education and community referral to deeper interventions, such as restoring effective problem-solving, improving patterns of communication, or improving attachment and care-giving bonds."[28]

Loved ones who seek to help these patients as much as possible must become aware of how previous maladaptive behaviors can tragically worsen the care that they give patients.[29] As Kitwood noted, issues of "power, dependency, control, envy, jealously, rage, fear, deception, disappointment, grief, fear [are and may] need to be re-worked in [this] new context."[30] If loved ones don't pursue these goals, unresolved conflicts might lead loved ones to make decisions that they might not otherwise even consider. As Pochard and colleagues note, "The fastest way to obtain relief from ambivalence and uncertainty may be to make an end-of-life decision, which might be considered as an ethical risk."[31]

AFTER PATIENTS LOSE CAPACITY

Postponing Assessment of Capacity

As indicated above, it may be best, in some cases, for patients and loved ones to postpone a request for a careprovider's assessment of a patients' capacity, as patients may see such an assessment as proof that their loved ones and their careprovider think they are incapable of making their own decisions, and want to make decisions for them. If careproviders teach patients and loved ones early on how to discuss two tasks that they can accomplish together, it may be possible to postpone assessment. First, loved ones can learn to accept patients' "poor choices" so long as they aren't potentially calamitous. Second, if and when patients' choices become potentially calamitous, the patients may still be able to choose to defer such decisions to their loved ones. If patients can discuss this with their

loved ones beforehand, and there is sufficient trust in them, patients may be able to do this, even though it means giving up what they want.

An example illustrating this second situation is when patients with AD can no longer safely drive. If patients can't see that they are no longer safe, this is a situation in which loved ones simply can't let them have their way. Continuing to drive would be calamitous. Yet it may be possible for loved ones to avoid having to ever overrule a patient. The patients and their loved ones may be able to discuss this situation long before it occurs; then, remembering these discussions, using whatever means they can to do this, patients may accept their loved ones' decision, even though they disagree with it.[32] The possibilities for this approach are without limits.

On the other hand, it may be possible for careproviders to assess patients' capacity without alienating the patients. That is, if careproviders discuss performing an assessment and its potential problems often, and in advance, with patients, the patients themselves may request a formal assessment for capacity, and may request it at the earliest, most optimal time. In the same way, if patients have early and repeated discussions with loved ones about making decisions for the patient in the future, if it becomes necessary, patients may request that their loved ones make decisions for them as their capacity to make decisions decreases. Rather than resenting their loved ones for disagreeing with them on a decision, patients will be able to see this process as something they planned, themselves, in advance.

Using a Sliding Scale to Determine Capacity

When careproviders assess patients' capacity, they may use a fixed standard, or a so-called sliding scale. If they use a fixed standard, careproviders must apply set criteria, such as patients' being able to understand and state the pros and cons of their different alternatives. With a sliding scale, careproviders may be able to apply a more or less strict or demanding standard. They may use a less demanding standard, for example, when patients choose the outcome that will clearly provide them the most gain.

Since careproviders have greater flexibility when they use a sliding scale, this may be another way to postpone a determination that a patient lacks capacity, if and when this is desirable. Drane provides the basic rationale for doing this when he states, "A properly performed competency assessment should eliminate two types of error: preventing competent persons from deciding their own treatments; and failing to protect incompetent persons from the harmful effects of a bad decision."[33] A sliding scale may go further in eliminating the first kind of error. It may allow patients to retain legal competency to make decisions so that they can continue to decide for themselves regarding the treatments they want.

AFTER THE PATIENT'S CAPACITY IS ASSESSED

Careproviders can provide support by offering to help the patient's loved ones make difficult decisions. For some time, careproviders have known that, if at all possible, they should support the loved ones who care for patients with AD, because, in addition to the benefits the provides loved ones, it benefits patients. Studies conducted over the last half decade indicate that loved ones may be traumatized when they make decision for incompetent patients.[34] Axoulay and colleagues note, "This contains an important message [that careproviders] are in a unique position for providing families with support."[35] Research indicates also that even though "caregivers frequently desire more support and reassurance from health care professionals, [they] may not often ask for help."[36] The implications for careproviders, once again, are clear.

Legally, loved ones may have the task of making decisions by themselves. Careproviders may offer their own views if loved ones ask, but there is also a good reason that they

should be hesitant to volunteer them. First, loved ones may resent them taking this initiative. Second, careproviders' views may reflect their own, rather than the patients' or the loved ones' preferences. Third and most importantly, although careproviders have medical expertise, they may not have ethical expertise. Yet, not withstanding these and other common and obvious objections, when careproviders offer their views, it may greatly help a patient's loved ones emotionally, if they can share both what they think and why. At minimum, careproviders should inform loved ones of the potential personal trauma they may undergo if they make decisions alone. Careproviders could also tell loved ones that they would be very willing to share their own views, if only to help loved ones reduce the trauma of making decisions, and not be so alone — if, but only if, loved ones want to ask.

Studies indicate that loved ones may be most vulnerable to harm as they make end-of-life decisions for incompetent patients.[37] Winzelberg and colleagues suggest that physicians could give loved ones "permission" to choose palliative care, so that "they may not feel the entire emotional weight of an end-of-life care decision."[38]

Finally, if patients' loved ones don't know that they could have careproviders' help, they may prematurely distance themselves from the patient emotionally, whether or not this is what they really want, because they anticipate the stress of having to make these difficult decisions. Careproviders can prevent such unnecessary distancing, which will harm the patients and the loved ones, by sharing how and why they are willing to help, early on. The stress of making decisions and its resolution may be additional topics that careproviders can pursue with patients and their loved ones from the very beginning.

Careproviders can support loved ones by not using solely a substituted-judgment legal standard. The previous discussion presupposes that loved ones will have some legal discretion in choosing what careproviders will do. This may or may not be the case. Loved ones may or may not have to decide, legally, solely on the basis of what they think the patients would want for themselves.[39] As this is the case, careproviders sometimes directly inform loved ones that they should not decide on the basis of what they want, for example, but only on the basis of what they believe the patient would want. But this is not what loved ones or careproviders usually do. According to one study, only two of 50 spouses of patients with dementia chose what to do solely on the basis of so-called pure substituted judgment.[40]

In another study, Hardart and Truog asked 327 physicians how they would decide what they would do for several kinds of patients who were incompetent. Some patients had dementia. A "sizable majority" of the physicians queried favored a strategy other than basing judgments solely on pure substituted judgment. Most said that they use a standard "not even offered as an option (let alone taught as a standard) in commonly read medical texts or the curricula of American medical schools."[41] Decision-making strategies that center on the family, not the patient, "may actually be more the rule than the exception."[42] Finally, Hardart and Truog asked physicians, "Should the medical system be refashioned to support, perhaps, even encourage, family-centered decision making?"[43] The pure substituted-judgment approach is, in principle, problematic for several reasons, but particularly so for patients who are incompetent due to AD, because they may be less able to foresee what they will undergo and experience after they are incompetent — their brains may become impaired to a greater degree than most other patients. This difference is illustrated by the possibility that, rather than feeling worse over time, as AD progresses, the patients may instead become "happier," as described above.

As this is the case, careproviders may support loved ones when they prefer to use a strategy to make decisions other than the pure sub-

stituted-judgment standard. As one author says, "Physicians who discuss substituted judgment as the ideal decision-making principle may leave caregivers feeling conflicted. . . . Physicians should instead present substituted judgment as one of the factors considered by families when making decisions for loved ones."[44]

How can they do this legally? Careproviders could tell loved ones how the law works; that is, they could say, "We legally can only do what you believe this patient would have wanted. What this means is that if you think other factors should play a role, such as what you think is in the patient's best interest, you must state this as if this is what the patient also would want." Careproviders who do this are more clearly part of the decision-making process, so that loved ones may feel less alone, whether or not they ask careproviders what to do. If loved ones choose to use an approach other than the pure substituted-judgment standard, careproviders who do this will be "complicit" in helping loved ones "get around the system."

CONCLUSION

When careproviders see patients with AD, most often a time will come when they must assess mental capacity. Before, during, and after this time, they may be able to offer a variety of assistance to patients and their loved ones. The core assumption underlying these approaches is that although patients have a disease that leads to progressive cognitive impairment, at all stages of AD patients are sensitive and responsive (to different degrees) to interpersonal cues. By remaining conscious of these interpersonal effects, and doing all they can to enhance the benefits that patients may gain, careproviders may be able to significantly enhance the quality, if not the quantity, of patients' lives.

NOTES

1. *Capacity* refers to careproviders' clinical assessments; *competency* to the status legally determined by a court. If careproviders find a patient clinically to lack capacity, this usually will result in the court determining that the patient is incompetent.

2. R.B. Reilly, T.A. Teasdale, L.B. McCullough, "Projecting Patients' Preferences from Living Wills: An Invalid Strategy for Management of Dementia with Life-Threatening Illness," *Journal of the American Geriatric Society* 42 (1994): 997-1003, at 1011.

3. K. Wachter, "Genetic Screening for AD Appears Beneficial," *Clinical Psychiatry News* (February 2006): 26. See also, H.L. Paulson, "Diagnostic Testing in Neurogenetics: Principles, Limitations, and Ethical Considerations," *Neurology Clinics of North America* 20 (2002): 627-43; J.S. Goldman and C.E. Hou, "Early-Onset Alzheimer Disease: When is Genetic Testing Appropriate?" *Alzheimer Disease and Associated Disorders* 18 (2004): 65-7.

4. Wachter, see note 3 above.

5. L.S. Parker, "Rethinking Respect for Persons Enrolled in Research," *ASBH Exchange* 9, no. 2 (Spring 2006): 1, 6.

6. D.I. Shalowitz and F.G. Miller, "Disclosing Individual Results of Clinical Research," *Journal of the American Medical Association* 294 (2005): 737-40; D.I. Shalowitz and F.G. Miller, "In Reply: Implications of Disclosing Individual Results of Clinical research," *Journal of the American Medical Association* 295 (2006): 37-8.

7. Wachter, see note 3 above.

8. See, e.g., A.E. Pfeiffer, "A Short Portable Mental Status Questionnaire for the Assessment of Organic Brain Deficit in Elderly Patients," *Journal of the American Geriatrics Society* 23 (1975): 433-41; D.J. Connor et al., "Performance of the Three Clock Scoring Systems Across Different Ranges of Dementia Severity," *Alzheimer Disease and Associated Disorders* 19 (2005): 119-27; U. Beinhoff et al., "Screening for Cognitive Impairment: a Triage for Outpatient Care," *Dementia and Geriatric Cognitive Disorders* 20 (2005): 278-85.

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Features

An Intimate Collaboration: Prognostic Communication with Advanced Cancer Patients

Paul R. Helft

INTRODUCTION

As a young oncologist, I find myself wrestling with many of the most difficult issues in the practice of oncology: helping patients to make difficult trade-offs between the risks and benefits of arduous treatments, finding sources of strength to deal emotionally with the devastating realities of patients' situations, and communicating important information to patients in ways that give them honest and useful information, but still allow them to preserve some hope for the future. It is this last issue on which I offer my thoughts here.

I have noticed that, although common wisdom about the communication of prognosis with advanced cancer patients holds that we should give accurate and honest prognostic information to patients at all times, in practice this is hard to do. So, I find myself engaging in a process of communication about prognosis with patients which, in a sense, allows the cold, hard facts to come out over time, as opposed to presenting them all at once. I have found other oncologists who seem to use a similar strategy. I do this because it is a style of communication that, I think, "works" for me and my patients: patients come to deal with the painful knowledge of their ultimate outcomes over time in ways that I think allow them to cope and maintain hope along the way. But I have continuously asked myself whether this is the "right" way to communicate. Is it ethically acceptable to support some patients' desires to avoid the cold, hard facts about their prognosis? If so, how can one do this and avoid the harms that could come from complete denial and avoidance? What purpose could the provision of less than "all of the information" serve?

I will argue in this article that artful communication of prognosis with advanced cancer patients often involves a kind of "intimate

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collaboration," with both the prognostic communicator (in this case, the oncologist) and the prognosis receiver (that is, the patient) contributing to a collaborative process that controls the flow of devastating prognostic information in a way that allows patients to come to an understanding of their prognosis on their own terms.

DEFINITIONS

For the purposes of this discussion, it is helpful to distinguish between two periods in the disease course of advanced cancer patients. After diagnosis, most advanced cancer patients enter a period that I will call the "ambulatory period." The ambulatory period may be brief for some patients (for example, advanced pancreatic cancer patients), and long for others (for example, colon cancer, ovarian cancer patients). It is the period in which, arguably, most prognostic communication between oncologists and cancer patients actually occurs. It is often much longer than the terminal phase of disease, and is, in many respects, paradoxical. The paradox is that many patients with advanced cancer in the period between diagnosis and the terminal phase are ambulatory and otherwise fairly *well*. This extraordinary set of circumstances — possessing a life-ending disease and yet being functional and alive — is one of the defining features of the ambulatory period and inevitably shapes the perceptions of patients about their disease, their prognosis, and their own views of their ultimate outcomes.

However, all advanced cancer patients eventually enter what I would call a "terminal phase." This later period is generally recognized by those familiar with advanced cancer patients, and begins around the time when it becomes clear rapid clinical decline is imminent, further anticancer therapy is not advisable, and a shift to a purely palliative mode of care is warranted. Obviously, having specific knowledge of numerical time frames takes on more urgency during the terminal phase, as time grows short, and many patients must attend to practical details surrounding their imminent death during this time.

In this article, I will also distinguish two modes of prognostic communication. When I refer to *prognostication* in advanced cancer patients, I mean communication of specific numerical estimates of life expectancy. This may take several forms in practice: "I believe you have about four months to live" would be a typical way to deliver such information. Others might offer other formulations: "Average patients live around four months," or "I would estimate that you have three to five months to live." In my view, there is little practical or emotional difference for patients between hearing a specific numerical estimate ("four months") and a narrow range estimate ("three to five months"). Obviously, some communicated numerical estimates of life span would not meet this definition. Examples include the communication of broad ranges (for example, "Patients can live anywhere from three months to more than two years with your condition") or the communication of chances of survival beyond a given time frame (for example, "10 percent of patients live beyond five years"). I will distinguish such specific, numerical estimates of life span from a process-based method of prognostic disclosure, for which I will borrow the term "forecasting." The "collaboration" to which I will refer encompasses the spoken or tacit agreement we sometimes enter into with patients to avoid, or delay, discussing a specific, numerical estimate of life expectancy. I will attempt to argue later that when patients desire such a style of communication — or appear to desire it — oncologists are ethically bound to honor this.

ACCEPTANCE AND AWARENESS OF PROGNOSIS

Much of the literature about prognostic communication with advanced cancer patients suggests that the majority of patients want accurate estimates of their prognosis and that accurate estimates benefit them by allow-

ing them to make end-of-life plans consistent with their values, and that open awareness and acceptance of a terminal prognosis is a normative ideal for patients facing life-ending diagnoses.[1] On this view, such awareness may be achieved through a careful, thoughtful, realistic, and empathetic conversation about prognosis.[2] This conversation allows patients to reach an open understanding and acceptance of the inevitability of their ultimate outcomes, that, it is argued, helps them to make better decisions about their care by allowing them to prioritize certain activities according to their own values.[3]

It is probably more realistic to presume, however, that for most advanced cancer patients, acceptance and open awareness of the ultimate outcomes of their disease evolve and change over time. For example, many patients initially react against their diagnosis and the prognosis it entails through hope, denial, avoidance, and other psychological coping mechanisms. As a consequence, they fall back to a much lower level of outward awareness. Their level of open awareness generally increases over time, however, reinforced by the inevitable periods of setback in the illness: disease progression, complications requiring hospitalization, or delay and denial of further therapy. In my experience, most patients eventually reach a level of acceptance that end-of-life experts would consider appropriate, but the process rarely occurs early or all at once.

It is my view that the normative goal of open awareness throughout the disease course, and particularly during the ambulatory period, is both unrealistic and ethically problematic. Although it is easy to see why this model of prognostic acceptance might ethically apply to patients during the terminal phase of their disease (when decisions regarding momentous issues of hospice enrollment, do-not-resuscitate orders, and intensity of therapy take on special significance), ethically, this model does not take account of ambulatory advanced cancer patients' need to "fight," to "beat the odds," and not to accept what those around them — and often their own hearts — tell them is inevitable.[4] Their need (at times) to deny their prognosis stems from their need to maintain hope. Hope, I will try to argue, is so vital a part of patients' psychological experience of advanced cancer that it must be balanced carefully and valued as much as realism.

COLLUSION IN DOCTOR-PATIENT COMMUNICATION ABOUT PROGNOSIS

Ann-Mei The and colleagues attempted to evaluate what they called "false optimism about recovery" among patients with small cell lung cancer by following 35 patients intensively through the course of their illness.[5] The authors report that, in discussing clinical care, including prognosis, doctors and patients communicated in ways which the investigators characterized as "collusive." This was done, according to them, so that optimism could be retained through much of the treatment course until patients began to deteriorate physically themselves or saw other patients around them do so. The collusion they describe usually centered on shifts in the conversations between oncologists and patients from the bad news of diagnosis and prognosis to the "good news" of treatment planning. Because much of the course of illness was defined by the treatment calendar, patients infrequently asked about prognosis, and doctors rarely offered such information, assuming that when patients did not ask, they did not want to know. The authors of this study portray collusion as a strategy by which oncologists and patients avoid the truth about prognosis. The truth about prognosis is seen in this study as being "swept under the rug" — just beneath the surface, but not overtly acknowledged.[6] Other studies have noted similar collusive tendencies in doctor-patient communication in oncology.[7] Although the authors of this study clearly portray such collusive communication on the part of patients and their oncologists negatively, I believe it is helpful to examine the roots of this kind of collusion and to consider why it might be ethi-

cally justified. First, however, I must clarify the term "collusion," which the authors of this study identify, and which I think is a real phenomenon in clinical oncology.

This very real phenomenon, which The and colleagues identify in their study, refers to the efforts that oncologists and their patients consciously or unconsciously make to avoid specific, numerical estimates about expected life span. In some cases, such collusion follows from a specific conversation in which, after being asked how much information a patient would like to know about his or her prognosis, the patient responds that he or she does not want to hear a specific estimate. In my own experience, this exchange is often followed by a comment such as, "Only God knows anyway; you are only human," or, "I just can't take any more bad news right now; maybe we can talk about it later." These sorts of comments set up the expectation that the patient will dictate the timing of a return to the subject of their expected life span.

Again in my own experience, such collusive communication may also follow from a *tacit* understanding about the limits of specificity for prognostic information that an individual patient wants or can tolerate. For example, newly diagnosed cancer patients often do not ask about their prognosis during their initial meetings with their oncologist, although their family members more commonly do. If a family member asks on behalf of the patient or if prognostic information comes up naturally in the course of the discussion of treatment or treatment goals, I will commonly ask the patient if he or she wants to know about his or her prognosis and, if so, how much information he or she wants. Some patients tell me that they want a straight answer, a realistic time frame to help them make decisions about their remaining lives. I try to honor such requests by including in my answer a prognostic estimate involving a realistic time frame for persons in their condition. Other patients state explicitly that they are not ready to hear anything at that time, and I usually respond that I would be happy to talk more about the subject at a later time when they feel more ready. Finally, some patients seem to hesitate at this question, never actually answering it. Reflection on that hesitation or ambiguity in response has often given me the sense that the patient is not ready to tackle "the whole, naked truth" all at once during that meeting. When patients tell me explicitly that they are not ready to hear specific prognostic information or when I sense such hesitation, I often adopt a strategy of progressive disclosure of prognosis over time. This "dance" that the patient and I do together around numerical prognostic estimates — sometimes skirting the issue, sometimes brushing up against it, sometimes backing away from it entirely — continues until there are clearer indications that the patient is ready to hear more specific information.

Just to clarify: although in these early conversations with patients I am willing to avoid providing a specific, numerical estimate of prognosis, I personally do not ever avoid specifying the goals of patients' therapy: unless there is a realistic chance that a patient can be cured of her or his disease, then I always specify that the goals of therapy are palliative (to prolong life and improve cancer-related symptoms). I often use a phrase such as, "This therapy is not meant to cure the cancer, but rather to slow it down as much as possible, and thus to buy time." Helping patients to accept that their disease is incurable is the first step in guiding them toward acceptance of their ultimate prognosis.

Just as was noted in the study mentioned above, I and other oncologists at times avoid direct discussion of specific estimates of life expectancy when the estimates are uncertain and when patients appear unready to tackle such information. Some might argue that this kind of collusion is not honest, and thus not ethical. Others would say that in maneuvering around specific, numerical estimates of life span we are "abandoning our patients prognostically."[8] I believe, however, that this kind of collusive communication can be justified ethically. This justification stems from

two empirical assertions: (1) it is consistent with many patients' stated and unstated wishes, and, (2) it preserves hope by acknowledging the initial uncertainty surrounding prognosis in advanced cancer patients, allowing prognostic information to emerge over time. This progressive disclosure takes advantage both of the progressive degree of prognostic certainty that emerges over time, and of the increasing receptiveness to prognostic information that patients experience as their physical situation worsens. I will examine both of these assertions in turn.

COLLUSION IS CONSISTENT WITH SOME PATIENTS' WISHES

Many published studies suggest that the overwhelming majority of cancer patients want to know everything about their disease, including prognosis.[9] These studies have been used to justify the belief that advanced cancer patients all want accurate prognostic information all of the time. However, there are a number of problems with the interpretation of the studies that examine patients' desires for information, the most important of which is that many of the studies that are used to support these assertions included both curable and incurable cancer patients. The conceptual flaw in this study design is that curable patients receive and perceive prognostic information (including the chances that they will be cured) in totally different ways from those who have incurable disease. The conclusions about information preferences among cancer patients drawn from such studies must therefore be interpreted with caution.

Two classic studies about information-seeking in cancer patients from the early 1980s found that the overwhelming majority of cancer patients wanted maximum amounts of information, but these studies included both curable and incurable patients.[10] Other studies suffer from the same flaw. Meredith and colleagues' study of cancer patients in West Scotland found that 91 percent of patients wanted to know their prognosis, but this study also included both curable and incurable patients.[11] Judith R. Davidson and colleagues found that patients have a high desire for all of the information in their study of lung cancer patients, but their sample included mostly curable patients.[12]

In other published studies in which only terminally ill cancer patients were included, a different picture emerges. Such studies suggest that patients' individualized needs for information in terminal illness should be the guiding ethical rule, and that blanket rules about providing prognostic information may not be appropriate at all times for all patients. Leslie Fallowfield and colleagues found that most people want "all the information," but that older patients and patients with poorer prognoses wanted less information.[13] Andrew Steptoe and colleagues found in a mixed population of cancer patients that some patients avoided stress by avoiding information.[14] In a study of information needs in terminal illness (60 percent of the study subjects had cancer), Jean S. Kutner and colleagues found that 100 percent of interviewed patients wanted their doctors to be honest, and 91 percent wanted them to be optimistic.[15] Only 60 percent of patients in this study wanted to know their life expectancy, fewer than the proportion of patients who wanted to know if they would be able to eat.[16] The authors conclude that the information needs of the terminally ill are extremely diverse. As Ami Schattner points out in a 2002 editorial, a considerable number of patients express significant reservations about their doctors being completely frank with them regarding their prognosis.[17] Patients have a right not to know or to delay knowing difficult information, and complete respect for patients' ability to make their own decisions dictates that an assessment of patients' actual and current desires (which may change over time) be attempted. Benjamin Freedman even suggested that an ethical approach to prognostic disclosure, when the wishes of a patient are not known, is to "offer truth," and then to respect the answer the patient gives.[18]

COLLUSION PRESERVES HOPE BY ACKNOWLEDGING UNCERTAINTY

I think everyone would agree that the preservation of hope is a vital goal for advanced cancer patients. Many studies confirm the importance of the concept of hope for cancer patients,[19] and several studies present evidence that the ability to maintain hope, specifically through avoidance of prognostic information, may be important. In a qualitative study of patients' need for information among mixed cancer patients (most of whom had theoretically curable cancers) conducted by Geraldine Leydon and colleagues, the authors found that information needs varied considerably over time, that patients described hope for the future as essential, and that hope could be maintained by denial and by avoiding information.[20] Phyllis Butow and colleagues found that 15 percent of 80 mostly curable cancer patients (67 percent of whom had a prognosis of years or of a normal life expectancy) desired to have minimal detail about their illness.[21] In one study of terminally ill patients that included cancer patients, maintaining hope was universally important to patients, and among the cancer patients in this study, hope and a positive attitude were the most frequently raised emotional support topic.[22]

But one question is, How can oncologists communicate in a way that is honest and yet preserves hope? Honest answers require that we take the extreme variability of cancer biology and of individual cancer patients into account. For example, providing information about the median survival for a given cancer in response to a question about life expectancy is an honest answer, but it only communicates part of the story. Median estimates say nothing about the variability around the median or about outlying cases on either end of the spectrum. Thus, a truly honest answer must include as much information about the uncertainty of prognostic estimates (especially at the outset of disease after diagnosis) as about medians, averages, and one-year rates of survival.

It follows from this inherent uncertainty that when patients either do not ask or request *not* to be told a specific, numerical estimate of life expectancy, it is permissible to avoid devastating (and often inaccurate) estimates until there are clear indications that a patient is ready to hear them *and* a more specific estimate may be honestly provided. Although it may sound as if I am advocating a controlled withholding of information from patients, I am really arguing for allowing the honest uncertainty that surrounds disease outcome and prognosis to be marshaled into the service of patients' sense of hope and open-endedness.[23] Allowing patients to come to terms with their terminal prognosis over time respects both the variable biology of cancer *and* the tremendous emotional pain that accompanies the knowledge of a terminal prognosis.

HOPE

It seems important at this point to discuss what I mean by *hope* in advanced cancer patients since, inevitably, some will raise objections that we should encourage true hope but not false hope, and hope for some goals, but not other, unattainable goals, such as cure. Traditionally, hope in cancer patients has meant hope for cure. However, advanced cancer patients clearly hope for many other goals. There is evidence that persistent hope to go on living for advanced cancer patients is often cultivated in the context of understanding the incurability of their situation. [24] In my experience, patients generally switch fairly early on in their course from naïve hopes for definitive cure of their disease to hope for as long a life as possible. When patients say (as they commonly do), "Doc, I will be the one to beat it!" I do not understand them literally, believing that they do not understand their situation. I take them to mean that they will be the ones that outlive everyone's expectations.

Some have argued that such attempts to preserve patients' ability to maintain hope through avoidance of specific prognostic estimates about life span are dishonest, and that we can preserve hope in other ways, for example, by helping patients to shift their hopes from surviving their cancer to hopes for a "good death." Take Nicholas Christakis' argument:

> [P]atients might . . . be harmed if erroneous predictions of imminent death resulted in the withholding of interventions that would otherwise save a life. But my study has convinced me that, most of the time, the problem is the other way around. Rare are the cases where making or offering a carefully considered and framed prognosis results in choices that are harmful to a patient. If seriously ill patients had better information about their chances of survival and about the likely success and implications of proposed treatments, and if they were supported by their physicians in how they chose to use this information, they might make different choices at the end of their lives. . . . With it, they might be empowered to plan for, and achieve, the kind of good death most Americans say they want: free of pain, at home, with loved ones, having said good-byes and put their affairs in order.[25]

I believe that such arguments in favor of shifting advanced cancer patients' hopes for more life to hopes for a "good death" are misguided. While it is a virtuous and admirable goal to assure comfort, dignity, and the pleasures of social interaction for dying patients of all kinds, in my experience the hopes of advanced cancer patients can only be redirected toward "a good death" in the terminal phase of disease, when patients actually feel they are dying. Such hopes rarely cross the minds of patients with terminal cancer during the often much-longer ambulatory period. I have never had a patient say to me, even when I have asked about the patient's hopes for the future, "Doc, what I really hope for is a good death." I have had many patients tell me their hope is to live as long as they can; it is interesting that they rarely add, "and as well as I can."

COLLUSION ALLOWS PATIENTS TO DIGEST DIFFICULT INFORMATION OVER TIME

I have argued previously that patients nearly always reach a point in their illness when "open awareness" is possible. In my experience, this comes very late in the course of cancer for some patients. Although some advanced cancer patients are able to ask about and handle specific prognostic information almost from the time of their diagnosis, in many cases it is possible to discuss time frames in completely naked terms only when patients have come to see the inevitability of their own deaths on their own, when their disease has made their bodies weak, and when increasing signs and symptoms of progressive disease become a constant reminder of their approaching death. A strategy of progressive prognostic disclosure fits well with this increasing receptiveness to the prognostic information many patients experience over time.

The strategy of communication I am advocating can obviously serve to bolster patients' avoidance and denial, and clearly has the potential to contribute to maladaptive end-of-life decisions for some patients. However, given the empirical evidence that denial may be a means of supporting hopefulness[26] and that the ability to maintain hope for survival is critical to quality of life during terminal illness,[27] careful and reflective "collaboration" in denial may be permissible.

I recognize that denial is a powerful coping mechanism for some patients, in others, denial may have negative consequences. Rare patients may deny until the very end the internal signs of their illness, and ignore the external reminders those around them — both the medical team and, often, their family members — attempt to provide them. This

"terminal denial" causes them to postpone the important life tasks that dying patients must often face: preparing a will, writing letters to children, attempting to heal relationships.

I can think of several patients over the years like this: the young mother of three with advanced colon cancer who put off telling her children about her rapidly approaching death and never had time to say the many things to them she surely wanted to say; another young mother who, because she did not want to face her imminently terminal esophageal cancer, traveled to an East Coast medical center under the illusion that she would receive life-prolonging cancer therapy there, and died within 24 hours of arrival, leaving her husband and two young children back home, never having said good-bye.

These are painful examples of the harm that can come from excessive denial, and one can see how, without careful consideration of the risks and benefits of various strategies of prognostic communication, one might actually contribute to such potentially harmful denial. However, I think that such "terminal deniers," while illustrating real, potential harms that could be exacerbated by collusive avoidance of prognostic discussions, are rare. They represent the edge of the spectrum of challenge that prognostic communication represents: how to lead patients through and into an understanding of their prognosis in a way that is consistent with their desires, that respects the emotional pain of their situations, that provides them with useful information with which to make decisions, and that allows them to sustain some hopes for the future.

Although we would like to protect such patients from themselves and their seemingly harmful denial, it is not clear to me that such patients with "terminal denial" will ever hear and accept their prognosis, no matter how often we repeat our expectations to them. In such cases, I usually attempt to help the loved ones around such patients to prepare in a more adaptive way for the patients' eventual deaths. Examples such as those I have provided above are used to illustrate the harms of denial and to justify the provision of prognostic information, even against a patient's wishes. I am cautious of such facile justifications, however, under the complicated circumstance of terminal cancer. While complete denial of the difficult issues that an approaching death raises is not the way most of us would want to lead our lives (or deaths), rare individuals simply cannot face devastating prognostic information in an open way. They use denial as a means of coping with what is for them untenable emotional pain, even though the negative outcomes illustrated in the cases I mentioned above are sometimes the real consequence. So, as a clinician who frequently deals with dying patients, I must find a way to confront, in a respectful way, these individuals' psychological makeup and the pain that leads them to behave in this way. In "terminal deniers," I have rarely found that repeated reminders of an approaching death are heard, understood, and acted upon; sometimes, such verbal reminders cause patients to run away to find an oncologist who will not "pound them over the head" with their prognosis. In both cases mentioned above, the patients had been repeatedly warned by me and others of the gravity of their situations, but did not or could not act on the information.

Hence, I have concluded that working in a cooperative way with patients, and within the psychological confines and limits that they draw, is the most productive way to communicate about prognosis over time. Given the complex considerations I have attempted to outline, I have found that one strategy for balancing hope, useful information, and patients' desires is to "forecast" the future at multiple points along the way.

FORECASTING IN INCURABLE CANCER PATIENTS

I borrow the term "forecasting" from the sociologist Douglas Maynard, who has written about this concept in the context of delivery of bad news. This concept, which derives

from empirical qualitative studies of social interactions involving the delivery of bad news, might be summarized as follows.

> Forecasting is a strategy for delivering bad news and is compared to two other strategies, stalling and being blunt. Forecasting involves the provision of "some warning that bad news is forthcoming without keeping the recipient in a state of indefinite suspense (stalling) or conveying the bad news abruptly (being blunt). Forecasting appears to be more effective than stalling or being blunt in helping a recipient to "realize" the bad news because it involves the deliverer and recipient in a social relation: the deliverer of bad news initiates the telling by giving an advance indication of the bad news to come; this allows the recipient to calculate the news in advance of its final presentation, when the deliverer confirms what the recipient has been led to anticipate. Thus, *realization of bad news emerges from intimate collaboration,* whereas stalling and being blunt requires recipients to apprehend the news in a social vacuum.[28] [Emphasis added.]

Maynard's work focuses on relatively isolated instances of the delivery of bad news in which specific verbal and nonverbal cues (for example, pre-announcements or a somber demeanor) are used by the deliverer to presage the bad news in some way, often leading the recipient to reach the conclusion ahead of the receipt. But the principle underlying this strategy — that the act of forecasting allows difficult information to emerge from a kind of collaboration between the deliverer and recipient — may be applied more broadly to the process of prognostic communication with advanced cancer patients. As Maynard explains, the "collaboration" that develops through forecasting between the deliverer and the receiver leads to a "deeply collaborative, orderly achievement" that makes the bad news event more tolerable to the receiver, while at the same time promoting and strengthening the underlying relationship.

Whereas prognostication emphasizes numerical estimates of a patients' life expectancy, a process that includes uncertainty of estimate, but no uncertainty of outcome, forecasting is a strategy in which the future is predicted, although without absolute certainty, leaving room for the uncertainty that surrounds every patient's eventual outcome after diagnosis. As successive events are realized ("The chemo will eventually stop working" or "A cancer's response to a second or third line of treatment is usually shorter than to the first line"), patients are in Maynard's sense *led to* their own understanding of their prognosis, anticipating negative events in advance. Forecasting allows both the oncologist and the patient to face and prepare for likely outcomes, and to maintain hope about unlikely ones, and does so in a way that involves them in a social relation (again, in Maynard's sense), and so is implicitly supportive of the patient and the doctor-patient relationship.

OPEN-ENDEDNESS

One of the strengths of using forecasting over a more narrow view of prognostication for those patients who do not want a precise, numerical estimate of life expectancy is that it preserves a sense of open-endedness about time frames. For example, a patient may understand that his or her disease is incurable, but may still be able to hope that treatment will prolong his or her life for as long as possible, something that the communication of a numerical estimate of life expectancy ("You have three to five months to live") does not allow. Some will argue that leaving such uncertainty about eventual outcomes can lead to false hopes about the possibility of being cured. However, as Nicholas Slevin and colleagues have argued, the hope that patients with terminal cancer experience is often not related to false hopes of cure, but rather the need to feel that life still retains some open-endedness, something that he argues is nec-

essary for people to have meaning in life.[29] Empirical evidence supports (and personal experience confirms) that patients are able simultaneously to understand that their disease is life-ending and to maintain hope that, even against all odds, they may be the statistical anomaly who survives.[30]

Fulfilling the physician's obligations to tell the truth under such circumstances seems impossible on the surface. How does one simultaneously leave patients with a sense of open-endedness about their terminal cancer and inform them about their life-ending disease in a way that is useful for deciding how best to spend their time? One solution lies in presenting a clear-eyed view of what is likely, unlikely, and possible. Because of the inherent uncertainty and biological variability of cancer and of individual cancer patients, we can honestly tell our patients that a disease is curable or incurable, provide a range of prognoses, including outlying examples, and make certain that patients understand what the goals of therapy are. This kind of hope, hope that recognizes the obstacles and odds, but that still allows room for unlikely outcomes, is what Jerome Groopman calls "true hope," which he distinguishes from false hope. In his view, false hope is the pervasive belief that everything will turn out all right.[31]

CONCLUSION

I have tried to argue that prognostic communication with advanced cancer patients may ethically be collaborative, that is, it may ethically privilege open-endedness and uncertainty about specific time frames over certainty in prognosis, especially during the ambulatory period of disease, because of the inherent variability of cancer patients and the crucial role that hope plays in their lives. I have contrasted this with an approach to prognostic communication that attempts to provide an accurate, numerical estimate of life span, aimed at bringing about open awareness of prognosis that, it is hoped, will contribute to excellent decision making about cancer treatment and end-of-life goals. The "collaborative" strategy ultimately relies on a series of conversations, during which the technique of forecasting is used to bring about incremental awareness of the ultimate course and outcomes of the disease, and on careful and honest maintenance of hope through the preservation of open-endedness.

While I believe that the strategy of prognostic forecasting I am advocating here works well for many patients as a means of balancing useful information and hopefulness over time, it is dependent in many ways upon the sensitivities of the oncologist to the verbal, nonverbal, and other cues that patients give us about their needs and desires for information. We inevitably get these cues wrong from time to time, and, in doing so, risk leaving some of a patients' needs unmet. Certainly, humility toward our ability to "read" patients and account for their needs (in the absence of specific, verbal direction) is warranted.

Faced with such a situation, can we ethically enter either a tacit or an explicit agreement with patients (which I have called "an intimate collaboration") to avoid dire and specific numerical prognostic estimates about life span, until patients ask for them or appear ready to hear them? Recognizing that the natural history of any individual's cancer is extremely variable, I think we can justifiably and honestly outline a range of prognostic estimates and include descriptions of outcomes that are unlikely — even highly unlikely — as long as such outcomes are within the range of clinical possibility. This honest prognostic picture, which forecasts the future in probabilistic terms while including some honest open-endedness about time frames, is the means by which hope may be maintained for patients. Over time, we should refine these prognostic estimates, delivering information through a measured series of "forecasts" about the future. As each successive forecast is realized, patients gain confidence in their oncologist, and the inevitable outcome of their disease is revealed to them. Through the course of this, patients become engaged in a

beneficial, healing relationship that our efforts to preserve hope engender in them.

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Are Organ Donors after Cardiac Death Really Dead?

James L. Bernat

Organ donation after cardiac death (DCD), formerly called non-heart-beating organ donation, has become a widespread practice in the United States over the past decade.[1] Although DCD was practiced in the 1950s and 1960s before the brain-death era, thereafter it was discarded in favor of the heart-beating brain-dead organ donor. Brain-dead patients were superior organ donors because mechanical ventilation and maintained circulation permitted their continued organ perfusion and oxygenation until the moment of organ procurement. In the early 1990s, in response to the growing demand for organs to transplant, and in response to the desires of the families of patients who were brain-damaged, but not brain-dead, that these patients be removed from life-sustaining therapy in ICUs, and to have their loved ones serve as organ donors, the University of Pittsburgh Medical Center established the first modern DCD program.[2]

Since then, greater numbers of organ procurement organizations (OPOs) have encouraged the creation of DCD programs so that, currently, approximately half of the OPOs in the U.S. permit DCD.[3] The growth and acceptance of DCD programs was spurred by two influential reports from the Institute of Medicine in 1997 and 2000, which concluded that DCD was legitimate and desirable, and hospitals should be encouraged to implement DCD protocols.[4] In 2004, the former secretary of the U.S. Department of Health and Human Services, Tommy Thompson, publicly encouraged further growth of DCD programs.[5]

But, from the beginning, the practice of DCD has been dogged by an unresolved controversy over its conceptual foundation: are organ donors truly dead when they are declared dead after five minutes[6] of asystole?[7] Several scholars have argued that DCD patients are not dead after five minutes of asystole,[8] and have criticized the Institute of Medicine for sidestepping this critical question.[9] I will argue here that whether DCD patients are actually dead or should be considered as dead after five minutes of asystole turns on the distinction between the concepts of "irreversible" and "permanent" loss of vital functions. I then consider whether it constitutes prudent public policy to permit substituting "permanent"

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for "irreversible" in the test for death using a cardiopulmonary criterion.

THE PROBLEM INHERENT IN DCD DEATH DETERMINATION

DCD protocols permit a hopelessly dying, ventilator-dependent patient (or, more commonly, his or her legally authorized surrogate) to consent to organ donation after death, once further life-sustaining therapy has been refused and discontinued. In the most common case, the patient has sustained profound brain damage from trauma, stroke, or cardiac arrest, that creates ventilator dependency and offers no hope for meaningful neurological recovery. Such a patient does not meet brain-death criteria, but is hopelessly ill because of profound brain damage, with a very poor prognosis. Based upon the patient's prior wishes for stopping treatment in light of the poor prognosis, the family then refuses further life-sustaining therapy on behalf of the patient to permit him or her to die. They also request or consent to organ donation after death.

DCD protocols coordinate the timing of withdrawing the ventilator with the organ procurement team's readiness to procure organs. Once withdrawn from the ventilator, patients usually cannot breathe at all or breathe insufficiently to maintain life.[10] As the patient's oxygenation rapidly declines, the heartbeat then stops from lack of oxygen. After five minutes of absent heartbeat, the patient is declared dead and rushed to the operating room where organ procurement is rapidly performed, usually yielding transplantable kidneys, liver, and occasionally other organs.

Skeptics have criticized DCD protocols on several grounds, but the most serious claim is that the patient is dying but is not yet dead after only five minutes of asystole.[11] What if the heart could be restarted at that point, and, with restored circulation, the brain retains some degree of function? The patient then would not be considered dead, using either a brain or a cardiopulmonary criterion. If a patient could be resuscitated after five minutes of asystole, then clearly the patient was not dead at that point, because the cessation of brain function would not have been irreversible, a condition that is required by both the concept and statute of death.

Supporters of DCD counter that the five-minute asystole practice is defensible on two grounds. First, there is firm empirical evidence that after five minutes of asystole resulting from apnea, DCD patients will not "auto-resuscitate," that is, they will not spontaneously regain heartbeat and circulation.[12] Second, no attempt will be made to artificially resuscitate the patients because the intent of withdrawing the ventilator was to permit them to die in accordance with their wishes. Therefore, whether they have the capacity to be resuscitated after five minutes of apnea and asystole is not a practical concern. Although these statements are true, a solely pragmatic defense without further analysis fails to address the principal issue.

THE STATUTE OF DEATH

In 1981, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research advocated a brain-based death standard of death and proposed the Uniform Determination of Death Act (UDDA) as a model statute that it urged each state to adopt. In its relevant clause, the UDDA states: "An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead."[13]

Subsequently, nearly all states adopted the UDDA or a variation of it. In their influential work, *Defining Death,* the President's Commission defended the UDDA as the logical outcome of a unitary, brain-based concept of death.[14] It held that any person with irreversible cessation of all brain functions was dead, irrespective of mechanically supported ventilation and circulation. It pointed out that this unitary death standard could be tested in two

ways: using brain-death tests if the patient's ventilation was being mechanically supported, or by showing the cessation of circulatory and respiratory functions if ventilation was not being supported.

But in drafting the UDDA, the President's Commission erred in proposing a bifurcated legal criterion of death comprising two separate standards of death without explaining their relationship within the statute. My Dartmouth colleagues and I criticized the UDDA at the time for not articulating a single brain standard (as the President's Commission itself had argued in *Defining Death*), which could be simply tested by physicians in two ways, because it was clear that the tests showing the irreversible cessation of circulatory and respiratory functions were adequate tests of death only because they inevitably led to the irreversible cessation of all brain functions.[15] Because patients who were successfully resuscitated prior to the complete loss of brain functions were not dead, the loss of all brain functions was the unitary criterion of death. Thus, despite the absence of this clarification within the UDDA, its seemingly separate bifurcated criteria are not independent.

The UDDA stipulates that the cessation of brain functions or of circulatory and respiratory functions must be irreversible. This reasonable requirement derives from the concept that death is, by definition, an irreversible state.[16] Because no mortal can return from being dead, any resuscitation or recovery must have been from a state of dying, but not from death.[17] Thus, the concept of irreversibility is intrinsic to the concept of death. But what precisely did the statute framers mean by "irreversible" when applied to cessation of organ functions? In the UDDA, the President's Commission did not define "irreversible."

THE DISTINCTION BETWEEN *PERMANENT* AND *IRREVERSIBLE*

In many analyses of the definition of death, the adjectives *permanent* and *irreversible* have been applied loosely and interchangeably in referring to the cessation of vital functions.[18] At first hearing, they sound synonymous. But they have an important distinction that becomes especially relevant in determining the death of an DCD patient. The *Oxford English Dictionary* defines *irreversible* as "that cannot be undone, repealed, or annulled; irrevocable."[19] Thus, a loss of a function can be said to be irreversible if that function cannot possibly be regained spontaneously or restored through intervention. *Irreversible* is an absolute and univocal statement that reflects the physical reality of immutability, a condition that exists independently of our intent or action. By contrast, the *OED* defines *permanent* as "continuing or designed to continue indefinitely without change; abiding, lasting, enduring, persistent (opposed to 'temporary')."[20] Thus, a loss of function can be said to be permanent if that function will not become restored either spontaneously or through intervention. *Permanent* is an equivocal and contingent condition that permits possibility. It may rely on our intent and action to be realized, and does not refer directly to a possibility of reversal.[21]

Despite their distinct definitions, a spatial and temporal relationship exists between the sets of permanently and irreversibly lost functions. The set of permanently lost functions encompasses the set of irreversibly lost functions. Thus, all functions that are irreversibly lost also are permanently lost, but not all functions that are permanently lost are necessarily irreversibly lost, at least at the moment that permanence is established.[22] And all functions that are irreversibly lost first are permanently lost; that is, once a function becomes permanently lost, it quickly evolves to also being irreversibly lost.

The philosopher David Cole pointed out that the term "irreversible" is inherently ambiguous, because it belongs to a class of modal terms in the philosophy of language that resists consensus analysis.[23] Cole identified two principal construals of "irreversible" functions. The strong construal of the term means

that the function cannot be restored by anyone under any circumstance at any time, now or in the future. The weak construal means that the function cannot be restored by anyone now, using available contemporary technology, but possibly may be able to be restored elsewhere now, where emerging technologies are available, or in the future with the development of new technologies. Thereafter, David Lamb pointed out that Cole's strong construal of irreversible (essentially, a return of functions that is logically impossible) fails the test of plausibility, and should be rejected when applied to the definition of death.[24]

I agree with Lamb that the weak construal of *irreversibility* of vital functions is our intended usage in determining death. First, it is difficult to predict the capabilities and effects of future technologies, even to assess biological possibility. Second, the availability of unanticipated future technologies may alter the concepts in question, requiring a reanalysis at that time. For example, we may need to redefine human death if future technologies permit brain synthesis or brain transplantation. But, most importantly, the issue of death determination that is governed by a statute of death concerns the current possibility of the reversal of vital functions. As John Lizza recently pointed out, our use of *irreversibility* in a definition of death implicitly refers to practical and not logical factors about the physical state of the person.[25]

In Cole's critique of the ambiguity of "irreversible," he explained that some scholars, in discussing DCD, have used the term in a third and an even weaker construal that corresponds to my usage of *permanent.*[26] In a later analysis of the question, "When is dead?" Stuart Youngner and colleagues further explored this weakest construal of *irreversibility* and noted that it means that the function may be potentially reversible, but that it will not reverse spontaneously or be restored therapeutically because physicians have decided not to attempt to reverse it once it stopped. Youngner and colleagues criticized this weakest construal of *irreversible* because it was inconsistent and counter-intuitive, and failed to solve the DCD death issue.[27]

Critics may question if parsing the words *irreversible* and *permanent,* as I have done, gains any conceptual ground or merely is a linguistic legerdemain that avoids the conceptual issue. I believe that clarifying terminology is a first step in studying the problem. Insisting upon a strong correspondence between the ordinary, consensual understanding of the words we use and the concepts to which they refer is critical in our analysis of complex biophilosophical concepts. It is inaccurate and misleading to classify the cessation of a function as *irreversible* (using the weakest construal of the word according to Cole and Youngner and colleagues) when it remains reversible. This usage fulfills Humpty Dumpty's claim in *Through a Looking Glass: And What Alice Found There,* that words can be made to mean whatever we want them to mean.[28] Although I agree with Lamb and Lizza's rejection of Cole's strong construal of *irreversibility* for the reasons they cited, the weakest construal falls outside the domain of *irreversibility* altogether, and resides properly within the domain of *permanence.* I explore later how reclassifying the weakest construal of *irreversibility* as *permanent* is relevant to death determination in DCD.

Although *permanent* and *irreversible* are separable concepts, they have a causal relationship that is of particular importance when applied to the loss of circulatory and respiratory functions. Once the loss of these functions has been determined to be permanent, it rapidly and inevitably progresses to become irreversible during the minutes it takes for the brain to be destroyed by lack of oxygen and blood flow. Thus, *permanence* in this context represents an earlier stage of an inevitable process that rapidly and with complete certainty yields *irreversibility. Permanence* is the absolute prognosis of *irreversibility.*

In the DCD context, after five minutes of apnea and asystole, given the empirical data showing no occurrences of auto-resuscitation, and based on physicians' respect of the

patient's wishes not to be mechanically resuscitated, it is clear that the patient's circulatory and respiratory functions have ceased *permanently*, even though they may not yet have ceased *irreversibly.* The following prudential question then is raised: is permanence of the cessation of circulatory and respiratory functions a sufficient condition for a death test without also requiring irreversibility?

DETERMINING DEATH IN CLINICAL PRACTICE

One way to address this question is to inspect how physicians commonly employ the test showing the absence of circulatory and respiratory functions in their clinical practice of determining death outside the DCD circumstance. Let us consider the common clinical example of a hospitalized patient dying of widely metastatic cancer who is receiving palliative care and is expected to die within a few days. On 6:00 a.m. hourly rounds, a nurse finds the patient without breathing or heartbeat. The intern is summoned to declare death. Her examination discloses a motionless patient who is not breathing, has no pulse or heartbeat, and whose pupils do not react to light. She declares the patient dead at the time of her examination at 6:04 a.m. The patient was last seen alive during 5:00 a.m. rounds. The patient could have lost heartbeat and breathing at any time between 5:00 and 6:00 a.m., including at 5:59 a.m. The question is whether the patient's documented absence of circulatory and respiratory functions is irreversible at the time the intern declared death at 6:04 a.m., given that the statute of death requires irreversible cessation of these functions.

In clinical practice, declaration of death using the test for cessation of circulatory and respiratory functions almost never requires showing that the cessation of functions is irreversible. It requires showing only that the cessation of functions is permanent. The dying patient portrayed above certainly has permanently lost circulatory and respiratory functions, because we know from data and experience that once breathing and heartbeat cease in a patient dying of widely metastatic cancer, they do not spontaneously restart. Further, we know that because the patient has a DNR (do-not-rescusitate) order and is expected to die, that no resuscitation will be attempted. But physicians do not attempt to prove that the patient's cessation of circulatory and respiratory functions is irreversible at the moment they declare death. That the cessation of circulatory and respiratory functions is permanent comprises sufficient grounds for ordinary determination of death. Thus, there is a disconnect between the apparent requirements of the criterion of death, articulated in death statutes like the UDDA, and the test of death that physicians actually conceptualize and employ. The criterion requires an irreversible cessation of functions, but the test requires only their permanent cessation.

Critics correctly observe that, in the large majority of hospital death determinations, a significant amount of time elapses between the time the loss of vital functions is detected and the time a physician is summoned to declare death and completes an examination. This elapsed time usually is sufficient to allow the permanent loss of vital functions to progress to becoming irreversibly lost. Some physicians I know even purposely dawdle when declaring death, to permit additional time to elapse to more confidently establish irreversibility. Thus, how often does the distinction between a permanent and irreversible loss of vital functions actually arise in clinical practice? Probably, it occurs infrequently. But despite its infrequency, the inescapable point remains that when physicians declare death, they generally do not care, or attempt to prove, that the loss of the patient's vital functions is irreversible; only that the loss is permanent. Thus, the implicit medical practice standard in death determination is permanence.

In an article analyzing the precise timing of death, Joanne Lynn and Ronald Cranford asserted four possible choices for stating the

time of death, based on the loss of functions critical to life: "T1" when the critical function is lost; "T2" when the critical function is observed to be lost; "T3" when the critical function is irreversibly lost; and "T4" when the critical function is demonstrated to be irreversibly lost.[29] I have argued elsewhere that T4 is the most defensible time, because determination of death is made in retrospect.[30] Altering Lynn and Cranford's analysis (which was designed for the brain criterion of death) to apply to the cardiopulmonary criterion, T4 could be said to be the moment at which breathing and circulation are demonstrated to be permanently lost.

DETERMINING DEATH IN DCD

Now we can analyze determination of death in the DCD patient after five minutes of asystole. The reason that DCD advocates hold that the DCD patient is dead is not simply that the patient will not auto-resuscitate and will not be mechanically resuscitated. Instead, it is that the cessation of circulatory and respiratory functions is permanent, and that this permanence is identical to the permanence test implicit in physicians' usual determinations of death that are performed in other hospitalized patients using the cardiopulmonary criterion. Why should determination of death in DCD require a stricter standard of practice than determinations using the same criterion elsewhere in the hospital? And why do the critics of declaring death after five minutes of asystole in DCD patients not equally criticize physicians' use of a permanence standard in applying the cardiopulmonary criterion for determining death in patients elsewhere in the hospital, especially given that those determinations are performed much more commonly?

Physicians are secure in their reliance on a standard of permanence in their death tests, despite the statutory standard of irreversibility, for three reasons. First, the permanence standard has been accepted implicitly, if not explicitly, by the medical profession and society for the usual determination of death. No one is arguing that it is wrong, has produced incorrect results, and should be revised. Second, employing a test requiring only permanent cessation of respiratory and circulatory function always produces incipient, rapidly developing, and absolutely inevitable irreversibility of these functions. Therefore, using a standard of permanence rather than of irreversibility creates an inconsequential difference in outcome. And third, the weakest construal of *irreversibility* (permanence) was the one probably intended in death statutes when they were drafted, because that interpretation follows prevailing medical practices.[31]

But is changing to a permanence standard in DCD truly inconsequential in outcome? Jerry Menikoff, a critic of the report by the Institute of Medicine, who argues that DCD patients are not necessarily dead after five minutes of asystole, also points out the inconsequentiality of shifting from an irreversibility standard to a permanence standard. Menikoff explains that even though the DCD patient is not dead at the moment of organ retrieval, because the patient's brain is not yet fully destroyed, removing the patient's organs has *no effect* on the timing of the patient's subsequent death, because that timing is determined solely by the rate of decay of brain cells, which, given the permanent cessation of breathing and circulation, is utterly unaffected by the removal of vital organs. Thus, even granting that the DCD patient remains alive (though incipiently dying) at the point of organ procurement, the organ procurement neither kills the DCD patient nor hastens death.[32] For this reason, employing a permanence standard produces an inconsequential outcome for the DCD patient.

Critics may point out an additional important practical difference between determining death in a DCD patient and using the cardiopulmonary criterion in other hospital death contexts. They may claim that while the distinction between permanent and irreversible may not matter in ordinary death declaration, as in the case of the dying cancer patient pre-

sented above, it does matter in the explicit death declaration in DCD. According to this argument, no harm is done to the ordinary dying patient by using a permanence standard, because death is expected and natural, and no intervention of any kind will be done to the patient as a result. By contrast, in using a permanence standard in the DCD patient, physicians may remove vital organs before respiratory and circulatory functions are irreversibly lost, an act that violates the dead donor rule and thus can produce harm.[33] I address this question next.

SHOULD WE ALTER PUBLIC POLICY ON DETERMINATION OF DEATH?

I have shown the presence of at least some degree of mismatch between the irreversibility standard required by the definition, criterion, and statute of death, and the permanence standard that physicians currently practice in their tests of death using a cardiopulmonary criterion.[34] Is there a compelling reason to correct this mismatch, either by changing the statute to permanence or the tests to irreversibility? I think not. As it is currently practiced in both ordinary hospital situations and DCD, this mismatch produces no adverse consequences because the outcomes are identical. It is not necessary to await rigor mortis or other unequivocal evidence of death before physicians declare death in the hospital and there are compelling social reasons not to do so.[35] Neither is it necessary to change the five-minute recommended guideline for asystole in determination of death in DCD, and there are compelling reasons involving organ viability not to do so. It is interesting that it is not that the advent of DCD has introduced a new standard of determination of death. Rather, DCD protocols simply have made explicit the presence of a long-standing practice of determination of death using the cardiopulmonary criterion that previously had not been clarified.

Permitting physicians to use a permanence standard instead of an irreversibility standard constitutes a compromise on biological reality, because, although the patient is incipiently dying at the point of permanence, the patient is not dead until the point of irreversibility. As a matter of public policy, is such a compromise justified? And is the compromise a violation of the dead donor rule? If so, is it a justified violation? And if it is a justified violation, is it one that the public will accept?

Enacting successful public policy on issues of life and death may require compromises on certain biological facts. Compromises may be acceptable if they satisfy three conditions: (1) they facilitate a socially desirable goal; (2) they are acceptable to the public and professional communities; and (3) they produce no differences in outcomes from the stricter practice or produce differences in outcome that are inconsequential. The use of a permanence standard for tests of death to demonstrate an irreversibility standard for the criterion and statute of death is an acceptable compromise because it satisfies the three conditions above. Therefore, we can defend permitting physicians to use a permanence standard in cardiopulmonary tests of death, as they do presently in cases of in-hospital death determination, including DCD.

Substituting a permanence standard for an irreversibility standard may violate the dead donor rule, the ethical axiom of procuring multiple vital organs which requires that the donor of multiple vital organs must first be dead.[36] If so, is this violation of the dead donor rule justified?[37] I have been a strong advocate of the dead donor rule, because I believe that it helps maintain public confidence in the organ transplantation enterprise, which remains precarious at best. We know from past experience that the public needs reassurance that physicians will not declare living patients dead to procure their organs.[38]

For several reasons, I have concluded that if DCD does violate the dead donor rule, it comprises a justified exception. First, as I have shown, if the DCD patient is not dead at five minutes of asystole, the patient is incipiently and unequivocally dying, and will certainly

be dead within minutes. Second, a state of irreversibility of cessation of breathing and circulation rapidly and inescapably follows the demonstration of permanent cessation of functions. Third, the outcome difference between a permanency and an irreversibility standard is inconsequential. Fourth, the patient or surrogate has provided consent to permit organ removal at this stage, saying that a condition of permanence comprises sufficient grounds for determining death from the patient's perspective.[39] Fifth, other patients benefit from donation of the organs, so it constitutes a socially desirable goal. Sixth, the U.S. Department of Health and Human Services and expert advisory bodies (for example, the Institute of Medicine) favor and encourage this type of transplantation activity. And, finally, the dead donor rule was developed to prevent organ donors from being killed for their organs. But violating it in this case does not lead to the death of the patient, so its *raison d'être* does not apply in DCD.

Will society tolerate knowing that patients are serving as vital organ donors before they are unequivocally dead, once this fact is better publicized? I conclude that our society will permit the practice for three reasons. First, the claim of some critics that "DCD is killing an almost dead patient for organs" is simply false. As Menikoff explains, the organ donation does not cause or even accelerate the patient's death. DCD patients are dead when their brains are destroyed by cessation of breathing and circulation, as evolving inevitably over minutes from being permanently lost to irreversibly lost. If critics wished to assign causation to the death of the patient, what "killed" the DCD patient was the earlier withdrawal of life-sustaining therapy, an act that is widely practiced and constitutionally protected, and, according to DCD protocols, would have been performed irrespective of organ donation. Second, most DCD patients will not care if they are declared dead earlier in a process that quickly and inevitably achieves irreversibility, because they wish to donate, and the difference to them is utterly inconsequential. And third, in my experience, most physicians seem to express no problem declaring DCD patients dead at five minutes of asystole, because doing so is consistent with their current practice of using a permanence standard for death declaration elsewhere in the hospital.

FUTURE DIRECTIONS

There are several areas in research and education that demand further attention before DCD determination of death can be fully and successfully implemented. First, we need additional studies to enhance the modest body of empirical data on the frequency of autoresuscitation in ICU (intensive care unit) patients who develop asystole after cessation of ventilator therapy. It takes thousands of patients to comprise an adequate sample to assert the minimum duration of asystole necessary to confidently state that the cessation of circulation is permanent. Although there is no current evidence that the five-minute interval recommended by the Institute of Medicine is wrong, further study would enhance its validity and clarify the precise and optimal duration of asystole.

Second, we need greater standardization of physicians' practices in determining death in DCD patients. It is well known that DCD protocols for determining death vary somewhat among organ procurement organizations, particularly in the duration of asystole necessary to determine death. Just as there is disturbing evidence that some physicians continue to perform and document brain-death determinations inadequately,[40] standardizing optimum practices for physicians in determining death in DCD patients is clearly desirable. We should work toward developing an evidence-based, optimum practice standard for determining death in DCD.

Third, we need studies of physicians' practice behavior in the DCD context. In my discussions with colleagues during the implementation of a DCD protocol in my hospital, I discovered two common areas of concern surrounding the question of determination of death. Several ICU physicians opposed the

DCD protocol because they feared that, if patients' families knew of its existence, this might influence conversations about withdrawing life-sustaining therapy. In particular, the physicians worried that knowledge of the protocol might subtly encourage family members to withdraw life-sustaining therapy that they otherwise might continue. Several nurses expressed their concern that if a DCD patient did not develop asystole quickly enough following removal from the ventilator, that physicians would purposely end the patient's life by administering high dosages of opioid drugs, because of the obvious pressure exerted by surgical staff, who would be scrubbed and anxiously awaiting the donor patient. Although there are no data to validate these concerns, these are legitimate areas for study, because DCD protocols are based on the premises that the decision to withdraw life support will be made independently of the decision to donate organs, and that optimal palliative care will be given to DCD donors following withdrawal of life-sustaining therapy, but that they will not be euthanized.

Fourth, education on determination of death in DCD obviously is needed for physicians and the public. Just as Stuart Youngner and colleagues have shown that in brain-death, that physicians, nurses, and the public inadequately understand the conceptual and practical issues involved,[41] a similar ignorance undoubtedly exists regarding DCD. Surveys can accompany the educational process to assess the degree to which members of the public and of the professional community accept the concept of DCD, and, in particular, the practice of determining death at the point that respiratory and circulatory functions cease permanently, but before they cease irreversibly.

Finally, it would add clarity to the analyses of the concept and determination of death if scholars more consistently separated the meanings of *irreversible* and *permanent* when describing cessation of vital functions. I have shown that using the term *permanent* for Cole's weakest construal of *irreversible* conforms to ordinary understanding and usage, follows physicians' prevailing practices of determining death, and may have been the meaning of *irreversible* that was intended by the framers of the UDDA.

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NOTES

1. The total number of DCD donors in the U.S. more than tripled between 1999 and 2003. DCD now accounts for up to 24 percent of organ donation in the organ procurement organization of the most active DCD program. See F.L. Delmonico et al., "Organ Donation and Utilization in the United States, 2004," *American Journal of Transplantation* 5, part 2 (2005): 862-73.

2. University of Pittsburgh Medical Center Policy and Procedure Manual, "Management of Terminally Ill Patients who May Become Organ Donors after Death," *Kennedy Institute of Ethics Journal* 3 (1993): A1-15.

3. The most current DCD data were reported in J.L. Bernat et al. "Report of a National Conference on Donation after Cardiac Death," *American Journal of Transplantation* 6, (2006): 281-91.

4. Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement* (Washington, D.C.: National Academy Press, 1997) and Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Practice and Protocols* (Washington, D.C.: National Academy Press, 2000).

5. Former Secretary of the DHHS, Tommy Thompson, appointed the Advisory Council on Transplantation that recommended active pursuit of DCD in all hospitals. See Council Recommendation #14 in *http://www.organdonor.gov/acotrecsbrief.html.* Thompson also supports the Health Resources and Services Administration (HRSA) Organ Donation Breakthrough Collaborative, whose goal is to increase the rate or organ donation in the U.S., one of whose six key strategies is DCD.

6. Organ procurement organization DCD protocols vary on the stipulated length of time of asystole required to declare death. Most have

adopted the recommendation by the IOM of five minutes, but some use two minutes. In the Netherlands, they wait 10 minutes.

7. I use the term *asystole* hereinafter not in its strictest sense, meaning an absence of recordable electrocardiographic activity, but in its more general sense, meaning an absence of cardiac activity sufficient to generate a pulse or blood flow. When the heart stops after apnea, the cardiac rhythm usually diminishes gradually before stopping, but the resultant weak cardiac electrical signal is insufficient to produce a cardiac contraction necessary to create a pulse or blood flow. This condition of absent pumping, despite a present cardiac rhythm, known as "electromechanical dissociation," precedes the total absence of cardiac electrical activity. But it is simpler merely to say *asystole* because heartbeat and circulation stops even if an ineffectual cardiac signal persists temporarily. This phenomenon has been studied in a series of patients. See E.F.M. Wijdicks and M.N. Diringer, "Electrocardiographic Activity after Terminal Cardiac Arrest in Neurocatastrophes," *Neurology* 62 (2004): 673-74.

8. J. Lynn, "Are the Patients Who Become Organ Donors under the Pittsburgh Protocol for 'Non-Heart-Beating Donors' Really Dead?" *Kennedy Institute of Ethics Journal* 3 (1993): 167-78; R.D. Truog, "Is it Time to Abandon Brain Death?" *Hastings Center Report* 27, no. 1 (1997): 29-37; and S.J. Youngner, R.M. Arnold, and M.A. DeVita, "When is 'Dead'?" *Hastings Center Report* 29, no. 6 (1999): 14-21.

9. J. Menikoff, "Doubts About Death: The Silence of the Institute of Medicine," *Journal of Law, Medicine & Ethics* 26 (1998): 157-65; and J. Menikoff, "The Importance of Being Dead: Non-Heart-Beating Organ Donation," *Issues in Law and Medicine* 18, no. 1 (2002): 3-20.

10. Approximately 25 percent of patients in DCD protocols, following ventilator removal, continue to breathe and have heartbeat for greater than one hour before they die, rendering them unsuitable for DCD for logistical reasons. See note 1 above.

11. See notes 8 and 9 above.

12. The absence of auto-resuscitation comprises a critical point of the argument and is one that is answerable using empirical data. There are relatively few studies, but all report no instances of auto-resuscitation after five minutes of asystole. These data are summarized in M.A. DeVita, "The Death Watch: Certifying Death Using Cardiac Criteria," *Progress in Transplantation* 11 (2001): 58-66; M.A. DeVita et al., "Observations of Withdrawal of Life-Sustaining Treatment from Patients who Became Non-Heart-Beating Organ Donors," *Critical Care Medicine* 28 (2000): 1709-12; and Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Practice and Protocols,* see note 4 above.

13. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death: Medical, Legal and Ethical Issues in the Determination of Death* (Washington, D.C.: U.S. Government Printing Office, 1981), 72-84.

14. Ibid., 31-43.

15. J.L. Bernat, C.M. Culver, and B. Gert, "Defining Death in Theory and Practice," *Hastings Center Report* 12, no. 1 (1982): 5-9.

16. Elsewhere I have defended the assertion that death is intrinsically irreversible. See J.L. Bernat, "The Biophilosophical Basis of Whole-Brain Death," *Social Philosophy & Policy* 19, no 2. (2002): 324-42 and J.L. Bernat, "A Defense of the Whole-Brain Concept of Death," *Hastings Center Report* 28, no. 2 (1998): 14-23. For an opposing opinion, see D.J. Cole, "The Reversibility of Death," *Journal of Medical Ethics* 18 (1992): 26-30.

17. E.T. Bartlett, "Differences Between Death and Dying," *Journal of Medical Ethics* 21 (1995): 270-76.

18. My colleagues and I also used the words *permanent* and *irreversible* interchangeably in the past in this context. See, J.L. Bernat, C.M. Culver, and B. Gert, "On the Definition and Criterion of Death," *Annals of Internal Medicine* 94 (1981): 389-94.

19. *The Oxford English Dictionary,* 2d ed. (Oxford: Oxford University Press, 2006).

20. Ibid.

21. I am grateful to Don Marquis and Jeff McMahan for first explaining this distinction to me. See J. McMahan, "The Metaphysics of Brain Death," *Bioethics* 9, no. 2 (1995): 91-126. But we all acknowledge that in some social and clinical contexts our usages of *permanent* do not necessarily rely on intent or action, and mean irreversible.

22. Others have attempted to make a similar distinction by offering multiple interpretations of *irreversibility.* See J.A. Robertson, "The Dead Donor Rule," *Hastings Center Report* 29, no. 6 (1999): 6-14, and Youngner, Arnold, and DeVita, "When is 'Dead'?" see note 8 above.

23. D. Cole, "Statutory Definitions of Death and the Management of Terminally Ill Patients who May Become Organ Donors after Death," *Kennedy Institute of Ethics Journal* 3, no. 2 (1993): 145-55 and see Cole, "The Reversibility of Death," see note 16 above.

24. D. Lamb, "Reversibility and Death: A Reply to David J. Cole," *Journal of Medical Ethics* 18 (1992): 31-3.

25. J. Lizza, "Potentiality, Irreversibility, and Death," *Journal of Medicine and Philosophy* 30 (2005): 45-64.

26. D. Cole, *Kennedy Institute of Ethics Journal* (1993): 149. Cole separates but criticizes all three construals of *irreversible.*

27. Youngner, Arnold, and DeVita, "When is 'Dead'?" see note 8 above.

28. L. Carroll, *Through the Looking Glass: And What Alice Found There* (New York: Books of Wonder, 1993).

29. J. Lynn and R.E. Cranford, "The Persisting Perplexities in the Determination of Death," in *The Definition of Death: Contemporary Controversies,* ed. S.J. Younger, R.M. Arnold, and R. Shapiro (Baltimore: Johns Hopkins University Press, 1999), 101-14.

30. J.L. Bernat, "The Biophilosophical Basis of Whole-Brain Death," *Social Philosophy & Policy* 19, no. 2 (2002): 324-42.

31. According to Alexander M. Capron, Executive Director of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, in the seminal work *Defining Death: Medical, Legal and Ethical Issues in the Determination of Death* (see note 13 above), the President's Commission used the words *permanent* and *irreversible* interchangeably (see example on pp. 83-4), although they chose *irreversible* for the UDDA. Alexander M. Capron, communication with the author, 7 April 2005.

32. J. Menikoff, "Doubts About Death: The Silence of the Institute of Medicine," *Journal of Law, Medicine & Ethics* 26 (1998): 157-65.

33. Jerry Menikoff, communication with the author, 4 February 2005.

34. There is no mismatch if only the weakest construal of *irreversibility* is understood as the implied meaning in death statutes. But most scholars presume a stronger construal. In the discussion that follows, I will assume the intermediate (Cole's weak but not weakest) construal.

35. For a history of physicians' determination of death in previous centuries that describes the variety of tests employed to assure that the patient was truly dead, including prolonged observation to the point of rigor mortis, see D.J. Powner et al., "Medical Diagnosis of Death in Adults: Historical Contributions to Current Controversies," *Lancet* 348 (1996): 1219-23.

36. J.A. Robertson, "The Dead Donor Rule," see note 22 above.

37. See the discussion of this question in R.M. Arnold and S.J. Youngner, "The Dead Donor Rule: Should We Stretch it, Bend it, or Abandon it?" *Kennedy Institute of Ethics Journal* 3, no. 2 (1993): 263-78.

38. Elsewhere I have discussed the publicized cases showing the fragility of public confidence in the organ transplantation enterprise, particularly in physicians' determination of death in the organ donor. See, J.L. Bernat, *Ethical Issues in Neurology,* 2nd ed. (Boston: Butterworth-Heinemann, 2002), 262-65.

39. Tom Tomlinson criticized Cole's analysis of *irreversible* on ethical, not conceptual grounds. He claimed that "the possibility of reversal is not ethically significant" if the DCD patient has consented to organ donation, because declaring the patient dead at this point respects her or his wishes for organ donation. See T. Tomlinson, "The Irreversibility of Death: Reply to Cole," *Kennedy Institute of Ethics Journal* 3, no. 2 (1993): 157-65.

40. See, for example, R.E. Mejia and M.M. Pollack, "Variability in Brain Death Determination Practices in Children," *Journal of the American Medical Association* 274 (1995): 550-53, and M.Y. Wang, P. Wallace, and J.B. Gruen, "Brain Death Documentation: Analysis and Issues," *Neurosurgery* 51 (2002): 731-35.

41. S.J. Youngner et al., " 'Brain Death' and Organ Retrieval: A Cross-Sectional Survey of Knowledge and Concepts Among Health Professionals," *Journal of the American Medical Association* 261 (1989): 2205-10.

The Truth about "Donation after Cardiac Death"

Robert D. Truog and Thomas I. Cochrane

Donation after cardiac death, or DCD, is enjoying a resurgence as a pathway to organ procurement, to obtain more organs for transplantation. DCD has many controversial features, but James Bernat chooses to focus on what he regards as the most serious claim, that the DCD donor "is dying but is not yet dead after only five minutes of asystole." Bernat's logic is clear and compelling. We will reconstruct certain elements of his arguments here. First, he affirms that the concept of irreversibility is intrinsic to the concept of death: "Because no mortal can return from being dead, any resuscitation or recovery must have been from a state of dying, but not from death."

Second, he claims to be a strong supporter of the dead donor rule, the unwritten "ethical axiom . . . that requires that the donor of multiple vital organs must first be dead." Third, he asks whether patients who have been pulseless for five minutes (as required by most DCD protocols) have *irreversibly* lost cardiac function. He acknowledges that if by *irreversible* we mean they could never be successfully resuscitated, then the answer is probably "no." As such, he concludes our current approach to DCD probably violates the dead donor rule.

This is a remarkably candid assessment, especially given that Bernat was the first author on a "Report of a National Conference on Donation after Cardiac Death," published in 2006, that emphatically states, "This national conference affirmed the ethical propriety of DCD as not violating the dead donor rule."[1]

How does Bernat reconcile these two contradictory statements? He does this by introducing a distinction between the concepts of *irreversible* and *permanent.* According to Bernat, cardiac arrest is *irreversible* if it cannot be reversed with currently available medical therapy, but *permanent* if the likelihood of auto-resuscitation is virtually nil and if there is agreement that no attempt to resuscitate will be made. In a persuasive argument, not duplicated here, Bernat claims that even though the diagnosis of death by cardiac criteria requires *irreversible* loss of cardiac function, the standard of care in medicine has always been to make diagnosis of death on the basis of *permanent* loss of that function.

Bernat claims it is ethically acceptable to remove organs from individuals who are not

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yet dead, in violation of the dead donor rule, because the "permanent cessation of respiratory and circulatory function always produces incipient, rapidly developing, and absolutely inevitable irreversibility of these functions." In other words, since permanence is 100 percent prognostic of irreversibility, violation of the dead donor rule is acceptable. We think Bernat is essentially correct in his analysis of the dead donor rule in relation to DCD. This raises several interesting questions.

Is a 100 percent accurate prognosis of death sufficient justification for violating the dead donor rule? Bernat believes our current violations of the dead donor rule in the practice of DCD are justified, primarily on the basis of the absolute certainty of the prognosis that the patients will soon be dead. If this is a sufficient requirement for justifying exceptions to the dead donor rule, then it is worth examining other situations that also carry a 100 percent accurate prognosis of death. Consider the following two cases.

Case 1. A young man has been a quadriplegic for several years following a diving accident that transected his upper cervical spinal cord. He is unable to generate any breathing movements, and is completely dependent on mechanical ventilation. After long consideration, he requests his ventilator be withdrawn, knowing he will die. If his ventilator is withdrawn, his prognosis for death is 100 percent.

Case 2. A young man with acute severe cardiomyopathy is being supported with extracorporeal membrane oxygenation (ECMO), a form of cardiopulmonary bypass. Echocardiograms show that he has no cardiac function (his heart is at standstill). He has refused the option of being listed for a heart transplant, and has requested that ECMO be discontinued, knowing that he will die. If ECMO is withdrawn, his prognosis for death is 100 percent.

In each case, assuming the patient has decisional capacity to make this choice, the request to have life support discontinued would be supported by American law, ethics, and medical practice. Now assume that each of the patients passionately wants to be an organ donor, and desires to give as many organs as possible, and in a way that maximizes the chances for them to function well.

Under DCD protocols, the patient's doctor would discontinue life support, the transplant team would wait for five minutes of pulselessness, and then remove the kidneys (and perhaps liver) for transplantation. Suppose, however, that each of these patients instead requests that he be given a general anesthetic, so that as many organs as possible could be procured, without the damage caused by five minutes of ischemia. In addition to kidneys and liver, this could potentially include heart, lungs, pancreas, and small bowel.

Clearly, this approach would violate the dead donor rule. If, however, exceptions to the dead donor rule can be justified so long as death is absolutely certain, as Bernat argues for DCD, then these requests for donation under general anesthesia and before death should be honored. Bernat's views about *permanence* and *irreversibility* have implications for another type of case as well.

Case 3. A patient with amyotrophic lateral sclerosis (ALS) has swallowing dysfunction and must be fed through a gastrostomy tube. His pulmonary function is deteriorating, but he has firmly decided that he does not want to be mechanically ventilated. He has therefore decided to stop his tube feedings, so he will die from dehydration rather than respiratory insufficiency. He desperately wishes to donate his organs, but is told if he dies "naturally," by dehydration after stopping tube feedings, his organs will not be suitable for donation. Like the patients in the first two cases, he requests that his organs be procured under general anesthesia rather than lose the opportunity to donate.

Discontinuation of tube feedings is 100 percent prognostic of death. Bernat might argue the prognosis is not actually 100 percent, as it depends upon a decision made by the patient, and the patient may change his mind. But if Bernat does not agree that the ALS patient's decision not to be fed defines *permanence*, then he cannot claim that decisions not to resuscitate define *permanence* either.

Further, this patient would not have the opportunity to donate under current DCD protocols that require five minutes of asystole,

but Bernat's analysis permits the procurement of organs from dying, but not-yet-dead, patients. Although we doubt Bernat intended to argue for such an extension of the pool of potential donors, there is nothing in his analysis that would prohibit donation in this case.

All three cases therefore involve clinical situations that are 100 percent prognostic of death. If, as Bernat argues, a 100 percent prognosis of death is a sufficient justification to violate the dead donor rule, then it should be permissible for all three of these patients to request that their organs be removed under anesthesia before death, even though doing so would violate the dead donor rule.

Is it wrong for physicians to "kill" patients? Some might argue that these three cases are not analogous to DCD, because, in each of these cases, the physicians would "kill" the patients as part of procuring their organs, whereas, in DCD, the patients are not "killed," but die from their underlying disease. This objection, however, is based on a common misunderstanding of one of the classical distinctions in medical ethics, that is, the difference between *killing* and *allowing-to-die.*

As Dan Brock and others have explained, *killing* is defined as an act that is the proximate cause of a person's death. Killings can either be morally justified or morally unjustified (killing in self-defense being a commonly cited example of the former). Under current DCD protocols, withdrawing life support is the proximate cause of the patient's death. In the above cases, if donation is performed as the patients request, the procurement of vital organs is the proximate cause of their death. Assuming certain other necessary conditions (the accuracy of the prognosis, the patient's consent, et cetera) both types of actions should be considered cases of justified killing.[2]

In common practice, clinicians resist referring to withdrawal of life support as justified killing, preferring to use the inaccurate, but euphemistically more palatable, description of *allowing-to-die.* While understandable, this description is factually in error. Bernat also clearly recognizes that withdrawal of life support should be seen as an act of justified killing when he observes, "If critics wished to assign causation to the death of the patient, what 'killed' the DCD patient was the earlier withdrawal of life-sustaining therapy, an act that is widely practiced and constitutionally protected, and, according to DCD protocols, would have been performed irrespective of organ donation."

We therefore conclude that the three cases above are indeed analogous to DCD, since, strictly speaking, patients are "killed" in both situations. That is, in the three cases as well as in DCD, the physicians are the proximate cause of the patients' deaths — by withdrawal of life support in the latter and by removal of vital organs in the former. To be clear, we do not advocate that physicians refer to withdrawal of life support as a "justified killing" in casual conversations with colleagues or patients, since, in everyday life, the word *killing* carries negative normative connotations that are not a part of its strict definition. But for purposes of examining the ethics of practices at the end of life, precision of language is important, and use of the terminology we have described is helpful in avoiding misunderstandings and confusion.

Is violation of the dead donor rule socially unacceptable? Bernat has been a strong advocate of the dead donor rule because he believes that it helps maintain public confidence in the organ transplantation enterprise. He supports an exception to the dead donor rule for DCD, however, because he does not think that the public will care. He notes that "most DCD patients will not care if they are declared dead earlier in a process that quickly and inevitably achieves irreversibility, because they wish to donate, and the difference to them is utterly inconsequential."

This perspective raises the more fundamental question of what the public actually thinks about the dead donor rule. While one often hears that the public would be outraged about violations of the dead donor rule, there is some evidence to the contrary. Recently, more than 1,000 residents of Ohio were surveyed about their views on brain death and the vegetative state, and, of those who gave

consistent answers, fully 45 percent were willing to donate the organs of patients that they themselves considered to be alive, in violation of the dead donor rule.[3]

Newspapers frequently suggest violations of the dead donor rule, as when the *New York Times* stated, "The brain dead are candidates for a donation, but the operation generally must be performed before death,"[4] and the *Boston Globe* noted that a patient "was being kept alive so doctors could harvest his organs for donation."[5] If the public was so concerned about the dead donor rule, one might expect such stories to draw storms of protest, but they typically pass unnoticed. Even medical experts seem to be confused. On a recent episode of *Larry King Live*, Sanjay Gupta, MD, a medical correspondent for CNN and a practicing neurosurgeon, explained to a national television audience that a brain-dead woman was not really dead, but nevertheless could be an organ donor.[6] Both research and anecdotes therefore suggest that concern of the public about maintaining the dead donor rule may be somewhat exaggerated.

CONCLUSION

We agree with Bernat that DCD is an ethically acceptable approach to organ recovery. As he points out, however, "DCD" is a misnomer: it is not "donation after cardiac death," since we now see that the donors are "dying but not yet dead."

The problem is not with DCD, but with the dead donor rule. It is a poor foundation for the ethics of organ transplantation. Until recently, the distortions were mostly at the margins of practice, but now, with the emergence of DCD, they are becoming apparent at the heart of transplantation activities.

Elsewhere, one of us (RDT) has argued that the correct ethical benchmarks for organ donation should focus upon the prognosis of the patient and the patient's consent, not upon the dead donor rule.[7] Many people believe that patients who are in a persistent vegetative state should be allowed to donate their vital organs.[8] The current precondition for DCD, under which it is first necessary to make patients dead, serves no interest for those who would wish to donate under such circumstances, and undercuts their desire to maximize the number and quality of donated organs.

In the modern intensive care unit, where as many as 90 percent of deaths occur following withdrawal of life support, many old ethical guideposts have lost their clarity and usefulness. It is no longer helpful, for example, to ask whether a particular treatment is "ordinary" or "heroic," since any treatment, whether as simple as taking vital signs or as complex as ECMO, can only be evaluated within the context of the patient's prognosis and values. Similarly, the ethics of organ transplantation have outgrown the guidance provided by the dead donor rule, and need to be reoriented and focused on factors that are most relevant to the patients making donations.

NOTES

1. J.L. Bernat et al., "Report of a National Conference on Donation after Cardiac Death," *American Journal of Transplantation* 6 (2006): 281-91.

2. D.W. Brock, "Death and dying," in *Medical Ethics,* ed. R.M. Veatch (Boston: Jones and Bartlett, 1989), 329-56.

3. L.A. Siminoff, C. Burant, and S.J. Youngner, "Death and organ procurement: public beliefs and attitudes," *Kennedy Institute of Ethics Journal* 14 (2004): 217-34.

4. L.M. Krieger, "A life-and-death proposal," *New York Times,* 5 June 1996.

5. S. Ebbert and R. Mullin, "Police pursuit claims a life," *Boston Globe,* 14 December 1999.

6. Jason Torres, interview by Larry King, *Larry King Live,* CNN, 30 June 2005.

7. R.D. Truog, "Is it time to abandon brain death?" *Hastings Center Report,* 27 (1997): 29-37; R.D. Truog and W.M. Robinson, "Role of brain death and the dead-donor rule in the ethics of organ transplantation," *Critical Care Medicine* 31 (2003): 2391-6.

8. K. Payne et al., "Physicians' attitudes about the care of patients in the persistent vegetative state: A national survey," *Annals of Internal Medicine* 125 (1996): 104-10.

Donation after Cardiac Death: Consent Is the Issue, Not Death

Maryam Valapour

A significant challenge facing the organ transplant community is a critical shortage of organs. In the past decade, 83,928 individuals have become too sick to be transplanted or died while waiting for an organ.[1] As long as the supply of deceased organs remains stagnant and the net number of transplants remains the same, new sources of organs will be sought. One strategy has been to encourage the recovery and use of organs from donors after cardiac death. Donation after cardiac death (DCD) — although it predates donation after brain death — accounts for only 2.04 percent of all donors.[2] The disproportionate use of brain-dead donors is largely due to the fact that continued mechanical ventilation and circulation in brain-dead donors permits more optimal conditions for organ procurement. In addition, the practice of DCD has encountered some controversy — one of which is addressed in this issue of *The Journal of Clinical Ethics.*

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James Bernat tackles the question of whether organ donors after cardiac death are really irreversibly dead, the confirmation of which is required by the Uniform Determination of Death Act (UDDA). The UDDA provides that "an individual, who has sustained either *irreversible* cessation of circulatory and respiratory functions, or *irreversible* cessation of all functions of the entire brain, including the brain stem, is dead."[3] This article draws a distinction between *permanent* and *irreversible,* and clarifies that a permanent state is a contingent state that quickly progresses to irreversible if there is no intervention. Bernat convincingly argues and concludes that DCD does not violate the dead donor rule, and to alter public policy by employing the permanence standard produces an inconsequential outcome for DCD donors.

I agree with Bernat's conclusion. Furthermore, I believe that the more significant ethical dilemma in using DCD donors is *consent* — specifically, the consent of the recipient of the DCD organ, and not the donor. This point becomes clear when one reviews the effects of DCD on transplant outcomes. There is a higher risk of graft failure for DCD livers as compared to livers procured from standard criteria donors (SCD).[4] For certain popula-

tions, the hazard ratio of death following transplantation with a DCD liver exceeds the risk of death without a transplant. Kidney transplants from DCD and SCD donors have similar adjusted one- and three-year graft survival; however, the rate of delayed graft function is almost doubled for DCD kidneys (40.1 percent compared to 21.2 percent).[5] The national conference on DCD has recommended that the Organ Procurement and Transplantation Network require transplant centers to keep a list of candidates who are willing to accept DCD livers.

Organ transplantation is a field of medicine that is subject to rapid changes. New techniques, new drugs, and new technologies alter clinical practice routinely. The process of informed consent is especially problematic when transplant techniques are new and outcomes are uncertain, or worse when compared to standard practice, such as using the "ideal donor." In most areas of medicine, such procedures would never be offered to patients. However, with an average organ wait list mortality of 7,000 patients per year, not all patients can afford to wait for the ideal donor to become available.[6] Informed consent by recipients in these cases requires continued discussion based on varying risk as the health of the recipient changes, the status of the donor changes, and medical knowledge grows.

NOTES

1. Based on the U.S. Organ Procurement and Transplantation Network data as of 14 April 2006.

2. R.J. Howard, J.D. Schold, and D.L. Cornell, "A 10-year Analysis of Organ Donation after Cardiac Death in the United States," *Transplantation* 80, no. 5 (15 September 2005): 564-8.

3. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death: Medical, Legal and Ethical Issues in the Determination of Death* (Washington, D.C.: U.S. Government Printing Office, 1981): 72-84.

4. New York State Department of Health Workgroup, "Workgroup on Expanded Criteria Organs for Liver Transplantation," *Liver Transplantation* 11 (October 2005): 1184-92.

5. J.L. Bernat et al., "Report of a National Conference on Donation after Cardiac Death," American Journal of Transplantation 5 (24 November 2005): 1-11.

6. U.S. Department of Health and Human Services, "Table 1.6," *2005 Annual Report of the U.S. Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients: Transplant Data 1995-2004* (Rockville, Md.: Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation), *http://www.hrsa.gov/.* The data and analyses reported in the *2005 Annual Report of the U.S. Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients* have been supplied by the United Network for Organ Sharing (UNOS) and the University Renal Research and Education Association (URREA) under contract with DHHS. The authors alone are responsible for reporting and interpreting these data; the views expressed therein are those of the authors and not necessarily those of the U.S. Government.

How a Model Based on Linguistic Theory Can Improve the Assessment of Decision-Making Capacity for Persons with Dementia

Daniel J. Brauner and Susan E. Merel

INTRODUCTION

The process of obtaining informed consent, in which a competent adult voluntarily agrees or declines to participate in a study, is at the core of the practice of ethical research.[1] In the case of persons with Alzheimer's disease and related dementias, this process becomes more complicated because it is not obvious whether the individual possesses decision-making capacity. Making an accurate determination of the decision-making capacity of persons with dementia is of paramount importance to providing protection, as well as maximizing their autonomy. This is becoming increasingly necessary and important as more research is being targeted at this rapidly growing population.[2] This determination can be extremely difficult because it requires judging abilities in persons with varying degrees of cognitive impairment, including those affecting communication itself.[3]

The most widely recognized clinical guidelines for assessing competency rely on four decision-making abilities (see table 1). Grisso and Appelbaum have developed an instrument to measure these abilities in the setting of clinical research using a structured interview format.[4] But even with the help of these guidelines, the process of determining decision-making capacity still involves making judgments about whether the subject possesses the four decision-making abilities. More commonly, subjects are engaged in a less structured informed consent conversation about the proposed research, and the researcher or clinician then makes a judgment concerning the subjects' mastery of the four decision-making abilities. The clinician or researcher interprets this conversation through an extremely subjective, often intuitive process that frequently becomes the basis of the judgment about whether a person with dementia possesses decision-making capacity. Much of the research on validation of capacity assessment in persons with dementia uses cognitive models based on performance on neuropsychiat-

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ric tests of executive function, semantic memory, and delayed recall.[5] Considerably less attention has been paid to analyzing what actually occurs in the course of the informed consent conversation as a means for evaluating decision-making capacity; analyses of this type that do exist tend to focus on "error behavior," paying less attention to identifying behaviors that may provide positive evidence of decision-making capacity.[6] Conversation is a complex process in which participants can perform many intricate and subtle maneuvers. We present a novel approach regarding the determination of decision-making capacity based on a linguistic analysis of the informed consent conversation, with special emphasis on the subset of linguistic theory known as *discourse analysis*. We suggest that knowledge of certain concepts in linguistic theory could assist researchers and clinicians in communicating with people with dementia as well as in assessing their decision-making capacity. We also propose that a method based on linguistic theory could be used to assist researchers in determining the decision-making capacity of people with dementia by aiding analysis of the informed consent conversation.

DEFINITION AND RELEVANCE OF DISCOURSE ANALYSIS

Discourse analysis is well-suited to illuminating the informed consent process because it involves the linguistic study of naturally occurring speech.[7] We use a method of analysis proposed by Clark and Schaefer as the theoretical basis for an approach to the evaluation of decision-making capacity. The central tenet of conversational analysis is that conversation is a collaborative process with two goals. The first goal is the obvious one: transmitting information or content. The second goal, which is much less frequently appreciated, involves speakers establishing mutual agreement that understanding has been achieved. Using this model conversation can then be parsed into discrete elements: the "presentation," in which a speaker presents some information, and the "acceptance" in which the conversational partner then signals to the speaker some evidence of understanding or lack thereof. Together, a presentation and acceptance constitute a "contribution," the basic building block of conversation, with successful conversation being a collaborative process in which all participants work together to create mutual understanding and meaning, contribution by contribution.[8]

THE MODEL

In addition to providing a framework for a close analysis of the informed consent conversation, Clark and Schaefer's model also helps identify when the successful exchange of information has occurred. One important component of their model is what they call a hierarchy of evidence of understanding. This hierarchy characterizes various types of acceptances that can occur during a conversation and sorts them based on how strongly they evidence understanding. Starting with paying attention, their original hierarchy characterized five types of evidence, graded from weakest to strongest, presented in table 2. Their hierarchy serves as an important component of our model, because, with modification, it can be used as a guide to help assess the contributions made during the informed consent conversation.

APPLYING THE HIERARCHY TO INFORMED CONSENT IN DEMENTIA

We made several modifications of the original hierarchy to apply it to the informed

Table 1. Standards for Evaluating Capacity

The four abilities are as follows:

1. Ability to communicate a choice
2. Ability to understand information relating to disease and treatment options
3. Ability to appreciate a situation and its consequences
4. Ability to manipulate information rationally or reason

Adapted from P.S. Appelbaum and T. Grisso, "Assessing Patients' Capacities to Consent to Treatment," *New England Journal of Medicine* 319, no. 25 (1988): 1635-8.

consent conversation in which one of the participants has dementia. To avoid confusion, as understanding is also one of the standards for decision-making capacity, we call our version the "hierarchy of evidence of decision-making capacity." Many of our modifications involve reconsidering the weight given to various types of evidence of decision-making capacity from someone with dementia.

Revising the hierarchy with persons with dementia in mind forces us to more closely examine some of our assumptions concerning the understanding of our conversational partner. For example, cognitively impaired persons may retain the ability to respond appropriately by *backchanneling* (which are verbal or nonverbal reactions to a speaker that signal continued attention);[9] but, because persons can backchannel without truly understanding the content of a conversation, it is weaker evidence of understanding. Although backchanneling, such as a nod or an "uh-huh" in the course of a conversation, may represent true understanding in a cognitively intact person, the action itself conveys scant evidence of this understanding. Thus, in our hierarchy of evidence of decision-making capacity, we have given more weight to the ability to provide an appropriate next contribution; that is, to make a relevant addition to the body of the conversation beyond simply indicating attentiveness or backchanneling. Assigning less weight to backchanneling will also help minimize errors in interpretation that can come about because of cultural differences in the meanings conveyed by these actions.[10]

Stipulating that persons with dementia need to prove to us that they comprehend by offering evidence of decision-making capacity in their next relevant contribution, we can structure the hierarchy to reflect the varying degrees of evidence in different types of statements. There is a wide range of variability in the strength of evidence that can be engendered in the next relevant contribution, and this is where much of the challenge of evaluating conversation exists. For example, a low level of next relevant contribution would be a simple "yes" or "no" answer to a question. Adding an additional supportive statement to the "yes" or "no" answer (for example, "Yes, I agree with that,") further supports its authenticity and should be considered as better evidence than a simple yes/no. With these issues in mind, we modified the hierarchy (see table 3). The higher levels of evidence will be further discussed when we operationalize the standards in the next section.

This model provides a framework that encourages us to make more conscious and systematic judgments about what types of statements constitute evidence of decision-

Table 2. Clark and Schaefer's Hierarchy of Evidence of Understanding

1. *Continued attention.* At a minimum, the speakers must pay attention to one another for successful communication to occur.
2. *Initiation of the next relevant contribution.* This is an appropriate response to the previous presentation that does not add new information.
3. *Acknowledgment or backchanneling.* This consists of verbal or nonverbal reactions to a speaker such as a nod of the head or an "uh-huh" that are meant to signal continued attention.
4. *Demonstration.* Usually in the form of paraphrasing the previous presentation.
5. *Display.* Verbatim repetition is considered the highest level of evidence of understanding in Clark and Schaeffer's hierarchy.

Table 3. Modified Hierarchy of Evidence of Understanding = Hierarchy for Evidence of Decision-Making Capacity

1. Continued attention
2. Acknowledgment (backchanneling, for example, nodding, saying "yeah" or "uh-huh")
3. Next relevant contribution:
   a. Single word answers (yes, no, maybe, etc.)
   b. Single word answer plus confirmatory language (yes, I think so)
   c. Paraphrases
   d. New idea (that signals understanding of previous contribution)

making capacity. For a subject to be judged as possessing decision-making capacity, he or she should be able to demonstrate during the course of a conversation that he or she possesses the four commonly accepted abilities related to decision-making capacity, as described by Appelbaum and Grisso. By using our hierarchy of evidence as a guide to examine the acceptances of the subject in an informed consent conversation, we can begin to systematically review the subjects' participation in the conversation as part of an evaluation of their decision-making capacity. It is reasonable to hold a cognitively impaired subject in an informed consent conversation to a standard of more explicit evidence of decision-making capacity. However, previous studies report that even cognitively intact persons have difficulty understanding information in an informed consent form, suggesting that requiring better evidence of mastery of the information presented is not only a good idea for people with dementia but perhaps for cognitively intact people as well.[11] Requiring more explicit or higher level evidence from everyone who gives informed consent would make it more difficult to make erroneous assumptions about an individual's decision-making capacity.

OPERATIONALIZING THE STANDARDS

To use our model to assess a person's ability to understand, appreciate, reason, and make a choice, we need to operationalize these standards by characterizing how different types of acceptances evidence mastery of one or more of the four abilities related to decision-making capacity. In the next sections we will review the standards and suggest ways to operationalize them. Examples of actual conversations are provided from a cohort of subjects from the Dementia Research: Informed Proxy and Advance Consent (DRIPAC) Project, a National Institutes of Health-funded, multi-disciplinary study of consent for dementia research.[12] In this study, participants with mild to moderate dementia were videotaped having informed consent conversations after being presented with hypothetical research vignettes (see table 4). In these semi-structured interviews, participants were asked if they would agree to participate in a particular hypothetical research trial, and why, and were asked to identify a proxy decision maker in the event they were no longer able to decide for themselves. The interviews were transcribed and broken down into contributions for our analysis.

STANDARD 1: COMMUNICATING A CHOICE

This standard is meant to reflect whether the patient can make a choice between two or more options, and not the quality of that choice, and is "accepted universally as a sign of competence to consent to treatment, so much so that legal standards often neglect to mention it explicitly."[13] In a ground-breaking longitudinal study of the linguistic characteristics of a woman with dementia, Heidi Hamilton found that the number of instances in a conversation in which the subject did not respond at all to a question increased as the subject's disease progressed, suggesting that merely communicating a choice in response to a question may become difficult for patients with more advanced dementia.[14]

Communicating a choice usually involves simply answering "yes" or "no" to the question of whether or not one wants to participate in research. However, there are inherent problems in accepting the usual "yes" or "no" answer from a person with dementia. Hamilton found that isolated "yes" or "no" answers to yes-no questions did not always

Table 4. Five Hypothetical Research Vignettes

1. Blood drawing for research
2. Blood drawing for genetic test
3. Experimental medicine for Alzheimer's disease
4. Lumbar puncture to be used in development of diagnostic test
5. Brain surgery and "special cells" implanted in brain as experimental treatment for dementia

indicate comprehension of the question.[15] This holds obvious significance for the informed consent conversation with a person with dementia, and suggests that isolated yes-no answers to questions should be probed for further evidence that the participant did comprehend the question and is intentionally communicating a choice. This can be accomplished by either asking the participants to elaborate on their yes-no answer or restating the question so that an initial "yes" response should now be a "no" answer, and vice versa, to reflect consistency.

STANDARD 2: UNDERSTANDING

A widely accepted method of determining whether subjects understand information relating to their disorder and participation in research is to present the relevant information and ask them to paraphrase it.[16] However, it is usually not feasible for interviewers to ask participants to paraphrase each piece of information presented to them in the course of a conversation. Repeatedly asking participants to paraphrase information may change the interaction from a relatively natural conversation to a testing situation, which could increase the participants' anxiety and possibly make them appear less competent.[17] However, upon reviewing videotaped conversations from the DRIPAC study, we found that even without prompting, participants did sometimes paraphrase information given to them by the interviewer, as if to check their own understanding, as in the example below.

I: I understand that, but do you still feel comfortable having your daughter decide for you?
P: **To make the decision**
I: Right.
P**: Whether it should be done or not?**
I: Right.
P: **Over me. Uh, uh, uh, uh, uh, if I can't make the decision, then she can make this decision?**
I: Exactly.
P: **That's right. uh, huh. Yeah, I feel comfortable with her make the decision.**

By listening for paraphrases, a higher level of evidence on the hierarchy that are used in the course of the informed consent conversation, we can better assess for understanding.

Another useful type of evidence of understanding that has been empirically studied is the use of *anaphora.* Anaphora are words that refer back to prior words in the conversation or text.[18] Examples of anaphora used by the participant are shown in the following contributions from the DRIPAC interviews concerning picking a proxy decision maker.

I: All right now, if, for some reason, Eileen, you are unable to make the decision about this research yourself, would you feel comfortable having **Joyce** make a decision about this research for you?
P: It'd depend on what's involved whether I would or not.

I: If you were unable to decide for yourself (and um)
P**:** Well I guess **she'd** have to then.

I: Would you feel comfortable having her —
P: Yes.

I: Tell me a little bit about why you would.
P: Well, **she's** done everything else the last couple of years I've been sick. I may as well trust **her** with that too.

In this example, we can see that the anaphora **she** in the second and fourth contributions and the anaphora **her** in the fourth contribution derive their meaning by referring back to **Joyce** in the first contribution. These types of anaphora are termed *reference.* Of course, in the above example, the interviewer should check to make sure that the anaphora is being used correctly. Ellis and colleagues have reported that speakers use different patterns of anaphora in conversation and that proper use of anaphora signals attention to deeper meanings in a conversation.[19] Indeed, Ripich and Terrell found that people with dementia tend to use fewer anaphora, which may contribute to their decreased coherence.[20]

An example of another type of anaphora, substitution, the use of one word to take the place of another, is found in the following conversation from the DRIPAC study.

I: You're close, you're close with **him**?
P: **My son**? Oh yeah.

Here the substitution of **my son** for **him** is greater evidence that the participant understands the interviewer's question than if the participant had simply answered "yes" in response to the question. A method known as *indirect repair* can be used to help persons with dementia express themselves while gathering more evidence of understanding or lack thereof. When a participant with dementia uses confusing language, an interviewer or clinician can use indirect repair to attempt to clarify what the participant is trying to say. Indirect repair calls for interviewers to restate their understanding of the confusing language to allow the participant to confirm or deny the correctness of the listener's understanding.[21] A participant's response to the interviewer's indirect repair can also demonstrate the extent of his or her understanding. An example of indirect repair follows, in a conversation related to a brain surgery research scenario (indirect repair is in bold-face type).

P: When I was young and all that, I would go through and help them out.
I: **Really? You, If you were younger, you would let them, uh, drill a hole in your brain, and**
P: (interrupts) Absolutely, Yeah, I probably would, yeah.
I: Uh, huh.
P: Too late in the game now.

Of course, good judgment is required to assess whether an interviewer's indirect repair statement actually conforms to what the participant wanted to express. In the example above, the participant's agreement and further elaboration to the interviewer's repair is evidence that her age is a reason for not not agreeing to be involved in the research. Elaborating on a response to repair is stronger evidence of understanding than validating the interviewer's statement with "yes" or "no."

STANDARD 3: APPRECIATION

The third ability necessary to decision-making capacity is the ability to appreciate a situation and its consequences. This ability is related to understanding, but requires further insight into the implications that information about a disease, treatment, or research protocol has for one's own situation.[22] Dementia is a somewhat unique condition in that the disease itself affects the sufferer's ability to appreciate that she or he has a problem. Subjects with dementia may have trouble distinguishing treatment procedures or research relating to their dementia from those relating to other diseases from which they also suffer, especially if the procedures are similar (for example, a blood draw). These participants might understand the procedure of blood drawing, but not appreciate the context in which this information is relevant to them: for example, unlike the blood that was drawn from them earlier in the day during their medical appointment or in their last visit to their physician, this blood will be used for research and not for their medical care. Contributions in which the participant makes reference to his or her own disease or treatment suggest *appreciation,* while contributions in which the patient denies disease or indicates confusion about which disease is being discussed would evidence lack of appreciation.

Aside from demonstrating knowledge of one's disease, how does one evidence appreciation during a conversation? For evidence of appreciation, we turn to the highest level of evidence from our hierarchy, a new idea compatible with the previous presentations, and not merely paraphrasing. *Acceptances* that successfully demonstrate this property are often strong evidence of appreciation. These types of presentations stand out, so much so that when one hears them in the course of an informed consent conversation, it is like a light bulb switching on signaling that the participant "got it." Given the dramatic nature of this evidence of appreciation, we named them *Aha contributions* (an example follows in which the *Aha* contribution is in bold-face type).

I: As part of a research project, do you think you would give permission for a tube of blood to be drawn from you?

P: Mmm hmm.
I: Can you please tell me a little bit about why you would give permission?
P: **Because if it would help somebody else with their memory I knew that would be a, that would be really wonderful because right now, I need help with MY memory and I think if I could help somebody else with their memory, why, that would be good.**

These *Aha* presentations occur as a next relevant contribution, and are statements in which participants verbalize appreciation of the consequences of their decision, usually by explaining how the information applies to them. While these statements may include information from the interviewer's presentation, they are not merely a paraphrasing of the information presented by the interviewer, but involve new ideas. For example, the example above demonstrates a global appreciation of the situation; the subject appreciates that she is agreeing to have blood drawn as part of a research project that will not directly benefit her, but that may benefit others in the future.

STANDARD 4: REASONING

The fourth ability for decision-making capacity is the ability to reason or to manipulate information rationally. Reasoning is defined in this context as the ability to "engage in logical processes when using the information that they understand and appreciate in arriving at a decision."[23] That the reason be rational has been suggested as a criterion,[24] but this may be too nebulous a concept. Indeed Freedman called this notion "overly paternalistic" as it distinguishes between acceptable (rational) and unacceptable reasons for a decision. Instead, he suggested the term "recognizable reason," which can be identified as containing true premises and a conclusion related to those premises.[25] In our model, we suggest that the participant supply a "recognizable reason" for a decision, and that the reason appear rational to the evaluator. By breaking down a conversation into contributions, these premises and conclusions can be more easily located and judgments may be made about their validity.

Assessing ability to reason can also be enhanced by applying *frame analysis,* which involves "how people align themselves with what is happening environmentally." According to Goffman, conversations occur within "frames of meaning" that are socially defined.[26] When a speaker makes an utterance, that utterance carries with it a frame or context that is normally absorbed into the conversation. When competent speakers change the subject or context, they will usually provide transformational cues to signal a break (for example, "That reminds me. . . .") and/or temporal, geographic, or physiological cues to define the new frame (for example, a *temporal cue:* "Back in the seventies. . . .").

Persons with dementia may not provide the appropriate cues when they shift frames. Bohling speculated that this may occur because of problems with short-term memory and time and space orientation, as well as difficulty in appreciating what one's conversational partner needs to understand and follow the conversation.[27] A speaker's attention to frame and his or her use of appropriate cues when shifting can give important clues to a person's reasoning ability. Below is an example from the DRIPAC interviews of a participant who shifts frames without immediately providing transformational cues or brackets to the new frame (the patient's presentation introducing the new frame is in bold-face type):

I: Would you give permission for someone to draw a tube of blood from you for a research project?
P: I would.
I: You would. OK, can you tell me a little bit about why you would do that?
P: **Well, first of all, I never got hurt in one.**
I: Uh, huh
P: I always the same [?], my family never lost anything or got hurt. . . .
I: Hurt by what?
P: In a fire. Ah, um, er, what do you call that? What did you call that?
I: I said, would you be willing for someone to take a tube of blood from you to come up with a test for Alzheimer's disease?

Here, the participant shifts frames from the blood-drawing situation to a house fire without providing adequate cues. In this example, an uncued frame shift signals lack of ability to evidence sequential reasoning.

DISCUSSION

We have presented a theoretical basis for evaluating decision-making capacity in people with dementia that utilizes discourse analysis, linguistic theory, and established ethical standards to examine what we see as the primary data for this assessment — the words and actions of those involved in the informed consent interaction. This approach acknowledges the uniqueness of the assessment of decision-making capacity as a highly subjective evaluation of an internal state of mastery of explicit standards, and provides a compass for navigating the sometimes confusing terrain of the informed consent conversation with a person with dementia. The field of discourse analysis is extremely useful for illuminating this process on several levels.

An important insight gained from applying discourse analysis to these informed consent conversations is the need for both participants to collaborate in creating the conversation. Thoughtful actions by the interviewer, such as successfully repairing confusing language, can result in the participant being able to evidence mastery of a standard. On the other hand, a participant's repeated inability to repair confusing language could make us more confident in finding him or her to be currently incapable of understanding a particular concept. Sabat argues that repair and probing need to be applied to discourse with persons with dementia by the unimpaired conversational partner, to have a successful conversation.[28] As such, any method for effectively and consistently assessing decision-making capacity of a participant with dementia must necessarily involve instruction for the interviewer in techniques for improving communication with persons with dementia, as well as an assessment of the interviewer's ability to facilitate the communication.

From a research perspective, our theory provides a structure for approaching the informed consent conversation as data. This structure involves breaking down conversations into contributions, creating manageable pieces of information for analysis. It also provides the framework for evaluating these contributions in terms of the evidence they provide of the ethical standards for evaluating decision-making capacity. This theory could be translated into an instrument designed for an extremely close analysis of the informed consent conversation. This instrument would rate every contribution as to the evidence it provides of mastery of each of the four standards. An essential element of this instrument would be an evaluation of the interviewer and his or her ability to inform and respond to the communicative needs of the participant. We have presented our exciting initial results with such an instrument, one that we developed and tested on the DRIPAC data mentioned above.[29] Experimental validation of these concepts by comparing scores on the instrument with the opinion of experts and neuro-psych testing will yield a better understanding of the informed consent process and the ways we judge decision-making capacity.

From a more practical perspective, our approach could be applied to informed consent conversations in real time as a way of adding rigor to the evaluation of decision-making capacity. Interviewers could be taught

Table 5. Aids for Evaluating the Four Abilities in the Course of a Conversation

Choice	Continued attention: eye contact
	Acknowledgment: back channeling
Understanding	Paraphrasing
	Response to probing
	Anaphora
	Need for repair
	Response to repair
Appreciation	Reference to one's disease
	Aha contribution
Reasoning	Frame analysis
	Recognizable reason

the basic principles of discourse analysis to better appreciate what happens in a conversation and to more consciously consider the actual evidence that the participant is supplying. The ideas discussed under operationalizing the standards (see table 5), including linguistic concepts such as indirect repair and frame analysis, can be taught and applied to the discourse of persons with dementia as aids to help evaluate their mastery of the standards related to decision-making capacity. Instead of the usual gestalt impression of decision-making capacity, evaluators can point to specific instances in the informed consent conversation in which evidence for mastery or lack thereof of the four standards was given by the participant.

There are broader applications for discourse analysis in the medical and research setting. This approach could be useful for evaluating decision-making capacity for treatment decisions and could be applied more generally to the research and clinical settings for patients without cognitive impairment. Aspects of discourse analysis could be used for improving and evaluating other clinical encounters that involve conversations such as obtaining a medical history on a patient, as well as discussing difficult topics such as bad news, goals of care, and advance directives. By being more aware of the collaborative nature of conversation and the importance of eliciting evidence of understanding and lack thereof from their patients, clinicians could more effectively communicate with their patients. Clinicians would also become more aware of the importance of signaling their own understanding to their patients (conversational partners) and the importance of repairing misunderstandings on either end. In future articles, we will present the instrument we developed based on the theoretical constructs presented above, along with reliability and validation studies.

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Medical Education

How Can Medical Training and Informed Consent Be Reconciled with Volume-Outcome Data?

David S. Wendler and Seema Shah

Data from hundreds of studies indicate that, for a broad range of procedures, treatment by inexperienced physicians is associated with worse medical outcomes.[1] Because inexperienced physicians often work in low-volume institutions, previous studies did not indicate whether the worse outcomes were a function of the institutions, the clinicians, or some combination of both. More recent data, which separately analyze the impact of inexperienced physicians and low-volume institutions, provide compelling evidence that inexperienced physicians pose increased risks, independent of the institutions in which they happen to practice.[2] One study found that "performance of primary angioplasty by a physician who performed > 10 procedures annually resulted in a savings of 33 lives per 1000 patients treated," a dramatic benefit in regduced mortality that "persisted after risk adjustment."[3] Another study identified "an inverse association between the increasing number of palate repairs undertaken by a surgeon and poor speech outcome."[4]

The impact of physicians' experience on medical outcomes is so great in some cases that inexperienced physicians represent an important risk factor compared to receiving care from an experienced physician. Indeed, some commentators argue that the experience level of the physician is sufficiently important that it should be disclosed to patients.[5] This approach has been adopted in several states, including New York, California, and New Jersey, which now publish medical outcomes by physician for Coronary Artery Bypass Graft (CABG) surgery.[6]

Volume-outcome data also has led numerous commentators to encourage patients to avoid inexperienced physicians: "patients could significantly increase their chances of survival by selecting surgeons who perform

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the operations [cardiovascular procedures and cancer resections] frequently, regardless of the number of such operations performed at their hospitals."[7] The same editorial argues, "the sum of evidence should compel purchasers and health plans to adopt a default position of selective avoidance of very-low-volume providers."[8] The Leap Frog Group, a coalition of purchasers of over $60 billion of health insurance annually, encourages patients to avoid low-volume surgeons.[9] Recommendations that patients avoid inexperienced physicians have the potential to improve patient outcomes and decrease costs. These recommendations also have the potential to inadvertently disrupt medical training.

Numerous commentators, as well as American Medical Association policy, argue that medical trainees should disclose their level of experience to patients.[10] Patients who are informed that they are being treated by an inexperienced physician, and recognize that inexperienced physicians pose increased risks, may insist on an experienced physician, thereby precluding care by a trainee. Similarly, it is not hard to imagine that parents, once informed that surgery by an inexperienced physician is associated with significantly poorer speech outcomes in their children, will insist on an experienced surgeon. Indeed, widely held standards that parents should act in the best interests of their children would seem to require that they respond in this way. Recognizing these possibilities, it is vital to consider steps to ensure that new physicians can be trained in a context of increasing recommendations that patients avoid inexperienced physicians.

IS THE STATUS QUO TENABLE?

What are the policy options for reconciling medical training and informed consent with data that inexperienced physicians pose increased risks? First, one might hope simply that no policy changes will be necessary. Data collected to date focus on inexperienced physicians as a group; they do not show that medical trainees in particular pose increased risks to patients. Hence, current data might seem consistent with informing patients of trainees' experience level without suggesting that trainees pose increased risks to patients. This approach could be supplemented by information that trainees, unlike other inexperienced physicians, often are supervised by more experienced physicians, and typically are limited to relatively uncomplicated cases until their skills improve. These steps may be sufficient to reassure patients and, thereby, ensure the medical profession's long-term capacity to develop experienced physicians.

At the same time, there are reasons to be concerned about the long-term tenability of the status quo. Many recommendations to avoid inexperienced clinicians are aimed at purchasers of healthcare, not individual patients.[11] And these groups, especially for-profit purchasers of healthcare, may not be inclined to give trainees the benefit of the doubt. To save money, they may advise their patients to avoid all inexperienced physicians.

Patients also may not wait until complete evidence is in concerning the relevance of these data to trainees in particular. Would most parents, informed that inexperienced physicians in general have dramatically worse speech outcomes for cleft palate surgery in children, knowingly allow their child to be operated on by an inexperienced trainee? Or will those parents who have a choice insist on the best care possible for their children?[12] The intuition that many parents and adult patients will insist on experienced physicians is supported by a number of studies. One study found that approximately one-third of patients surveyed "did not want learning to take place on themselves by physicians-in-training."[13] Another found that "only a minority of patients would allow medical students to perform their first procedure on them" and "many patients prefer that medical students never perform a procedure on them."[14]

The prospect that many patients may avoid trainees does not preclude the possibility that other patients may continue to agree

to be treated by trainees. And other patients, for instance, those at public clinics, may have few options. As a result, society may be able to continue to train physicians by relying on the good will of some patients and the constrained options of others. Yet the importance of ensuring a steady supply of trained physicians underscores the potential costs of simply hoping the status quo will hold, and failing to consider potential alternatives. Reliance on the good will of some patients and the constrained options of others to train new physicians also raises the potential for exploitation.

Exploitation occurs when some individuals receive an unfair level of benefits as the result of a given interaction. Whether the benefits that individuals receive are fair depends on the risks and burdens they bear as part of the interaction, and the extent to which others benefit from their participation in the interaction.[15] If I employ you in my factory and pay you a paltry wage relative to how hard you work and how much I profit from your efforts, I have provided you with an unfair level of benefits and, thereby, exploited you.

The status quo, which provides the benefit of trained physicians to all by relying on the efforts of some, involves a similar unfair balance of risks and benefits. This approach allows all patients to enjoy the benefits of experienced physicians because a subset of patients agrees to be treated by trainees.[16] This potential for exploitation is especially worrisome, given that it likely falls disproportionately on certain groups.

Influential and highly educated patients are more likely to be aware of the correlation between experience and medical outcomes, and avoid trainees, leaving the burdens of training new physicians to the less educated and less well-connected. It is not hard to imagine, for example, that educated patients are more likely to access, understand, and act on a report entitled *The California Report on Coronary Artery Bypass Surgery: 1997-1998 Hospital Summary Data: Summary Report.* Even prior to publication of physicians' experience, the data reveal that less-educated patients are significantly less aware of the fact that training physicians requires that physicians-in-training learn their skills by practicing on patients.[17]

WHAT ABOUT INEXPERIENCED NON-TRAINEES?

Increasing promulgation of volume-outcome data also has the potential to result in patients avoiding inexperienced physicians who are not trainees, such as those working in rural areas. In these cases, only those who live in rural areas and are unwilling or unable to travel to urban centers may end up being treated by inexperienced physicians. This possibility ultimately may result in a situation in which some physicians are not able to treat sufficient numbers of patients to keep their skills current. Indeed, one study found that physicians who have been in practice for many years "may be at risk for providing lower-quality care."[18]

While this situation raises concern and deserves serious attention, it does not raise the same concerns of societal exploitation that arise in the case of medical trainees. Physicians working in rural areas benefit the individuals living there. In contrast, the system of training physicians benefits everyone in society, raising the potential for exploitation, if physicians receive their training by performing procedures on the poor and uneducated so that everyone in society can enjoy the benefits of experienced physicians. For this reason, we shall leave to the side the issue of inexperienced physicians in general, and focus on the question of how to reconcile physicians' training in particular with the volume-outcome data.

IS NON-DISCLOSURE ACCEPTABLE?

Disclosure and medical training may not be consistent, in the long term, with increasing data on the correlation between outcomes and experience. On these grounds, one might argue that it would be better to adopt a policy

of non-disclosure. Medical training benefits everyone. Thus, it makes sense to argue that everyone should be willing to accept the possible risks associated with training physicians, by adopting regulations that either withhold information from patients on the experience level of their physicians, or preclude patients from choosing their own physician based on level of experience.

This solution might be defended on the grounds that everyone in society benefits from trained physicians; hence, everyone has an obligation to participate in the process of training them. While this looks, in theory, like the beginnings of a promising argument, in practice, in the U.S. at least, it seems a non-starter. Individuals in the U.S. tend to be very skeptical and resistant to programs that restrict their autonomy for the benefit of society in general. Continued accumulation of data on the correlation between experience and medical outcomes may pressure courts to support this approach by acknowledging that physicians' experience level is relevant to informed consent.

In the 1996 case of *Johnson v. Kokemoor*, the court wrote,

> While there may be a general risk of ten percent that a particular surgical procedure will result in paralysis or death, that risk may climb to forty percent when the procedure is performed by a relatively inexperienced surgeon. It defies logic to interpret this statute [of informed consent] as requiring that the first, almost meaningless statistic be divulged to a patient while the second, far more relevant statistic should not be.[19]

As more data are collected, more courts are likely to agree, and some may assume that data on inexperienced physicians applies to inexperienced trainees. Hence, non-disclosure may place medical trainees and their institutions in legal jeopardy. In March 1996, the Wisconsin Supreme Court upheld the jury verdict in *Johnson v. Kokemoor*, and the parties settled for $6.2 million in damages.[20]

Finally, a number of organizations are making concerted efforts to inform patients that less-experienced physicians pose increased risks for many procedures.[21] These efforts, in a context in which medical trainees do not disclose their lack of experience, may lead patients to question whether their physicians are being honest with them. Eventually, non-disclosure may undercut the public's trust in medical professionals.

ARE TRAINEES DIFFERENT THAN INEXPERIENCED PHYSICIANS?

Defenders of the status quo might point out that trainees are unlike other inexperienced physicians in several relevant respects, and these differences imply that trainees' involvement in patient care may not alter the risk-benefit ratio of some procedures. Most importantly, trainees typically are supervised by more-experienced physicians. Moreover, the intense nature of the training period sometimes provides trainees a good deal of experience in a short period of time. Senior residents at busy hospitals, with more experience placing central lines, may be more likely to succeed with the first insertion, and avoid the increased risks of repeated attempts.

In other cases, however, the process of learning by doing that is at the heart of medical training likely poses increased risks to patients. Medical trainees are likely to pose increased risk of pain and infection, despite careful supervision by a trained physician, the first time they attempt placement of a central line. One study found that first-year residents are significantly more likely to have unsuccessful outcomes for a range of procedures, including epidural anesthesia and tracheal intubation, despite careful supervision, including verbal comments and suggestions by an experienced physician.[22] Similarly, supervision of trainees' medication orders does not always occur in real time, leaving patients at increased risk of mistakes. And, in the often busy and confusing world of real-life medicine, supervision of trainees does not always take place as planned. Data from the United

Kingdom suggest that "a fifth of all operations performed during weekday evenings and 7% during the day were done by apparently unsupervised senior house officers."[23]

COLLECTING DATA AND DISCLOSING IT TO PATIENTS

Patients should be informed when trainees pose significantly increased likelihood of minor harms, such as temporary pain, or somewhat increased likelihood of serious harm. Although judgment will be required to determine when these thresholds have been exceeded in individual cases, the necessary judgments are no different in principle from the kinds of judgments that are made routinely in clinical practice; for instance, deciding which risks of a particular procedure or medication are sufficiently worrisome that they should be disclosed to patients.

Data will be needed to determine when the risks posed by trainees exceed these thresholds. Because increased risks typically are defined in comparison to the common background or average, data collection should focus on whether medical trainees pose increased risks relative to physicians with the average level of experience for the procedure in question. To collect the data, ongoing assessments of medical outcomes based on physicians' experience could capture whether the practitioner is a trainee. For example, the Alliance for Quality Health Care currently ranks every hospital in New York State based on outcomes, and similar efforts are underway in California, New Jersey, and Pennsylvania.[24]

Systematically identifying when trainees pose significantly increased risks to patients will be a complex task. Patients' outcomes are influenced by a host of interacting factors. Isolating the impact of physicians' training on medical outcomes from these many other factors will be complicated, and will require multiple studies. Granting the difficulty of collecting these data systematically, it is worth noting that, in principle, this assessment is no different from numerous other examples in medicine in which the impact of a single factor is assessed in the context of multiple factors that influence a single outcome. For example, it is clear that numerous environmental, dietary, lifestyle, and genetic factors influence individuals' risk of mortality. Nonetheless, systematic analysis has established that the single factor of smoking increases one's risk of dying.

WHAT TO DO IN THE INTERIM?

It will take decades, at least, to develop complete data on the outcomes for trainees. To take a complicated example, surgery to remove a glioma from the visual cortex might involve medical trainees at numerous steps in the process, from prepping the patient, to making the initial incision, to actually removing the tumor, to closing the incision, to writing orders for follow-up medications. It will take a good deal of data to determine when and to what extent trainees' involvement in these various steps introduces increased risks. To determine how to proceed in the interim, until complete data have been collected, consider an analogous example.

The U.S. Food and Drug Administration (FDA) often faces the question of whether the patients who take a particular drug should be informed of side-effects found in a related drug. To make this assessment, the FDA first attempts to determine precisely what characteristic of the drug causes the side-effects, and whether this characteristic is shared by the related drug. Is a common mechanism of action implicated, or perhaps a moiety not shared with the related drug?

When it remains unclear, after further investigation, why a class of drugs poses a particular risk, the FDA makes a simple assumption. It assumes that the risk applies to all members of the class. For instance, based on data that nucleoside analogs pose risks of lactic acidosis and severe hepatomegaly with steatosis, the FDA required a black box warning for tenovir disoproxil fumate, even though there were no data showing the risks in this specific member of the class of nucleoside analogs.

Standard medical practice suggests, then, that potential risks found in a class are assumed to apply to all the members of the class, absent convincing evidence to the contrary. This standard practice suggests that data on risks posed by inexperienced physicians as a group should be considered relevant and disclosed, in the absence of convincing evidence that trainees do not pose a particular risk found in inexperienced physicians: "If superior outcomes cannot be demonstrated directly, then high volume can, at least for the time being, be used as a proxy for better outcomes."[25]

Presumably, data that inexperienced radiologists pose increased risks of misdiagnoses do not apply to trainees who work in settings where all scans are reviewed by an experienced radiologist before treatment decisions are made. Conversely, as individuals perform challenging tasks repeatedly, they become better at them; the tasks become more familiar, and the quality of the results improves. Hence, data that inexperienced physicians pose increased risks for invasive procedures should be considered relevant to trainees, unless it is clear that the presence of a supervising physician eliminates the otherwise increased risk to the patient.

This same conclusion casts further doubt on the status quo of informing patients of trainees' experience level without informing patients that trainees may pose increased risks. In the absence of compelling evidence to the contrary, the fact that trainees belong to a class that is known to pose increased risks implies that patients should be informed that trainees themselves may also pose increased risks. The fact that this approach seems most consistent with current standards of informed consent provides even more reason to begin considering alternative approaches to reconciling informed consent, physicians' training, and volume-outcome data.

COMPENSATION

How might the training of physicians be reconciled with informed consent when convincing evidence shows that trainees pose significantly increased risks to patients? Notice that disclosure has the potential to undermine medical training, because patients may not accept the increased risks sometimes posed by medical trainees, without compensating benefits. Similarly, non-disclosure has the potential to exploit some patients by placing them at increased risk, without compensating benefits, for the good of society. The important point is that both concerns trace to a lack of compensating benefits, suggesting that it may be worth considering the feasibility of reconciling disclosure with the training of new physicians by findings ways to equalize the risk/benefit profiles presented by medical trainees and experienced physicians.

To the extent possible, it will be important first to minimize the risks posed by medical trainees. Existing supervision of medical trainees by experienced physicians likely reduces the risk-gap for many procedures, and eliminates it for some procedures. Future data on the ways in which trainees pose increased risks may identify other methods to reduce risks.

Supervision and other targeted measures are unlikely to reduce the increased risks posed by medical trainees to a minimal level for all procedures, especially invasive and complicated ones. This suggests that equalizing the risk/benefit profiles of medical trainees and physicians with the average level of experience may require offering compensatory benefits in some cases. To avoid exploitation, patients who undergo procedures that pose significantly increased risks at the hands of trainees should be informed of these risks, and offered compensatory benefits. The benefits offered by teaching hospitals — more experienced senior staff, cutting-edge technology — may compensate for the increased risks medical trainees pose for some procedures.[2]6 In these cases, it should be sufficient to inform patients of the increased benefits offered by teaching hospitals when informing them of the increased risks posed by medical trainees.

This approach will not yield enough trained physicians if patients are able to re-

ceive the benefits of teaching hospitals, yet opt out of being treated by medical trainees. In addition, relying on some patients to agree to be seen by trainees, while others enjoy the benefits of teaching hospital without running the risk of being seen by a trainee, seems unfair. To address these concerns, teaching hospitals might adopt an explicit policy of assigning physicians to patients, precluding patients from insisting on a particular physician based on experience level. This approach would ensure that all those who enjoy the benefits of teaching hospitals also accept the possibility of being seen by a trainee. Prospective patients could then be informed of this practice and offered the option of either accepting it or finding a different hospital.

Future data may indicate that the benefits available at teaching hospitals do not compensate fully for the increased risks that medical trainees pose for more invasive or complicated procedures, such as cardiac surgery. In these cases, additional compensatory benefits could be provided at the level of the units where such procedures are performed. Alternatively, these benefits, or others measures such as reduced insurance rates or free future medical care, could be offered at the individual level to patients who are treated by a medical trainee.

With respect to compensatory benefits that translate into decreased morbidity or mortality, compensatory benefits could be added to directly compensate for these risks. For example, a recent study suggests that each additional patient per nurse is associated with a 7 percent increase in 30-day mortality for surgical patients.[27] Such data, together with data on the increased mortality posed by medical trainees for various procedures, could be used to provide patients with sufficient increases in nursing coverage to ensure an equivalent overall risk/benefit profile.

It is impossible to specify a priori what level of benefits that do not translate directly into decreased morbidity or mortality, such as free future medical care or private suites, will be needed to protect patients from exploitation and ensure a steady supply of trained physicians. If used, these benefits will have to be fine-tuned, with specific benefits added until patients regard the risk/benefit profile of being treated by a medical trainee as comparable to the risk/benefit profile of being treated by a physician with the average level of experience. Focus groups may offer one way to estimate what benefits should be offered initially.

Finally, the choice of compensatory benefits will have to be made in concert with insurance and reimbursement mechanisms. Since society benefits from a steady supply of new physicians, it seems reasonable to expect society to pay for the benefits needed to ensure that new physicians can be trained in a way that respects patients and is non-exploitative.

CONCLUSION

Physicians' experience is now recognized as an important factor in medical outcomes. Based on these data, some commentators argue that physicians' experience level should be disclosed to patients. Other commentators have argued that patients should avoid inexperienced physicians. Taken together, these recommendations may, in the long run, inadvertently undermine the medical profession's ability to train new physicians. One response would be to require that all patients share these risks by agreeing to the possibility of being seen by a medical trainee. Although this approach is supported by the fact that all patients enjoy the benefits of trained physicians, it seems unlikely to be adopted in the U.S., raising the need to consider alternative approaches. One possibility would be to develop and assess a system of providing compensating benefits to patients who agree to be seen by trainees, based on the extent to which trainees pose increased risks for the procedure in question. This approach has the potential to ensure society's long-term capacity to train new physicians; it also has the potential to ensure that society does not exploit some patients in the process of providing the benefit of trained physicians for all patients.

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Religious and Spiritual Concerns in Genetic Testing and Decision Making: An Introduction for Pastoral and Genetic Counselors

Mary Terrell White

Genetic testing, while still considered somewhat of a novelty, is nonetheless firmly established in mainstream medicine. Prenatal genetic testing, newborn screening, disease susceptibility testing, and diagnostic testing are now commonplace, such that at some point many of us can expect to be confronted with decisions involving whether and when we or our children should be tested, and how to respond to test results. Much of what we will want to know will require genetic and medical expertise, which will in most cases be a dominant factor in decision making. Religious values may also play a role in some kinds of decisions, although how and when is less predictable. Clearly, decisions regarding pregnancy termination may be based on religious values, as is evidenced by the abortion debate, and we might assume patients' religious backgrounds may influence their responses to genetic technology. However, a literature search of "religion," "spirituality," and "genetic counseling" reveals remarkably little information as to how religious values contribute to genetic decisions or the attitudes and behaviors of healthcare providers.

Religious values have been shown to be influential in certain kinds of testing decisions,[1] in how people handle the stress raised by genetic information,[2] and in the attitudes of genetics professionals,[3] but such studies are few in number and reveal no consistent patterns. Because genetic testing often raises issues that are, at root, existential, having to do with illness, suffering, loss, and death, we can anticipate that spiritual and religious values will influence how some people respond to genetic information. Spiritual and religious concerns are usually considered the domain of clinical pastoral counselors, who are specifically trained to address these needs in patients, families, and medical staff in hospitals and other healthcare settings. However, at present, pastoral counselors are rarely involved in genetic decisions.

A major study published in 2004 by the Park Ridge Center for Health, Faith, and Ethics explored the current and potential role of pastoral counselors in counseling individuals who face genetic decisions. Among its findings, the study revealed that because most pastoral counselors are unfamiliar with genetics,

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few genetics professionals refer their patients to them; moreover, genetics professionals rarely ask about their patients' spiritual concerns, as they feel they do not have the expertise to do so.[4]

This article is written for both genetics professionals and pastoral counselors who are interested in addressing the religious and spiritual concerns of those who pursue genetic testing. I begin with a brief discussion of the medical, moral, and existential challenges raised by genetic information, and why religious and spiritual concerns are rarely addressed in the care of genetics patients. After a review of basic genetics and types of genetic tests, the rest of the article focuses on the different ways that questions of religious faith and spirituality may arise in the genetics arena, in particular, the charge of "playing God" and responses to grief and loss. I emphasize the variety of religious and spiritual perspectives people may bring to their circumstances and suggest some resources and counseling skills that may be helpful. I write primarily from a Christian perspective; however, much of this discussion may also be useful for adherents of Judaism and Islam.

CHALLENGES OF GENETIC INFORMATION

Genetic tests can be said to include a number of methods of obtaining hereditary information or information about gene function, including taking a patient's family history and conducting laboratory tests for gene products. This discussion focuses primarily on genetic tests that examine human chromosomes or DNA sequences. These tests include prenatal testing, which examines chromosomal structure of developing fetuses *in utero,* tests for specific genotypes that confirm suspected genetic conditions in children and adults, and tests for known or unknown mutations that may identify people at high risk of developing diseases for which they have no symptoms at the time of testing.

While the medical benefits of genetic testing are well understood, testing is medically and morally controversial for a number of reasons:

- It is new, and calls for decisions most of us have never had to make before, some of which are tragic.
- It gives us information about our heritage, our health risks, and certain characteristics of our children that can create new burdens and/or new responsibilities.
- It raises questions about the sources of our identity, personality, and behavior.
- It offers hitherto inconceivable opportunities for reproductive choice by means of selective pregnancy termination based on genetic information, preimplantation genetic diagnosis for the positive selection of genetic traits, or, possibly in the future, by manipulating the genetic characteristics of our offspring.
- Decisions almost always take place in a context of uncertainty. Questions of whether to test, what to test for, when to test, how to interpret test results, and what to do if results indicate a disability or disease risk, all must be answered with inadequate information.

For all of these reasons, genetic testing is ideally accompanied by genetic counseling, a process in which a family's medical history is thoroughly examined, genetic risks are identified, and patients are given an opportunity to explore their questions and alternatives with an informed and supportive professional. Genetic counselors are trained in both genetics and counseling and serve as part of the healthcare team in which they provide the most current information on genetic risks and testing options. Counseling therefore focuses on genetic and medical information, as well as on psychosocial issues that pertain to pre- and post-test genetic decisions. At present, there are approximately 1,200 clinical geneticists in the United States[5] and less than 2,000 genetic counselors.[6] Given the increasing presence of genetic testing in medicine and a shortage of trained genetics professionals in many parts of the country,[7] it is likely that, in the near future, other professionals such as phy-

sicians, nurses, social workers, and pastoral counselors will find themselves counseling individuals and couples faced with genetic decisions.

In contrast to genetic counselors, pastoral counselors are typically trained in theology, psychology, and counseling, with little or no formal exposure to medicine or genetics. Their role is to address the existential, religious, and spiritual concerns that often accompany serious illness, dying, and caregiving. Given their experience in helping patients, families, and medical personnel cope with trauma and adversity, it is reasonable to expect that pastoral counselors could be an important resource for people facing genetic decisions.

The Park Ridge Center study is the first major research effort to examine the current and potential role of pastoral counselors in genetic counseling and testing decisions. Questions explored by the study include the following: (1) whether and how pastoral counselors might help people cope with the spiritual, religious, and ethical questions raised by genetic technologies; (2) what knowledge and skills they would need to acquire, and (3) what professional or institutional boundaries might promote or impede this involvement. The study involved 140 clinical geneticists, genetic counselors, pastoral counselors, and social workers representing 37 states, two Canadian provinces, and a broad range of denominations and minority religions. Participants were divided into 17 focus groups that met via computer-assisted telephone (CAT) interviews, which were audiotaped, transcribed, and analyzed.[8] Findings included the following:

- Genetic counselors were uncertain of the identity and qualifications of pastoral counselors.
- Genetic counselors were reluctant to refer patients to pastoral counselors, because they assumed that pastoral counselors did not understand genetics, and, if misinformed, might encourage inappropriate decisions.
- Genetic counselors feared that pastoral counselors might be too directive, dogmatic, or simplistic regarding the range of possible ethical norms and religious responses.
- Few genetics counselors said they routinely inquired about patients' religious or spiritual values; most said that they felt such questions were intrusive or inappropriate for them, as scientists, to raise.[9]
- Genetic counselors acknowledged that pastoral support for patients coping with grief and loss could be of significant value and that they had much to learn from pastoral counselors about the kinds of language and approaches they could use to explore the religious concerns of those counselled.

Overall, the findings suggest that genetics professionals and pastoral counselors recognize the need for discussion of religious and spiritual issues but are uncertain about each others' knowledge and expertise. This, combined with turf issues and other institutional barriers, interferes with the optimal involvement of pastoral counselors in the care of genetics patients. The study included a number of recommendations that emphasized pastoral counselors' need for education in genetics, genetics professionals' need for training in pastoral counseling, and ultimately greater dialogue and teamwork between them. The present discussion aims to fill in some of the knowledge gaps for both genetics and pastoral counselors, beginning with a review of basic genetics and types of testing.

GENETIC TESTING: OPPORTUNITIES FOR CHOICE AND CONTROL

Most of what we call genetic testing today has to do with the structure and composition of DNA, or deoxyribonucleic acid, which comprises our human genome. DNA consists of long sequences of nucleotide bases that, when coiled tightly during cell division, are visible as chromosomes. Each of our cells contains 23 pairs of chromosomes, one member of each pair inherited from each parent. Specific segments of DNA are responsible for the synthesis of proteins and other regulatory functions

within each cell. Errors in both chromosomal structure and nucleotide sequences, by interfering with cell function, can lead to disability and disease. We can look for these kinds of errors using a variety of genetic testing techniques.

The most common form of genetic testing is amniocentesis, which is a prenatal test that examines fetal cells for chromosomal abnormalities. Amniocentesis is usually recommended for couples who are considered to be at high risk of having a child with a genetic disorder, a determination that is based on the mother's age and medical history, and the couple's family history. The test is performed 12 to 16 weeks into a pregnancy and involves sampling fetal cells from the amniotic fluid surrounding the fetus *in utero.* The cells are then cultured for a few weeks and examined for extra, missing, or translocated chromosomes or pieces of chromosomes. The most common defect involves an extra twenty-first chromosome, a condition known as Down Syndrome. As with all chromosomal defects, the risk increases with maternal age, from roughly one in 1,250 at age 25, to one in 400 at age 35, and one in 30 at age 45.[10] If any chromosomal abnormality is found, the parents may either choose to continue the pregnancy and prepare for a child with special needs, or to terminate the pregnancy. The ethical and psychological issues involved in pregnancy termination at this stage are profound, as the pregnancy will be nearing the end of the first trimester by the time the test results are known. A similar procedure, chorionic villus sampling (CVS), can be performed at about nine weeks, permitting an earlier first-trimester termination if a problem is found. This test takes cells from the chorionic villi — tiny projections on the fetal membrane that eventually becomes the placenta — that are examined for chromosomal defects. Because CVS is thought to carry an increased risk of malformations and spontaneous abortion, amniocentesis is the more common of the two tests.

For prospective parents, the first question is whether or not to accept testing. Because a slight risk of spontaneous abortion accompanies either test, the risk of a birth defect must be weighed against the risks imposed by the test. This can be a hard decision, especially since those for whom the test is recommended often have had difficulty conceiving. Since the risks of a chromosomal abnormality are higher than average for these parents, they may strongly desire reassurance that their child is developing normally. For most prospective parents, prenatal testing offers this reassurance. But those parents for whom the test indicates an abnormality are faced with the decision of whether to continue or terminate the pregnancy. Much of the difficulty of these decisions is that they are usually based on limited or ambiguous information. First, depending on the abnormality, the test may indicate little about the severity of the condition. Some chromosomal abnormalities are relatively benign, others are incompatible with life, and many have a wide range of expression. For the latter disorders, the severity of the disorder cannot be anticipated from the genetic diagnosis alone. If the particular configuration is rare or its effects unknown, the meaning of the finding may be impossible to determine. Diagnosis of a genetic disorder also raises questions about the child's medical needs and prospects: the social, emotional, and financial resources required to raise the child, and the implications for existing children of having a sibling with a disability. Prospective parents may also wonder how others might respond to a decision to continue or terminate the pregnancy. Lastly, it is important to realize that a normal amniocentesis only means that the chromosomes are structurally intact; it does not rule out the possibility of genetic disorders caused by single gene mutations. For all of these reasons, while this test can offer limited reassurance, it by no means eliminates uncertainty.

Other kinds of genetic tests look for mutations — abnormal patterns — in the nucleotide sequences that make up the functional "code" of the human genome. Some of these tests look for specific genes or gene sequences in specific regions of a chromosome; others require analysis of the sequence of the nucle-

otide bases that make up particular chromosomes to search for particular mutations. To date, while the entire human genome has been roughly sequenced, we do not know the purpose of most of the genes, how genes work together, and how genetic, environmental, and behavioral factors can conspire to cause disease. Consequently, single-gene testing is still relatively limited in scope. Nonetheless, these tests may be used to confirm a suspected diagnosis in children or adults, to diagnose late-onset disease susceptibility, or, rarely, to diagnose disease-bearing mutations in embryos created through *in vitro* fertilization prior to implantation. But although single-gene diseases are relatively simple to diagnose, many of them have a wide range of expression, and the severity of symptoms over time cannot be known in advance. Consequently, decisions based on these diagnoses are also accompanied by a great deal of uncertainty.

The majority of diseases are multifactorial, caused by a combination of genetic, environmental, and behavioral factors. Genetic tests for susceptibility to these diseases are also limited; those that exist vary in predictive value, depending on what is known about the mutation in question — its frequency in the population and variation in expression — as well as the quality of the test. Moreover, because the diseases are also influenced by behavioral and environmental factors, it is sometimes difficult to know what the presence of a mutation signifies. While it is a source of concern, a positive diagnosis may only indicate an increased risk for disease over a lifetime. While risk assessments can be quite high, it is important to remember that they always reflect some number of people with the mutation who will never develop disease. From a psychosocial standpoint, however, testing also carries unknown risks of employment or insurance discrimination as well as potential social or psychological burdens that can compound uncertainty for the decision maker.

For most of us faced with genetic decisions, the sheer novelty of the choices reveal the limitations of our habitual patterns of moral reasoning, especially when there is no clear medically indicated choice. The fact that our genes are tied up with our identity as well as our past and future families challenges our cultural emphasis on individualism and independence, perhaps creating unwanted responsibilities. None of us is comfortable with uncertainty — we know that decisions made without adequate information can be disproportionately influenced by subjective factors, such as optimism, hope, and fear. For all these reasons, many turn to their faith for guidance and comfort when faced with these decisions.

VARIETIES OF RELIGIOUS AND SPIRITUAL EXPERIENCE

In any discussion of spirituality and religion, it is important to avoid assumptions about what constitutes religious belief, spirituality, or what it means to be a person of faith. Generally speaking, "religious beliefs" refer to beliefs that are formally articulated by a recognized religious tradition or faith community. By contrast, "spirituality" represents a personal view of one's relationship with other people, the natural world, and a larger framework of meaning or purpose that may or may not be understood theistically. But while many people identify themselves as denominationally religious — perhaps as a Presbyterian, Seventh Day Adventist, or Roman Catholic — their individual beliefs may have little to do with the doctrines espoused by the traditions with which they identify themselves. For some, religious identity may indeed be a considered reflection of denominational beliefs; for others, it may reflect the faith in which they were raised, the tradition of the community they primarily inhabit, their interest in a particular religious community or religious leader, or the most accessible house of worship in their neighborhood. Moreover, despite statistics that suggest the U.S. population is deeply religious,[11] American culture is still largely secular.[12] While many of our social values have religious origins, few, if any, are articulated in overtly religious terms, and, for most of us, religious language rarely appears outside of church-related activities. As a re-

sult, when faced with situations that provoke religious reflection — often those that involve suffering, loss, and death — many may have difficulty articulating their religious concerns. They may be confused if they find their faith at odds with what they know to be fact, or feel that religious language or categories are not meaningful in their present circumstances. Some may find religious language limiting or oppressive. For these reasons, careproviders must be acutely sensitive to patients' religious and spiritual perspectives, aware that religious identification does not indicate a person's beliefs or preferences, and that questions involving religion and spirituality may not always be framed in clear or obvious language.

That said, across the field of healthcare, the religious beliefs and spiritual orientations of patients and their healthcare providers can powerfully impact both how people respond to their illnesses and what kinds of care are provided. Patients may find their religious beliefs offer hope and strength, or compound their suffering. Physicians may find their motivation for service in their religious beliefs or spiritual values, or may feel their beliefs constrain or inhibit their ability to provide some forms of care. Because individual beliefs take many forms, are generally grounded in faith rather than reason, and may shift with time and circumstances, negotiating their influence in healthcare can be challenging.

PLAYING GOD

Questions of faith and spirituality generally arise in two ways in the genetics arena. The first has to do with the ethical concern that in our use of genetic technologies we are somehow "playing God"; the second encompasses the pastoral issues that accompany genetic testing and decision making, which include grief, suffering, and loss. The charge of playing God is often used to suggest that humans, through our genetic technologies, are exceeding the bounds of what we ought to be doing. Because adverse reactions to new technologies are common and often diminish over time, some may dismiss this charge as stemming from anxiety and fear of change. However, in the context of reproduction, the new choices open to us do suggest powers of design and control that we formerly ascribed to God. As in the abortion debate, some people feel human life is a gift from God; that at every conception God has endowed a new soul with a divine mission, and human interference in who survives to birth is a violation of God's intentions. Similarly, some critics of prenatal testing view selective pregnancy termination as suggesting a kind of "quality control" of the characteristics of children — or a medically sanctioned form of discrimination against people with disabilities or undesired traits.[13] From perhaps a more secular standpoint in Western cultures, some parents may feel that part of the wonder of parenting is the continuing discovery of who their child is becoming, and that unconditional acceptance of one's child is essential if the child is to successfully develop as a unique individual.

Part of the concern underlying charges of playing God is that, as medical technology advances, much of what was once attributed to God, such as control over life and death, has been challenged by medical technology. We can now manipulate and sustain life to a considerable degree; as a result, we sometimes find ourselves confused about where our human capabilities and responsibilities end. At its root, the issue of how much one should control human life, disease, death, and the genome is a moral question about how we perceive ourselves in the world and in relation to God. Here the Christian tradition offers a variety of perspectives. In one view, humans are perceived as God's creation, part of the natural world, and thus subject to the same natural laws as other living things. In another, we stand apart from nature, perhaps as "co-creators" with God or made "in the image of God," and by virtue of our reflective capacities and intelligence, empowered to manipulate nature. These two images often come into play in decisions at the beginning and end of life and are likely to surface in genetic decisions, depending on the decision maker's personal attitudes, values, goals, and beliefs.

Some people may try to discern what counts as playing God in terms of a "natural" versus "unnatural" distinction. But this is also a difficult dichotomy to draw in the medical arena. Many medical treatments are described as unnatural, but most function by harnessing existing biological systems. Vaccines work by stimulating the body's immune system to develop resistance to infectious disease. Assisted reproduction technologies may seem extremely unnatural, but largely consist of manipulating intact biological systems. In fact, there are no medical interventions that are not in some way grounded in natural mechanisms and biological processes. Like the charge of "playing God," the primary purpose of the natural-unnatural distinction seems to be to categorize those technologies of which we approve and disapprove; as a moral guideline, it is otherwise not very illuminating.

Most frequently, charges of playing God refer to events some believe *should* be left to God, to chance, or to nature, even if the means for intervention exist. These are usually life events that are to some extent mysterious and beyond our control — typically those involving life and death. In these contexts, claims that God's powers are infinite serve to remind us of our fallibility and limitations. For example, we hesitate to make beginning or end-of-life decisions for others, knowing our decisions are irreversible and profound and that to be done properly require wisdom beyond our grasp. Similarly, we may recoil at the thought of "designing" children, knowing our attempts at creation are poor imitations of the evolutionary process or the wisdom of God's design. In these contexts, charges of playing God may be useful, reminding us that we are prone to error, bias, arrogance, and ignorance, and that those who would overreach our human limitations are playing with high stakes, with consequences for other lives.

Equally compelling is the belief that God is beneficent, our protector and loyal companion. It is this view that assures us that God is always with us, supporting us, guiding us, and providing us with adequate strength for whatever life delivers. And if God is beneficent, we might assume God also hopes we will do our utmost to help ourselves, to reduce suffering, and to act humanely. Thus it is possible to argue that the effort to control disease by manipulating the human genome is a highly moral activity, and to the extent that our technological capabilities are construed as God-given, we can and should use them to serve God's purposes. Along these lines, advocates of genetic testing may argue testing is morally legitimate if it is done out of a loving impulse, such as trying to maximize a child's opportunities in a highly competitive world. Some may feel testing is socially responsible if it enables parents to avoid burdening the world with the suffering and expense of a disabled child. Noticeably, framing our capabilities as God-given fails to set any moral guidelines on how much manipulation of human life is acceptable, suggesting that if something can be done that will benefit others, there is no reason why it shouldn't be done.

PASTORAL CONCERNS

Once the decision is made to go forward with genetic testing, there is always a risk that testing will bring unfavorable results. In the prenatal arena, when faced with a choice between continuing or terminating a pregnancy, most parents want to find out all they can about what the disorder would mean for their future child and their family. They may want to meet children with the same diagnosis and speak with their parents. They may need financial advice and psychological support. Possible resources include advocacy organizations for the the genetic disorder, support groups, and genetics specialists. Pastoral counselors who wish to address genetic concerns need to know what and where these resources are in their communities. Prospective parents may wish to evaluate their emotional, social, and spiritual resources, and whether they feel they have the strength, support, and faith to raise the child. They may reconsider their feelings about abortion and worry about how their family, friends, and religious communities may react. They will undoubtedly

worry about what the future might bring for the child, knowing that life is, at some level, always a struggle, but that it may be harder for those who are different or disabled.

Genetic and pastoral counselors can be a tremendous help to parents grappling with these questions. Specifically, they can help parents identify their psychological, social, and spiritual resources, seek to dispel any misperceptions about the cause or effects of a genetic abnormality, and minimize destructive thought patterns such as guilt or blame. But counselors also need to know their limitations. If pastoral counselors do not understand the mechanics of genetics or the significance of a diagnosis, they need to enlist the help of people who do. If a genetic counselor feels ill-equipped to assess or address spiritual concerns, she or he should be prepared to refer to a trusted pastoral counselor.

How a counselor offers his or her counsel is a central question. Since its inception, the genetic counseling profession has been committed to being nondirective, meaning that counselors provide information and support but not advice, unless there are clear medical reasons to recommend a certain choice. In this way, counselors hope to avoid coercion and maximize the chances that decisions made will be ones their clients can live with.[14] A significant point of disagreement noted in the Park Ridge study was whether counseling should be directive or nondirective. Genetic counselors repeatedly voiced concern that pastoral counselors might be rigidly dogmatic and impose their religious values on their clients. Conversely, some pastoral counselors felt that the people in their faith communities want and expect directive guidance.[15] While some counselors agreed that some patients are comforted when their decisions are approved by their religious authorities, respect for autonomy is likely to remain the foundational ethical principle in genetic counseling. That said, some flexibility for patients that clearly wish directive guidance may be advisable.

The overriding message from participants in the Park Ridge study is that counselors — whether genetic or pastoral by training — must be sensitive to the needs of those counselled, and remain flexible in their responses, which precludes easy retreat to dogmatic answers. For people of faith, one of the most intractable questions is why an omnipotent and loving God would permit suffering and death, especially of children and premature or newborn infants. Traditional responses are often unsatisfying or oppressive, including notions of sin, blame, and destiny, or the mystery of God's wisdom or design. Rather than, or in addition to, appeals to traditional theological explanations, counselors may wish to explore how patients interpret their loss, taking special care to dispel destructive interpretations such as those that would impose burdens of guilt. It may be helpful to ask patients how (or if) faith in God can provide hope in times of crisis and loss, or to ask what they feel their faith requires of them in terms of a response. It may also be worthwhile to discuss notions of natural error. Approximately one in every 28 children born has some kind of birth defect due to a variety of genetic defects, developmental errors, and environmental factors.[16] Moreover, there is a long path between conception and a living, healthy baby, such that more than half of conceptions, perhaps up to 80 percent, do not result in the birth of a child.[17] This is nature's way of correcting mistakes. That mistakes are a natural occurrence is something many people, when stricken with grief and remorse, may fail to appreciate.

Similar questions arise in genetic testing of children and adults, which is usually done to confirm a suspected diagnosis or to identify people at high risk of hereditary disease. Testing in these circumstances is usually a considered decision, made with the understanding that an underlying risk exists. While reassurance that one does not carry a suspected mutation is often sought, most patients are aware that test results may carry bad news. As in much of medicine, after receiving unexpected and disappointing news, patients' first reactions may include shock, grief, guilt, and confusion. Many will attempt to answer the universal questions: "Why me?" "Why now?" "What did I do wrong?" They may turn

to their faith to ask, "Why is God doing this to me?" "What should I do now?" "What does God want me to do?" It is not uncommon for people to blame themselves when facing bad news, to assume the diagnosis is a consequence or punishment for some act of stupidity or moral flaw. Or they may blame God, angry that a supposedly powerful God has let this misfortune occur. Or they may simply be morally and theologically confused, wondering if and how their faith can help them. Each person will find a different answer for these questions, drawing on her or his understanding of science and medicine, notions of fate, destiny, or chance, and the person's perception of her or his relationship with God.

Again, God may be construed in a variety of ways. Some may see God as the Ultimate Judge, one who hands out blessings or punishments depending on a person's life choices. Those who perceive God as such may blame themselves for their misfortune, feeling that their diagnosis is a response to some prior fault or action. Or God may be seen as omnipotent and omniscient. Those who feel this way may accept their misfortune, but have trouble understanding why an all-powerful God permits suffering to happen. Or God may represent something like an ideal parent, whose boundless love, support, and wisdom can be counted on through all adversity. Seen this way, some people may accept their suffering with confidence that there is a purpose for it, and that, with God's help, they will get through it. There are many variations on these perspectives, but it is likely that, if pressed, most people will have a difficult time articulating their beliefs about God and why a God that is claimed to be omnipotent, merciful, and beneficent would permit humans to suffer. The counselor's task is to help patients explore their questions and beliefs as constructively as possible. This may entail finding images of God that provide strength, hope, and forgiveness as necessary, clarifying medical or biological mechanisms, and providing rational explanations when appropriate. Doing this well requires counselors to take time with patients to search for their primary concerns and a religious or spiritual perspective that best meets their needs.

The Park Ridge study participants made a number of recommendations for pastoral counselors. In addition to substantial training in genetics, these included counseling skills such as being a "good listener," being compassionate and patient with the patient's decision-making process, knowing individuals and families well, and supporting them as they make difficult decisions and deal with loss. They also encouraged counselors to "meet people where they are," to ask them what meaning they find in their situation, and to be "open and teachable." Valued skills of pastoral counselors include the ability to conduct religious assessments and rituals, helping people draw on their religious beliefs to make sense of their circumstances, interpreting and affirming patients' decisions in view of their religious background, and helping them cope with tragedy and loss. Correspondingly, genetic counselors were encouraged to learn about different religious belief systems, how to conduct a spiritual assessment, and how to use language and religious frameworks effectively to explore patients' spiritual needs.[18] Beyond that, integration of pastoral care into genetics services requires that genetic counselors become acquainted with qualified pastoral counselors and be willing to make appropriate referrals. In short, both groups recognized that each could benefit from better understanding of the skills and expertise of the other. But, while the study recommendations clearly called for flexibility and responsiveness to individual needs, there was lingering disagreement over if and when counseling may be appropriately directive. Both genetic and pastoral counselors may wish to be cautious about directive counseling, but remain open to the possibility that some people expect and appreciate guidance and affirmation.

CONCLUSION

Religious and spiritual frameworks have long provided comfort and strength for people

in adversity. The questions they address — "Why do we live? Why do we suffer? Why do we die?" — are universal, existential, and cannot be satisfactorily answered by science and reason. This article introduces some of the ways that religious questions may arise in the genetics arena, but there are many variants on these themes and many other faith-related questions that have been neglected. The range of religions represented in the U.S. and the diversity of interpretations within each one makes it extremely difficult to generalize how counselors might address questions of faith and spirituality. But being acquainted with the kinds of questions that commonly arise, and prepared with the knowledge, language, and tools necessary to explore these questions, will better enable both pastoral and genetic counselors to offer comfort and support for their patients as they grapple with some of the most challenging circumstances in their lives.

NOTES

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2. L.A Keenan et al., "Family Environments of Women Seeking BRCA1/BRCA2 Genetic Mutations Testing: An Exploratory Analysis," *Journal of Genetic Counseling* 13, no. 2 (April 2004): 157-76.

3. F.A. Poppelaars et al., "Attitudes of Potential Providers toward Preconceptual Cystic Fibrosis Carrier Screening," *Journal of Genetic Counseling* 12, no. 6 (February 2004): 31-44; M.A. Albar, "Ethical Considerations in the Preventions and Management of Genetic Disorders with Special Emphasis on Religious Considerations," *Saudi Medical Journal* 23, no. 6 (June 2002): 627-32.

4. P.J. Boyle, "Genetics and Pastoral Counseling: A Special Report," *Second Opinion* 11 (April 2004): 4-58.

5. According to the American Board of Medical Genetics, as of 2002 there were 1,226 boarded (MD or PhD) clinical geneticists, *http://genetics. faseb.org/genetics/abmg/abmgmenu.htm*.

6. See note 4 above.

7. National Society of Genetic Counselors, *Education, Certification and Regional Representation Statistics: Membership Data Base* (Wallingford, Pa.: National Society of Genetic Counselors, 1998); see note 4 above.

8. See note 4 above.

9. Ibid.

10. March of Dimes, *www.marchofdimes.com,* accessed 1 June 2005.

11. Of 1,000 adults, 90 percent claimed to believe in God, 55 percent said religion is "very important" in their lives, and 29 percent said it was "fairly important" to them. Gallup Poll, May 2004, *www.pollingreport.com/religion.htm*.

12. Of 1,000 adults, only 28 percent reported attending a church or synagogue "at least once a week," and 31 percent reported that they "seldom" attended. Ibid.

13. B.K. Rothman, *The Tentative Pregnancy: Prenatal Diagnosis and the Future of Motherhood* (New York: Viking, 1986); G. McGee, *The Perfect Baby: A Pragmatic Approach* (Lanham, Md.: Rowman and Littlefield, 1997); T. Duster, *Backdoor to Eugenics* (New York: Routledge, 2003).

14. L.J. Ciarleglio et al., "Genetic Counseling throughout the Life Cycle," *Journal of Clinical Investigation* 112, no. 9 (November 2003): 1280-6.

15. See note 4 above.

16. See note 10 above.

17. John Opitz, MD, Professor of Pediatrics, Human Genetics, and Obstetrics/Gynecology, School of Medicine, University of Utah, testifying before the President's Council on Bioethics, 16 January 2003 on the rate of natural embryo loss, stated: "Estimates range all the way from 60 percent to 80 percent of the very earliest stages, cleavage stages, for example, that are lost." *http://bioethics.gov/transcripts/jan03/session1.html;* see also E.R. Norwitz, D.J. Schust, and S.J. Fisher, "Implantation and the Survival of Early Pregnancy," *New England Journal of Medicine* 345, no. 19 (2001): 1400-9.

18. See note 4 above.

Ethics Consultation

Evaluating the Outcomes of Ethics Consultation

J.M. Craig and Thomas May

First motivated by cases involving high-profile debates (such as *Quinlan*[1] and *Cruzan*[2]), the practice of ethics consultation has become integrated into daily care, and a "mechanism for addressing ethical issues" is now explicitly required by accrediting bodies.[3] Because of this integration, there is a growing need to evaluate ethics consultation and to establish criteria for effectiveness. One of the key characteristics of successful interdisciplinary team approaches in a clinical setting is the establishment of "clear goals with measurable outcomes."[4] Ethics consultants themselves are aware of this need to evaluate effectiveness. Most strive to achieve the most morally appropriate resolution to value conflict. It is important to know, then, which components or methods of ethics consultation yield positive results.[5] As bioethicists, we are well aware of the theoretical goods such services might achieve, but should insist on evidence regarding the effectiveness of ethics consultation relative to these goods.[6] Additionally, ethics consultants should be held accountable for their recommendations, and standards are needed to judge the merit of the work any particular consultant does. This concern is especially important because ethics consultation represents a new and relatively mysterious service for many clinicians, administrators, patients, and patients' families. Lack of familiarity with this service can result in evaluating the service on the basis of inappropriate criteria. Perhaps the most important reason offered in support of the need for evaluating ethics consultation, however, is that sustaining the viability of this service may require a demonstration of its value. In the words of Ellen Fox and Robert Arnold, "In this era of escalating healthcare costs, health planners, policy makers, and administrators are increasingly demanding that providers justify the resources they expend by demonstrating measurable results."[7]

In this article, we argue that while all attempts to evaluate ethics consultation will have their share of problems (for reasons we expound upon herein), some proposals are more problematic than others. We appreciate the need for, and advantages of, quantifiable

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measures of evaluation, but we must stress that these quantifiable measures represent contingent (or contextual) values. It would be problematic indeed to mistake outcome measures that are characteristic of clinical medicine or the social sciences for the true goals of ethics consultation because they are related to the goals of ethics consultation and are more easily measured. To see this more clearly, consider the relative ease with which one might measure such things as length of stay in the intensive care unit (ICU), number of hours on a ventilator, patients' satisfaction scores, et cetera, versus such things as the promotion of moral values, clarification and respect of patients' and providers' values, optimizing good decision making, et cetera. Further, we worry that the emerging trends in evaluation of ethics consultation, focusing either on empirical data such as costs, or more subjective data, such as satisfaction scores, run the risk of undermining the project of ethics consultation, or winning favor among certain parties (such as hospital administrators) for the wrong reasons. We register our concerns here.

Existing literature evaluating the effectiveness of ethics consultation can be grouped into three categories: first, there is a literature on the theoretical justification of ethics consultation,[8] which explores the nature, role, and methods of this service and proposes to evaluate it in terms of justified theoretical goals. This literature primarily focuses on issues of justifiable process, neglecting to provide an evaluation mechanism for the outcomes resulting from this process. Since here we are concerned with evaluation of the outcomes of ethics consultation, we will not offer a critique of this "meta-literature." Second, there is a small literature on the effect of ethics consultation on patients', families', or health workers' satisfaction.[9] This literature attempts to measure either how helpful ethics consultation was perceived to be, or how satisfied one or more of the parties involved were with the process or recommendations made. While attempts to measure satisfaction have a history in clinical medicine,[10] many of the studies concerning satisfaction for ethics consultation utilize samples too small to draw statistically sound conclusions or have other methodological flaws that prevent general conclusions regarding ethics consultation from being drawn. In our opinion, the most significant problem with this approach, however, is that "satisfaction," by itself, may not be an appropriate criterion for evaluating the success of ethics consultation, as we discuss below. Finally, there is a small but growing literature looking at the effect of ethics consultation on clinical outcomes, evaluating ethics consultation in light of these outcomes. It is this literature we are most concerned with here.

Measurement of effects on clinical outcomes have, unsurprisingly, been a domain dominated by interest in standardized, empirical criteria. As Fox and Arnold observe, "Outcomes research is the accepted method for establishing the utility of health services."[11] This observation is significant for two reasons. First, outcome research relies, unsurprisingly, on quantifiable measures that may reflect traditional goals in medicine quite appropriately, but may not fit the goals of ethics consultation. This fact may have contributed, in part, to the selection of criteria employed to evaluate the effectiveness of ethics consultation, creating problems for this evaluation, because, by nature, ethics consultation involves contingent empirical goals. Second, because evaluation measures are likely to be taken by hospital administrators (and others) as a demonstration of the worth of ethics consultation, it is of paramount importance that we take care to frame criteria for evaluation that does not undermine the basic nature of the service.

The need to evaluate ethics consultation is not easy to address due to the nature of the intervention itself, and the contingency of specific measurable goals for ethics consultation. Fundamentally (and historically), ethics consultation is concerned with value conflicts as they arise in the acute patient care setting,[12] but measuring success in the resolution of a value conflict is no inconsequential task. This

is true because moral and social values like liberty, autonomy, and beneficence (to name just a few) are not easily calculated, quantified, or exchanged. Indeed, it has been argued that many such values are incommensurable, which might suggest any attempt to quantify and balance at this level is doomed.[13]

Prior attempts to measure the outcomes of ethics consultation have focused on outcomes that are not, and should not, be the central aim of ethics consultation itself. While we acknowledge the value of the outcomes in question (which we examine in detail below), these outcomes are valuable only in certain specified circumstances (that is, the value of these outcomes is contingent), a feature not explicitly recognized in attempts to evaluate ethics consultation. To avoid evaluation criteria that undermine the basic nature of ethics consultation, the contingency of practical outcome values must be recognized and accounted for. Any attempt to evaluate ethics consultation, then, must proceed very carefully.

Furthermore (and most importantly for our discussion below), it must account for the fact that the strength and relevance of the contingent features of the cases themselves will differ from case to case. An attempt to universally define the value of a treatment option (for example, developing a universal concept of "nonbeneficial" as we discuss below), will surely encounter problems if it is defined in any terms other than purely physiological. To evaluate the success of ethics consultation, then, it is necessary to appeal to a criteria system that allows for the contingent nature of practical goals and their relationship to the more general or fundamental goals of ethics consultation. First, at a practical level, what ethics consultation is meant to do will itself differ from case to case. Typically, the goals of ethics consultation might include:

- To help clarify and articulate patients' preferences,
- To bridge the gap between patients' preferences and reality when there is a discrepancy,
- To ensure respect for individuals' values among not only patients and their families, but providers as well,
- To reduce moral distress among all parties,
- To optimize good decision making.

It is important to note that, in one instance ethics consultation may be meant to help resolve conflict between family and physician, while, in another, it may be meant to help identify what would be in the best interests of a nonresponsive patient. What is important in most instances is that the ethics consultation respond to the problem for which the ethicist was consulted.

Second, the criteria used to measure success for any of the goals described above will themselves will serve as "placeholders," whose content will be filled in by reference to specific features of a particular case. For example, the content of the specific criteria used to measure the success of "ensuring respect for individuals' values" will be contingent on the specific values of the patient and/or other parties involved.

The "dual contingency" just described creates problems for many attempts to measure the success of ethics consultation, as we will discuss below. Nonetheless, if we are to examine the impact of ethics consultation, it is important to know whether the lofty ambitions of this enterprise are met. It is possible, for example, that we find ethics consultation does not contribute to realization of the goals that justify it, or even is counterproductive in the context of these goals. A 1995 Conference on Evaluation of Case Consultation in Clinical Ethics identified, as a major problem, the paucity of empirical literature measuring these effects, a relative paucity that continues to exist.[14] This paucity, however, exists for a reason: ethics consultation is unlike most other interventions in the clinical setting, requiring criteria that are difficult to translate into empirical measures. While we believe that the empirical studies that have attempted to measure the success of ethics consultation do have

value, it is very important to recognize that the results of these studies must be mitigated by an appreciation of their contingent nature.

MEASURING THE OUTCOMES OF ETHICS CONSULTATION

As noted above, one reason for evaluating ethics consultation in terms of outcome research is that this is the accepted method of clinical evaluation. As a patient care service meant to influence the formulation of treatment plans in a hospital setting, there is a temptation to evaluate clinical ethics consultation according to criteria used to evaluate more traditional clinical interventions. In this context, as Ann Mills, Patricia Tereskerz, and Walt Davis have observed, "Evaluation of consultation outcomes has generally followed the familiar cost and quality approach."[15] Economic criteria for evaluating ethics consultation, Matthew Bacchetta and Joseph Fins argue, "helps administrators compare the value of one clinical activity to another."[16] As Fox and Tulsky observe concerning the increasing pressure for ethics consultants to demonstrate their worth: "What . . . will it take to convince others that ethics consultation is worthy of support? One approach would be to show that by reducing expenditures for unwanted and wasteful resources, ethics consultation can save money for institutions."[17]

This trend is clear in a recent study by Schneiderman and colleagues published in *Journal of the American Medical Association.*[18] The study compared ICU days, hospital days, and use of life-sustaining treatments for patients who did not survive to discharge (as well as mortality for those who did survive to discharge) in two groups: those offered ethics consultation, and those who received "usual care." The stated objective of the study was to determine if ethics consultation in an intensive care setting would reduce the use of life-sustaining treatments for patients who failed to survive to discharge, and, at the same time, measure whether there was a significant effect on mortality for patients overall. The study also incorporated a measure of physicians' and families' perceptions of the helpfulness of ethics consultation. This is not the first attempt to discuss the impact of ethics consultation in terms of objective, measurable outcomes. Dowdy and colleagues examined the effect of proactive ethics consultation on documented patient care communications and on decisions regarding high-risk intensive care unit patients in terms of frequency of communications, frequency of decisions to forego life-sustaining treatment, and on reduced length of stay for ICU patients on continuous mechanical ventilation for more than 96 hours.[19] The SUPPORT study, while it did not utilize the mechanism of ethics consultation, did look at issues commonly associated with ethics consultation. These included attention to DNR (do-not-resuscitate) orders, patients' and physicians' agreement on preferences to withhold resuscitation, days spent in an ICU receiving mechanical ventilation or comatose before death, frequency and severity of pain, and hospital resource use.[20]

The study by Schneiderman and colleagues offers an examination of the effects of ethics consultation in quantifiable terms that demonstrate the contribution of such a service to goals that are easily identifiable for clinical medicine more generally. In this, the overall goal of the study project is laudable: as we discussed above, there is an imminent need to measure the effects of ethics consultation so that we are better able to evaluate and improve such services. A problem arises, however, concerning the specific criteria that should be employed within this method of assessment. As Tulsky and Stocking observe, "one challenge limiting investigation in this field has been identifying suitable study designs. Ethics consultation differs significantly from drugs and medical procedures for which a wealth of evaluation techniques exist."[21]

Tulsky and Stocking do not elaborate on the ways in which ethics consultation differs from traditional medical interventions; indeed, to facilitate much needed research in the area, they focus on the similarities that

might allow lessons to be drawn from outcome research in these other areas. However, identification of these differences (and, most importantly, their relevance for the acceptability of criteria that could be used to measure the effectiveness of ethics consultation), is crucial to the creation of study designs. Below, we will first examine our concerns with the most recent study to evaluate ethics consultation (that of Schneiderman and colleagues), then turn to the broader problems faced by attempts to measure the effectiveness of ethics consultation that ground these specific concerns.

THE CONTINGENCY OF BENEFIT

In assessing the attempt by Schneiderman and colleagues to measure the effectiveness of ethics consultation, our first concern relates to their assumption that the hospital days and treatments provided to patients who did not survive to discharge were "nonbeneficial." According to the authors, the assumption is that since an outcome of death before discharge represents "a failure to achieve a fundamental goal of medicine," continued intervention (administration of antibiotics, ventilator support, tube feedings, and so forth) leading to such outcomes is "nonbeneficial." If such treatment is in fact nonbeneficial, reducing the extent of the intervention is "good" for a number of reasons; the burdensome aspects of continued nonbeneficial treatment have been extensively documented and discussed in the literature.[22] However, this assumption is extremely problematic. It is not always the case that treatments provided to those who fail to survive to discharge are nonbeneficial or unwarranted. As can be seen in the bioethics literature, assessing "benefit" is quite complex, and must include a consideration of the effect of treatment on a patient's quality of life.[23] In this, benefit cannot be assessed simply on the basis of survival to discharge (although this is important). Pain medications for terminal patients are the clearest example of treatment provided to patients who will not survive to discharge, but that are universally seen as benefiting the patient. Scheiderman and colleagues would likely point to the fact that the goal of pain medication in these circumstances is realized, and thus such medications are beneficial, while the goal of ICU days, ventilator support, et cetera is to lead to discharge from the hospital. But is this always the case? Cannot aggressive intervention at times be meant to accomplish goals that do not depend on survival to discharge, but that do allow the patient to experience benefit? We believe it can.

Consider a case in which a patient in her mid-sixties, with a history of chronic COPD, diabetes, cardiomyopathy, and ventricular arrhythmia, is admitted to the ICU, suffering from respiratory failure and T5 & T6 fractures after falling. It is likely that she will need long-term ventilator support. Several years earlier, she had made the decision to have cardiopulmonary resuscitation (CPR) withheld (DNR), and stated that she did not want her life to be prolonged through ventilator support if the time should come that such support would be long-term. She has even taken the steps of making future hospice arrangements. Upon the current admission, however, she has requested that her code status be changed to "full-code," and that ventilator support be continued. She has been intermittently confused but was believed to be decisionally capable when she requested reversal of code status. The physician in charge of the case is uncomfortable with these requests for several reasons. First, he does not believe that the treatment (CPR) will benefit the patient, as the patient is unlikely to improve to the point that she could be discharged from the hospital, and would likely not leave the ICU. Second, he believes that her wishes, as stated prior to the current admission, are more reflective of her deeper values, and that her current change in attitude may simply reflect fear, or, perhaps, confusion. He believes counseling and support are more appropriate than ventilator support. An ethics consultation is called. In the course of investigating the patient's values, it emerges that the reason for her change in attitude is that her daughter is pregnant, and will

likely give birth in about four weeks. The patient would like to stay alive to see the birth of her only grandchild, even if that means chronic ventilator support and aggressive medical interventions. The physician remains uncomfortable with this approach, as he believes she will not survive for even that time frame, but better understands the patient's concerns.

The above case lacks the complex features that characterize most ethics consultations, especially in regard to conflicts of deeply held values that lead to intractable disagreement. Indeed, the case above may be nothing more than a simple communication problem. However, it is useful for illustrating the problem at hand because of this very simplicity, which makes the assessment of benefit clear. Most would argue that an appropriate recommendation, if not *the* appropriate recommendation from the ethics consultant in this case, would be to allow the patient to fulfill her wish to see her only grandchild before she dies, even though it is highly unlikely that she will survive to discharge, and even though this recommendation will result in significantly more ICU days and time on the ventilator.

Here, "benefit" to this patient clearly cannot be measured accurately if survival to discharge is a *prerequisite* to the value of ICU and ventilator time in the standard of measurement. In fact, even if she does not survive to actually see her grandchild (in fact failing to attain the "benefit" she desired), a recommendation allowing the patient a *chance* to realize this goal is arguably an appropriate recommendation. In short, the concept of benefit is contingent by nature (to use language we employed earlier, a "placeholder concept" to be filled in by reference to particular cases): whether a treatment "benefits" a patient will depend on what that patient values, as well as that patient's circumstances. At root, because the idea of "benefit" is value-laden, it does not lend itself to the types of standardized criteria for measurement that many clinical intervention outcome studies seek. The criteria employed in the study are a legitimate measure of the success of ethics consultation *only if* ethics consultation is limited to conflicts involving insistence on continued treatment that does not benefit the patient (no values outside mere survival are realizable). However, since the idea of benefit is itself contingent by nature, criteria that does not acknowledge this contingency will not measure the effectiveness of realizing the goals of ethics consultation appropriately. This leads to our second concern: that the criteria employed by Schneiderman and colleagues might lead to the adoption of inappropriate criteria for measuring the effectiveness of ethics consultation.

CAN CRITERIA OF SUCCESS IN ETHICS CONSULTATION BE STANDARDIZED?

To the extent that ethics consultation involves the value-laden task of "assessing benefit to the patient" at a fundamental level (as we believe it should), the ethics intervention will reflect significant differences from outcomes measured in the context of most traditional interventions in the clinical setting. First, the effects measured from most clinical interventions tend to be physiological in terms of what is measured; in this, common standards apply to each person. This means that the outcomes to be measured are not *conceptually* value-laden in regard to effect, but merely value-laden in regard to when that effect is appropriately sought. One need only compare the role of ethics consultation in the task of assessing "benefit" (as described above) to the task of antibiotic administration to see a clear example of how the inherent outcomes of ethics consultation are more conceptually value-laden than that of traditional interventions in the clinical setting, in terms of effects to be measured. For example, whether the goal of killing off a bacteria through the use of an antibiotic is an appropriate goal is an issue that is subject to values (if we do not value the outcome, it is not an appropriate goal); however, whether or not the antibiotic in question actually kills the bacteria in question is not an issue. It is the latter that is the focus of most evaluation of clinical intervention: how effective is this intervention at achieving an

outcome (bracketing the question of when the outcome in question *should be* sought)? Thus, measuring the effect of an antibiotic does not require criteria that accounts for differing patients' values, as the outcome measured is not value-laden at a *conceptual* level. In this, it is amenable to standardized criteria.

Ethics consultation, however, is concerned with the formulation of appropriate outcome goals: in this, it is concerned with value-laden issues as an inherent focus. As articulated in a report published by the American Society for Bioethics and Humanities (ASBH), *Core Competencies for Health Care Ethics Consultation,* "To the extent that consensus exists about the goals of ethics consultation, it is that ethics consultation should facilitate the development of treatment plans that are more consistent with a particular patient's life values and goals."[24] In this respect, the general goal of an ethics consultation may be standardized; however, what *specific* outcome is appropriate will, *necessarily,* change from circumstance to circumstance, and from patient to patient. Thus, ethics consultation will be less amenable to standardized criteria for outcome measurement, since the very outcomes to be measured will be value-dependent.

In addition, the measurement of the effects of traditional clinical interventions normally relate to outcome *goals* that are, empirically, less susceptible to patient-by-patient differences, making these goals more amenable to across-the-board criteria for outcome measurement. The reason for this is that the outcome goals that are measured are normally already assumed to be valued: if they are not, the patient (presumably) would not have accepted the intervention. Thus, universal standards of "good" are more easily established within the more narrow context of patients who have already deemed this intervention to be of value. The goal of a heart transplant, for example, is for an outcome of extended life. This goal normally is consistent across the patient population of transplant recipients. However, the existence of an outcome goal that is clear and consistent (across patients) is not normally the case in regard to ethics consultation. In fact, it is lack of clarity on this very issue that gives rise to ethics consultation: the *Core Competencies for Health Care Ethics Consultation* begins by stating, "Health care ethics consultation is a service provided to . . . address uncertainty or conflict regarding value-laden issues that emerge in health care."[25] Thus, ethics consultation is normally concerned with issues of *establishing what outcomes are valued,* and thus which interventions offer outcomes that are appropriate for a particular patient. Such a goal is, by nature, not amenable to measurement using across-the-board criteria that fail to account for differing values and goals *of particular patients.* Indeed, it is this feature of ethics consultation that grounds our concern with the attempt to deem, for example, days in an ICU or time on a ventilator to be, universally, "nonbeneficial" for patients who do not survive to discharge.

ETHICS CONSULTATION AND COST REDUCTION: AN UNINTENDED SIDE-EFFECT?

There is a very real danger in representing ethics consultation in a way that glosses over the unique and specialized role of ethics in healthcare and that minimizes the fundamental differences between ethics consultation and traditional clinical interventions. Since the benefits that can be assessed through patients' values are contingent by nature, the criteria that are meant to measure effectiveness in the context of benefit must have a contingent dimension if patients' values are to be taken seriously. Thus, the absence of a contingent dimension in the criteria employed by Schneiderman and colleagues can be taken to imply that the goods that are measured take priority over patients' values, rather than being weighed in the context of patients' values. If this is the case, the specific criteria employed by Schneiderman and colleagues further imply that ethics consultation is a mechanism to reduce costs, since ultimately

the criteria reflect these types of concerns. Each of the criteria employed by the study (length of stay, time in the ICU, and time spent on a ventilator) often are associated with hospital costs.[26] Thus, the implied "good" measured by the study in question (given how the criteria employed normally are used) is that of ethics consultation's usefulness as a mechanism that reduces costs through reduction of ICU time, hospital days, use of ventilators, and so forth. It is important to note that we do not wish to claim that this was the position of the authors of the study. Our concern is with the (*likely* unintended) implication that might be drawn from the authors' criteria: that reduction of the use of resources is how ethics consultation contributes value to clinical medicine. Even if ethics consultation *does* have this effect in some cases, our point is that to consider this a goal of ethics consultation is a mistake.

Further, we do not wish to claim that costs are, or should be, at all times irrelevant to ethics consultation. There may well be situations in which justice-related issues of resource allocation, in terms of the value returned for the use of resources, are appropriate dimensions of ethics consultation. In an age of increasing financial crisis within the healthcare system, it is simply not feasible to provide expensive treatments to patients who are unable to benefit, or even to some who might benefit (in all cases).[27] Thus, the reduced use of resources in "nonbeneficial" circumstances would be a positive outcome. However, our point is that, while ethics consultation *should* contribute to the value gained in the use of resources, it should do this *not* through reduction in resource use *per se,* but instead through formulating treatment plans that are more oriented toward goals that are deemed to be valuable. This, in turn, must involve a contingent dimension that incorporates a recognition that "benefit" will be assessed differently, given the values of different patients. In this, the treatment plan that is most appropriate may cause a reduced length of stay, a similar length of stay that is deemed to be more beneficial, or even a longer stay in which significant benefit is present. It may often be the case that ethics consultation causes a reduced use of resources, but this reduction is contingent on the case in question, and should not *itself* be the goal of ethics consultation.

The dangers of "unintended consequences" from using quality assessment tools is problematic throughout clinical medicine.[28] By attempting to measure the effect of ethics consultation through standardized criteria, the danger is one of creating benchmarks for the evaluation of ethics consultation that undermine its very goals.[29] This is true whether the study seeks to use the criteria as a goal, or simply to measure the effect not as a goal, but because of interest in the phenomenon itself. That is, even if one simply wished to measure the effect of ethics consultation on the use of resources without implying that this is a goal, if the effects of ethics consultation on length of stay indicate that it is associated with reduced length of stay, while it does not increase mortality, administrators (and others who are peripherally familiar with ethics consultation) are likely to take this as a benchmark for the contribution of ethics consultation to institutional goals (as other clinical interventions would be evaluated accordingly). This is especially true in an era when hospital services are increasingly required to demonstrate their financial viability or improve efficiency. Once established, however, such a benchmark would clearly provide an incentive for ethics consultation to cause outcomes that contribute to this benchmark. Our point, however, is this: even treatment planning that utilizes similar (or even more) resources than alternative plans, but that aim toward goals that are of more fundamental value, would contribute value to the improved utilization of resources and should be considered successful.

A benchmark of cost reduction might result in bias toward withholding or withdrawing a therapy, because forgoing it would result in a reduced length of stay. This phenomenon was raised as a criticism of a report on a

pilot study that was written by Schneiderman and colleagues[30] several years prior to their study published in *Journal of the American Medical Association:* "The use of 'reducing unwanted and inappropriate treatments' as an outcome measure and the comments in the discussion that the ethics consultation helped in clarifying the legal basis for forgoing treatment suggest that the ethics consultation may have been one-sided, possibly leaning toward persuasion to forgo therapy rather than independently clarifying the views of all parties and recommending their enactment. Would not a measure of 'fulfilling the patient/proxy's expectations' have been an outcome measure more accurately reflecting the true objective of the ethics consultation?"[31] We share the commentators' concern with the potential bias for cost-saving, as well as the general need to incorporate patients' and family members' values into outcome measures, as our previous comments make clear. It is worth noting a potential problem, however, with the suggestion of using "fulfillment of patient/family expectations" as a measure of effectiveness. If the expectations of a family are not appropriate — for example, perhaps they wish for active euthanasia — then the ethics consultant *should not* attempt to fulfill these expectations. It is to this general area of concern that we shall now turn our attention.

MEASURING SATISFACTION WITH ETHICS CONSULTATION

The complexity of the goals of ethics consultation are not only a problem for traditional medical criteria of outcomes measurement, but also for traditional social science criteria. Consider one attempt to evaluate ethics consultation through the satisfaction of patients and family members.[32] This study conducted interviews with patients or surrogates for whom an ethics consultation was provided, within a few weeks after hospital discharge. Using a five-point Likert scale, interviewees were asked if the ethics consultation was helpful to the family, and asked whether the consultation had been helpful or detrimental to the patient (a similar tool was also employed by Schneiderman and colleagues). The authors concluded that ethics consultation had been helpful in a majority of cases, and rarely detrimental.

As was the case with attempts to evaluate ethics consultation through objective outcomes criteria, such as length of stay, attempts to evaluate ethics consultation through traditional "social science" satisfaction criteria can be problematic. In this case, the benchmarks established may provide an incentive to make recommendations that maximize the contentment of one (or both) parties with a recommendation by ethics consultants. Given the fundamental goals of ethics consultation, the ethics consultant should be aligned with no particular party.[33] While, in general, it is a good thing to have patients, families, and healthcare workers express positive attitudes toward ethics consultation, the integrity of the service requires that we separate these attitudes from the consultation process.

In some instances, cases that result in the discontent of one (or more) parties may be cases in which ethics consultation was most needed. Imagine, for example, the case of a severely retarded patient, when the physician believes that the patient's (healthy) baseline quality of life does not warrant aggressive intervention (because he is severely retarded), but family members have grown weary of the "burdens" of caring for him. Imagine that, due to the patient's severe retardation, he is unable to participate in decision making (or, for that matter, offer valid assessment of satisfaction with the ethics consultation process). Both the physician and family, then, believe that lifesaving intervention should be foregone, despite the fact that the patient would be expected to make a full recovery and return to what, for him, is a happy baseline quality of life. The ethics consultant's role may well be one of protecting the patient's access to aggressive intervention that would benefit him, despite the family's and the physician's unhappiness with this recommendation. If

this were the case, the "correct" recommendation *may* result in low satisfaction scores from both the family *and* the physician.

At root, ethics consultation is not about making friends or becoming popular. Indeed, attempting to bring about an appropriate moral outcome can be difficult, inconvenient, and, in some cases, even burdensome. This may, in some cases, lead to bias in the evaluation of the consultation process: assessments of "helpfulness" might be subject to others' perception of ethics consultation's ability to assist in bringing about the outcomes that *they* desire in circumstances where an individual's values are not the appropriate framework for decision making. Here, we do not wish to claim that satisfaction is *irrelevant* to assessing the effectiveness of ethics consultation. Rather, satisfaction *by itself* should not be the basis of assessing ethics consultation, but should be placed in context with the fundamental goals of the intervention. Ethics consultants should seek to help allay moral distress in these circumstances through assistance in understanding the basis of appropriate decision making. This itself *may* lead to perceptions of helpfulness *or* appreciation with the ethics consultation process, which is always desirable. However, satisfaction with the outcome of a decision or a process *per se* is not the outcome goal.

CONCLUSION

It is understandable how some phenomena that are commonly associated with ethics consultation become identified and employed as criteria to evaluate such services. In fact, ethics consultation does (based upon our own observations) seem to result in more withdrawal of treatments that are deemed "nonbeneficial" by patients (rather than continuing contested interventions), and does commonly result in the increased satisfaction of patients and families. This, perhaps, due to circumstances that leave patients and families vulnerable and create power differentials between patients and families and physicians; thus, ethics consultants more often find themselves advocating for patients than not. It is no surprise, then, that evaluations of ethics consultations find these services to be both cost-effective and value-added services.[34] Because both of these phenomena are positive, there is an understandable desire to systematically demonstrate these effects. However, it is important to recognize that these are *contingent* phenomena that are associated with ethics consultation through circumstance, not phenomena that can be *directly* tied to the foundational goals of ethics consultation itself. That is, these goals are appropriate for many, but not all, cases, and have value if properly framed as contingent. If they are allowed to be used as benchmarks for evaluating the effectiveness of ethics consultation, however, "outlying cases" that do not conform to these common phenomena (as described throughout this article) will either evaluate ethics consultation as ineffective when it has been, possibly, its most effective; or will provide incentives for consultants to (consciously or subconsciously) make recommendations that are in line with the benchmarks, rather than with the goals of ethics consultation itself (the worst scenario of all). This is profoundly important when one considers that ethics consultation nearly always involves difficult "outlier cases" in some respect: it is this feature that normally leads to a request for ethics consultation.

One foundational issue we have pointed to concerns the relation of ethics consultation to clinical outcomes *per se.* Here, it may be instructive to consider some issues raised by attempts to measure the effects of spiritual interventions in the clinical setting. Ethics consultation and pastoral care consultations serve different functions in the clinical setting. This is true not only because ethics consultation is grounded in a secular concern with values, but also because ethics consultation is focused on resolving problems in clinical decision making. Nevertheless, as ethical issues involve subjective, normative dimensions that are in some respects analogous to spiritual matters, some lessons may be drawn from attempts to assess spiritual practices in

the acute care setting; the focus of ethics on intangible values shares some characteristics with spiritual matters that are relevant to assessing appropriate evaluation criteria. For example, one study that attempted to measure the clinical effects of prayer[35] met with criticisms that questioned whether the function of prayer is such that it can or should be measured through observable clinical results.[36] Likewise, the role and importance of many values (particularly moral values) in an individual's life may not be readily apparent, observable, or quantifiable.

Furthermore, in circumstances in which intervention can only offer outcomes that are at odds with a patient's values, the patient may reject the intervention to maintain his or her values. Indeed, the value of independence or dignity, for example, may be most apparent when these are threatened or undermined, at which time a person may risk all (including life) to maintain these values. Like prayer, the worth of ethics consultation is not simply a function of its clinical effects. As Ezekiel and Linda Emanuel have observed, there are good reasons for pursuing greater respect of patients' rights and wishes, *even when there will be little or no cost-savings.*[37] Close attention to these important differences leads to significant questions about the suitability of the criteria employed by Schneiderman and colleagues to evaluate ethics consultation.

Attempts to measure the effectiveness of ethics consultation must take into account a variety of complex goals and features, some of which are objective, and some of which are subjective. Studies that focus on one or the other of these do contribute to our understanding, but must be careful not to create other difficulties. Effective measurement studies must find a way to measure quality of life during and after treatment for those patients who receive an ethics consultation, contrasting this to the quality of life for similar patients who do not. To the extent that justice-related allocations of resources are a part of ethics consultation, a mechanism that uses, for example, quality adjusted life years (QALYs) might be employed. Similar difficulties in measuring the effectiveness of complex clinical services have been identified within the hospice movement, which has sought multivariable measurement devices that include both more objective components (for example, pain, functional status) as well as subjective components (such as satisfaction, anxiety).[38] A similar multivariable measurement scheme is surely needed for ethics consultation. Whatever measure is developed, it is important to recognize that the best measure of the success of an ethics consultation is the extent to which it contributes to the creation of treatment plans that are more appropriate for the patient in the contexts described above. While this may at times result in treatment plans that involve reduced length of stay, reduced length of stay should not, itself, be the measure used in evaluating ethics consultation. Nor is the satisfaction of surrogates, family members, or health providers, *per se,* equivalent to the goals described.

NOTES

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Organizational Ethics

Clinical Ethics and the Managerial Revolution in American Healthcare

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INTRODUCTION

The healthcare industry, particularly healthcare delivery organizations, is awash in "quality" movements. Because the techniques, initiatives, and mechanisms associated with the quality movements affect delivery of care, they affect clinical encounters.

This essay will spell out why clinical ethicists and other clinicians should take a closer look at how quality initiatives are implemented in their institutions. To do this, we briefly review important aspects of the American quality movement, its potential impact on the processes of healthcare delivery, and its relevance to clinicians and clinical ethicists. We discuss some of the obstacles to developing quality improvement programs — obstacles that may prevent the appropriate introduction of quality initiatives in healthcare organizations. When these obstacles are ignored in the design of quality programs, the roles and relationships surrounding clinical encounters may become distorted, and impede delivery of quality care. We conclude by suggesting that, in the absence of a fully functioning organizational ethics program, the clinicians and individuals associated with institutional ethics committees should develop or enhance their skills to recognize, understand, and address the potential effects of quality programs on patient care.

Problems in clinical care come to ethics committees in the form of specific impediments to providing care to individual patients. While some ethical issues result from personality clashes or faulty interactions, others stem from misaligned goals within the healthcare organization. Patterns of consults — repeated consults from the same unit, or consults that indicate the same structure of problem — can alert clinical ethicists to structural problems: processes, policies, or procedures that systematically thwart providing excellent care.

Our attention is directed toward quality improvement strategies that may be intro-

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duced by healthcare organizations to improve the processes of delivering healthcare. Strategies and mechanisms that prioritize efficiency over effectiveness may degrade or interfere with human relationships, the exchange of information, and interactions that are central to excellent healthcare.

THE AMERICAN QUALITY MOVEMENT

Quality initiatives, either in manufacturing or service industries, make two key assumptions.[1] The first is that *quality* is defined through customers' expectations. The customer is profiled, so that expectations can be derived, depending on the customer's socioeconomic background. These expectations can then be defined and measured and translated into specific aspects of the product. This definition gives management the tools to develop the accountability mechanisms that are associated with outcomes, that is, answering the question, "Were the customer's expectations met in purchasing the product?"

The second assumption is that, by concentrating on the processes by which a product is produced, and perfecting those processes in light of expectations for it, the quality of the end product will be improved or its cost lowered. In a service industry, often the process is part of the product. For instance, the diner's experience depends as much on the service received as it does on the excellence of the food. Nevertheless, process improvement is a key element in both the manufacturing and the service industries. Expectations give management a precise product to deliver, and so the job of operations management is to continually review processes, and the components of the processes, so that the processes can be improved, and the product will conform to an appropriate standard of quality.[2]

Quality initiatives are often explicitly or implicitly associated with various philosophies of management. Most initiatives are implemented to effect some sort of change in the beliefs and behaviors of the stakeholders of the organization (that is, employees, administrators, managers, consumers).[3] When consistency, uniformity, precision, reliability, standardization, and predictability in performance are the characteristics of excellence in a product, improving processes of production is an engineering task. Deviations can be identified and appropriate corrections made. Because the organization has a precise idea of customers' expectations, by using the techniques derived from the two key assumptions discussed above, an organization can presumably increase its market share by retaining the loyalty of old customers and attracting new customers.[4] It is important to note that these advantages accrue in the context of "free" market competition, in which informed customers may select among competing products whose quality they can judge using their own prioritizations regarding cost and quality — priorities that are known to the producer.

In some service industries, consistency, uniformity, precision, and standardization are also strong criteria for the excellence of the service provided, such as banking or other financial industries. Their application can effect improvements in process, which, in these industries, cannot be divorced from the product. But "quality" is a relational term in several respects: it applies to comparisons with other products that have been designed or intended for the same purpose, and in terms of the adequacy of a product in respect to filling the human needs it is designed to fill. If the criteria and context are carefully enough spelled out, "quality" can become a descriptive term, but it is remarkably uninformative as a descriptive term outside this context.

QUALITY INITIATIVES IN HEALTHCARE

Although some leaders in the healthcare industry have urged the industry to apply quality initiatives to the processes of healthcare for some time,[5] the report, *To Err is Human,* by the Institute of Medicine (IOM), made importation of quality initiatives inevitable.[6] The report ended any debate about the quality of healthcare delivery in the American system by revealing the magnitude of medical error, as well as the variation in treatment

patterns in different localities. Even when the quality of healthcare is poor, its cost is still high, and quality initiatives promise to reduce costs while enhancing quality.[7] Interestingly, and entirely congruent with the philosophy of many quality initiatives, the IOM report was not interested in assigning individual blame for the ineptness of some of the current processes of healthcare delivery.[8] Rather, it noted that much of the variation in quality could be attributed to systemic causes, not human error. It stressed the need for the development of initiatives to highlight, measure, and identify deviations from appropriate care, which was ultimately identified by the IOM as a matter the under use, overuse, or misuse of resources.[9] The use of resources is precisely what quality initiatives promise to control.

It is a truism that the healthcare delivery organization hosts a daunting array of different processes. Some of these processes are mechanical. For instance, billing procedures are expected to proceed in much the same way, time after time. Packing surgical kits, deriving requested lab values and conveying them rapidly and precisely to the requester, scheduling utilization of medical devices or operating room space, are all processes that profit from attention to their efficiency, and we are not concerned with the application of quality initiatives in these areas. In fact, their application, depending on the circumstances, should be encouraged, as efficiency and standardization are characterizations of "quality" services of this type.

But not all healthcare processes are equally mechanical. At the patient-clinician interface, mechanical processes must yield to human interaction, with all the complexity, variability, and unpredictability that characterizes human relationships, exacerbated by a context that is often characterized by uncertainty and vulnerability.

The role of clinical ethics in case consultations is to facilitate the making of difficult decisions. Often consults result from poor communication or the delivery of care that is not in alignment with a patient's values and preferences. Initiatives designed to inhibit communication, or essentially disregard the patient's values and preferences by requiring adherence to a strict process, are of concern to us, as clinicians and as ethics consultants.

Quality improvement initiatives are designed to change the processes through which care is delivered. Since the "product" in healthcare includes the process through which care is delivered, this means that quality initiatives promise to change the clinical encounter, by affecting the roles and relationships that are the context of care. Quality initiatives come in many varieties, of course, and some quality initiatives promise to support these roles and relationships.[10] Others do not. These other initiatives are often rationing devices, "dressed up" as quality control,[11] and their introduction may result in care that is not appropriate.

For instance, a quality initiative may be implemented in the emergency room — ostensibly to reduce waiting time and increase appropriate access. The design of the initiative may include mechanisms that are calculated to measure and control the time that each clinician spends with each patient. But the implementation of such an initiative may be disastrous without backup routines that are designed to accommodate those patients who represent a "deviation" from the usual services provided. Moreover, the role of clinicians and their relationships with both their peers and patients become more automated — controlled as they are through rationing and measurement. Bottlenecks may develop when clinicians do not adhere to a predetermined schedule, and communication between patients and clinicians may become tense, limited, and imprecise.

Or consider the implementation of a quality initiative that supplies a benchmark for treatment, and that includes measurement and accountability mechanisms that are designed to hold the physician accountable for deviations from the benchmark. Even though routines for exceptions may be provided, physicians are confronted with a disincentive to weigh patients' values and preferences when they recommend treatments — especially

when such accountability mechanisms can be used punitively.

One fundamental premise of the quality movement is that an excellent production process will be both effective and efficient. *Efficiency* is a characteristic of a process, and describes how it is done — how safe, rapid, or precise it is. *Effectiveness* is a characteristic of the result of a process or activity. It refers to how satisfactory the result is, whether that result is a product or a service. It is effective if it fulfills the goal of the activity, and its effectiveness is measured in terms of how well it satisfies the recipient or beneficiary, and meets some independent standards of excellence.

There is little doubt that an effective process or service will be even better if it is efficient as well, and all stakeholders in healthcare delivery processes can agree upon this common goal. It is not as obvious that efficiency alone can serve as a criterion of effectiveness. The judgment of the effectiveness of a process or service may be open to more dispute, as the evaluative criteria on which the judgment is made depends, in healthcare, on the place of the evaluator in the system.

HEALTHCARE IS AN ANOMALOUS INDUSTRY

Organizations introduce quality improvement mechanisms to improve healthcare delivery, and care of high quality for a reasonable cost may fairly be seen as an appropriate goal for such an organization. But healthcare organizations are complex, and different stakeholders in the organization — administration, staff, financial directors, physicians, and patients — may have different responsibilities, and thus may prioritize their criteria for what "counts" as "improvement" differently.

Those responsible for the financial viability of the organization must look to cost-control, and many quality initiatives in healthcare were initially borrowed from other industries and introduced on the assumption that improving care processes will automatically reduce costs, without imperiling quality. But, as we noted above, the advantages of balancing the cost/quality conundrum by improving processes accrue in many industries in the context of free-market competition. The challenge of introducing quality initiatives in healthcare is particularly difficult, because of some of the idiosyncrasies in the kind of service industry that healthcare is. It is these idiosyncrasies that may produce ethically unacceptable processes and outcomes in the delivery of care if not allowed for in the design of quality programs. First, there is an imbalance of knowledge between patients and careproviders. Second, there is a split in the "customers" in healthcare (payers and patients), as well as a split in the "providers" (physicians and healthcare delivery organizations).[12] Third, the beneficiary of health services and the raw material of the process of healthcare is the patient, and each patient may have some idiosyncratic characteristics that preclude a uniform approach to the treatment of illness. Fourth, healthcare organizations often do not control their environments.[13] These sources of possible variation create radically different, and sometimes incompatible, criteria in what it means to provide care that is of good quality; and the quality of care may be measured differently, depending upon the evaluator's place in the system — as payer or provider, patient, purchaser, or enrollee.

1. KNOWLEDGE IMBALANCE

The criteria by which physicians or other clinicians judge the effectiveness of a treatment or intervention are subtle and demanding, as is appropriate, considering the difference in knowledge between professionals and their subjects. It is exactly that difference in the knowledge base, inculcated by education, honed by experience, and assured by professional self-regulation, that explains why people seek professional care. An effective intervention is one that achieves the intended outcome. An intervention that fails to achieve the intended outcome may be satisfactory to me as the patient (the staff was courteous, the doctor listened attentively, the tonic tasted fine), but unsatisfactory to the more demand-

ing judgment of my physician or his or her peers. Thus, the patient and the clinician may evaluate the effectiveness of a clinical encounter from totally different perspectives.

2. SPLIT IN CUSTOMERS AND PROVIDERS

The bifurcation of the "customer" is particularly important, because of the role of customers' expectations in quality initiatives. The typical market model decrees that the savvy customer — who both pays for and consumes the object purchased — can freely choose whether to purchase an excellent product at an appropriately high price, or a lower quality product for a lesser price, with the desired priority between cost and quality to be determined by the customer. If the payer for the process or product is not its beneficiary, the market mechanism is disrupted. In healthcare, the payer is the one who finances the health plan; typically, financing is through the employer or the government; and it is the patient who receives the care.

This calculation is further complicated, since, on one understanding, the enrollee in a health plan is one of the payers, if not the sole or major payer. The status of the enrollee as the customer of a given health plan is bifurcated as well, since the healthy enrollee might well prioritize cost, while the enrollee as a patient who is actually in need of the care that the plan represents, will have different priorities.[14] It is worrisome to note that some structural constraints — restrictions in a patient's particular health plan, or variation in the skill-base and service constraints of the primary physician — often cause patients to become a captive consumer base, rather than a group of informed individuals who are free to make informed deliberations between cost and quality that represent actual "choice."[15]

Although it is common to speak of "individual and institutional care providers," to lump together the individual and institutional agents in healthcare delivery is to occlude the important differences between them. Patient care in healthcare organizations includes services provided by the institution that are similar to those of a good (or mediocre) hotel, up-to-date (or outmoded) technologies, and competent (or callous) personal attention to patients' expectations. It also includes medical treatments, diagnoses, and interventions by clinicians, whose relation to the hospital often seems to be that of an independent contractor. The criteria for what "counts" as effectiveness or quality may differ between the institution and its clinicians, and the priorities between different criteria may differ as well. The relation between the clinician and the hospital has been described by one observer as "a built-in tension,"[16] with management of treatment modalities — control — as the object of dispute.

3. PATIENTS: RECIPIENTS OF CARE, OR THE "RAW MATERIAL" OF A PROCESS?

The individual enters the healthcare system with a particular question or problem. Patients are individuals, each of whom has slightly different physical characteristics. Patients also have a variety of values and preferences. So patients cannot easily be neatly folded into a one-size-fits-all process — even if those patients present with similar symptoms. In its second report, *Crossing the Quality Chasm,* the IOM addressed how the healthcare system could improve the quality of its delivery processes.[17] That report made "patients' values and preferences" a supporting prong for evidence-based medicine.[18] Our concern is that the processes that are designed to control flows and eliminate variation in treatment patterns are generally more rigid than flexible — for, after all, the intent of process control is control, not flexibility, and it is a truism that it is easier to design for standardization than it is to design for flexibility.

4. THE HEALTHCARE DELIVERY ORGANIZATION: CONTROL OF ITS ENVIRONMENT

Finally, some of the greatest impediments to the appropriate design of quality programs may come from the environment in which healthcare organizations operate. In spite of many conflicting values and beliefs about healthcare and healthcare policies, our soci-

ety does not yet believe that healthcare is purely a market commodity.[19] However, healthcare organizations have been forced to behave as though it were. They are subject to the competing pressures of their environment, which may, to a greater or lesser extent, depend on the organization's market position. For instance, there may be only one large employer in a geographic allocation — and several healthcare organizations. Or there may be only one healthcare organization that dominates the competitive landscape in a region. In addition, most healthcare organizations rely on some reimbursement through federal and state agencies. Conflicts between various elements of an environment may cause healthcare organizations to be exposed to simultaneous, conflicting imperatives: "improve quality, at whatever cost," and "reduce costs, no matter what effect that has on quality."[20]

All of the above idiosyncrasies make it difficult to design quality initiatives that produce outcomes that are desired and evaluated as "quality" by all associated stakeholders. Conflicts among stakeholders' values often lead to ethics consultations, which places those interested in clinical encounters, and the ethical issues surrounding such encounters, in a particularly privileged position to evaluate the ethical implications of quality initiatives.

QUALITY IMPROVEMENT REMAINS AN IMPORTANT GOAL

Despite the difficulties of implementing appropriate and flexible quality initiatives, there are good reasons why healthcare organizations consider the adoption of a flexible, focused quality initiative appropriate. First and foremost is the fact that quality in healthcare delivery has been deemed unacceptable. Processes that can help with decision making, help eliminate unnecessary waste, and contribute to the development of clinical knowledge and skills should be encouraged. All stakeholders agree that treatment should be efficient and effective. It is when one goal is prioritized at the expense of the other that a process can produce ethically unacceptable outcomes — and, given the emphasis of many quality initiatives on quantification and accountability, without some explicit mechanism to ensure an appropriate balance, efficiency or cost-control will be emphasized at the expense of effectiveness or quality.

Although members of clinical ethics committees are in a position to receive "early warning" of disruptions of patient care by the introduction of inappropriate quality initiatives, the tradition of ethics consultation does not always encourage committee members to look beyond individual cases. Here, we suggest one mechanism and two strategies that may increase the usefulness of ethical oversight by ethics committees.

ORGANIZATIONAL ETHICS PROGRAMS

In 1995, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recognized that increasing pressure to constrain healthcare costs was a growing threat to the quality of healthcare, and urged each of the institutions it accredits to institute a process or program to scrutinize business practices for possible impact on patient care.[21] Such "organizational ethics" programs can provide a mechanism to balance quality and cost.[22] However, not every delivery organization has formed an organizational ethics program, and many extant programs are floundering.[23] To date, there is no consensus on the activities of such programs, let alone the identification of appropriate educational requirements. If the organizational ethics movement does not provide leadership by reminding the designers of quality initiatives of the mission and values of healthcare organizations, it will fall to clinicians and clinical ethics programs to address cases in which the poor design of quality initiatives produces ethically unacceptable outcomes. For this, the designers may need to develop new skills, for they are dealing with systems that are designed to produce the very outcomes deemed unacceptable. Below we discuss the foundations of a skill set that we believe will be needed.

A SYSTEMS APPROACH

Susan Wolf has argued that a systems perspective is needed to think about important issues in healthcare. Wolf used the example of informed consent to argue that merely considering the process of informing a patient of the options of treatment, and getting consent at the point of treatment (a dyadic approach) is an oversimplification of the complex arrangements in healthcare systems and bypasses many elements that affect patients' consent. As our healthcare system is presently configured, it is necessary to have information concerning patients' subscription to an insurance plan, insurance and healthcare coverage, information sharing and transfer, rationing, and other points of care. It is precisely in this network or web of relationships that patients become ill informed, and the degree to which patients are actually able to provide "consent" becomes problematic. To consider informed consent only in patient-healthcare professional one-on-one encounters does not take into account how the patient is insured, how the professional and the healthcare center are reimbursed, limitations on capitation and rationing (which may be prescribed by the employer of the patient, the insurer, the state, Medicare, or Medicaid, or by other criteria), patients' and physicians' options in treatment (many of which are financially constrained), and whether the patient has the option to go to another healthcare center. Obligations to inform patients run all the way through the healthcare system, and not merely at entry or before treatment. And it is not merely the physicians' duty to inform patients, since that places an undue burden of knowledge on healthcare professionals. Moreover, many clinical ethical issues arise because disclosure and full information have not been disseminated at every stage, not merely at the point of treatment.[24]

Wolf goes on to argue, "A truly systemic view [of current healthcare] . . . considers how [this set of individuals, institutions, and processes] operates in a system with certain characteristics. The system involves interactions that extend over time, a complex set of interrelated decision points, an array of [individual, institutional, and governmental] actors with conflicting interests . . . and a number of feedback loops."[25]

Quality initiatives can be thought of as system initiatives, in that they are designed to change processes or components through which a prescribed outcome is anticipated. The outcomes from these initiatives cannot be understood in isolation from the processes or components that produce them. To understand, and effectively address, the ethically unacceptable outcomes that arise from quality initiatives, clinicians and clinical ethicists should take a systemic view in analyzing them, and put them in their context. They may have to understand how management issues, financing, costs, capitation guidelines (and other regulations), patient information (as well as patient autonomy), professional standards, and the quality of healthcare delivery are affected by the design of the process under consideration — any of which may represent different criteria for judging quality for different stakeholders or groups of stakeholders.

A systems approach acknowledges that most of our reasoning, experiencing, practices, and institutions are interrelated and interconnected. Almost everything we experience or think about exists in a network of interrelationships, such that each element of a particular set of interrelationships affects the other components of that set and the system itself, and almost no phenomenon can be studied in isolation from these relationships.

Ramo notes, in a systems approach, "concentration is on the analysis and design of the whole, as distinct from . . . the components or parts."[26] Systems thinking requires conceiving of the system as a whole with interdependent elements, subsystems, and networks of relationships and patterns of interaction. Studying a particular component of a system or a particular relationship is valuable under this rubric, but one needs to acknowledge that the component under consideration is also embedded in, and affected by, other systemic considerations. Mitroff and Linstone note,

because "the fundamental notion of interconnectedness or nonseparability forms the basis of what has come to be known as the Systems Approach, every problem humans face is complicated and must be perceived as such."[27] Thus, each system or subsystem, because it is complex and entails a multitude of various individual, professional, clinical, managerial, and financial and sometimes even political relationships, must be analyzed, and must be analyzed from multiple perspectives.

ACKNOWLEDGING MULTIPLE PERSPECTIVES

We noted above that quality improvement strategies are typically introduced on the organization level, rather than by individuals. But individuals within the organization have a central role in maintaining the quality of the clinician/patient interaction, and a responsibility to scrutinize the strategies and mechanisms that further the important goal, common to both organizational and individual providers, of providing care of high quality for reasonable cost. By acknowledging the importance of this shared goal, clinicians can best contribute to its achievement. But this may involve adopting, for purposes of analysis, a multi-perspective method to evaluate and improve quality improvement strategies.

A multi-perspective method postulates that problems arising for or within a system should be dealt with from a number of perspectives, to maximize the values represented by the alternatives. Each perspective may illuminate a different value, which will challenge other values in dynamic exchanges of questions and ideas. In a healthcare delivery organization, one needs to look at problems from a technical or fact-finding point of view, from an organizational and financial perspective, from the perspective of professional expertise, and from the perspective of individual patients and their values, priorities, and particular illnesses. Then one can rank problems, perspectives, and alternate solutions and evaluate a problem and its possible resolution from the multiple perspectives.[28]

While it is never possible to take into account all the factors involved in a particular case analysis, to consciously attempt a multi-perspective approach forces us to think more broadly, and to look at particular problems from different points of view. This is crucial in present day clinical dilemmas, because, as Mitroff and Linstone note, each perspective usually "reveals insights . . . that are not obtainable in principle from others."[29] This is also invaluable in trying to understand other points of view. A multi-perspective approach is essential to understand the limitations that financial pressures and guidelines place on healthcare delivery, what is at stake for the uninsured, or what is at risk when professional staff are overburdened with efficiency requirements or their numbers are decreased. This can explain how medical errors might occur, as well as help provide fresh insights to their prevention. Such a process does not require clinicians and clinical ethicists to be experts in all these fields. Rather, it helps clinical ethicists to contextualize the issues, to become more informed, and to figure out where to look for outside expert assistance, when needed.

Clinicians are familiar with the idea of a multi-perspective approach. In the clinical encounter, clinicians often evaluate a plan of care from several perspectives, such as whether or not a family can accommodate the care required by a patient. Clinical ethicists also know the importance of considering the interests of all persons who have a stake in a given case. Indeed, most methodologies that outline how case consultations should proceed stress that facilitating the making of difficult decisions requires considering all relevant facts and the perspectives of all concerned.[30] We suggest that this same approach should be brought to bear on the processes and relationships that form the context of care, outcomes as well as processes.

CONCLUSION

We have discussed some of the obstacles that may preclude the appropriate implementation of quality initiatives in healthcare in-

stitutions and suggested that if these obstacles are not considered in the design of quality initiatives, this may produce outcomes that are ethically unacceptable. *Quality* is a relational term. In healthcare, quality depends on the place of the evaluator in the system and the differing criteria through which the evaluator judges the effectiveness and efficiency of the product or service, and which stakeholders have their expectations met through the initiative. A systems approach, combined with a multi-perspective view, may be useful in designing or modifying such initiatives.

A warning, however; there are two provisos to using a systems approach. First, because we are talking about clinical ethics programs in healthcare delivery organizations, the values of patient care, patient autonomy, and professional expertise are the core, primary values. Prioritizing the best interests of the patient is, and must be, the first consideration. This is obvious, but it is sometimes in danger of being overlooked when decisions that involve cost are at stake.

Second, a systems approach does not mitigate individual professional, managerial, organizational, or patient responsibilities. A systems approach should not be confused abdication of individual responsibility. As individuals, we are not merely part of or determined by the systems and relationships in which we are involved. Each of us is a byproduct of, character in, and author of the organizations, institutions, and systems in which we live; thus, each of us bear responsibility for the quality of healthcare delivered and its weaknesses.

Use of a systems approach indicates that clinicians and clinical ethicists should become aware of the complex dimensions of the healthcare system in which they and their organization are operating, and that they should bring those considerations into play when necessary in ethics consultations. This may require evaluating roles, relationships, and the context of a quality initiative, and working to make changes that improve the system. This is an example of what Patricia Werhane has called *moral imagination:* "the ability in particular circumstances to discover and evaluate possibilities not merely determined by that circumstance, or limited by its operative mental models, or merely framed by a set of rules or rule-governed concerns."[31] In healthcare delivery, the clinical setting requires such moral imagination, operating on the organizational and systemic levels, as well as within specific clinical settings.

ACKNOWLEDGMENT

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NOTES

1. R.W. Grant, R. Shani, and R. Krishnan, "TQM's Challenge to Management Theory and Practice," *Sloan Management Review* 35, no. 2 (1994): 25-35.

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3. J. Detert, R.G. Schroeder, and J.J. Mauriel, "A Framework for Linking Culture and Improvement Initiatives in Organizations," *Academy of Management Review* 25, no. 4 (October 2000): 850-63.

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5. G. Laffel and D. Blumenthal, "The Case for Using Industrial Quality Management Science in Health Care Organizations," *Journal of the American Medical Association* 262, no. 20 (November 1989): 2869-73.

6. Institute of Medicine, *To Err is Human: Building a Safer Health System* (Washington, D.C.: National Academy Press, 2000).

7. See notes 1, 2, 4, and 5 above. Also see R. J. Bringewatt, "Making a Business Case for High-Quality Chronic Illness Care," *Health Affairs* 20, no. 6 (2001): 59-608.

8. Quality initiatives are "system initiatives," as they look at each component of production or service processes, and many purport to eliminate fear of blame or mistakes in the workplace by empowering workers to identify

problems in processes and suggest improvements. See note 2 above.

9. M.R. Chassin, R.W. Galvin, and the National Roundtable on Health Care Quality, "The Urgent Need to Improve Health Care Quality," *Journal of the American Medical Association* 280 (1998): 1000-5.

10. Quint Studer used a modified version of a management tool, the "balanced scorecard," to improve the relationships of hospital clinicians and staff with each other and their patients. There is some evidence that he has been successful in supporting these relationships — and this has resulted in improved performance, as measured by management indices. *Modern Healthcare* has published a number of essays on his accomplishments.

11. M. Bailit, "Ominous Signs and Portents: A Purchaser's View of Health Care Market Trends," *Health Affairs* 16, no. 6 (November/December 1997): 85-8.

12. This anomaly of the healthcare system was noted in 1995 by E. Haavi Morreim, who writes: "in this sense the term purchaser is systematically ambiguous; we could be referring either to patients or to payers." See E.H. Morreim, *Balancing Act: The New Medical Ethics of Medicine's New Economics* (Washington, D.C.: Georgetown University Press, 1995), 22.

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16. R. Stevens, *In Sickness and in Wealth: American Hospitals in the Twentieth Century* (Baltimore: Johns Hopkins University Press, 1998), 12.

17. Committee on Quality and Health Care in America, Institute of Medicine, *Crossing the Quality Chasm: A New Health System For the 21st Century* (Washington, D.C.: National Academy Press, 2001), see the executive summary.

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25. Ibid., 1647.

26. S. Ramo, *Cure for Chaos* (New York: D. Mackay, 1969): 11-2.

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28. Ibid., see chapter 6.

29. Ibid., 98. For further development of a systems approach to healthcare, see P.H. Werhane, *Moral Imagination and Management Decision-Making* (New York: Oxford University Press, 1999), 93.

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31. Werhane, see note 29 above.

Personal Perspective

A Part of Life, A Part of Me, and "The Quality of Life"

Ilia Volkov

As physicians, we should not only take into account a specific life-threatening condition that is presented to us, but also the general well-being of the patient and his or her quality of life. This is true of health problems that the patient is not aware of, or chooses to ignore, and also decisions concerning considering the patient's feelings when a standard medical practice is used for a specific condition.

Very often all of us — doctors and patients alike — become accustomed to our annoying but tolerable health problems, and usually do not pay much attention to them in our everyday life. They tend to become an integral part of our life, our body, even our very being. As a rule this does not happen all at once, but as a result of prolonged or ineffective treatment of a condition, or possibly because, at the time that we tried to treat the condition, there was no effective treatment. Also, we shouldn't forget the common "dollars and cents" orientation, plus the bureaucratic structure of health services!

Why did I, a doctor with 20 years of medical experience, decide to address this problem now? We are all proud of the achievements we have made in medical practice, with the successes in treatment of life-threatening diseases and chronic medical conditions, increasing the duration of people's lives, but we often forget about the most important aspect, the quality of that life.

Once a young man visited me, complaining about pain in his shoulder. During our talk he frequently had to wipe his running nose with a tissue. I asked him, "Do you suffer from chronic rhinitis?" He looked at me wistfully and answered, "Let's leave it alone. I tried to take care of it, without any success many years ago. Now I have learned to live with it; it's become a part of me!" When I offered to try to treat it anyway and explained to him that today we have more possibilities for treating rhinorrhea successfully, he agreed hesitantly.

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After a few weeks he was surprised at the transformation in his condition and in his life; at last, he could breathe freely. He even came to the follow-up exam without his habitual tissues.

Reviewing our case studies in treating recurrent aphthous stomatitis (RAS — canker sore) with vitamin B_{12}, we were amazed by statistics that 10 to 50 percent of the general population suffers from RAS, and up to 60 percent of the medical staff! Why were we surprised? RAS is not considered a reason to pay a visit to the doctor. Patients rarely complain of RAS, except for how it influences their daily lives. When we started to elucidate the phenomenon, we understood that at some moment aphthae in one's mouth was accepted as "a part of life."

I look at two photos of a 25-year-old woman: the first one is before dental implantation, the second one, after. In the second photo, she is smiling, and I know that it is for the first time in her life. . . . What we consider to be a usual procedure changed her whole life around.

A 75-year-old patient with suspected prostate cancer was preparing himself for a biopsy. He was depressed at the very thought of the procedure. He asked my advice. After discussing the problem with him at length, we agreed to get a second opinion about whether a biopsy was necessary. In a week the pacified patient brought me a letter from a famous urologist with a confirmed clinical diagnosis of prostate cancer, in which he mentioned the problem of the quality of life for this particular person, and I can add, millions like him. The urologist recommended weighing the necessity of biopsy for this particular patient again, and instead to do careful follow-up exams for a while to monitor the progress of the cancer. Teaching students and young doctors, I use this letter as example of a thoughtful approach of an experienced doctor and the changing of values in modern life, when the quality of a relatively "shortened" life span becomes more important than sustaining life.

Not long ago I told my colleagues about unexpected improvement in the condition of an 83-year-old patient. She decreased her physical and social activity after two mild cerebral vascular strokes (CVAs). She was seriously depressed after these two incidents. Analyzing her blood test, I noticed an increase in the level of thyroid-stimulating hormone, with normal T3 and T4. I considered that it was subclinical hypothyroidism; I started treatment with low doses of thyroxine. In a few weeks I didn't recognize my patient — she again became an active, cheerful woman. I was glad for her sake. However, recently I read an interesting article in which it was mentioned that thyroxine treatment can hasten metabolic processes and even shorten life in older patients.[1] What should be our concern? Quality or duration of life? How much should a doctor help his patient decide, and how? Certainly it is no secret that our patients believe in and rely upon us, and that we can affect their decisions. What is the real answer considering the best interests of the patient?

Our life today is very dynamic. Often our patients ask us questions, and the answer we are looking for is not always in a textbook, but in that "other book," the one we are writing all the time together with each of our patients. Because of the changes in our lifestyle and the changing values of modern life, "little problems" are becoming more and more important. Maybe by solving them today, we will have the right to take part in the solution of "bigger problems" in critical periods of our patients' lives tomorrow.

NOTES

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